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HIMA-PMA REPORT

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HIMA/PMA Report is based on a series of educational conferences held in New York, Chicago, Los Angeles, and Atlanta on June 21, 25, 29, and July 1, respectively. The program chairmen for the conferences were Messrs. Frank E. Samuel, Jr., HIMA, and Rodney R. Munsey, PMA.

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Preface

This document contains the information on the Medical Device Amendments of 1976 presented at the Health Industry Manufacturers Association/ Pharmaceutical Manufacturers Association educational conferences held in New York, Chicago, Los Angeles, and Atlanta. The conferences were attended by approximately one thousand medical device and diagnostic product industry representatives.

The proceedings cover the essential information presented by the speakers, including handouts and certain additional materials included in this publication's appendix.

The undersigned wish to thank all participants, and hope that the material contained herein will be of substantial value in preparing to operate and comply under the new law.

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WELCOME AND INTRODUCTION

C. Joseph Stetler
President
Pharmaceutical Manufacturers Association

Harold O. Buzzell
President
Health Industry Manufacturers Association

Ladies and Gentlemen:

I am pleased to be here today and welcome you to these briefing conferences on the Medical Device Amendments of 1976. PMA was more than happy to join HIMA in the sponsorship of these conferences. The memberships of both associations are sure to gain by the combining of the resources of the two associations in the presentation of pertinent considerations under the new legislation.

1969 was the year that medical device legislation first became the subject of serious consideration. There had been several bills introduced in the Congress prior to that time but none of them had received serious attention. In 1969, however, a Supreme Court case held that some products previously considered devices could be considered drugs and subject to premarket clearance requirements. The Government was concerned because it lacked sufficient resources to adequately regulate devices. The industry was concerned because of the uncertainty the Court decision created. It was difficult if not impossible, in some cases, to determine which devices would be regulated as drugs. Congress became aware of the gaps in the regulatory scheme for devices. Pursuant to Presidential directive, a commission chaired by Theodore Cooper, then the Director of the National Heart Institute, was appointed to recommend the type of medical device legislation that should be enacted. The recommendation of that commission, in the so-called "Cooper Report", became the backbone of several bills which culminated in the passage of the new devices law on May 28 of this year.

Industry was able to exert considerable influence on the legislation especially in its early development stages. Under the leadership of PMA, an informal group of trade and professional associations was formed, a primary function of which was to exchange views on matters involving legislation. The two predecessor associations of HIMA, HIA and MSMA, were very active in this group. All the associations involved were in agreement on a surprisingly large number of issues. Rod Munsey was able to work quite effectively on the legislation at the early stages primarily because of the agreement of the various associations. Incidentally, the inter-association group continues in existence primarily as a communication mechanism. HIMA and PMA are, of course, very active in its activities.

The major bills evolving from the recommendations in the Cooper Report were those introduced by Congressman Staggers and Senator Javits on behalf of the Nixon Administration and those sponsored by Senator Ted Kennedy and Congressman Paul Rogers. The Rogers and Kennedy bills were virtually identical on introduction. Although many of the concepts appearing in the final law received initial consideration during discussion of the Kennedy bill, it was the Rogers bill that became the basic framework for the final law. Earlier versions of the Rogers bill were completely rewritten.

As you will hear today, the Medical Device Amendments of 1976 will present tremendous problems for both industry and the Food and Drug Administration. Hopefully, the bulk of problems will be resolved to the satisfaction of the public, the industry, and the Government. It is hoped that these conferences will be a start in the right direction.

in P.L. 94-295. I suggest that you read the Cooper Commission findings, which appear on pages 10-11 of the House report on H.R. 11124.

3. As the legislation came closer to enactment, the authority given to FDA to regulate the industry became more extensive, more detailed, and more complex. In other words, delay was the incubator for more regulation.

4. The legislative consideration of the bill showed that manufacturer positions could be effective if they were supported by well-founded patient care implications. Increased cost alone was not enough to win legislative arguments. Where manufacturer costs alone were the issue, Congress believed that they are simply passed on through the economic system and borne ultimately by health care consumers and taxpayers generally. In other words, Congress treated them as society costs, not manufacturer's costs.

5. Perhaps the most important lesson to be drawn from the five dates I mentioned is that the medical device amendments are not a free-standing regulatory scheme. They are amendments to the Food, Drug and Cosmetic Act. Their full impact cannot be assessed without reference to pre-existing provisions of the Act. This is true in more than a strictly legal sense. The administrative experience which FDA has gathered over the years in regulating the food, cosmetic, and especially the drug industries may well have a pervasive effect on their attitudes toward the medical device and diagnostic product industry. This may prove true in spite of the welcome recognition in many parts of FDA that devices and diagnostics *are* different from drugs.

C. *Overview of the Structure of the Medical Device Amendments of 1976*

With this historical sketch in mind, I would like to turn to the legislation itself. First, two preliminary points:

The drafters of the legislation, building upon the recommendations of the Cooper Commission, attempted to establish a comprehensive regulatory scheme for the device and diagnostic product industry. To put the matter negatively, the drafters of the legislation did not attempt to deal with separate problem situations. Instead, they designed authority to deal with all kinds of products and all kinds of situations, regardless of whether or not significant public health hazards had been historically demonstrated for any product or process. In this sense, the bill is a preventive measure rather than a corrective one, although there have clearly been situations where corrective action was necessary but unavailable.

The second point rises from the first: A prime feature of the Amendments is the interrelationship of the various sections. This means that you cannot obtain a clear idea of the treatment of a particular product or class of products by reading one section or one group of sections of the bill. It is necessary to have in mind the entire bill, as well as other provisions of the Food, Drug and Cosmetic Act, before the full range of FDA authority can be appreciated.

Obviously, your company's situation is somewhat simplified if you produce today only products which fall into Class I - General Controls. But it would be shortsighted if you ignored the possibility that some of your products might, in the future, be reclassified into Class II or conceivably Class III, or—more significantly from a practical point of view—that new products which you might hope to develop or acquire fell into one of those classes. In short, there is virtually no section of the Amendments or of the Food, Drug and Cosmetic Act which relates to device and diagnostic products which can be safely ignored by manufacturers as we try to plan for the impact of P.L. 94-295.

Let me turn now to the copy of P.L. 94-295 which is in your registration materials. This is the text of the actual bill signed by the President. It is the House version of the bill, in structure and most of its provisions. It may be confusing to note at the top of the Act the notation S. 510, indicating that it is the Senate bill which was enacted into law. I won't go into the legislative technicalities of the matter. Take my word for it that P.L. 94-295 is essentially the House-passed version of the bill, H.R. 11124, with certain changes made by the Conference Committee. Therefore, if, in your advance preparations within your own company, you have been focusing on the House-passed bill, that focus was not misplaced.

I would like you to review the table of contents briefly with me:

- *Section 513* is the section to look at to determine how the classification process works and how classification panels are organized.
- *Section 514* provides for the development and establishment of performance standards.
- *Section 515* has the special provisions dealing with products which are in Class III, covering premarket approval and product development protocols.

the basis for their action and thus to show that explicit regulation is unnecessary to achieve the purposes which the Act is intended to achieve.

This period of uncertainty also means that, at any given moment, many manufacturers may well be technically out of compliance with the Act but will nevertheless have no regulatory problem unless there's a problem with their product. This may result in visible inequity: two companies in comparable technical violation of the Act; one subject to regulatory action for the violation because a product problem was brought to light, perhaps by the manufacturer; the other getting off "scot-free" because no product problem had been discovered.

There is simply no way to avoid either the uncertainty or the inequity. Both will be with us for a long time, although it is heartening to note that there are some indications that FDA will approach the initial implementation period with reasonableness.

My second point is hardly speculative at all. One development that is virtually certain to occur is the increased costs for products supplied by our industry to the health care system. In the areas of regulatory affairs, product design and development, and quality control, these costs are likely to be the most visibly increased. The key question, of course, is whether these costs will have any relationship to increased benefits to the patient. That question will probably go unanswered. And as I noted earlier, increased manufacturing costs alone will be no argument against regulation.

Thirdly, the defensibility of industry positions on regulatory matters and the public acceptability of FDA regulatory initiatives will be determined in significant part by a factor over which neither FDA nor industry has a great deal of direct control. That is the general attitude on the part of consumers, including the Congress, toward business enterprise as a whole. Although our industry may play a negligible role in effecting overall public attitudes on this question, we are inescapably affected by it and probably will be increasingly in the future.

Finally, I would like to point out that, with an Act as complex and detailed as the Medical Device Amendments of 1976, the desirability and the need for amendments to it are likely to become plainly, if not painfully clear, over the next few years. Our ability to effect salutory changes in either the law—or for that matter, FDA regulations or operating policies—will be significantly linked to our ability to document the patient care implications of those changes. Irritation with the effect of FDA's activities under the new law, fond expectations about the effect of our recommendations, and generalized convictions about health care costs or patient benefits will simply not be enough to convince legislators and the general public that regulatory changes should be made.

Our final observation: there are two groups of people who are going to play key roles in assuring that the health care system has high quality products available to it. One group is composed of the men and women who design and manufacture products. The other group is composed of those who will implement the new law, realize the intent of Congress, and achieve fair and effective regulatory decisions. These groups are, in my view, largely the same, and they are represented by the people here today. Your attendance is yet another indication of this industry's commitment—regulation or no—to do its best for patients and health care professionals.

Thank you.

diction of the Act such as foods and drugs, some connection with interstate commerce has to be shown in order for a violation of the Food and Drug Act to take place. Also, provisions in the Food and Drug Act which generally permit the Government to *seize* only one shipment of a product alleged to be misbranded until the suit is adjudicated do not apply to devices. Thus, in a case alleging adulteration or misbranding of a device, FDA has the authority under the new law to go to court in several different districts at once and ask for writs of seizure of products in those districts. Another provision relating to enforcement in the new law involving devices is elimination of the requirememt for the Government to affirmatively prove the connection with interstate commerce in those cases where such connection is needed. With regard to criminal and injunction cases involving foods and drugs, the interstate connection must be affirmatively proven by the Government. In the case of devices, it is presumed; that is, the defendant must prove there was no shipment in interstate commerce.

Enforcement provisions are not the only provisions in the law which are effective immediately but which do not require any actions by manufacturers. One of the others is the provision requiring FDA to assist small manufacturers with compliance problems. A mechanism has already been established within FDA to handle this function. This should be of some help to companies, especially to those who have had little or no dealings with the Food and Drug Administration in the past. A word of caution is appropriate here, however. Before raising a question with FDA or bringing a problem to its attention, a manufacturer should consider the potential consequences of the various possible answers as well as the consequences of the facts that the Agency will know who the questioner is, what the question or problem is, and what answer was given. For example, suppose a question is raised in good faith with FDA by a manufacturer as to the proper labeling or regulatory status of a product and the manufacturer disagrees with the answer given. If the manufacturer then fails to follow the FDA-suggested course of action, what are the possible regulatory actions FDA might take or what would be the effects on the relationship between that manufacturer and the FDA? And believe me, the continuing relationships between FDA and individual manufacturers are going to be extremely important. My words of caution should not be misunderstood, however. There are many occasions when you should raise questions with FDA. The Bureau of Devices has usually taken reasonable positions in dealings with industry.

Another section of the law having immediate application which involves FDA action is the classification process. After receiving recommendations from the classification panels, FDA will classify all devices into one or more of three regulatory categories—general controls, standards, or premarket clearance.

In discussing which provisions of the new law should receive immediate attention from manufacturers, I think it makes sense to subdivide devices into two major groupings, that is: those devices on the market on May 28 and those which manufacturers will want to market for the first time after May 28. Further, the group of products on the market on May 28 may be treated differently under the law depending upon which of three categories they are in: (1) devices which were nonprescription devices in general commercial distribution on May 28; (2) devices which were prescription devices in general commercial distribution on May 28; and (3) both prescription and nonprescription devices which were being distributed only for investigational purposes, that is, they were not in general commercial distribution on May 28.

For the next few minutes I will confine my remarks to the three categories of devices on the market on May 28. Later, I will get into the new devices.

First, nonprescription devices which were in commercial distribution. Their regulatory status on May 28 was not immediately changed. They are permitted to be on the market during the time they are being classified into the premarket clearance, standards, and/or general controls categories. Further, even after classification, their status will not be changed until a standard is actually promulgated and made effective or FDA has imposed a requirement for premarket clearance and manufacturers have had opportunity to submit applications and have them ruled on. However, certainly the activities of FDA's classification panels should be watched closely. You may want to make submissions to the panels to make sure that sufficient information is known by the panels about your products (or perhaps your competitors) to make proper classifications. Both HIMA and PMA keep careful watch of panel activities and keep those member companies who wish to be informed up to date on panel deliberations and results.

Since there will be stepped-up enforcement of all the provisions of the Food and Drug Act with regard to devices because of the new law and expanded staff, this would be a good time to review all your products and their labeling and other promotional materials for compliance with the adulteration and misbranding provisions of the FDC Act applicable to devices which existed before the new law. For example,

cially marketed as of that date. That is, there is no basic change in their regulatory status. However, FDA took the position in a notice published in the *Federal Register* on June 4 that a prescription device on May 28 automatically becomes a restricted device under the terms of the new law. A restricted device is one limited to sale on prescription of a physician or subject to other limitations as to the persons who may use or prescribe the device or who may distribute it. In addition to its possible effects on sales, the imposing of restricted status on the devices presents two immediate problems for manufacturers. First, according to the new law, any advertisements for such products must contain "a brief statement of the intended uses and relevant warnings, precautions, side effects, and contraindications". We do not know how extensive the information will have to be in ads but similar requirements with regard to prescription drug advertisements resulted in a tremendous increase in the amount of information required to be contained in advertisements. In my view, however, FDA will not immediately search for violative ads but will allow a reasonable transition time as long as the ads are not false or misleading. The second problem associated with FDA's published notice is that the new law greatly expands the previously existing inspection authority for devices that are restricted devices. A great many more records, files, and papers concerning restricted devices are subject to inspection than is the case with most other devices. This is the real purpose behind the notice. FDA wants the expanded inspection authority now. There is a serious legal question as to whether FDA has the legal authority to make an across-the-board class finding that all prescription devices on May 28 are automatically restricted devices under the new law. PMA believes that a device may be made a restricted device only after FDA has proposed an order relating to an individual device or type of device. The proposal must describe the device, set forth the specific restrictions being considered, and give manufacturers full opportunity to comment on it. Two weeks ago, Joe Stetler, on behalf of PMA, wrote FDA objecting to its arbitrarily classifying prescription devices as restricted devices. We found out last week that Congressman Paul Rogers, author of the bill, wrote FDA voicing the same objection. HIMA has taken the same position with FDA. We are pleased that industry views coincide with Congressman Rogers in this important matter. I suggest that you carefully consider with counsel the various alternatives before you decide what action to take concerning FDA's view that all prescription devices are now restricted devices and that FDA now has expanded inspection authority over plants that make them. The first time you are likely to be confronted with the issue is the next FDA inspection of your plant. You should have your policy decided upon before that time.

We believe that cooperation with the Food and Drug Administration is desirable whenever possible, but we also believe that if FDA attempts to sidestep legal requirements to our detriment, we must take steps to require the Agency to comply with the law.

You will recall that I described the third category of devices on the market on May 28 as devices (both prescription and nonprescription) which were on the market for investigational purposes only. These could be either devices that were being investigated under an investigational drug exemption or devices, which were not considered drugs, which were being investigated by the manufacturer as devices. Suffice to say, our best information is that both types of investigations may be continued until FDA puts out new investigational regulations. The programs should then be modified to conform to the new regs. New device investigations may be commenced at any time but consult the statute for guidelines.

The second basic group of devices are those not on the market on May 28. This group, too, can be divided into subcategories for the purpose of applying those new requirements that are immediately effective. First, those devices which are not substantially equivalent to, and of the same type as, those on the market on May 28. They cannot be marketed until either a device application has been submitted and approved by FDA or a petition to reclassify the devices to standards or general controls categories has been filed with FDA and approved. Further, they cannot be exported to a foreign country unless both the FDA and the government of the foreign country approve the exportation.

That leaves for consideration those devices a manufacturer wants to introduce which are both substantially equivalent to, and of the same type as, devices on the market on May 28; that is, similar or "me-too" devices. The new law is clear that such a device may be marketed and is subject to all the rights and privileges of the device it resembles which was on the market on May 28. An example of one of the rights and privileges is the following. Generally, no device on the market on May 28 may be required to have an approved application until at least 30 months after the date on which the device is classified into the premarket clearance category. A device similar to that device, but which is first marketed after May 28, also cannot be required to be subject to an approved device application until 30 months after the classification

CLASSIFICATION OF MEDICAL DEVICES

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Becton, Dickinson and Company

We will briefly review the medical device classification procedure which the Agency has been using since July of 1973 when it first announced its intention, through the *Federal Register,* to form certain classification panels. I would also like to summarize the FDA's progress in what we can refer to as the interim classification process. In the context of these remarks, interim classification of medical devices means the efforts and accomplishments of the Agency prior to May 28, 1976, the effective date of the new law.

The remainder and greater portion of these remarks this morning will focus on Section 513 of the Medical Device Amendments of 1976, entitled "Classification of Devices Intended for Human Use"

Toward the conclusion of these remarks, I will offer some suggestions as to how to follow the classification process; how to participate if desired and how to plan for both the short-range and long-range effects of product classification.

The FDA has undertaken to classify medical devices over the past three years. Following the recommendations of the "Cooper Committee Report of 1970" and early versions of medical device bills, the Agency created medical device and diagnostic product panels or committees. The 14 original panels/committees are now being expanded so that there will be 13 medical device panels and 6 diagnostic product panels. The device panels will have some 20-25 subcommittees. Each of these panels (or more specifically the subcommittees) represents a certain medical specialty where medical devices are routinely used. To quote the FDA, each panel is "comprised of experts skilled in the use of, or experienced in the development, manufacture or utilization of medical devices".

Each of the panels and certain of the subcommittees have been meeting regularly to consider extensive lists of device products. The lists were derived from an initial inventory of medical devices developed by the Agency in 1971 and updated since then. The 13 device panels have completed approximately 98% of their preliminary classifications. These are broken down as follows:

General Controls	44%
Performance Standards	50%
Premarket Approval	4%

Within these overall figures, however, are very wide variations by individual panels, particularly in the general controls and standards categories. Leaning heavily towards standards were the Cardiovascular, Anesthesiology and Gastroenterological Panels who placed over 80% of products in this category. Between 67% and 85% of all devices classified by the E-N-T, General Hospital, General and Plastic Surgery and Ophthalmology Panels were assigned to general controls. The Cardiovascular Panel at 14% and the OB-GYN Panel at 16% were the highest in requiring premarket review of products classified.

Unlike the average of the device panels, the trend of the classification of diagnostic products has been more toward performance standards (about 70-80%) and probably less than 1% into the premarket approval category.

I have recited the foregoing figures to indicate the wide range of classification results which may be anticipated under the new medical device law. As a final contrast, we can cite the Cardiovascular Panel which did not assign a single product to general controls—as opposed to the General and Plastic Surgery Panel which did not classify any products in premarket review.

The procedures which FDA has been using to classify medical devices are adequately defined in their "Notice to Manufacturers" which was published in the *Federal Register* of May 19, 1975. The notice includes a discussion of the requirements for panel membership; the device classification logic scheme; the general rules for open or closed panel meetings; the rules for submission of data and opportunity for presentations before the panels; release of data and information submitted to the panels and release of the tentative classification recommendations by a panel. Much of the information in the notice is likely to apply to the official classification of devices in the forthcoming months.

*This presentation was given by Timothy M. Wendt, Group Counsel, American Hospital Supply Corporation in Chicago, Illinois and Los Angeles, California, June 25 and 29, respectively, and George F. Smith, Manager of Medical Devices, Pharmaceutical Manufacturers Association in Atlanta, Georgia, July 1, 1976.

If one were to review the procedures used by all of the classification panels over the past three years, I am certain that valid questions would arise with respect to the legality of the classification panels' efforts to date; one could ask, for example, whether the panels have reviewed all product labeling within a given class of devices. Since most manufacturers did not open their files to the panels, how could "effectiveness" determinations be made on the basis of well-controlled investigations, documented case histories or other valid scientific evidence? The new law requires that "effectiveness" be determined in accord with regulations promulgated by H.E.W. Where no such regulations have been issued, is there not a serious issue with respect to the entire three years of classification activity? An interesting point to ponder.

We have now discussed the general philosophy of classification as well as certain rules which the panels are required to follow. With this background in mind, we can now review the actual mechanics of classification.

By this time most people are well aware that devices will be classified within three regulatory classes of control. These classes are nonexclusive—meaning that a certain device might be assigned to more than one class and perhaps all three. To review these classes, we can start with the least restrictive one. A device will be assigned to Class I-General Controls, if certain provisions of the new law, by themselves or in any combination, would be adequate to give a reasonable assurance of safe and effective performance. These controls are designated in the statute as adulteration, misbranding, registration of manufacturers, banned devices, notification and other remedies, records and reports and lastly, general provisions for control which include such regulatory measures as good manufacturing practices, restricted and custom device provisions and the exemption procedure for investigational use of devices.

Before we discuss the criteria for the other classes, one important point should be understood. Some devices will be assigned exclusively to general controls and may never have to be concerned with the requirements associated with other device classes. However, *all* devices irrespective of additional classification are subject to the provisions of general controls. In this sense, Class I is a baseline requirement of the law which must be met by all products.

Having said that, I can now mention an important exemption available to some products classified only in Class I. When the classification panels apply the criteria for Class I and when the FDA reviews the panel recommendations for Class I devices, these two bodies must also determine if certain general controls need not apply. Requirements for manufacturer registration and product listing, requirements for records and reports, and requirements for good manufacturing practices may not apply to a Class I device if the panel recommends and the FDA concurs that they would serve no realistic purpose. To assure that each Class I device receives appropriate attention to these possible exemptions, the panels are required to affirmatively indicate their exemption findings for every product or grouping of products.

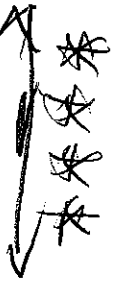
The next highest classification is that of Performance Standards - Class II. Devices will be assigned to this classification if two findings are made by the panels. First, the panel must conclude that general controls, by themselves, would not be sufficient to satisfy the statutory requirement for safety and effectiveness. Second, there must be enough known about the device so that a performance standard could be written—and that standards when written would provide a reasonable assurance of safety and effectiveness for the product or a generic group of products.

Two comments can be made about this classification. It is important to note that devices classified in standards are really general control devices until a regulatory standard is written and required to be met. In some cases, devices classified in Class II might not have to comply with a standard for many years —especially if the classification panels have not assigned a priority status for the standard. Secondly, when a standard is promulgated, the product in question will remain subject to general controls. However, if certain of the general controls would be inconsistent with the standard, then the requirements of the standard would take precedence.

The last class of devices is Class III - Premarket Approval. This is the most restrictive classification and is the only one of the three where the government can require proof of safety and effectiveness from each manufacturer and give FDA approval before a product is marketed. Class III is the logical extension where a device cannot be adequately regulated by the two lower classes. Thus, a Class III device in the first instance is one where there is not enough known about the product to determine if general controls would be adequate or a standard could be written to give a reasonable assurance of safety and effectiveness. Assuming these findings are made about the product, it will be assigned to Class III if: (1) the device is represented for a use in supporting or sustaining human life or for use of substantial importance

A *new device* is any product first marketed after the enactment date which is neither of the same type nor substantially equivalent to an old device.

The classification of "new devices", using the term as I just defined it, requires very little elaboration. According to Section 513(f), new devices are automatically assigned by law to Class III and may not be introduced to the market without premarket approval by the FDA. In other words, neither the panels nor the FDA need make any findings about the product because the statute does this for them. You should be aware, however, that there is a means under the statute to apply for reclassification into Classes I or II through a petition route which does involve findings by the panels and the FDA. Let's discuss this petition mechanism.



Under Section 513(f)(2), any manufacturer or importer of a new device may petition the FDA for classification as a Class I or II device which would, of course, permit the product to reach the market without undergoing premarket approval. FDA regulations will set forth the form and manner of this petition. A decision on the petition must be rendered within a maximum of *210* days. During the consideration period for the petition, the law specifies that there shall be opportunity for submission of data and views on the petition as well as a possible assignment of priority for standards if Class II is approved for the device.

FDA's decision on the petition may be appealed to the courts not only by the affected manufacturer or importer, but also by any person adversely affected by it. Therefore, under the judicial review provisions of the law, a public interest group, for example, might appeal an approved petition if they believe the procedure was defective or the FDA decision was contrary to the facts or the statute.

The petition procedure I have just discussed is the general rule for all new devices. The law provides that classification panels who receive a petition concerning an implant or life-sustaining/life-supporting device must recommend *denial of the petition* unless Class III is not necessary to give a reasonable assurance of safe and effective performance. If the Agency decides to approve the petition - meaning classification in Classes I or II - then the order must be accompanied by a *full statement* of justification. Like the general petition procedure, classification petitions involving implants, etc. may be appealed to the courts.

Let's now cover the classification of a me-too device which is, as you remember, a product introduced after enactment which is of the same type and substantially equivalent to an old device or a pioneer device which has been classified in Classes I or II. Devices which meet the criteria of type and equivalency will, according to Section 513(f), be classified in the same class as their counterparts already on the market. Thus, new products can get to the market on the basis of substantial equivalency regardless of whether they fall under Classes I or II or III. This sharing of the classification also involves a sharing of regulatory controls. For example, if a standard was in force, the new market entry in Class II would have to comply with the applicable standard.

In the first few years of implementation of the law, a me-too device in Class III, because of substantial equivalency, gets special consideration. These new products get to piggyback on the thirty-month grace period before the FDA can require an application for premarket approval. Devices introduced early on will get the full 30 months, while those introduced later will receive a portion of the period if their counterparts are already classified in Class III.

To complete the discussion of me-too devices, we should say a few words about substantial equivalency. No definition now exists. More than likely, the Agency, either by interpretative regulation or practice, will define the scope of the term. Other speakers will discuss Section 510(k) concerning the 90-day advance notice of new product marketing. Suffice it to say for now, that Section 510(k) enables the manufacturer to assert substantial equivalency for the product about to be introduced. The FDA then has what I call a negative option. If it makes no response to a 90-day notice claiming substantial equivalency, then the manufacturer might assume agreement with his findings. Where the Agency disagrees, further discussions might be in order or a reclassification petition could be submitted. Without going into the substance and procedure for reclassification, merely be aware that efforts can be made to seek reclassification - higher or lower - and, that in certain situations one can seek judicial review of classification determinations.

You should by now have a general understanding of classification. One fact is obvious. The FDA has already made substantial progress in this area and, in the words of one FDA official, intends now to "beef-up" the logic scheme for immediate utility. During the next several months to one year, the classification

GENERAL CONTROLS-MANUFACTURER COMPLIANCE

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This morning I will discuss that area of medical device legislation which has come to be known as "General Controls". "General Controls" consist both of existing requirements and a number of new requirements established by the Medical Device Amendments of 1976.

This morning I will be focusing on some of the new requirements which will include

SLIDE 1—GENERAL CONTROLS

1. Establishment Registration,
2. Product Listing,
3. Ninety-Day Notification Provisions for New Products,
4. Good Manufacturing Practices,
5. Record and Reports Responsibilities, and
6. FDA's Inspection Authority.

Following this discussion, Marsh Abbey will discuss several existing requirements as well as several new enforcement techniques which fall within the "General Controls" category and which are available to the Food and Drug Administration.

It is important to emphasize that some of the general controls applicable to devices predate the new Amendments, others became effective upon enactment, while still others are dependent upon future promulation of regulations. As is true with many of the issues that will be discussed today, several of these controls are subject to various interpretations by industry and the Agency. I will attempt to point out both viewpoints, recognizing that many of the issues may not be resolved for some time.

SLIDE 2—ESTABLISHMENT REGISTRATION

The new Amendments extend to medical device manufacturers FDA's existing authority to require drug manufacturers to register their establishments. Those of you who represent *in vitro* diagnostic manufacturers know that since 1973 such manufacturers have also been requested by FDA to register their establishments with the Agency. In the future, all manufacturers of medical devices will be required to register their existing establishments on an annual basis. (Section 510) New facilities will have to be registered immediately upon opening. The Agency has indicated that it plans to commence initial device registration by late July or early August.

Despite its appearance, the drug establishment registration form is relatively easy to complete. A review of existing drug regulations at this point may be helpful in understanding when and which facilities will have to be registered. First, those regulations define "establishment" as a "place of business under one management at one general physical location" (21 CFR 207.3(B)). Secondly, drug regulations indicate that the term "immediately register" means within 5 days after the commencement of manufacturing operations (21 CFR 207.21).

You may be interested to learn that FDA is proposing to change its existing system for handling annual drug registrations. Earlier this year, FDA published a proposal to revise the time for annual registration of drug and *in vitro* diagnostic manufacturers (43 *Fed. Reg. 9183, March 3, 1976*). In essence, FDA proposed to amend its existing regulations and (1) establish a separate registration date for manufacturing facilities according to their location within Agency regions and (2) to reduce response time for registration from 45 to 15 days. In general, industry and the trade associations have opposed this proposal because it would place an undue burden on multi-state companies. I recommend that you follow this proposed regulation closely because if finalized, it will likely be applied to medical device manufacturers.

ther or not it is or may be substantially equivalent to a product marketed by another manufacturer. Under this theory, for example, if manufacturer "A" intends to market a thermometer which he had not marketed before, but which is a "me-too" device, substantially equivalent to a product marketed by manufacturer "B", the 90-day notice would be required.

Others believe that a section 510(k) notification is required only for those devices which are not substantially equivalent to a device on the market.

Another potential problem also exists. Let us suppose that manufacturer "A" has been marketing a thermometer for years and now desires to *modify* the product. Does a modification of a previously marketed product trigger the 90-day advance notification requirement? A reasonable interpretation would seem to indicate that notification is not required if the improvement or refinement does not present a fundamental change with respect to the product's safety or effectiveness. An opposite interpretation would introduce an additional hurdle to market entry for device manufacturers without regard to the safety and effectiveness parameters of the device. Again, I don't have the answers for these questions and can only recommend that these issues be followed closely until they are ultimately resolved.

Let us now turn to another of the general controls which will be made applicable to all manufacturers of medical devices; that is, Good Manufacturing Practice requirements, commonly referred to as GMP's.

SLIDE 6—GOOD MANUFACTURING PRACTICES

The Food and Drug Administration is authorized under Section 520(f) to promulgate regulations requiring that the methods used in, the facilities and controls used for, and the manufacture, packing, storage and installation of a device conform to Current Good Manufacturing Practices to assure that the device will be safe and effective and otherwise in compliance with the Act. Before FDA may promulgate GMP regulations, it must afford an advisory committee composed of nine persons, including two industry representatives, an opportunity to submit recommendations with respect to the proposed regulations and provide opportunity for an oral hearing.

Manufacturers may petition FDA for an *exemption* or *variance* from GMP requirements. FDA may, but is not required to, refer the petition to the advisory committee. A petition for an exemption from a GMP requirement will be granted if the Agency determines that compliance with that requirement is not required to assure that the device will be safe and effective and otherwise in compliance with the Act. A petition for a variance from a GMP requirement will be granted if the alternative procedure likewise assures the device's safety and effectiveness. FDA is required to act on a petition within 60 days of receipt or within 60 days after referral to the advisory committee, whichever is later. An informal hearing may be requested after a decision is rendered.

In anticipation of legislation, FDA has for some time been developing medical device GMP's. In August of 1975, the Agency made available its draft GMP regulations for comment. At that time industry responded with substantial comments putting into issue several concepts contained in the draft. The Agency has indicated that it is currently working on a document which is significantly different from the 1975 draft. Reportedly, FDA will take a more "goal-oriented" approach to GMP's with requirements in part dependent upon the critical or non-critical nature of the medical device. In the future the Agency is expected to develop supplemental GMP's, governing specific classes and characteristics of devices.

For those of you who may be unfamiliar with the concept of Good Manufacturing Practices, let me briefly discuss what you may expect.

Quality control and documentation of each step in the manufacturing process is at the very heart of GMP's. In addition, it is not unlikely that final regulations will touch upon your organization and personnel as well as your facilities and equipment. Production and process control requirements, a substantial documentation system, distribution and post-distribution practices, some form of product traceability, and complaint files and reworked product requirements will almost certainly be included in the GMP regulations.

If you have not already done so, there are a number of ways which you can begin to prepare for these regulations.

First, I would recommend that you review the August 1975 draft GMP for medical devices as well as existing and proposed GMP's for drugs. They will serve as a good indication as to those areas for which you should be concerned. Second, you should recognize that compliance with certain GMP's may require

SLIDE 10—INSPECTIONS

I would like to turn your attention to FDA's inspectional authority under the new Amendments *(Section 704)*. Under the new Amendments, the scope of FDA's authority is dependent upon whether the device is a "restricted device".

SLIDE 11—(Inspection Authority for All Devices)

As indicated by this slide, FDA's general inspection authority with respect to establishments where devices are manufactured, processed, packed or held extends to physical inspection of factories, warehouses, vehicles and all pertinent equipment, finished and unfinished materials, containers and labeling. This authority existed even prior to enactment, and is, of course, currently effective. As mentioned previously, the new Amendments also authorize the Agency to inspect records that are required to be maintained under the record and report and IND provisions. This authority exists for all devices, regardless of whether or not they are "restricted devices."

SLIDE 12—(Inspection Authority for Restricted Devices)

Under the new law, however, the Agency will have even greater inspection authority with respect to "restricted devices". For these devices, inspectors will have in addition to their general inspection authority, the right to review your records, files, papers, processes, and controls to determine whether a restricted device is adulterated or misbranded. In essence, the new law places FDA's inspection authority for restricted devices on a parity with its existing authority to inspect prescription drugs.

The question as to when a device becomes a "restricted device" and open to greater inspection scrutiny is subject to several interpretations. The Agency has taken the position in a June 4 *Federal Register* notice that the duty to permit FDA representatives to inspect records concerning restricted devices is immediately effective and declared all "prescription devices" as now defined by regulation, *21 CFR 801.109*, to be "restricted devices". Several manufacturers and several trade associations have taken issue with this interpretation. They contend that a device cannot obtain restricted status until the Agency formally promulgates a regulation with respect to that device. This would mean that the Agency's extended inspectional authority is presently inoperative.

SLIDE 13—(Limitations on Inspection Authority)

It should be pointed out that FDA's inspection authority is subject to several limitations. Inspections may not extend to financial data, sales data (other than shipment data), pricing data, personnel data (other than that relating to the qualifications of technical and professional personnel), or research data.

In closing, it should be remembered that the process of interpreting and implementing the provisions of the new Amendments is only beginning. During the course of this meeting and during the next few months, you will no doubt read and hear different interpretations of many of these new provisions. Perhaps this should not be unexpected in view of the comprehensive nature of the Act and the interrelationships of its provisions. However, until such time as the requirements become clarified definitively, it would appear that common sense and good faith attempts to comply will go a long way.

Thank you.

GENERAL CONTROLS-ENFORCEMENT TECHNIQUES

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PROVISIONS DEALING WITH ENFORCEMENT TECHNIQUES

I start with the hope that none of you will ever have any personal involvement with my subject. However, if the past is, indeed, prologue, my hope will probably not be fulfilled; and therefore we should look at those provisions of the Act which define violations of the Act and provide remedies for the FDA in the event that violations occur. (Slide 1) The provisions dealing with violations are those which spell out *prohibited acts* and those defining which devices are either *adulterated* or *misbranded.* Finally, I will cover three new remedies which are applicable to devices only and have been given to the FDA in connection with device enforcement by the Medical Device Amendments of 1976.

The statutory pattern of the Food, Drug and Cosmetic Act both before and after the recent Amendments, is built on definitions.

The Act states that a drug or device shall be deemed to be *adulterated*[1] or *misbranded*[2] if certain specified conditions or events have occurred in connection with the drug or device. Other provisions provide that a drug or device can be seized by the FDA once the product is adulterated or misbranded.

I have been asked to digress here and to describe seizure proceedings, which Rod Munsey discussed briefly. A seizure[3] is a court action by the FDA against certain goods. The drug or device may be seized at any time after it is adulterated or misbranded, whether in the hands of the manufacturer, distributor, or customer. The manufacturer or distributor that has a drug or device seized is then required to defend the seizure action in the courts, and these court actions are lengthy and time consuming. In addition, in serious cases the FDA may make multiple seizures and may seize all products everywhere the products can be found. The effect of the seizure is that the products seized cannot be sold or otherwise used unless the seizure action is concluded in favor of the owner of the products. The owner of the seized products frequently ends the seizure action by agreeing to a consent decree. The consent decree will require the manufacturer or distributor to do certain things, and this may include the recall of all similar products which may be on the market.

Returning to the statutory pattern—after defining adulterated and misbranded drugs and devices, the Act sets out various *prohibited acts,*[4] most of which deal with the shipment in interstate commerce of a drug or device which is either adulterated or misbranded. The FDA can obtain injunctions against the performance of the *prohibited acts.* In injunction proceedings[5] the FDA seeks to get the court to order to take some affirmative action, such as recalling the product or to stop doing some act, such as manufacturing or shipping products. The varieties of relief are limited only by the imagination of the FDA and the court. Frequently in an injunction proceeding the FDA will attempt to get a temporary restraining order or TRO. In acute situations, the TRO can be obtained *ex parte,* that is by the FDA going before a court with little or no opportunity for participation by the defendant. The FDA usually gives the manufacturer notice that it is going for a TRO, but the notice is very short—sometimes less than one hour. If the judge grants the TRO, the manufacturer can find that it is prohibited from shipping products until the TRO is lifted. This is obviously a major blow to the defendant, since it will usually shut down the facility until the manufacturer does everything the FDA wants.

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[1] 21 USC 501
[2] 21 USC 502
[3] 21 USC 304
[4] 21 USC 301
[5] 21 USC 302

in unregistered facilities,[16] those devices not listed with FDA, and devices for which the required notice of proposal to begin marketing has not been given.

Through the new definitions of adulteration and misbranding, and the procedure by which they invoke the old enforcement remedies, there are ample teeth in the newly imposed regulatory obligations. However, the device amendments go even further, and give the FDA three new enforcement remedies. These are applicable to devices only, not drugs, and are further evidence that the FDA's authority over devices is now greater than its authority over drugs.

Now the new enforcement remedies. (Slide 4.)

BANNED DEVICES[17]

A new provision has been added to the Act dealing with *banned devices.* If the FDA finds that a device presents "substantial deception or an unreasonable and substantial risk of illness or injury", the FDA can start a proceeding to promulgate a regulation to make a device a banned device. The Act requires that the FDA give the manufacturer an opportunity for an informal hearing on the regulation.

Because this remedy is extreme, the statute provides both procedural and substantive checks on its use.

Four steps are involved in the banning of a device. First, the Agency must find that continued marketing of a device presents a substantial deception or an unreasonable and substantial risk of illness or injury.

Second, the FDA is required to consult with the appropriate classification panel on the Agency's findings. However, legislative history indicates that this procedure should not act to delay substantially the banning process.

Third, the FDA must make a positive determination that additional labeling or changes in labeling would not be adequate to correct or eliminate the deception or risk. Conversely, if the FDA determines that revised labeling would rectify the problem, the banning process will be suspended. The involved manufacturer must be notified in writing and be given the opportunity to comply with the Agency's directives on labeling. The manufacturer will be afforded a reasonable but defined period in which to comply. If the manufacturer fails to comply, the banning process will be resumed.

Fourth, the banning process is consummated by publication of a proposed regulation in the *Federal Register* to ban a device. At this juncture, interested persons (which would include the manufacturer) will be afforded an informal hearing before the Agency. A device subject to a proposed banning regulation may remain on the market until a final order is published in the *Federal Register.* The final order will either affirm, modify or revoke the proposed banning regulation. Any final banning regulation will require the expeditious removal of the device from the market since, as I have noted, a banned device is an adulterated device.

All that I have said so far represents what the Amendments call the "General Rule". You should also be aware of the special procedure found under the innocuous title, "Special Effective Date". Under this provision the regulation banning the device can be made effective *immediately* upon its publication in the *Federal Register,* if the FDA finds an "unreasonable, direct, and substantial danger to the health of individuals". The FDA must notify the manufacturer before the order becomes effective, but all the procedural steps take place after the effective date. Since banning is a drastic remedy in all cases, I personally doubt that the FDA will often invoke it under the "General Rule" and that we will find that the "Special Effective Date" provision, in fact, becomes the general rule.

ADMINISTRATIVE RESTRAINT[18]

I have already noted that the FDA had, and continues to have, the power to *seize* a device which is adulterated or misbranded. However, the seizure procedure is somewhat cumbersome and is generally not invoked unless the FDA is relatively sure that the seizure will be upheld by the courts. This left the FDA with little remedy when it came across a product that it thought might be adulterated or misbranded, but one in connection with which the necessary data and other information were not available. This minor gap

[16] 21 USC 502 (o)
[17] 21 USC 516
[18] 21 USC 304 (g)

couraged the use, by the manufacturer, of *product recalls* which might consist, in the FDA's definition, of a letter to customers warning of risks, a correction of the product in the field or the actual return of the product from the field. The recall is a non-statutory remedy, not mentioned in the Act, and, in cases where the manufacturer felt it was not warranted, performed by the manufacturer only to avoid the imposition of other statutory remedies. Only experience will tell us whether notification and the 3R's will replace recalls; I doubt it. I believe recalls will still be favored by the FDA since they can be conducted promptly and enable the FDA to avoid making the findings and going through the other procedures which are required before the new remedies can be invoked. The real significance of the new remedies lies in the fact that the FDA can use the threat to invoke them as a means for getting the manufacturer to agree to a recall.

In those cases in which the new remedies are invoked, the FDA will be getting involved in our customer relations. When that involvement occurs, it will be more expensive for us than ever before to have a defective device or one which the FDA might conclude presents an unreasonable risk. In short, the price of non-compliance with the Act has increased further.

Slides 1 and 4

OVERVIEW

Violations and remedies
- Prohibitive acts
- Adulterated devices
- Misbranded devices
- Banned devices
- Administrative restraint
- Notification, repair, replacement and refund

Slide 2

DEFINITION OF ADULTERATED DEVICES

OLD
- Filthy substance
- Unsanitary conditions
- Strength or quality differs from labeling

NEW
- Doesn't conform to performance standards
- Doesn't have required premarket approval
- Is a banned device
- Non-conformance with GMP's
- Fails to comply with investigational use exemption

Slide 3

DEFINITION OF MISBRANDED DEVICES

OLD
- False labeling
- Omits required language
- Dangerous to health

NEW
- False advertising
- Advertising omits required language
- Omits language required by performance standard
- Does not bear established name
- Failure to keep records and make reports
- Devices produced in unregistered facility
- Devices not listed
- Required notice of proposal to begin marketing not given

Slide 5

RISK NOTIFICATION AND COMMERCIAL REMEDIES (NEW SEC. 518)
- Notification
- Repair
- Replacement
- Refund of purchase price

vant to technical characteristics of the device on a sample or individual basis as indicated by the situation.

The regulatory standard may also include a provision for measuring the performance characteristics of the device by quality control procedures or means for users to ascertain device performance.

The regulatory standard may also require that the results of the tests required demonstrate that the device is in conformity with the portion of the standard for which the test was required. Congress gives direction to the Agency in how to implement this provision by suggesting that the Agency direct the manufacturer either to certify to the purchaser that the device conforms to an applicable performance standard or to periodically make such certification to the Agency.

According to the statute, the standard may also include provision restricting the sale and distribution of a device, but only in accordance with a regulation issued under the restricted device provision which will be discussed later in the program.

Where appropriate, the standard may also control labelling for the installation, maintenance, operation, and use of the device by dictating instructions, warnings, storage and transportation information, expiration dates, results, accuracy of diagnosis, maintenance instructions, and accessory equipment to be used. It can also specify that the device is only considered safe and effective when used on a patient properly diagnosed as having a condition for which the device is indicated.

With all these provisions available, the obvious problem is that if the Agency is not careful in stating the risk identified and directing the means it believes necessary to control it, the regulatory standard could be too all-inclusive a document. That is not what Congress seems to have mandated, but our Associations are concerned that it may be happening today.

Before the present law passed, FDA began activity in the standards field. FDA has let contracts and received drafts, and voluntary groups have submitted documents as proposed standards. PMA and HIMA have watched these developments closely and are concerned that FDA has not exerted enough influence to direct the process in the right direction. We're worried that FDA hasn't sufficiently identified the problem associated with the products involved and outlined what provisions it feels are necessary to control the problem. So the drafts being submitted are much broader than we think they should be. And in at least one instance, documents generated by standards drafters have even specified that a rationale as to why the standard is necessary will be developed after formulation of the standard. Unfortunately the proposed contracts do ask the contractor to do this job—which logically should be an Agency function.

The House states in its Report that it intends for the Agency to make the statement of risks and a summary of the data showing the need for a standard. This need not be exhaustive, but it seems clear that the Agency must do more than make a token effort. Whether it has done so is somewhat debatable. I saw a contract where the Agency directed to do a comprehensive literature search; a survey of national and international standards; and a survey of manufacturers in the field. Then the contractor was to review and summarize the collected data for use in drafting a standard, and he was to draft and mail the proposed standard to interested persons for comment. The flaw is the combination of the information gathering with the standard writing. It would make much more sense for FDA to separate the two. FDA must get information, but it should not do it at the expense of the statutory process Congress created.

The question of how FDA should get the necessary information is an interesting one. The Agency has a limited number of options. It could do the work itself; it could pay someone to do it; or it could ask us to do it. I doubt FDA will bo the work itself. Since the panels need the data, I think FDA will develop a mechanism for them to get it either from contractors or from us directly. Either way the bottom line is that someone will undoubtedly be asking us for information. At that point we may have a problem.

We've argued FDA should not act hastily; we've argued the panels should identify risks. Now they want the information to make those determinations, and we'll have to respond in some fashion. We could say, let FDA contract to have someone get it and not cooperate with them, but then we'd be at the mercy of an outsider who might collect data about our products and not do a good job, or do it but draw the wrong conclusions from the data. An additional complication is that efficacy under the bill can be proved by other than well-controlled investigations, and our use experience—which may not be in the public domain—could be vital in support of a claim for lower classification, or no or a lesser standard. So we may want to cooperate with groups hired by FDA to gather data or we may have to help the panels or be at risk. The form and exent of that effort is something we all need to be thinking about, for the requests have already started to come.

Once the panels get the data, they will have to analyze it and identify the risks they feel warrant plac-

degree of safety and efficacy or the use of technology so advanced and so costly that the device would not be readily available to the health care field. This does not mean that reasonable safety and efficacy should not be a desired goal; it merely means that there is a level of performance which is readily acceptable by the medical profession.

The Agency has not officially reacted to these suggestions. Instead it appears to be continuing its present effort, which seems to be divided into two parts. The first is the development of so-called baseline standards, for such things as electrical safety, biocompatibility and the like. These are to be developed in conjunction with specific performance standards.

The baseline standard may pose the biggest problem, for presumably it will apply to all devices it could conceivably apply to—regardless of whether a real need has been shown for any particular device.

The thinking behind this type of standard is undoubtedly influenced by the work which has been going on for years with the so-called voluntary standards. These documents are for the most part extremely broad in format and content, and set forth objectives with which a manufacturer may comply. But these voluntary standards are not what we believe Congress mandated for a performance standard. Congress didn't dictate a 25 or 30-point format, each aspect of which had to be covered in the standard. It suggested provisions that could be included where necessary. The voluntary standards have been evolving for a long time. They're written by groups who really have no other function. Quite naturally, these groups are shifting gears and drafting documents to be submitted for acceptance as regulatory standards. Our people involved in this effort have reported that the groups are drafting the same kind of documents they've always drafted; however, I think FDA must watch this process very closely, and give even more guidance to the voluntary groups than to contractors. The Agency will have to delineate clearly to these groups what the law requires and what the Agency will accept as complying with the law. The groups themselves need to reexamine their charters and drafting procedures, and to more carefully channel their efforts, so that great expenditures of time are not made in drafting provisions which are not necessary for the regulatory standard Congress directed. For while these sweeping documents had no legally binding effect as consensus standards, as regulatory standards they will be the basis for legal action—including criminal prosecution—if adopted by FDA. As with the contract process, much of this extra effort can hopefully be eliminated when the Agency more clearly identifies the risk associated with use of a device and outlines the provisions it feels are necessary to control or eliminate that risk.

Opinions differ widely on the importance of the standard process. Many people feel we don't need to worry about the problem now, for it will take a couple of years before there are any standards and 30 or 40 years before they are all written. That is undoubtedly true, but it's clear that over one half of our products will be in standards and we'll eventually have to comply. So we need to resolve the format question early on, or when the standards start coming, they'll cover far more than we think they should.

In order to participate intelligently in this whole process you need information on what's going on. How can you get it?

The FDA is one good source. It is supposed to respond to requests for information on classification. It also puts out a standard survey, which includes information on voluntary groups involved in the process, contractors who have received bids and the status of its various projects.

HIMA and PMA can also provide this information. They are set up to monitor FDA's activities, give out information on what's going on, and coordinate comments on proposed drafts. Mary Lynch and Jack White of HIMA, and Jan Donelson and George Smith at PMA can get you this information.

To conclude, let me just briefly run through some of the standards being drafted. If you're not familiar with some of them, you may want to note ones that could affect you.

The current draft standards include a cardiac defibrillator standard, a cardiac pacemaker standard, a disposable insulin syringe standard, and a hearing aid standard. Contracts have also been let for research on spirometers, endotracheal tubes, cardiovascular implants, cardiac monitoring systems, incubator/infant warmers, and continuous flow anesthesia machines. Baseline standards underway include electromagnetic compatibility, electrosurgical unit standards, performance and safety of electrosurgical devices, general safety requirements for electric equipment used in medical practice, high-frequency electric equipment in hospitals, dental materials, and orthopedic implant materials. PMA or HIMA can get you additional information on any of these if you need it.

PREMARKET APPROVAL/PRODUCT DEVELOPMENT PROTOCOLS

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"It's not the law that is important, it's the execution of the law that is important." This adage was never more applicable than with the premarket approval of medical devices.

I. THE NEED FOR PREMARKET APPROVAL OF CERTAIN MEDICAL DEVICES

The need for premarket approval of certain medical devices was stated at the 1973 hearings before the Senate Subcommittee on Health. Senator Kennedy stated that: "The people of this Nation are at risk today of suffering serious injuries from defective medical devices. It is a situation which cannot, need not and will not be tolerated any longer." Dr. Edwards (Assistant Secretary for Health, Department of Health, Education and Welfare) testified further that: "The increasing sophistication of medical devices has outpaced the Department's ability to protect the public from those that are faulty. One reason for this is that current law imposes no duty upon medical device manufacturers to establish the safety or efficacy of their products prior to marketing."

A. History of Medical Device Regulation

1. *Medical Device Regulation under the 1938 Act*

Any discussion of medical device regulation should begin with the 1938 Federal Food, Drug and Cosmetic Act. At the time the 1938 Act became law, many of the devices on the market were relatively simple items which could be readily determined to be functioning properly or improperly by the physician using them. Under the 1938 Act, the FDA's authority was limited to taking action *after* a medical device was offered for introduction into or within interstate commerce; and then the FDA could take action *only* with respect to devices which were "adulterated" or "misbranded" (the 1938 Act was not amended with respect to its device authority prior to the Medical Device Amendments of 1976). With respect to a device deemed adulterated or misbranded, the FDA's enforcement mechanisms were (1) seizure, (2) injunction and (3) criminal prosecution. All of these enforcement mechanisms require court action, and are somewhat cumbersome and time consuming to effectuate.

2. *Early FDA Concerns and Activity*

Prior to 1960 much of the FDA's activity was with respect to protecting the American public from bogus devices. In fact, bogus devices were the major concern of Congress in 1938 when it gave the FDA the authority to regulate devices. Although, at first blush, the fantastic claims which were made for bogus devices may now seem amusing and harmless, such claims induced purchasers to forego seeking timely and appropriate medical treatment and instead to use the bogus devices.

The difficulty the FDA encountered with respect to the regulation of bogus devices is illustrated by the vast amount of effort they expended in taking the diapulse device from the market. The diapulse device was a heat-generating device which was marketed to medical practitioners for some 121 therapeutic claims, none of which could be substantiated by scientifically valid data. The first seizure of a diapulse device occurred in December of 1965. As a result of lengthy court proceedings against the device and company appeals, it was not until 1972, seven years after the initial seizure, that an injunction against the manufacturer was finally obtained.

3. *Recent FDA Concerns and Activity*

About 1960 the FDA began focusing its attention on the hazards associated with the use of legitimate medical devices. The medical device industry grew tremendously in the 1950's and 1960's due to medical technological advances which led to the development and widespread use of artificial implants, electronic,

ter of (1) 30 months after the device was classified into Class III, or (2) 90 days after promulgation of the regulation requiring premarket approval of the device. [§515(b)(1) and §501(f)(2)]

Note that the 30-month period runs from the date the device was classified into Class III and not from the enactment date. Note further that the proceedings required to promulgate a regulation requiring premarket approval is to be initiated in each instance by a *Federal Register* notice of the proposed rulemaking. Only upon expiration of the period for comment upon the proposed rulemaking and after consideration and denial of any comments for classification other than Class III, may the FDA promulgate the regulation requiring premarket approval of the "old device". [§515(b)(2)]

C. *"New Device" Requirements*

"New devices" are deemed in Class III pursuant to §513(f) and will stay in Class III, absent entitlement to Class I or II pursuant to a petition for such classification under §513(f)(2).

The consequences of having a "new device" in Class III are grave indeed. The reason: There is no grace period for "new devices" which are in Class III—these "new devices" must have an approved application for premarket approval or an effective notice of completion of a PDP before they may be marketed.

However, please note that just because a device was not in commercial distribution on the date of enactment does not necessarily mean that the Class III device has no grace period.

For example, a device introduced after enactment and "substantially equivalent" to a Class III "old device" will be regulated in a manner identical to the "old device." That is, this later-introduced Class III device will share all or a part of the statutory grace period afforded to its pre-enactment Class III counterpart. Thus, if a pre-enactment device is classified in Class III as of September 1, 1976, it would have until February 28, 1979 (30 months) to secure premarket approval. The later-introduced "substantially equivalent" Class III device would share the full 30-month grace period, if introduced before September 1, 1976; but if introduced after such date, for example, on January 1, 1977, the "substantially equivalent" Class III device would have a grace period of 26 months (until February 28, 1979) to secure premarket approval.

The net effect is a grace period[1] for each *type* of Class III device in commercial distribution at the date of enactment. During this grace period, it will make a difference whether the Class III device which is proposed to be marketed is or is not "substantially equivalent" to another Class III "old device" of that same type. However, once this initial grace period has expired for that type of device, it will make no difference whether or not the Class III device proposed to be marketed is or is not "substantially equivalent" to another Class III device of that type. That is, once the grace period for a type of Class III device has expired, any additional Class III device within that type will be treated as a "new device" and will need to have an approved application for premarket approval or an effective notice of completion of a PDP in effect prior to being marketed.

With respect to a device which is to be marketed—whether next month or 10 years from next month—if it is "substantially equivalent" to a device in Class I or Class II, it may be marketed pursuant to the requirements of that Class.

D. **Implants and Life Supporting or Sustaining Devices**

Devices intended to be implanted in the human body and devices purported or represented for use in supporting or sustaining human life are subject to special requirements. [§513(c)(2)(C) and §513(f)(2)(c)] Implants and life-supporting or life-sustaining devices will be termed "critical devices" for purposes of this discussion. All other devices will be termed "non-critical devices".

It's difficult to find any legal difference between the criteria used for classifying the "critical devices" and those used for classifying the "non-critical devices". "Critical devices" must be subject to Class III premarket clearance requirements unless general controls and/or standards are sufficient to provide a reasonable assurance of safety and effectiveness. "Non-critical devices" will be subject to general controls and/or standards and not to premarket clearance if general controls and/or standards are sufficient to provide reasonable assurance of safety and effectiveness. In some senses, these criteria seem the same; how-

[1]The grace period is: The period beginning upon the date of enactment and terminating at the later of (1) 30 months after the device was classified into Class III, or (2) 90 days after promulgation of the regulation requiring premarket approval of the device.

clined and find it easier to declare a PDP completed because it had a hand in developing that PDP, than it will be to approve an application for premarket approval.

A. Choosing Between PDP and Premarket Approval

Chart I*sets forth the sequence of events with respect to the PDP and premarket approval approaches, and may be helpful in comparing the two approaches.

Before going through the events one-by-one, it may be helpful to review two of the more significant differences between the two approaches. First, under the investigational use exemption of §520(g) of the premarket approval approach, the plan for proposed clinical testing of a Class III device is required to be submitted to a "local institutional review committee," and, if no such committee exists, to the FDA for review. No comparable peer review committee requirement is set forth for a PDP in §515(f). Second, under the PDP approach, the FDA has 120 days to approve or disapprove a proposed protocol submitted to it pursuant to the requirements of §515(f)(2). Contrariwise, under the premarket approval approach, the FDA may disapprove an investigational use exemption only if they find that the application does not conform to the procedures and conditions prescribed by the regulations established under §520(g), and any such application shall be deemed approved on the thirtieth day after the submission, unless the FDA by order disapproves the application on or before such date.

B. Product Development Protocol (PDP) Sequence of Events

The PDP sequence of events (assuming no complications) is as set forth in the top portion of Chart I. The Amendments encompassing the PDP approach were enacted May 28, 1976, and, thus, May 28, 1976, is the sequence of events' starting point.

Event 1

A proposed PDP for a Class III device is submitted to the FDA. [§515(f)(2)] Assuming that the proposed PDP meets the statutory requirements, then: (a) the FDA has 30 days to determine whether or not it is appropriate to apply the PDP requirements to this device [§515(f)(2)]; and (b) the FDA has 120 days to approve or disapprove the proposed PDP. This 120-day time period can be extended only upon agreement of both parties. [§515(f)(4)]

The proposed PDP must include:

(a) a description of the device and the changes which may be made in the device;

(b) a description of the preclinical trials (if any) and the clinical trials;

(c) the preclinical and clinical trial results which are required;

(d) a description of the process and control utilized in manufacturing the device;

(e) a requirement of submission of progress reports and records showing compliance with the PDP; and

(f) such other information as is deemed appropriate and relevant. [§515(f)(3)(B)]

Event 2

The FDA determines that the proposed PDP appears to be appropriate for the Class III device. [§515(f)(2)]

Event 3

The FDA submits the proposed PDP to an advisory panel for its recommendation respecting approval of the protocol. [§515(f)(2)]

Event 4

The FDA approves the PDP. [§515(f)(4)]

Event 5

A notice of completion of the approved PDP is submitted to the FDA. According to §515(f)(5), this notice of completion may be submitted at any time after the FDA approves the PDP (Event 4). However, since this notice is to be submitted only upon completion of the PDP, and, according to §515(f), is required to state that there is no known reason bearing on safety or effectiveness why a notice of completion should not become effective, the time between FDA approval of the PDP (Event 4) and submission of a notice of completion of the approved PDP (Event 5) will, in most instances, likely be several

*Consult Appendix L for references to Charts I, II and III.

Event 6

The FDA, by order, approves the application for premarket approval. [§515(d)(1)(A)]

This process may sound rather simple and short; however, it probably will not be simple, and, most assuredly, will not be short. The following paragraph, contained in the Report of the House Committee, may be illuminating in this regard:

> "As noted above, action on the application [for premarket approval] must be taken by the Secretary [FDA] within 180 days of its receipt. Of course, 'receipt' of an application should be construed by the Secretary as receipt of an application containing all information required by the proposed legislation and regulations issued thereunder. However, the Committee is well aware of a current practice of the Food and Drug Administration with respect to new drug applications (which also must be approved or disapproved within 180 days of receipt) whereby such applicants are often notified of a need for more information only a few days before the 180-day statutory period expires. The Committee does not intend that this be the practice with respect to applications for premarket approval of devices. Applicants should be notified of deficiencies promptly and should be afforded statements of the measures required to place their applications in approvable form so that they may be submitted to classification panels."

D. **Product Development Protocol (PDP) Procedural Complications**

The sequence of events illustrated in Chart I which led the device to the full marketing status assumes FDA approval at each and every stage. In the process of obtaining either premarket approval or an effective notice of completion of a PDP, certain complications can occur. These complications are illustrated in Chart II. If these complications occur, then, in each case, the applicant is prevented from proceeding further until and unless the complication is removed or resolved.

Potential complications in the PDP approach are set forth in the top portion of Chart II.

Complication 1

The FDA determines that the proposed PDP is not appropriate for the device and does not submit it for recommendation to the advisory panel. [§515(f)(2)]

Complication 2

The FDA disapproves the proposed PDP. [§515(f)(4)]

Complication 3

The FDA, by order, revokes approval of the PDP. [§515(f)(6)] The specific provisions under which the FDA can revoke approval of the PDP are set forth in §515(f)(6)(A). These conditions relate to: (1) substantial failure to comply with the requirements of the PDP; (2) further trials cannot be justified based upon the results obtained under the PDP; (3) the results or new information do not demonstrate that the device does not represent an unreasonable risk of health and safety as tested under the PDP. [§515(f)(6)(A)]

Complication 4

The FDA, by order, declares the PDP not completed. The specific provisions under which the FDA can declare the protocol not completed are set forth in §515(f)(6)(B). These conditions relate to: (1) failure to comply with PDP requirements; (2) the results of the PDP trials are substantially different from the results required by the PDP; or (3) there's a lack of a showing of reasonable assurance of safety and effectiveness of the device. [§515(f)(6)(B)]

Complication 5

The FDA, by order, revokes the approval of a device provided by the notice of completion. [§515(f)(7)] The grounds for making such revocation are set forth in §515(e)(1) and are identical to the grounds for withdrawing the approval of an application for premarket approval.

E. **Premarket Approval Procedural Complications**

Potential complications in the premarket approval approach are set forth in the bottom portion of Chart II.

Those instances include:

a. with respect to a PDP;

(1) upon petition filed on or before the thirtieth day after receipt of notice of an order, where the manufacturer was entitled to an informal hearing before the order was issued. [515(g)(1)(B), §515(f)(6)(A), §515(f)(6)(B)]

b. with respect to premarket approval;

(1) upon petition filed on or before the thirtieth day after receipt of notice that an application for premarket approval was denied. [§515(g)(1)(A), §515(d)(3)]

(2) upon petition filed on or before the thirtieth day after receipt of notice of that approval of an application for premarket approval was withdrawn. [§515(e)(2)]

3. *Advisory Committees*

Advisory committees shall be established (which may not be panels established under §513 for classification purposes) as an alternative remedial mechanism to formal hearings. [§515(g)(2)(B)] In any instance in which an applicant is entitled to a formal hearing, review by an advisory committee may be elected instead. The advisory committee shall, after a study of the data and information before it, prepare a report setting forth its recommendations and the reasons or bases for the recommendations. [§515 (g)(2)(A)]

Whether, and if so, in what circumstances it would be advantageous to select the advisory committee review over a formal hearing is difficult to answer until the regulations are promulgated prescribing the procedures to be followed by the advisory committee. However, please note that instead of the trial type proceeding that the formal hearing offers, the advisory committee offers an advisory committee staffed by experts in the field who are to independently study the data and information before them and to prepare a report which will be made public. [§515(g)(2)(B) and §515(g)(2)(C)]

4. *Judicial Review*

Persons adversely affected by the regulations or orders enumerated in §515(a) may file a petition for judicial review in the United States Court of Appeals for the District of Columbia or for the circuit where such person resides or has his principal place of business. With respect to the PDP process and the premarket approval process, judicial review under §517 is available with respect to the following orders:

a. orders with respect to a formal hearing under §515(g)(1);[3]

b. orders with respect to an advisory committee under §515(g)(2)(C);[4]

c. orders disapproving an application for an exemption of a device for investigational use under §520(g)(4); and

d. orders withdrawing an exemption of a device for investigational use under §520(g)(5).

In addition, judicial review is available to a person suffering a legal wrong because of final agency (FDA) action or adversely affected or aggrieved by final Agency action. [5 USC §702] FDA approval or denial of approval of a proposed PDP is specifically identified as constituting final agency action subject to judicial review. [§520(f)(4)]

5. *Third Party Remedies*

Third parties are entitled to procedural review at certain stages in the PDP and premarket approval processes.

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[3]When the formal hearing mechanism of ¶515(g)(1) is used, judicial review is available for the following orders:

1. the order approving or denying approval of an application for premarket approval;
2. the order withdrawing approval of an application for premarket approval;
3. the order revoking an approved PDP;
4. the order declaring the PDP not completed; and
5. the order revoking the notice of completion of the PDP.

[4]When the advisory committee mechanism of §515(g)(2) is used, judicial review is available for the following orders:

1. the order approving or denying approval of an application for premarket approval;
2. the order withdrawing or denying the withdrawal of approval of an application for premarket approval;
3. the order revoking or denying revocation of an approved PDP;
4. the order declaring or refusing to declare the PDP not completed; and
5. the order revoking or denying revocation of the notice of completion of a PDP.

Note the additional orders which are subject to judicial review under ¶517 when the advisory committee mechanism of ¶515(g)(2) is elected instead of the formal hearing mechanism of ¶515(g)(1).

INVESTIGATIONAL USE EXEMPTION/CUSTOM DEVICE/ RESTRICTED DEVICE

John Kuchta
Vice President, Governmental Affairs and Product Assurance
Zimmer-USA, Inc.

INTRODUCTION

It has been only a few weeks since the Medical Device Amendments were signed into law by President Ford. At that time, the Legislation was applauded by some as "a landmark piece of legislation", ***"supported by both industry and consumers with all the critical issues resolved adequately for both groups." The Bill was also referred to as an important "symbol for the kind of regulation that *** is most appropriate to government". The events thus far today, undoubtedly indicate that a great deal of work is required before all issues are appropriately resolved and before the law becomes a symbol of good regulation and no less ideal regulation.

This afternoon, I will be talking about the sections of the law relating to Restricted Devices, Custom Devices, and Devices for Investigational Use. For the most part, I will be sharing with you my understanding of these sections as well as suggesting to you guidelines for compliance.

My first topic will be Restricted Devices.

RESTRICTED DEVICES

What is a Restricted Device?

Section 520(e) tells us that the Secretary may by regulation require a device be restricted to sale, distribution or use:

- on a prescription basis, or
- upon such other conditions as the Secretary may prescribe.

These restrictions are conditioned upon a published finding that the device or the collateral measures necessary to its use are potentially harmful and there cannot otherwise be reasonable assurance of the device's safety and effectiveness.

Restrictions may limit the use of a device:

- to persons with specific training or experience in its use, or
- for use in certain facilities.

Use restrictions, however, cannot be based upon a finding that the person does not have:

"The training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such board."

Briefly then "Restricted Devices" are devices which may be sold or distributed only upon the oral or written authorization of a licensed practitioner or upon such other conditions as the Secretary may prescribe. Conditions limiting the use of a device to health professionals including physicians having certain training or experience may be imposed, but not on the basis of their certification or lack of certification by the American Board of Medical Specialties. Moreover, a "Restricted Device" could be limited to use within certain facilities such as hospitals and clinics.

What additional controls or prohibitions are placed upon "Restricted Devices" as compared to non-restricted devices?

The label of a "Restricted Device" must bear such appropriate statements of the restrictions as required by regulations (Section 520(e)).

- That the device or the collateral measures necessary to its use are potentially harmful,
- that "Restricted Device" controls are necessary to reasonably assure protection from the potential harm, and
- that other reasonable and lesser controls cannot provide such assurance.

What can we as manufacturers do about FDA's June 4th notice?

Review the June 4th regulations. If you question FDA's interpretation of the Act and its right to designate prescription devices as "Restricted Devices" without determinations of safety and effectiveness and without utilization of the regulatory process, file your comments with FDA. Your comments should include concrete examples why FDA's approach is inappropriate. These examples can be developed through an analysis of the risks associated with your currently marketed prescription devices and analysis of the need to apply "Restricted Device" controls to deal with such risks.

A simple starting point for such an analysis is intrinsic to the Code of Federal Regulations Title 21, Section 801.109. It involves the examination of your products with respect to the following package insert headings which we at Zimmer have devised and found suitable for a wide range of our products which require package inserts.

The headings are:

Description
Indications
Contraindications
Warnings
Precautions
Adverse Effects
Utilization or Implantation
Sterility
How Supplied

The *DESCRIPTION* section relates generally to the composition, structure, design and functionality of the device. Joint replacements and pacemakers by their very description and required training for application would strongly indicate "Restricted Device" classification.

The *INDICATION* section is one of the best guides. A condition that the device is used for, that must be diagnosed by a licensed practitioner would normally indicate the device should be "restricted". This is especially true in those instances where some form of instrumentation diagnosis is used; that is x-ray, myelograms, blood tests, etc.

CONTRAINDICATIONS, not readily definable or understood by the ordinary individual, would also suggest "Restricted Device" control.

The *WARNINGS* and *PRECAUTION* sections are good guides. If special training and experience are required to understand device warnings or to understand precautions or to avoid serious consequences, then "Restricted Device" status would seem appropriate.

ADVERSE EFFECTS - A device with the capability of causing serious side effects from improper use would most likely be "restricted". A literature search may be appropriate in determining "side effects", potential and risk.

UTILIZATION - Precision of application, certain anatomical considerations, or a duration of treatment with a specific end point obviously would in many cases require certain experience and training for safe use. Consequently, these considerations may suggest "Restricted Device" classification for many devices.

Similar consideration should be given to the headings *STERILITY* and *HOW SUPPLIED.*

Such a review should provide you with sufficient data to make an initial determination of whether the device should be regulated as a "Restricted Device". If the potential for harm uncovered by your review can be overcome by adequate directions for safe use by the layman, the device should not be designated a prescription device or a "Restricted Device".

Parenthetically, many of you I'm sure will find that some of your products carry a prescription label for other reasons than required by current or past device legislation. For example, a prescription designation may have been necessary to comply with the State Drug Abuse Laws (as an example, hypodermic syringes). You may have utilized prescription labeling and distribution because of problems relating to

1. The device must not generally be available for commercial distribution or be generally available to other health professionals, and
2. The device must be intended for a specific patient named in the device order, or intended to meet the special needs of the authorized health professional for use in his professional practice.

The exemption does not exempt "Custom Devices" from otherwise applicable provisions of the law, such as provisions relating to investigational use, restricted devices, adulteration, misbranding, good manufacturing practices, etc.

It is important to understand that there is a distinction between "Custom Device" in the legislative sense and "Custom Device" as the term is used commercially. "Custom Device" in the commercial sense relates generally to tailor-made products. Unless the tailor-made product must deviate from an applicable performance standard or must comply with premarket clearance criteria, the device would not be a "Custom Device" in the legislative sense.

In order to utilize the custom device exemption, it will be necessary for manufacturers to establish a control system for identifying situations which will permit the use of the exemption and insure that the requirements of the Act are met.

A suggested approach is as follows:

1. Determine whether the product order necessarily results in a deviation of an existing performance standard. At the present, this should be a relatively simple task, as no standards have been promulgated for medical devices. A standard determination, however, may become extremely burdensome in the future.
2. Determine whether the product is a Class III device.
   The critical questions here are:
   a) Is the product substantially equivalent to a device which has been classified in Class III, or
   b) Is the product substantially different from other marketed devices?

Care should be taken in making a Class III determination, since while a product may seem destined for classification in Class I or II, Section 513(f) requires all new devices to be automatically classified in Class III where they remain until declassified.

Substantial equivalence or substantial difference determinations must relate to differences or similarities which are material to the safety and effectiveness of the product. As a rule of thumb, simple variations of existing products such as variations in size, shape, or color would have a tendency to fall out of the area of premarket clearance. On the other hand, premarket clearance would seem more likely for orders which:

change the function or intended use of an existing product, or

are not substantially equivalent to existing products in terms of characteristics material to safety and effectiveness.

If a decision is made that the product requires the "Custom Device" exemption, it will be necessary to have documentation confirming that the order is being filled for an authorized health professional. Documentation should also indicate whether the device is to be utilized for a specific patient or for the purchaser's individual practice. Reorders of a particular "Custom Device" will have to be monitored to determine whether they are of such a frequency that the device has become "generally available" or is "generally" being used by the medical community. It is difficult to speculate when a device will become generally available or when it is being generally used; however, practice and *ad hoc* experience will certainly result in guidelines for such determinations.

It also will be necessary for manufacturers to monitor their labeling and advertisements in order to assure that "Custom Devices" are not being offered through such commercial avenues. This may prove to be extremely difficult since, under food and drug law, advertisements not only include traditional sales material appearing in printed and broadcast media, but also relate to such items as brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, etc. Moreover, labeling refers to all written, printed or graphic matter which may or may not physically accompany a device in commerce. Thus, labeling can include displays, booklets, leaflets, circulars, etc., and may also include oral representations.

While the "Custom Device" provision offers some relief to the medical device community, the many restrictions and limitations placed upon its use will require extensive scrutiny and review by industry.

4. A description of any benefits reasonably to be expected;
5. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
6. An offer to answer any inquiries concerning the procedures;
7. An instruction that the subject is free to either decline entrance into the project or to withdraw his consent and to discontinue participation in the project or activity at any time without prejudicing his future care;
8. The anticipated scope of the investigation; and
9. The approximate number of subjects to be involved in the study.

An application submitted in accordance with FDA regulations for an Exemption (other than an Exemption from the Banned Device Provision, Section 516) is automatically approved on the 30th day after the submission unless expressly disapproved by the Secretary prior to that time. The Secretary may disapprove an application only if he finds that the investigation does not conform to procedures and conditions prescribed by FDA regulations.

A flow chart of the Investigational Exemption Procedure and Zimmer's Clinicial Investigator's Agreement is set forth in Attachment 1.

What can you as a manufacturer do in anticipation of FDA regulations on the Investigational Use Exemption?

As discussed, there are sufficient requirements in the legislation to enable manufacturers to develop a system to obtain and monitor exemptions for the investigational use of medical devices. Systems developed for clinical investigations should consider the following ingredients and sequential events:

1. Finalize the prototype device.
2. Design a clinical protocol outline.
3. Approach and recruit investigators. Discuss the protocol details with the investigators.
4. Finalize the protocol, complete with all case record forms and other forms.
5. Finalize investigator's "agreements", and have the "agreements" signed by the investigator.
6. Design an investigator's "notebook" containing: product design; product literature history; product testing history; investigator's protocol and recordkeeping instructions.
7. Design a valid informed consent form.
8. Submit the protocol, investigator's "notebook", informed consent form, and investigator's "agreement" to investigator's local institutional review committee and submit a summary of the plan and prior investigations to FDA.
9. Obtain local institutional review committee approval, and notify FDA of approval; or, submit protocol;, investigator's "notebook", informed consent form, and investigator's "agreement" to the FDA.
10. Wait 30 days (except for Exemption to Banned Device).
11. If no disapproval is received from the FDA:
    (a) Instruct the investigator in person on the device, techniques involved, protocol, regulations, and forms.
    (b) Ship the investigational device (with appropriate labeling) to the investigators.
12. Maintain communication with investigators with periodic in-person follow ups.
13. Maintain effective recordkeeping systems that allow continual examination of the records, forms, and testing results.
14. Comply with all FDA reporting requirements.
15. If favorable results are obtained:
    (a) Notify FDA of completion.
    (b) Notify investigators of termination of the investigation, and
    (c) Assure yourself of the location and/or use or non-use of all investigational devices.

Finally, it is important to understand in designing your protocol and testing plan, that you allow room for minor deviations that arise in all testing situations. By planning for minor deviations to be allowed within your investigation, you will be able to proceed throughout the investigation without having to terminate the study while obtaining re-approval from FDA.

ATTACHMENT I

CLINICAL INVESTIGATOR'S STATEMENT AND AGREEMENT

CLINICAL INVESTIGATOR'S STATEMENT AND AGREEMENT

Name of Investigator _____

Date _____

Name of Device _____

(to be completed by ZIMMER · USA)

1. The education and training that qualifies me for clinical trials is:
   (Fill out below or attach complete curriculum vitae)

a. Colleges, universities, and medical or other professional schools attended, with dates degrees were awarded.

Schools	Dates of Attendance	Degrees	Date Awarded

b. Postgraduate medical or other professional training: Dates, names of institutions and nature of training.

Name of Institution	Dates	Nature of Training

3. The expert committees or panels responsible for approving the experimental project are:
(to be completed by investigator)

4. The estimated duration of the project, and the maximum number of subjects that will be involved are:

Estimated duration _____
(to be completed by investigator)

Maximum number of subjects _____
(to be completed by ZIMMER · USA)

5. A general outline of the project to be undertaken is: *(to be completed by ZIMMER · USA)*

6. I understand that the following conditions generally applicable to clinical investigators govern my receipt and use of this device for clinical investigation.

a. ZIMMER · USA is required to supply me with full information concerning the preclinical investigation that justifies clinical trials.

b. I am required to maintain adequate records of the disposition of all receipts of the device including dates, quantity, and use by subjects, and if the clinical trial is suspended or terminated to return to ZIMMER · USA any unused supply of the device. ZIMMER · USA retains the right to suspend or terminate this clinical study at any time. This clinical study may be extended by ZIMMER · USA upon a showing of clinical need or to comply with Federal law.

j. It is understood that knowledge of product development and marketing introduction is commercially valuable information and considered confidential in nature. I therefore agree not to disclose to any persons other than those involved in this study the fact of the undertaking of the study or its parts. I further agree not to disclose any other proprietary development, material, or other information that ZIMMER · USA makes known to me by virtue of my participation in this study, provided ZIMMER · USA identifies in writing that information which it considers proprietary and confidential. Below or attached is an identification of information and documents to be confidential: *(to be filled in by ZIMMER · USA)*

_____

_____

_____

_____

k. It is understood that I am not to be paid a fee by ZIMMER · USA to conduct this study. As consideration for this study, ZIMMER · USA agrees to pay all administrative costs and costs to the patient that are additional by reason of this protocol. In this respect, ZIMMER · USA agrees to the following: *(to be completed by ZIMMER · USA)*

_____

_____

_____

_____

As additional consideration, and solely for reason of support for this investigation, ZIMMER · USA agrees to the following: *(to be completed by ZIMMER · USA)*

_____

_____

_____

_____

1. In addition to the above, I agree to the following: *(to be completed by ZIMMER · USA)*

_____

_____

_____

_____

(Signature of Investigator) Date

_____

(Address)

_____

_____

(Signature of Officer of ZIMMER · USA) Date

IN VITRO DIAGNOSTICS - SPECIAL CONCERNS

Jaxon A. White
Assistant General Counsel
and
Director of Diagnostic Regulatory Affairs
Health Industry Manufacturers Association

[Note: This presentation was made only at the Los Angeles and Atlanta Conferences in response to program evaluations from the first two conferences that called for more express discussion of legislative implications for diagnostic product manufacturers. Mr. White's remarks are presented below in narrative outline form.]

I. Rationale and Format of Presentation

The HIMA-PMA medical device conferences were structured to focus the attendees' interest in ten regulatory areas that can be extrapolated from the new law. Each of these areas set forth in the conference program have a direct relationship to diagnostic products although some are less significant than others such as Class III, premarket approval requirements. There are, of course, essential differences in the prospective regulation of in vitro diagnostic products even though they will be included within broad rulemaking under the new law. Accordingly, this presentation was inserted in the conference program to highlight those "special concerns" which diagnostic product manufacturers need to be aware of as implementation of P.L. 94-295 begins.

The issues discussed in this presentation are those which are most easily distinguished in the ten areas of the conference program. Other conference speakers have also attempted to identify diagnostic product concerns in their respective presentations. When the proceedings of these conferences are issued, it will be instructive to review all presentations for subtle distinctions between device and diagnostic interests which will play a major role in helping to shape future regulatory policies of the FDA.

II. Overview

The overview presentation applies to all manufacturers of products covered under the new law without any essential differences between devices and diagnostics. It should be reemphasized that the Medical Device Amendments of 1976 apply, for statutory purposes, equally to all products (including IVD's) deemed to be "devices" under the new definition found at Section 201(h). But the new law does not relieve diagnostic manufacturers of their principal responsibilities under the general labeling regulations of FDA in force since 1974 even though they were based upon the Federal Food, Drug and Cosmetic Act before its recent amendments. Having noted the basic compliance duty, it should also be pointed out that several provisions in the diagnostic regulations (now Part 809 of Title 21, Code of Federal Regulations) must yield to more specific provisions in the new law.

As a general legal principle, we can state that only those provisions in the IVD regulations which are consistent with the Act as now amended are enforceable after May 28th (the date of passage). For example, the section on procedures for establishing, amending or repealing standards is not consistent with new statutory Section 514 on performance standards. Therefore, it will either have to be rewritten or more likely repealed in favor of one regulation for standards for medical devices and diagnostic products. Other examples of inconsistent provisions in Part 809 are plant registration and product listing requirements (809.20(a)), GMP requirements, (809.20(b)) and investigational use requirements (809.10(c)). In these areas, the IVD regulations are either incomplete or premature when compared to the requirements of or implementation periods under the Medical Device Amendments. Most of these discrepancies should be cleared up in the first six months beyond enactment. Even though there is an interim period before conforming changes are made, it would be prudent to maintain compliance with the control principles, especially in the GMP area.

There is some understandable confusion about the relationship between those products which have in vitro applications but are also biologics both licensed and unlicensed by FDA. Section 809.35 of the IVD regulations currently expresses the FDA view of compatability between the Public Health Service

VI. **General Controls - Enforcement Techniques**

The new provisions on notification and other remedies (Section 518) will bear close watching by diagnostic manufacturers. The legislation requires notification of recognized hazards to health professionals and even patients under extreme circumstances. In as much as a majority of diagnostic products are used in clinical laboratories, the hazard notification would be properly directed to the institution. Thus, when regulations are proposed for Section 518, it may be necessary to explain the most expedient route for hazard notification with respect to diagnostic product uses and the lesser need to reach requesting physicians or their patients.

Another point about Section 518 is its relationship to the Laboratory-Medical Product Problem Report program sponsored by FDA and administered by the United States Pharmacopeia. These reports are now encouraged by most of the professional societies involved with laboratory medicine. Manufacturers have leveled criticisms at the program because of inadequate study of perceived problems and failure to contact the producer before individuals submit the reports. Since these reports could precipitate FDA actions under Section 518, it will behoove manufacturers to document their evaluations and assessments of problems to contain use of the enforcement technique by FDA.

VII. **Performance Standards**

The first standard promulgated under the new law could be for an in vitro diagnostic product. The standard for quantitative measurement of glucose in serum and plasma is well advanced within the FDA. This outlook for glucose assumes that the Agency will be able to rely upon prior procedures for review and comment in satisfaction of the new law. It is not clear at this point whether the FDA legal staff will authorize continuation of the procedural steps toward publication or cause the process to be repeated to satisfy the elements in Section 514 on performance standards. Even if the Agency chooses to repeat the procedural steps, there is little doubt that they will be expedited to advance the standard toward final promulgation. Manufacturers of all diagnostic products will gain familiarity with Section 514 procedures by watching the progress of the glucose standard.

The FDA has stated that standards development is a low priority at least for the first year after enactment. Industry observers in the diagnostic product area have also noticed that FDA is not aggressively pursuing a number of standards once thought to have high priority for promulgation. Thus, it comes as no surprise that the Division of Diagnostic Standards and Research has begun to discuss baseline standards for whole classes of products by methodology. Mentioned frequently is a labeling standard for radioimmunoassay (RIA). Drawing upon commonalities in RIA techniques, FDA personnel have suggested that a labeling standard could be written to enable users to draw more useful comparisons among products. Given the complexities of performance standard development and the extensive authority in the new law, there is some likelihood that the FDA may choose the standards approach just described as an expedient control for selected classes of products. FDA intentions in this area should be sufficiently forecast to allow time for manufacturer participation.

VIII. **Premarket Approval/PDP**

The transitional provisions for diagnostic products in competition with those that have approved new drug applications (NDA) are of importance to certain manufacturers. Under Section 520(l), a product closely similar (me-too) to one with an approved NDA is given only a limited amount of time to pursue premarket approval or seek down classification out of Class III.

The processing of premarket approval applications by the FDA will require sensitivity to the types of investigations and proof of safety and effectiveness most relevant to diagnostic products. FDA's organizational outlook suggests that one element of the Bureau may be the reviewing authority for both devices and diagnostics. If this approach is adopted, it will be important for manufacturers to urge competent and adequate staffing for diagnostic product submissions. The alternative is to encourage formation of a separate reviewing authority within the Division of Diagnostic Product Standards and Research.

IX. **Investigational Use Exemption - Custom Devices - Restricted Devices**

A fundamental issue in the investigational device exemption is adequate accommodation of informed consent problems relative to diagnostic products. Because the informed consent provisions apply to all

STATUTORY/DISCRETIONARY EXEMPTIONS IN THE MEDICAL DEVICE AMENDMENTS OF 1976

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Running throughout the Medical Device Amendments of 1976 are several exemptions to the basic requirements of the new law. These exemptions are generally classified as statutory exemptions or discretionary exemptions. Statutory exemptions are those required by the new law itself and available to those subject to the legislation as a matter of right, while discretionary exemptions are those provided for in the new law, but which require the FDA's approval and are subject to Agency discretion. The exemptions are important because they allow, under certain circumstances, the manufacturer or practitioner to be excused from compliance with an unusually restrictive statute. To be so excused could save a substantial amount of time and money. I will start with the discretionary exemptions and then get into statutory exemptions.

1. *Classification Procedure* - The classification procedure which you have heard discussed earlier at this conference is a maze of discretionary exemptions in itself. While a device is never exempt from the general controls, except in rare instances with Class I devices, a device classified in Class II may be exempt from the requirements of a Class III device, and similarly, a device classified in Class III may be exempt from the requirements of Class II, all depending upon the requirements the FDA feels are necessary to assure safety and effectiveness when it classifies a device. Those devices determined to be safe and effective when used in conjunction with instructions for usage and warnings of limitation adequate for the user are exempt from requirements for scientific review or performance standards.

2. *Class I Device Exemptions* - When an advisory panel classifies a medical device, that panel must include a recommendation as to whether the device should be exempted from the requirements of Section 510, requiring plant and product registration; Section 519, concerning records and reports and/or Section 520(f), relating to good manufacturing practices. Section 510 was amended to require registration of medical device facilities. The Agency has already indicated that one of the first published regulations will relate to this registration. The FDA will exercise its discretionary authority in exempting a manufacturer from the requirements of these three sections depending upon whether the Agency can conclude that granting the exemptions will not jeopardize the public health and upon whether the safety and efficacy of the device can still be assured.

3. *Product Development Protocol - Section 515(f)* - As you have previously heard today, where a Class III device is required to have an approval of an application for premarket clearance, that device shall be considered as having such an approval, if a notice of completion of testing conducted in accordance with a product development protocol has been declared completed by the agency pursuant to the provisions of the Act. Consequently, the FDA has the discretion to exempt the manufacturer from the requirements of premarket approval and, if appropriate, allow the manufacturer to go the product deveopment protocol route.

4. *Good Manufacturing Practices - Section 520(f)(2)(A)* - As you know, the FDA may prescribe regulations requiring that the methods used in the production of a medical device conform to good manufacturing practices. Any person subject to such a regulation may petition the Secretary for an exemption or for a variance from that requirement. The Agency may refer the petition to an advisory committee which must report its findings within 60 days of the referral. The FDA may approve the petition for an exemption if the good manufacturing practices requirement is not necessary to assure safety and effectiveness and may approve a petition for a variance if facilities and controls available are sufficient to assure safety and effectiveness.

All of these discretionary exemptions must be pursued, at least to some extent, by the manufacturer or any other person regulated by the FDA. These exemptions must be requested, and in all likelihood will only rarely be granted unilaterally by FDA.

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*This presentation was given by Timothy R. Craig, Assistant General Counsel, HIMA, in Atlanta, Georgia, July 1, 1976.

(4) A device within a type as described in 1, 2 or 3 above and substantially equivalent thereto.

(5) A device which the FDA has indicated in the *Federal Register* before the enactment date is a new drug.

(6) A device with respect to which, on the enactment date, an action is pending in a United States court for an alleged violation of the prohibited acts section of the Food, Drug and Cosmetic Act on the basis that a new drug application is required.

All these devices are classified in Class III unless, in respect to a petition, the FDA has classified the device in Class I or Class II.

Where a device has an approved NDA in effect and is in Class III, that device is considered a device with an approved application under Section 515—the premarket approval section. The requirements of Section 505 (the new drug section) and, we assume, the regulations promulgated thereunder, will remain in effect until a new regulation is issued by the Agency. A device for which an application was filed before the enactment date and is in Class III shall be considered as having an application on file under Section 515. The FDA has 180 days from the enactment date to act upon that application, minus the number of days the application has been on file under Section 505 prior to the enactment of the Medical Device Amendments. A device having an investigational exemption, and in Class III, will be considered a new drug until the expiration of 90 days beginning with the date of the promulgation of the regulation required under the investigational use section of the new device amendments. After that period, the device is required, unless exempt under the investigational exemption section, to have in effect an approved application for premarket clearance.

Devices substantially equivalent to those devices in these first three categories I just walked through, or for which a notice was published before the enactment date declaring the device to be a new drug, or a device in litigation where it is alleged that an NDA is required and the device is in Class III, an approved application under Section 515 is required 60 days after enactment of the Amendments, unless a petition for reclassification or application for premarket approval has been filed during that 60-day period. There are further requirements relating to certain uncommon situations I have mentioned which I will not discuss in detail, but they include the requirements pertaining to the certification of antibiotic drugs. That information may also be found in Section 520(l).

6. *State and Local Regulations - Section 521* - Under the new Amendments, no state may establish any requirements different from or in addition to the requirements of the Act which relate to any matter included in a requirement applicable to a device under the new law. This provision, the Federal "pre-exemption clause", pre-empts state laws in conflict with Federal requirements, thus eliminating the possibility of having in effect at the same time several differing laws in the various states. But Federal pre-emption is not total. A state may apply to the Agency for exemption under the pre-emption clause if the state's regulation or requirement is more stringent than the requirement under the Federal Food, Drug & Cosmetic Act as amended or if the requirement is necessitated by compelling local conditions and compliance with the requirement will not cause the device to be in violation of the Federal law. This provision allows the states to prove to FDA that they may have unusual circumstances prevalent requiring more restrictive regulations.

7. *Export of Medical Devices - Section 801(d)* - Under the old law, a food, drug, device, or cosmetic intended for export was not considered to be adulterated or misbranded if it was (1) in accord with the specifications of the foreign purchaser, (2) was not in conflict with the laws of the foreign host country, (3) was labeled for export, and (4) was not offered for domestic sale. Under the new law, this exemption does not apply to any device not in compliance with an applicable performance standard or a premarket approval requirement or which is exempt under the investigational use provision or which is a banned device unless, in addition to the above four requirements, the FDA has determined that such exportation is not contrary to the public health and safety and has the approval of the country for which it is intended for export. Foreign approval will likely be through the foreign health ministry or health department. Thus, devices not having premarket approval or not in compliance with the appropriate standard, if required, may still be exported with the required approval. The big question is what, in addition to the above, the FDA might require of the exporter to obtain Agency approval.

8. *Color Additives - Amendments to Section 706* - The new addition to the color additive section states that the color additive is subject to the requirements of this section only if it comes in direct contact with the body for a significant period of time.

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STATUTORY EXEMPTIONS

1. RECORDS & REPORTS EXEMPTIONS—SEC. 519 (b)
2. CUSTOM DEVICES—SEC. 520 (b)
3. TRADE SECRETS—SEC. 520 (c)
4. EXEMPTION FOR DEVICES FOR INVESTIGATIONAL USE—SEC. 520 (g)
5. TRANSITIONAL PROVISIONS—SEC. 520 (l)
6. STATE & LOCAL REQUIREMENTS—SEC. 521
7. EXPORT OF DEVICES—SEC. 801 (d)
8. COLOR ADDITIVES—SEC. 9 (AMEND. OF SEC. 706)
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DISCRETIONARY EXEMPTIONS

1. CLASSIFICATION IN GENERAL
2. PRODUCT DEVELOPMENT PROTOCOLS—SEC. 515 (f)
3. EXEMPTION OF CLASS I DEVICES—SEC. 513 (c) (2) (B)
   A. Registration—SEC. 510
   B. Records & Reports—SEC. 519
   C. GMP's—SEC. 520 (f)
4. GMP's—PETITION FOR EXEMPTION OR VARIANCE—SEC. 520 (f) (2) (A)

Slide 3
CLASSIFICATION IN GENERAL

GENERAL CONTROLS

PERFORMANCE STANDARD AND/OR PREMARKET CLEARANCE

Slide 4
EXEMPTION OF CLASS I DEVICES

SEC. 513 (c) (2) (B)
AT THE RECOMMENDATION OF THE PANEL EXEMPTS:
1. Registration
2. Records & Reports
3. GMP's

Slide 5
PRODUCT DEVELOPMENT PROTOCOL

SEC. 515 (f)
A class III device required to have approval of application, shall be considered as having such approval if a notice of completion of testing has been declared completed

Slide 6
GMP's—PETITION FOR EXEMPTION OR VARIANCE

SEC. 520 (f) (2) (A)
A. Person subject to GMP requirements may petition for exemption or variance.
B. The FDA may approve—
   1. A petition for exemption if GMP not required to assure safety and effectiveness.
   2. A petition for variance if other methods and controls are sufficient to assure safety and effectiveness.

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1. RECORDS AND REPORTS ON DEVICES

PERSONS EXEMPT
SEC. 519 (b)
NOT APPLICABLE TO:
A. Practitioner licensed to prescribe or for own use.
B. Person for own use in research or teaching and not for sale.
C. Exempted persons.

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CUSTOM DEVICES—Sec. 520 (b)

A. Compliance with the order of a practitioner.
B. Not generally available in finished form for purchase.
C. Not offered for commercial distribution.
D. For use by designated individual patient.
E. Made in specific form for such patient or special needs of practitioner.
F. Not generally available or used by other general practitioners.

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3. TRADE SECRETS

A. Information exempt from disclosure under Freedom of Information Act.
B. May not be used as basis for reclassification from class III to class II or to establish a standard for device reclassified from class III to class II.

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4. EXEMPTION OF DEVICES FOR INVESTIGATIONAL USE SEC. 520 (g)

Application disapproved only if investigation not in conformance with required procedures and conditions set forth in this section.

INTRODUCTION OF NEW PRODUCTS

Jaxon A. White, Jr.*
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INTRODUCTION

Many times during this program, you have been reminded that the new law permits new products to be introduced to the market without prior approval if they are of the same type and substantially equivalent to products which were in commercial distribution before May 28, 1976. That is a comforting thought because it assures, at least from a business perspective, that new product introductions will not bottom out in the near term beyond enactment. However, the business outlook for continued sales must be reconciled with the extra effort and cost which will be expended to assure that a new product introduction is accomplished in compliance with the law. Stated another way, you could say there is now a new factor in the equation of product competition. That factor is the presence of a government agency which can, in large part, focus its attention on the new products about to be introduced in forthcoming months and years. What I hope to leave you with at the conclusion of these remarks is a personal and eventually company sense that new product introduction deserves close monitoring.

In the discussion which follows, I have attempted to construct a checklist for new product introduction. There has to be, of necessity, a great deal of emphasis on the enforcement provisions because these areas of the law are the means by which the FDA can discover and perhaps prove that a manufacturer's action was at variance with the law or he failed to do something which was required by the law. However, once you know the rules of the game then it is much easier to succeed. In this case, I hope the discussion of enforcement provisions will enhance your company's awareness of precautions to take, and pitfalls to avoid.

To a limited extent, we will review certain strategies on compliance which may be drawn from the law or could be advanced by the industry as reasonable interpretations which both the FDA and manufacturers could accommodate. To close out this introduction, allow me to summarize how I intend to cover the subject. At the outset, we will review certain aspects of introducing a Class I or II or III device. Also, the introduction of a restricted device will be reviewed. The remaining time is allocated to discussion of labeling and advertising, records and reports, and distribution and traceability.

Notice of Device Introduction-Section 510(k)

The precursor to the introduction of any new product irrespective of its actual or eventual classification is the notice of device introduction to the FDA. Section 510(k) is subject to numerous interpretations on when it becomes operable and to which introductions it will apply. If anything should be certain about Section 510(k), it should be that it applies to those devices which are intended for commercial distribution after enactment of the new law. Certain FDA officials, however, have implied that the 90-day notice of introduction could apply to some devices which were on the market before May 28th. They have suggested that the purchase of a product or line of products from another manufacturer or perhaps the acquisition of an entire company with adoption of the products would trigger the 90-day notice. Obviously the products involved in these types of corporate transactions are unaffected by the exchange except with respect to legal ownership. We know that these exchanges of ownership or of marketing rights are reasonably frequent in this industry. However, products which were on the market would generally remain on the market. Thus, in my estimation, section 510(k) was not intended to apply to such situations and the FDA would be in error and not supported by the law if it attempts to enforce a 90-day advance notice shortly after these corporate transactions are consummated. Therefore, it is prudent to be aware of this potential interpretation of section 510(k) should it be pursued by the Agency.

*This presentation was given by Thomas E. Hubbard, Director of Clinical Affairs, Zimmer-USA, Inc. in Los Angeles, California, June 29 and John Kuchta, Vice President-Governmental Affairs and Product Assurance, in Atlanta, Georgia, July 1, 1976.

it is well known that standards for the bulk of Class II devices will not be undertaken for sometime. Therefore, the provisions of general controls are the primary regulatory interest for a majority of products in Class II. That is not to say that standards priorities are cast in concrete. For example, any number of standards groups are now and will in the future continue to develop voluntary standards. When these standards come to the attention of the FDA, there is at least some likelihood that they would be considered as the basis of a regulatory standard.

Assuming the Agency follows a measured plan for standards development, the new product manufacturer should also pay close attention to these activities. Opportunities to reclassify, participate in drafting of the standard and to comment on the proposed standard will or may be extended. Finally, the new product manufacturer, like other manufacturers of the device, will have to anticipate possible changes in the product as a result of requirements in the final standard.

Introduction of a Class III Device

Because Class III is reserved for what we might call critical devices, the manufacturer of a new product may encounter some problems in satisfying the FDA that the product is, in fact, of the same type and substantially equivalent. The special focus in the law on implants and life-sustaining or life-supporting devices suggests that manufacturers of these kinds of devices give ample thought to justifications for substantial equivalency well before the notice of device introduction.

Assuming that the FDA may be reluctant to afford substantial equivalency classification to new products resembling those already in Class III, manufacturers of such products should anticipate resorting to petitions to reclassify the device to Classes I or II. Therefore, those faced with this situation would be well advised to familiarize themselves with the time periods and procedures involved in the reclassification petition under Section 513(f)(2). Even though this emphasizes the negative classification situation, you can regard such preparation as an insurance policy against an adverse classification in Class III.

The other matter involving new products in Class III by virtue of substantial equivalency is the need to pay close attention to the final classification date of the pre-enactment counterpart. That date will determine when the thirty-month grace period will expire and after which the new product must be approved by the FDA. The classification date is particularly important for new products introduced after it because they are only entitled to the unexpired portion of the thirty months.

One final point about classification in Class III is worth noting. Sometime in the future, a Class III device could be reclassified in Class II or even Class I if new information about the product is developed and indicates that a lower classification is appropriate. Reclassification under authority of Section 513(e) could be accomplished either before or after premarket approval is required. The point to be remembered about this opportunity is that under Section 513(e), a reclassification from Class III to Class II may, at the option of FDA, not be made effective until a performance standard has been established for the product. Clearly, new products in Class III by virtue of substantial equivalency would be similarly affected by the delayed effective date and later be required to meet the performance standard.

Introduction of Restricted Devices

If a new product is substantially equivalent to a device regulated as a restricted device, there is a strong likelihood that the new product will also be restricted upon introduction. A device in any class may be restricted by regulation with respect to sale, distribution or use. However, it is unlikely that many devices in Class I should be restricted by the FDA.

When a manufacturer plans to introduce a new product, it would be prudent to review restricted device regulations published by the FDA up to that time. If there is a restricted device regulation applicable to the intended new product, knowledge of this fact is essential to plan for the claims which can be made and the markets where the product should be promoted. Finally, restricted devices come in for significant attention with respect to labeling and advertising. I will discuss these aspects of the restricted device designation shortly.

Labeling and Advertising

I would like to continue this reminder or checklist approach but from a different perspective. Certain characteristics of a new product and aspects of its manufacture could be focused on by the FDA as implementation of the law developes. These characteristics and aspects are not unique to new products since

cates that custom device labeling (or advertising) may not offer the product for commercial distribution. In other words, no advertising at all is allowed.

After this long discourse, you're probably asking yourself why the speaker placed so much emphasis on labeling and advertising. Therefore, I will offer my justification. If you look at the revisions in Section 510(j) of the Act, you will find rather extensive authority whereby the FDA can require submission of labeling and advertising copy for devices. How extensively the FDA will interpret these provisions is uncertain. However, the fact remains that labeling and advertising could be readily available to the Agency for review and compliance evaluation.

Records and Reports

So soon after passage of the law, we can't tell you what records a manufacturer must keep or which reports he must file—at least with any certainty. Those requirements will be established by regulations. However, by looking at Section 301 on prohibited acts there is a means to discover the pitfalls to avoid in recordkeeping and reporting. I would like to summarize these for you. Section 301(e) tells the manufacturer that it is unlawful to fail to establish or maintain any *record* required by the provision on product development protocols and the specific section on records and reports. Subsection (q) of 301 cites additional problem areas. It notes that a manufacturer cannot fail or refuse to furnish any notification, material or information required by the sections on records and reports and on the investigational use exemption. Also, subsection (q) warns that any *report* required for a device cannot be false or misleading in any material respect.

To finish this checklist on records and reports, we are obliged to reference Section 301(p) on still more prohibited acts. Talking about specific reports due to the FDA, this provision advises that a manufacturer cannot fail to register or provide information required by product listing. Neither may a manufacturer who is required to register fail to give the 90-day notice of device introduction or fail to give FDA semi-annual notices of device introduction or removal from the market.

What I have just covered should be placed in context. First, these prohibited acts do not all apply at once, nor will they apply to all products. Secondly, the development of regulations for records and reports should provide the bulk of items which a manufacturer needs to focus upon.

Distribution and Traceability

When a new product is introduced, there are numerous aspects of the law which will or may affect distribution plans or one's ability to locate and perhaps recover the product even to the user level. I don't wish to place undue emphasis on product traceability because by and large, it should be limited by the FDA to narrow circumstances. Indeed, the express provision in the new law, Section 520(j), states that traceability should not be required unless necessary to assure the protection of the public health. However, in the discussion of this provision the House Report suggests that the FDA has some authority to establish categories of products for the purpose of defining a necessary degree of distribution traceability. If this authority is used, it could first appear in the forthcoming regulations for good manufacturing practices.

You have heard ample discussion of enforcement techniques during this program. Therefore, I would just remind you that distribution and traceability should be a consideration in any contingency planning related to the provisions on banned devices, notification, the three R's and the non-statutory remedy of product recall.

To close out this survey of distribution concerns, I would like to mention four additional areas where distribution may be a factor. Little noticed in the major sections on performance standards and premarket approval are similar requirements with respect to sales and distribution. The new law states that a performance standard may contain a provision to restrict product sales or distribution. Likewise, a premarket approval application can require restricted sales or distribution as a condition for approval by the FDA. Fortunately, both of these requirements go on to say that the constraints on sale or distribution may not exceed those of the restricted device section.

The other two areas where distribution is a factor of note are restricted devices and custom devices. I would just remind you that distribution of a restricted device could be influenced by the prescription requirement and any regulations which might preclude certain health care practitioners or institutions from obtaining the product. Custom device distribution is, of course, affected by the requirement of

Introduction of New Products

Jaxon A. White, Jr.
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Outline and Section Citations

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   2. Checklist approach.
   3. Attention to enforcement provisions.
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   5. Coverage of subject.

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   3. Thirty-month grace period-Section 501(f)(2).
   4. Change of classification from III to II, delay of effective date - Section 513(e).

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VII. **Labeling and Advertising**
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   2. Emphasis on enforcement provisions.
   3. Prohibited acts - Section 301
      a. Representations on labeling - Section 301(l).
      b. References in labeling or advertising to compliance with factory inspections - Section 301(n).
   4. Misbranded drugs and devices - Section 502.
      a. Use of established name - Section 502(e)(2).
      b. Uniform identification - Section 502(o).
      c. Restricted devices, false or misleading advertising - Section 502(q).
      d. Restricted devices, elements of advertising - Section 502(r).

APPENDICES

IN VITRO DIAGNOSTICS-SPECIAL CONCERNS

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INTRODUCTION OF NEW PRODUCTS

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Public Law 94-295
94th Congress, S. 510
May 28, 1976

An Act

To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE AND TABLE OF CONTENTS

Medical Device Amendments of 1976. 21 USC 301 note.

SECTION 1. (a) This Act may be cited as the "Medical Device Amendments of 1976".

(b) Whenever in this Act (other than in section 3(a)(1)(B)) an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act. 21 USC 301.

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"(b) Special effective date.
"Sec. 517. Judicial review.
"(a) Application of section.
"(b) Additional data, views, and arguments.
"(c) Standard for review.
"(d) Finality of judgments.
"(e) Other remedies.
"(f) Statement of reasons.

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of substantial importance in preventing impairment of human health, and

"(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

"(B) CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.

21 USC 351, 352, 360.

Post, pp. 560, 562, 564, 565.

Post, p. 546.

"(C) CLASS III, PREMARKET APPROVAL.—A device which because—

"(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

"(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

"(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

Post, p. 552

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

"(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

"(A) with respect to the persons for whose use the device is represented or intended,

"(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

"(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

"(3) (A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

"(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

"Classification Panel Organization and Operation

"(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

"(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

Post, pp. 546, 552.

"(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 510, 519, or 520(f).

21 USC 360.

Post, pp. 564, 565.

"(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

"(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

"(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, or

"(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

"(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section.

introduced or delivered before such date and has been classified in class I or II, and

"(ii) is substantially equivalent to another device within such type, or

"(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II.

"(2)(A) The manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Petition. Notification.

"(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary shall refer the petition to an appropriate panel established or authorized to be used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

"(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 510, 519, and 520(f)) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A). 21 USC 360. Post, pp. 564, 565.

"(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

"(ii) The requirements of paragraphs (1) and (2)(A) of subsec-

clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

"(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

Post, p. 565.

"(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device. Labeling.

"(4) The Secretary shall provide for periodic evaluation of performance standards established under this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data. Periodic evaluation.

"(5) In carrying out his duties under this section, the Secretary shall, to the maximum extent practicable—

"(A) use personnel, facilities, and other technical support available in other Federal agencies,

"(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

"(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

"Initiation of a Proceeding for a Performance Standard

"(b)(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification. Notice, publication in Federal Register.

"(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

Ante, p. 540.

"Invitation for Standards

"(c)(1) If, after the publication of a notice under subsection (b), no action is required under paragraph (2) of such subsection or the Secretary denies a request to change the classification of the device with respect to which such notice was published, the Secretary shall publish in the Federal Register a notice inviting any person, including any Federal agency, to— Notice, publication in Federal Register.

"(A) submit to the Secretary, within sixty days after the date of publication of the notice, an existing standard as a proposed performance standard for such device, or

"(B) offer, within sixty days after the date of publication of the notice, to develop such a proposed standard.

"(2) A notice published pursuant to paragraph (1) for an offer for the development of a proposed performance standard for a device—

"(A) shall specify a period within which the standard is to be

"(B) determines that such performance standard is based upon scientific data and information and has been subjected to scientific consideration,

he may, in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to subsection (c), accept such standard as a proposed performance standard for such device or as a basis upon which a proposed performance standard may be developed.

"(2) If a standard is submitted to the Secretary pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such standard, he shall publish in the Federal Register notice of that fact together with the reasons therefor. Notice, publication in Federal Register.

"Acceptance of Offer To Develop Standard

"(e)(1) Except as provided by subsections (c)(4) and (d), the Secretary shall accept one, and may accept more than one, offer to develop a proposed performance standard for a device pursuant to a notice published pursuant to subsection (c) if he determines that (A) the offeror is qualified to develop such a standard and is technically competent to undertake and complete the development of an appropriate performance standard within the period specified in the notice, and (B) the offeror will comply with procedures prescribed by regulations of the Secretary under paragraph (4) of this subsection. In determining the qualifications of an offeror to develop a standard, the Secretary shall take into account the offeror's financial stability, expertise, experience, and any potential conflicts of interests (including financial interest in the device for which such standard is to be developed) and other information submitted pursuant to subsection (c)(3), which may be relevant with respect to the offeror's qualifications.

"(2) The Secretary shall publish in the Federal Register the name and address of each person whose offer is accepted under paragraph (1) and a summary of the terms of such offer as accepted. Publication in Federal Register.

"(3) If such an offer is accepted, the Secretary may, upon application which may be made prior to the acceptance of the offer, agree to contribute to the offeror's cost in developing a proposed standard if the Secretary determines that such contribution is likely to result in a more satisfactory standard than would be developed without such contribution. The Secretary shall by regulation prescribe the items of cost in which he will participate, except that such items may not include the cost of construction (except minor remodeling) or the acquisition of land or buildings. Payments to an offerer under this paragraph may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

"(4) The Secretary shall prescribe regulations governing the development of proposed standards by persons whose offers are accepted under paragraph (1). Such regulations shall, notwithstanding subsection (b)(A) of section 553 of title 5, United States Code, be promulgated in accordance with the requirements of that section for notice and opportunity for participation and shall— Regulations.

"(A) require that performance standards proposed for promulgation be supported by such test data or other documents or materials as the Secretary may reasonably require to be obtained;

"(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity; Notice.

"(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information sub- Records.

"(B) If the Secretary issues under subparagraph (A)(ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

Post, p. 560.
Ante, p. 540.

"(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.

Notice of proposed rulemaking.

"(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (2), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

Regulation.
Publication in Federal Register.
Notice.

"(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

"(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (2) and (3)(B) of this subsection, amend or revoke a performance standard.

"(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines, after affording all interested persons an opportunity for an informal hearing, that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

Publication in Federal Register.

"(5)(A) The Secretary—

"(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

"(ii) shall, upon the request of an interested person unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation, to an advisory committee of experts, established pursuant to subpara-

"(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

"(2) (A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain— Notice, publication in Federal Register.

"(i) the proposed regulation;

"(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

"(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

"(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

"(B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e). Publication in Federal Register. Ante, p. 540.

"(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2) (A) (ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice. Publication in Federal Register. Post, p. 560.

"(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

"Application for Premarket Approval

"(c) (1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

"(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

"(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

"(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f); Post, p. 565.

"(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

"(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard. Ante, p. 546.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary). Statement.

"(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application. Review.

"Withdrawal of Approval of Application

"(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds— Notice, hearing. Ante, p. 540.

"(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(C) that the application contained or was accompanied by an untrue statement of a material fact;

"(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510; Record retention. Post, p. 564. 21 USC 374. 21 USC 360.

"(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or

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requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

"(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

"(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device, Ante, p. 546.

"(vi) if appropriate, specimens of the labeling proposed to be used for such device,

"(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and Ante, p. 540.

"(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol. Progress reports.

"(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, United States Code. 5 USC 701 et seq.

"(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion— Notice of completion.

"(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

"(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

"(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that— Hearing.

"(i) such person has failed substantially to comply with the requirements of the protocol,

"(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

"(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

"(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

"(2)(A) Upon petition for review of—

"(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

"(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

Report and recommendation.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

Advisory committees.

5 USC 5332 note.

"(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

"Service of Orders

"(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

market application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 515(g)(1) or 515(g)(2)(C),

Ante, p. 552.

"(5) the promulgation of a regulation under section 516 (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

Ante, p. 560

"(6) the issuance of an order under section 520(f)(2), or

Post, p. 565.

"(7) an order under section 520(g)(4) disapproving an application for an exemption of a device for investigational use or an order under section 520(g)(5) withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28, United States Code. For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

"Record."

"Additional Data, Views, and Arguments

"(b) If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

Modifications.

"Standard for Review

"(c) Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided by section 515(g) shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

5 USC 701 et seq.

cial distribution presents an unreasonable risk of substantial harm to the public health,

"(ii) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture,

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

"(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

"(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

Hearing.

Hearing.

"(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

"(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

"(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this Act.

"(C) To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more—

"(i) at the time of notification ordered under subsection (a), or

"(4) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act; and

"(5) may not require a manufacturer, importer, or distributor of a class I device to—

"(A) maintain for such a device records respecting information not in the possession of the manufacturer, importer, or distributor, or

"(B) to submit for such a device to the Secretary any report or information—

"(i) not in the possession of the manufacturer, importer, or distributor, or

"(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (4) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

"Persons Exempt

"(b) Subsection (a) shall not apply to—

"(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

"(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 520(g)); and

"(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

Infra.

"GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

"General Rule

"SEC. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

21 USC 360j.
21 USC 351, 352, 360.
Ante, p. 564
Ante, pp. 540, 546, 552.

"Restricted Devices

"(e)(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

"(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

"(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

"(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe. Labeling.

"Good Manufacturing Practice Requirements

"(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act. Regulations.

"(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

"(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated, and Recommendations.

"(ii) afford opportunity for an oral hearing.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

"(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall— Petition.

"(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act,

"(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph. 5 USC app. I.

"Exemption for Devices for Investigational Use

"(g)(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

"(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 706 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices. Regulation. 21 USC 352, 360. Ante, pp. 546, 552, 560, 564.

"(B) The conditions prescribed pursuant to subparagraph (A) shall include the following: 21 USC 376.

"(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

"(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

"(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

"(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

"(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

"(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (includ-

conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

"Release of Safety and Effectiveness Information

"(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for— Regulations.

"(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device, Ante, p. 552.

"(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device, an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

"(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device, Ante, p. 560.

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

"(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order. Regulations.

"(3) Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

"Proceedings of Advisory Panels and Committees

"(i) Each panel under section 513 and each advisory committee established under section 514(g)(5)(B) or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential. Ante, p. 540. Ante, p. 546.

"(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

"(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

"(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

Ante, p. 552

21 USC 355.

"(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

"(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

"(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 515.

"(ii) If—

"(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

"(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

"(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

Notice, publication in Federal Register.

"(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

"(II) the Secretary may, during the period beginning one

CONFORMING AMENDMENTS

Amendments to Section 201

SEC. 3. (a)(1)(A) Paragraph (h) of section 201 is amended to read as follows: 21 USC 321.

"(h) The term 'device' (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— "Device." 21 USC 331, 343, 352, 362.

"(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

"(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

"(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.".

(B) Section 15(d) of the Federal Trade Commission Act is amended to read as follows: 15 USC 55.

"(d) The term 'device' (except when used in subsection (a) of this section) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— "Device."

"(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

"(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

"(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.".

(2) Section 201 is amended by adding at the end the following:

"(y) The term 'informal hearing' means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following: "Informal hearing."

"(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department of Health, Education, and Welfare who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

"(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

"(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action. Notice.

"(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

"(II) for which such an application was filed and approval of the application has been denied or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

"(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

Ante, p. 540.
Ante, p. 552.
Ante, p. 565.

"(ii) which does not have such an application in effect; or

"(C) which was classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which does not have such an application in effect.

"(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

"(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

"(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

"(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

"(g) If it is a banned device.

"(h) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

"(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.".

Amendments to Section 502

(e)(1) Section 502 is amended by adding at the end the following new paragraphs: 21 USC 352.

"(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

"(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's

or installation of the device do not conform to the requirements of section 520(f)". Ante, p. 565.

REGISTRATION OF DEVICE MANUFACTURERS

SEC. 4. (a) Section 510 is amended as follows: 21 USC 360.

(1) The section heading is amended by inserting "AND DEVICES" after "DRUGS".

(2) Subsection (a)(1) is amended by inserting "or device package" after "drug package"; by inserting "or device" after "the drug"; and by inserting "or user" after "consumer".

(3) Subsections (b), (c), and (d) are amended by inserting "or a device or devices" after "drugs" each time it occurs.

(4) Subsection (e) is amended by adding at the end the following: "The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.".

(5) Subsection (g) is amended by inserting "or devices" after "drugs" each time such term occurs in paragraphs (1), (2), and (3) of such subsection.

(6) Subsection (h) is amended by inserting after "704 and" the following: "every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III".

(7) The first sentence of subsection (i) is amended by inserting ", or a device or devices," after "drug or drugs"; and the second sentence of such subsection is amended by inserting "shall require such establishment to provide the information required by subsection (j) in the case of a device or devices and" immediately before "shall include" and by inserting "or devices" after "drugs".

(8) Subsection (j) is amended—

(A) in the matter preceding subparagraph (A) of paragraph (1), by striking out "a list of all drugs (by established name" and inserting in lieu thereof "a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name", and by striking out "drugs filed" and inserting in lieu thereof "drugs or devices filed";

(B) in paragraph (1)(A), by striking out "such list" and inserting in lieu thereof "the applicable list"; by inserting "or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515," after "512,", and by inserting "or device" after "such drug" each time it appears; Ante, pp. 546, 552.

(C) in paragraph (1)(B), by striking out "drug contained in such list" before clause (i) and inserting in lieu thereof "drug or device contained in an applicable list";

(D) by amending clause (i) of paragraph (1)(B) to read as follows—

"(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or"; 21 USC 353.

name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(4) Such section is amended by adding after subparagraph (3) (as so redesignated) the following:

"(4) As used in subparagraph (2), the term 'established name' with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.". "Established name." 21 USC 358.

(b) Section 508 is amended (1) in subsections (a) and (e) by adding "or device" after "drug" each time it appears; (2) in subsection (b) by adding after "all supplements thereto," the following: "and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)"; (3) in subsection (c)(2) by adding "or device" after "single drug", and by adding "or to two or more devices which are substantially equivalent in design and purpose" after "purity,"; (4) in subsection (c)(3) by adding "or device" after "useful drug", and after "drug or drugs" each time it appears; and (5) in subsection (d) by adding "or devices" after "drugs". Review.

INSPECTIONS RELATING TO DEVICES

SEC. 6. (a) The second sentence of subsection (a) of section 704 (21 U.S.C. 374) is amended by inserting "or restricted devices" after "prescription drugs" both times it appears.

(b) The third sentence of such subsection is amended to read as follows: "No inspection authorized by the preceding sentence shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j), section 507 (d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)).". 21 USC 355, 357. Ante, pp. 564, 565.

(c)(1) Paragraph (1) of the sixth sentence of such subsection is amended by inserting "or devices" after "drugs" each time it occurs.

(2) Paragraph (2) of that sentence is amended by inserting ", or prescribe or use devices, as the case may be," after "administer drugs"; and by inserting ", or manufacture or process devices," after "process drugs".

(3) Paragraph (3) of that sentence is amended by inserting "or manufacture or process devices," after "process drugs".

(d) Section 704 is amended by adding at the end the following new subsection:

"(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.". Records, accessibility.

respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

"PRESUMPTION

"SEC. 709. In any action to enforce the requirements of this Act respecting a device the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.". 21 USC 379a.

COLOR ADDITIVES

SEC. 9. (a) Section 706 is amended (1) by inserting "or device" after "drug" each time it occurs, (2) by inserting "or devices" after "drugs" each time it occurs, and (3) by adding at the end of subsection (a) the following new sentences: "A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.". 21 USC 376.

(b)(1) Section 501(a) is amended (A) by inserting "(3) if its" in lieu of "(3) if it is a drug and its"; (2) by inserting "(4) if (A) it bears or contains" in lieu of "(4) if (A) it is a drug which bears or contains"; and (3) by inserting "or devices" after "drugs" in subclause (B) of clause (4). 21 USC 351.

(2) Section 502(m) is amended by striking out "in or on drugs". 21 USC 352.

ASSISTANCE FOR SMALL MANUFACTURERS OF DEVICES

SEC. 10. The Secretary of Health, Education, and Welfare shall establish within the Department of Health, Education, and Welfare an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended by this Act. Office, establishment. 42 USC 3512.

Approved May 28, 1976.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 94-853 accompanying H. R. 11124 (Comm. on Interstate and Foreign Commerce) and No. 94-1090 (Comm. of Conference).
SENATE REPORT No. 94-33 (Comm. on Labor and Public Welfare).
CONGRESSIONAL RECORD:
Vol. 121 (1975): Apr. 17, considered and passed Senate.
Vol. 122 (1976): Mar. 9, considered and passed House, amended, in lieu of H. R. 11124.
May 13, House and Senate agreed to conference report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS:
Vol. 12, No. 22 (1976): May 28, Presidential statement.

CAUTION:

THIS DOCUMENT IS THE LEGISLATIVE REPORT ON A MEDICAL DEVICE BILL (H.R. 11124) PASSED BY THE HOUSE OF REPRESENTATIVES ON MARCH 9, 1976. THE REPORT DESCRIBES THE MEDICAL DEVICE AMENDMENTS BEFORE CONFERENCE ACTION. CERTAIN PROVISIONS DESCRIBED IN THIS REPORT WERE DELETED AND OTHERS MODIFIED IN CONFERENCE. SEE CONFERENCE REPORT NO. 94-1090 MAY 6, 1976, FOR DISCUSSION OF CHANGES.

PAGES 89-155 OF THIS REPORT (CHANGES IN EXISTING LAW) HAVE BEEN DELETED. SEE PUBLIC LAW 94-295 FOR TEXT OF LAW AS ENACTED. (PAGES 89-155 ARE AVAILABLE UPON REQUEST TO HIMA OR PMA)

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94TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 94-853

MEDICAL DEVICE AMENDMENTS OF 1976

FEBRUARY 29, 1976.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 11124]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 11124) to amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

Page 1, line 5, strike out "1975" and insert "1976".

Page 1, line 6, insert "(other than in section 3(a)(1)(B))" after "Act".

Page 8, line 4, insert "(other than devices classified by subsection (f))" after "such devices".

Page 11, line 13, strike out "on or".

Page 11, line 16, strike out "on or".

Page 12, line 8, strike out "on or".

Page 14, beginning in line 13 strike out "on or before such date" and insert in lieu thereof "before such date and which is to be classified pursuant to subsection (b),".

Page 14, line 15, strike out "on or".

Page 16, line 11, insert "516," after "515,".

Page 22, line 12, insert "this" after "pursuant to"; and in line 13 on that page strike out "(c)".

Page 27, insert after the period in line 16 the following new sentence: "The authority provided by this subsection is in addition to the authority provided by subsection (c)(4)".

Page 104, line 1, strike out "device or drug" and insert in lieu thereof "device, drug, or animal feed".

Page 107, line 12, insert "each place it occurs" before "; and".

Page 111, line 13, strike out "or," and insert in lieu thereof ", or".

Summary of Legislation

H.R. 11124 would provide significant new authority to the Secretary of Health, Education, and Welfare to assure the safety and effectiveness of medical devices intended for human use.

1. The bill requires the Secretary to classify all medical devices intended for human use into three regulatory categories (classes) based upon the extent of control necessary to insure the safety and efficacy of each such device. The three classes are——

Class I, General Controls.—A device for which controls other than standard-setting and premarket approval are sufficient to assure safety and effectiveness or for which insufficient information exists to determine that general controls are sufficient but which is not represented to be for a use of substantial importance to health and which does not present a potential unreasonable risk of illness or injury. Devices classified into this category will be subject only to general controls, which include existing controls prohibiting adulterated or misbranded devices, and new controls, which include registration of device manufacturers; authority to ban certain devices; requirements respecting notification of risks and repair, replacement or refund; requirements to keep records and make reports; requirements restricting the sale or distribution of certain devices; and requirements with respect to good manufacturing practices.

Class II, Performance Standards.—A device for which general controls are insufficient to assure safety and efficacy and for which there is sufficient information to establish a performance standard to provide such assurance. Devices classified into this category will be required to meet an applicable standard on such date as is prescribed by the Secretary. General controls would continue to apply to a device classified into class II unless superseded by a standard.

Class III, Premarket Approval.—A device for which insufficient information exists to assure that general controls and performance standards would provide reasonable assurance of safety and effectiveness and which is represented to be for a use of substantial importance or which presents a potential unreasonable risk of illness or injury. Devices classified into this category will be required to have approved applications for premarket approval.

2. The bill requires the establishment of panels of experts to make classification recommendations to the Secretary. After receiving the panel recommendations, the Secretary is to classify devices by regulation.

3. The bill requires that devices intended to be implanted into the human body which are on the market before the date of enactment (or which are substantially equivalent to such devices) must be classified in class III unless the Secretary determines that premarket approval is not necessary to provide reasonable assurance of safety and effectiveness. Implantable devices not on the market before the date of enactment and which are not substantially equivalent to those on the market before the date of enactment must undergo premarket approval.

Cost of Legislation

No line-item authorization of appropriations is provided to carry out the provisions of H.R. 11124. The Committee would anticipate that the Administration would request sufficient resources to implement this legislation through the appropriations process and estimates that an appropriation of approximately $15 million and an increase in the personnel ceiling to 500 positions would provide adequate resources to carry out the provisions of H.R. 11124 in its initial year of implementation.

In fiscal year 1975, the Food and Drug Administration obligated $6.7 million and allotted 228 positions to its medical device program.

The Department of Health, Education, and Welfare has advised the committee that, if H.R. 11124 is enacted, the Department intends to use both existing resources and a substantial part of the $17 million requested increase for FDA for fiscal year 1977 to implement the legislation.

Legislative Background

Legislation which would amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices for human use was first considered by the Subcommittee on Public Health and Environment in October of 1973 when legislative hearings were conducted on H.R. 9984, the Medical Device Amendments of 1973. No further action was taken on H.R. 9984 in the 93rd Congress.

On March 26, 1975, most members of the Subcommittee on Health and the Environment introduced H.R. 5545, a substantially revised version of the earlier legislation. Four days of legislative hearings were conducted on H.R. 5545 and similar legislative proposals on July 28 through 31, 1975. H.R. 5545 was subsequently considered in eight open markup sessions, significantly amended, and ordered reported to the full committee on November 13, 1975. The amended version was reintroduced as a clean bill, H.R. 11124, cosponsored by all of the members of the Subcommittee on Health and the Environment. H.R. 11124 was considered, amended, and ordered reported by unanimouse voice vote of the Committee on Interstate and Foreign Commerce on January 21, 1976.

Background and Need For Legislation

The first general Federal food and drug law, the Food and Drugs Act of 1906 banned from interstate commerce any traffic in adulterated or misbranded food or drugs. The Act defined "drug" to include all medicines and preparations recognized in the United States Pharmacopeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease in man or other animals. Any drug which did not meet the standards of strength, quality, and purity set forth on its label was deemed to be adulterated. A drug was considered misbranded if its label bore any statement, design or device regarding the contents which was false or misleading, or if its label failed to indicate any quantities of alcohol, narcotics or certain other specified substances which might be present in the pro-

Much of FDA's activity with respect to the regulation of medical devices during the first twenty years following enactment of the 1938 Act involved protecting the American public from fraudulent devices. In fact, fraudulent devices were a major concern of the Congress in 1938 when it gave FDA the authority to regulate devices. Although the fantastic claims made for many devices over the years may seem amusing and harmless, use of fraudulent devices can have serious health consequences. Making unwarranted claims for a device, or recommending use in serious disease conditions, may induce a purchaser to forgo seeking timely and appropriate medical treatment.

The limited authority of FDA to regulate medical devices is illustrated by the vast amount of effort the Federal government has expended in stopping the marketing of bogus devices. One such device, which was the subject of FDA action in the late 1940's, was the Spectrochrome developed by Dinshah P. Ghadiali, which consisted of a 1,000 watt lamp in a cabinet supplied with colored glass slides fitting an aperture through which the light could bathe the patient. Claims were made for its value in treating such diseases as diabetes, cancer, tuberculosis and syphilis, and several thousand lamps were sold. The first FDA action against the lamp was a single seizure. After a trial which lasted thirty days, the jury rendered a verdict for the government, and the court enjoined distribution of the lamp. Ghadiali, nevertheless, continued to ship it, despite the multiple seizure actions which followed the court decision. Criminal charges were then filed against Ghadiali and his corporation. After another lengthy trial and a guilty verdict, the court fined Ghadiali and his corporation $20,000 and imposed a three-year prison sentence which was to be suspended on the condition that the business be stopped.

FDA's experience in removing the Diapulse device from the market is yet another instance demonstrating the unwieldly procedures and lack of preventive provisions of the current authority. The Diapulse is a heat-generating device which has been marketed to medical practitioners for some 121 therapeutic claims. The firm lacked scientifically valid data to substantiate the efficacy of the device in any of the conditions for which it was promoted. The first seizure of a Diapulse device occurred in December of 1965. As a result of lengthy court proceedings against the device and company appeals, it was not until 1972 that injunction against the manufacturer was finally obtained, seven years after the initial seizure.

FDA began focusing more attention on hazards from legitimate medical devices around 1960. The post-war revolution in biomedical technology had resulted in the introduction of a wide variety of sophisticated devices. New developments in the electronic, plastic, metallurgy, and ceramics industries, coupled with progress in design engineering, led to invention of the heart pacemaker, the kidney dialysis machine, defibrillators, cardiac and renal catheters, surgical implants, artificial vessels and heart valves, intensive care monitoring units, and a wide spectrum of other diagnostic and therapeutic devices. Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated

suture, that sutures were listed in an official compendium as drugs, and, thus, the product was a drug. The court observed that since a suture could fall within either the "drug" or the "device" definition, a liberal interpretation of the Federal Food, Drug, and Cosmetic Act required classifying the product as a drug to better protect the public health through premarket clearance procedures.

In the second case (*United States* v. *Bacto–Unidisk*, 394 U.S. 784 (1969)), the Supreme Court sustained the determination of the Food and Drug Administration that a cardboard disc impregnated with eight different antibiotics in order to determine antibiotic sensitivity was a drug. The Court held that the legislative history of the Act, ". . . read in the light of its remedial purpose, directs us to read the classification 'drug' broadly, and to confine the device exception as nearly as is possible to the types of items Congress suggested in debates, such as electric belts, quack diagnostic scales and bathroom weight scales, shoulder braces, air-conditioning units, and crutches".

This liberal interpretation has allowed FDA to regulate as drugs certain diagnostic products, various weight reducing kits, hydrophilic contact lenses, and intrauterine devices employing drugs, heavy metals, or other active ingredients. This approach has not been entirely successful, however, as illustrated by a recent district court decision in *United States* v. *An article of drug . . . Ova II* (Civ. No. 745–72 D.N.J. 1975). In this unpublished decision, now on appeal, the district court held that a pregnancy detection kit is not subject to the new drug procedures, and, indeed, may not even be a "device" under present law.

The need for more comprehensive authority to regulate medical devices has been recognized by Presidents Kennedy, Johnson, and Nixon. In late 1969, the Secretary of Health, Education, and Welfare convened a medical device study group, composed of experts in medicine and technology, chaired by the then Director of the National Heart and Lung Institute, Dr. Theodore Cooper, now the Assistant Secretary for Health. Its task was to evaluate the alternatives and devise the best approach to new comprehensive device legislation. To this end, the Cooper Committee, as it has become known, held meetings with representatives of the medical profession, industry, consumers, and government agencies. It also conducted an extensive literature search which uncovered a startling 10,000 injuries directly related to medical devices over a ten year period, of which 751 had proved fatal; 512 deaths and 300 injuries were attributed to heart valves, 89 deaths and 186 injuries to heart pacemakers, and ten deaths and 8,000 injuries to intrauterine devices.

The Cooper Committee also reviewed the recommendations of national conferences and previous medical device task forces, position papers from concerned professional groups, publications of experts, previous legislative proposals, and existing legislative authority. Further data and recommendations, both solicited and unsolicited, were received from individuals and groups that were unable to attend the Committee's meetings.

The Cooper Committee completed its research in mid-1970 and its report was made public in September 1970. The report emphasized ". . . that problems do in fact exist and that a predictable increase in the complexity and sophistication of medical devices requires action now to prevent the emergence of even more serious and complex prob-

(5) There is an apprehension that medical devices have not been clearly delineated from drugs and that legislation directing the regulation of devices by the same system currently used for drugs would be inappropriate. Inappropriate regulatory standards could negatively affect the present pace of research and development in the field of biomedical technology.

(6) A system of "peer group" review of scientific data could inspire the confidence of the medical device community that regulatory decisions related to devices and their standards were soundly based. Such a "peer group" would include representatives from the medical device industry, the Federal government, the academic community, and other concerned organizations, including consumer groups.

The Cooper Committee stressed the scientific and technological sophistication of devices and recommended that the Secretary of Health, Education, and Welfare enlist the assistance of appropriate scientific organizations to determine the initial classification of devices for each regulatory category. As an initial step, it proposed a thorough and complete inventory and review of the medical devices that were on the market.

Following the issuance of the Cooper Committee's recommendations, FDA initiated an inventory of existing medical devices. By 1971, after sending out 4,000 questionnaires, FDA had compiled a list of 1,100 device manufacturers who produced approximately 8,000 separate devices.

Having completed its inventory, FDA began a more detailed classification of medical devices, dividing them into distinct categories as follows: Orthopedics; cardiovascular diseases; dentistry; anesthesiology; obstetrics and gynecology; gastroenterology; urology; radiology; neurology; ear, nose, and throat disorders; ophthalmology; plastic and general surgery; physical medicine; clinical pathology; and general and personal use. Advisory panels have already reviewed and made classification recommendations on all known devices on the market today according to the three basic regulatory categories originally recommended by the Study Group.

Presently, FDA is expanding its present medical device and diagnostic product programs by developing improved labeling for products such as intrauterine devices. Patient registries are being developed for cardiac pacemakers. Also under development are procedural regulations for standards development, and individual proposed standards for such products as hearing aids, syringes, and defibrillators.

Years of thoughtful consideration of proposed medical device legislation have produced a broad consensus as to the need for increased legislative authority over medical devices and what such authority should contain. The present law's inadequacy has become a matter of acute concern because of the rapid technological advances in the medical device field. In early regulatory actions FDA was able to carry its burden of proof that a device was unsafe or misbranded through expert testimony; more recently, FDA has had to test devices suspected of violating the law and undertake intricate maneuvers to classify certain device products as drugs. An even more serious drawback of the existing authority is that FDA cannot act against a hazardous medical device until after it is on the market and then must prove misbranding or adulteration. The present procedure is often difficult, time consuming, and expensive, and during the legal proceedings the device manu-

administrative informal hearing procedure as the principal vehicle available to interested parties. In addition, the bill would permit the agency to postpone even an informal hearing until after the banning of a device that presents an unreasonable, direct and substantial danger to health.

The reported bill would assuage a growing concern of the Committee that the inadequacies of the existing law have too often forced the Food and Drug Administration to regulate by administrative rule, relying upon the judicial branch to sustain its activities. Because the Committee recognizes that existing statutory authority is inadequate to assure the safety and effectiveness of medical devices, and that, in general, authority under the Federal Food, Drug, and Cosmetic Act to regulate food, drugs, cosmetics, and devices is too often vague thus lending itself to interpretive regulation having the force of law, the Committee has attempted to design device authority such that the law and the intent of the Congress is clear.

Several provisions of the proposed bill confer explicit authority on the Secretary to promulgate regulations or impose requirements with respect to medical devices that in some instances parallel requirements that the Food and Drug Administration has adopted under existing authority for other products under its jurisdiction. The specific conferral of these authorities with respect to devices is not intended, by negative implication, to cast doubt upon the propriety or validity of these other FDA actions.

Presented below is a general description of the major provisions of the proposed legislation and committee views with respect to its implementation. A detailed section-by-section analysis appears elsewhere in this report.

IMPLEMENTATION OF THE PROPOSED LEGISLATION

The authority to regulate medical devices under the proposed legislation is afforded the Secretary of Health, Education, and Welfare (referred to as the "Secretary" throughout this report). However, pursuant to regulations, authority vested in the Secretary under the Federal Food, Drug, and Cosmetic Act has been delegated to the Commissioner of Food and Drugs (21 C.F.R. 2.120). Thus, the Food and Drug Administration will be responsible for implementation of the provisions of the proposed bill and, under accepted concepts of primary administrative jurisdiction, will be initially responsible for determining its application.

PRODUCTS SUBJECT TO THE BILL

As noted earlier in this report, considerable legal controversy has ensued over the past decade as to which articles constitute medical devices subject to regulation under the Federal Food, Drug, and Cosmetic Act. Existing statutory definitions of "device" and "drug", although legally mutually exclusive, are functionally overlapping and, thus, confusing to the device industry, the general public and the courts.

Because of FDA's current limited statutory authority over medical devices, the agency has attempted to regulate as "drugs" some

mittee's intention that each use may, at the Secretary's discretion, be treated as constituting a different device for purposes of classification and other regulation.

Some products subject to regulation under other statutes such as the Radiation Control for Health and Safety Act, the Atomic Energy Act, and the biologics provisions of the Public Health Service Act (sections 351 and 352) are also "devices" regulated under the proposed legislation and existing provisions of the Food, Drug, and Cosmetic Act. If present regulatory controls are sufficient, the Committee does not intend that the proposed legislation result in promulgation of duplicative regulations. For example, where present standards and other regulations under the Radiation Control for Health and Safety Act deal adequately with safety and effectiveness of medical electronic products that emit radiation, new requirements applicable to these products under the proposed legislation would be unnecessary.

PRESUMPTION OF INTERSTATE COMMERCE

The authority to regulate medical devices under the Federal Food, Drug, and Cosmetic Act is defined under sections 501 and 502 of the Act and enforced principally by existing section 301 of the Act which prohibits the introduction or delivery for introduction into interstate commerce of any device that is adulterated or misbranded or the receipt in interstate commerce of any adulterated or misbranded device and existing section 304 which authorizes seizure of any such device in interstate commerce.

The requirement that an adulterated or misbranded device must be introduced, delivered for introduction or received in interstate commerce has been a burden to the effective enforcement of existing authorities. For example, before an adulterated device can be seized, proof of interstate commerce must be established. The Food and Drug Administration reports that its inspectors spend a major portion of their time tracing adulterated or misbranded products across state lines or establishing intent to ship across state lines in order to prove introduction, delivery or receipt in interstate commerce.

Obviously, whether or not a medical device actually crosses state lines has nothing to do with the principal intent of this proposal: to assure the safety and effectiveness of medical devices. For this reason, the bill would permit seizure of devices without reference to interstate commerce (section 3(c) of the bill) and would establish a statutory presumption that in any action to enforce the requirements of the Federal Food, Drug, and Cosmetic Act with respect to a medical device, the connection with interstate commerce required for jurisdiction is presumed to exist (proposed new section 708 of the Act). The Committee believes that these provisions will more effectively assure efficient enforcement of the proposed legislation.

SAFETY AND EFFECTIVENESS

Reasonable Safety and Effectiveness.—Contained in various provisions throughout the proposed legislation is the requirement that regulatory action be taken to provide reasonable assurance of the

ucts having the power to be useful in the healing arts also have the potential to do harm and that the determination of safety and effectiveness is to carefully balance these considerations. Regulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits to be derived.

Special Provisions Respecting Determination of Effectiveness.—The proposed legislation contains important provisions setting forth how effectiveness is to be determined for purposes of classifying devices, developing performance standards and taking action with respect to premarket approval of a device. First, the legislation states the general rule for determination of a device's effectiveness: Effectiveness is to be determined on the basis of well-controlled investigations by qualified experts, including clinical investigations where appropriate, from which it can be concluded by qualified experts that the device will have the effect it purports or is represented to have. This requirement is derived from existing provisions of the Act relating to drugs.

Secondly, the proposed legislation provides that the Secretary may authorize that the effectiveness of a device be determined on the basis of valid scientific evidence other than the well-controlled clinical studies required by the general rule. This provision is derived from regulations issued under drug law and it was adopted by the Committee for the same reasons that it adopted provisions authorizing that devices be subject to differing controls: Devices vary widely in type and in mode of operation, as well as in the scope of testing and experience they have received. Thus, the Committee has authorized the Secretary to accept meaningful data developed under procedures less rigorous than well-controlled investigations in instances in which well-documented case histories assure protection of the public health or in instances in which well-controlled investigations would present undue risks to subjects or patients. However, this provision is not intended to authorize approval on the basis of anecdotal medical experience with a device or unsubstantiated opinion as proof of effectiveness.

GENERAL CONTROLS

The proposed legislation establishes several controls generally applicable to all medical devices. These so-called "general controls" include the major existing authorities with respect to medical devices under the Federal Food, Drug, and Cosmetic Act—controls over devices which are "adulterated" or "misbranded"—and several new means of regulating devices to assure their safety and effectiveness. Under the proposed bill, certain of the general controls become applicable to medical devices immediately upon enactment of the proposed legislation; others are dependent upon promulgation of regulations by the Secretary. In the Committee's view, general controls, properly implemented, constitute important safeguards for the public health, and the Committee anticipates that these general controls should be sufficient to assure the safety and effectiveness of many medical devices.

The General Controls are—

Prohibitions Against Adulterated Devices.—Existing section 501 of the Act prohibits the introduction into interstate commerce of any medical device that consists of a filthy, putrid, or decomposed substance or that is prepared, packed or held under insanitary conditions. This

pending an informal hearing and final action on the proposed regulation. However, if the Secretary determines that the deception or risk can be corrected by labeling changes, he must first provide written notice to the device manufacturer specifying the labeling changes necessary, and only if the changes are not made within a reasonable time after such notice may the Secretary initiate a proceeding to ban the device.

The Committee believes that the proposed new authority will enable the Secretary to move quickly to protect the public from fraudulent or hazardous medical devices in commercial distribution in a manner which will not compromise the rights of device manufacturers.

First, the Secretary must find that the continued marketing of a medical device presents a substantial deception or an unreasonable and substantial risk of illness or injury before he can initiate a proceeding to ban the device. By using the term "substantial," the Committee intends that the Secretary make a determination that the decepion or risk incurred through continued marketing of such a device is important, material, or significant. In determining that a device is deceptive, it is not necessary that the Secretary find that there was intent to mislead users of the device. Nor is actual proof of deception of or injury to an individual required.

A finding that a device presents the requisite degree of deception or risk is to be made "on the basis of all available data and information", including information which the Secretary may obtain under other provisions of the proposed legislation, and information which may be supplied by the manufacturer in response to the proceeding relating to the safety, effectiveness, or labeling of the device.

Second, the Secretary must, before proposing a banned device regulation, consult with the appropriate panel or panels having expertise with respect to the type of device proposed to be banned. While the Committee does not intend this consultation to delay the banning process and thus has not established a time period for panel review or a requirement that a panel approve a proposed action, the Committee does believe that the expertise of panel members should be solicited and that they should be provided an opportunity to respond to the Secretary's proposal.

Third, the Secretary must make a positive determination that labeling changes would not be sufficient to correct or eliminate the substantial deception or unreasonable and substantial risk of illness or injury associated with use of the device. If he determines that labeling changes would be sufficient, the Secretary must notify the manufacturer of the device in writing, specifying the deception or risk of illness or injury involved, the labeling or change in labeling necessary to correct the deception or eliminate or reduce the risk, and the period within which such labeling or change in labeling is to be done. Only if the manufacturer does not take the required action within the specified time, which the Committee believes should be a reasonable time within which to accomplish the required action, may the Secretary initiate a proceeding to ban the device.

Fourth, the proposed legislation requires the Secretary to provide all interested persons an opportunity for an informal hearing on a proposed regulation to ban a device. In most instances, the informal

assure that all patients will be informed of newly identified risk associated with the use of a device to which they have been exposed in a manner which presents the least risk to health.

In determining whether a device presents "an unreasonable risk of substantial harm to the public health" the Committee intends that the Secretary consider such factors as the severity of the harm presented by the risk, the cause of the risk presented by the device, and the number of devices in commerce which present the risk. "Substantial harm to the public health" may include widespread nonserious harm to a large number of persons as well as serious harm to a few individuals.

The requirements for consultation with persons required to provide notification was adopted by the Committee in lieu of a requirement for an informal hearing in recognition of the need for rapid action in such serious situations. Although the Committee intends that this provision afford persons so required an opportunity to question the need to provide notification and to propose alternatives to it, the consultation requirement should not operate to delay the important objective of informing the public of risks to health. In some cases, it obviously would be impossible for the Secretary to consult with all persons required to provide notice, which could include distributors, retailers, and health professionals as well as manufacturers. Consultation with representatives of such persons will suffice where necessary.

The Committee intends that the persons who are to receive notification under this provision include hospitals and other health care institutions. Thus, the Committee expects the Secretary to require in notification orders that such entities receive notification where necessary to eliminate the risk presented by devices subject to the order.

The authority to require notification is intended to supplement, not preclude, other appropriate action by the Secretary, such as issuance of press releases designed to inform the public of risks presented by a device or promulgation of a regulation banning a device. New section 518(d) of the reported bill makes it clear that compliance with a notification order does not relieve any person from liability under Federal or State law.

The notification provision is similar to, and to some extent patterned after, comparable authority contained in the National Traffic and Motor Vehicle Safety Act of 1966, the Radiation Control for Health and Safety Act of 1968, and the Consumer Product Safety Act of 1972. These statutes also include requirements that manufacturers provide notification of defects in their products to appropriate Federal agencies. The Committee determined that a comparable provision in new section 518(a) with respect to devices would be unnecessary since the Secretary could require the reporting of such information under the recordkeeping and reporting authority provided in new section 519 of the Act.

Repair, Replacement or Refund.—The proposed legislation authorizes the Secretary to order manufacturers, importers or distributors of certain devices which present unreasonable risks to health to repair or replace such devices or refund their purchase price. This provision (proposed new section 518(b) of the Act), which is intended to be in addition to and not as an alternative to the notification requirements authorized under new section 518(a), is applicable

State law, although in awarding damages for economic loss, the value to the plaintiff provided by an order shall be taken into account.

The "repair, replacement, or refund" provision is designed to reduce or eliminate risks associated with devices as well as provide an administrative procedure whereby consumers can attain economic redress when they have been sold defective medical devices that present unreasonable risks. These provisions recognize that some devices present risks that are not unreasonable, and thus should not be subject to the remedies of repair, replacement, or refund. They acknowledge that there are instances in which a device presented a reasonable risk according to the state of the art at the time of its manufacture which becomes unreasonable due to a change in technology. In these instances, the Secretary could issue a notification order, but not require action under the repair, replacement, or refund provisions.

As noted above, in instances in which more than one person is ordered to submit a repair, replacement, or refund plan, the Secretary is directed to specify which person is to decide which action is to be taken under the plan. In most instances, the person specified is to be the person the Secretary determines bears the principal, ultimate responsibility, although this provision is not intended by the Committee to authorize the Secretary to render final legal determinations with respect to financial responsibility for any action required by him under an order. The ultimate determination of such financial responsibility remains with the parties, and, if no agreement between parties can be reached, with the courts.

Records and Reports on Devices.—Under proposed new section 519 of the Act, the Secretary is authorized to require, by regulation, that manufacturers, importers, and distributors of devices intended for human use establish and maintain such records, and make such reports, as may reasonably be necessary to assure that a device is not adulterated or misbranded and to otherwise assure its safety and effectiveness.

This provision will be extremely useful to the Secretary in determining whether a device complies with other requirements of the Act, such as a standard or a good manufacturing practice requirement. It will also assist the Secretary in determining whether to take certain actions with respect to a device, such as issuing an order requiring notification, repair, replacement or refund. Examples of reasonable reporting requirements include reporting defects, recalls, adverse reactions, patient injuries, and clinical experience with respect to class III devices.

The Committee is well aware of the tendency of regulatory agencies to impose industry-wide requirements for the keeping of records and the making of reports which are entirely appropriate for some segments of the industry without sufficient consideration of the expense of such requirements or the need for universal applicability. Thus, the Committee has included provisions designed to eliminate unnecessary record-keeping and reporting, consistent with the need to protect public health.

First, the reported bill requires that the Secretary may not impose requirements which are unduly burdensome, balancing the cost of compliance against the need to obtain information in order to protect

ditioned upon the use of a device only by or on the order of a licensed practitioner has been upheld by the courts.)

In addition to authorizing the Secretary to limit a device to prescription status, conditions on sale or distribution could include use only within hospitals or clinics. Also, there are categories of health professionals other than physicians that have unique skills appropriate to the use of medical devices such that certain devices which would not be appropriate for use by the ordinary layman could be authorized for use by trained nurses and technicians.

Good Manufacturing Practice Requirements.—As an ancillary measure to other provisions of the proposed legislation intended to prevent hazardous devices from reaching the marketplace, the Committee has designed a provision (new section 520(f) of the Act) authorizing the Secretary to promulgate regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage and installation of a device conform to good manufacturing practices.

To insure public involvement during the development and implementation of good manufacturing practices, the proposed legislation establishes a nine-member advisory committee comprised of three officers of State, local or Federal government; two persons who are representative of interests of the device manufacturing industry; two persons representative of the interests of physicians and other health professionals; and two persons representative of the interests of the general public. Prior to the promulgation of good manufacturing practice regulations, the Secretary must afford the advisory committee a reasonable time to comment on draft proposed good manufacturing practice requirements and provide opportunity for an oral hearing on such proposed regulations.

Because the Committee realizes that good manufacturing practice requirements must be flexible and that some requirements may not be necessary for certain segments of a highly diverse industry, the proposed legislation authorizes persons subject to such requirements to petition the Secretary for an exemption or variance from one or more of the requirements. The advisory committee may be utilized at the option of the Secretary to make a recommendation with respect to a proposed exemption or variance. Any such recommendation is to be submitted to the Secretary within sixty days after he refers a petition to the advisory committee. Any petition for a variance or exemption must be either approved or denied by the Secretary within sixty days of receipt or within sixty days after referral to the advisory committee, whichever is later.

A petition for an exemption for a device may be approved by the Secretary if he determines that compliance with the contested requirement is not necessary to assure safety and effectiveness and that the device is otherwise in compliance with the Act. A petition for a variance for a device may be approved if the Secretary determines that the methods, controls and facilities proposed by the petitioner as an alternative to the contested requirement are sufficient to assure that the device will be safe, effective, and otherwise in compliance with the Act. An order approving a variance shall prescribe conditions respecting methods, facilities and controls necessary to

applicable performance standard or periodically make such certification to the Secretary.

The Committee anticipates that the provisions of a standard requiring labeling for the proper installation, maintenance, operation, and use of a device may, where appropriate, include instructions or warnings, information as to storage and transportation, expiration dates, results to be expected from the device, ranges of accuracy of diagnosis, instructions as to proper care of the device, and equipment to be used with the device. Where necessary, labeling may also specify that the device is only considered safe or effective when used by or in the treatment of a patient who has been tested under certain diagnostic procedures by an appropriately skilled person and found to have an illness or condition for which the device is indicated.

Development of Performance Standards.—The reported bill sets forth in great detail procedures for developing performance standards that may be utilized by the Secretary in establishing performance standards applicable to class II devices.

First, the Committee recognizes that a considerable period of time may elapse between classification of a device into class II and development of a performance standard for it. Thus, the Secretary is to initiate a proceeding to develop a performance standard for a class II device by publishing in the Federal Register a notice of opportunity to submit a request for reclassification of the device. Any such request, which must be based upon new information with respect to the device, must be submitted within fifteen days and acted upon within 60 days of the publication of the notice, after the Secretary has consulted with the appropriate classification panel.

Second, unless the Secretary has reclassified the device, he shall publish a notice inviting any person (including any Federal agency) to submit an existing standard as a proposed standard or to offer to develop such a proposed standard. Submissions or offers must be made within 60 days of publication of the invitation. The invitation is to specify the time in which the standard is to be developed and include a description of the device, a statement of the risks associated with and intended to be controlled by the performance standard, a summary of data setting forth the need to develop the standard, and an identification of existing performance standards relevant to the proceeding.

The Committee does not intend that the invitation to submit or develop a proposed performance standard be construed as procurement. Therefore, it should not be subject to the requirements of section 8 of the Small Business Act (relating to procurement contracts) or requirements under 41 U.S.C. 5 (relating to the requirement of advertisement before contracting).

The Committee does not intend the requirements that the invitation include a statement of the risks associated with the device and a summary of data setting forth the need to develop a performance standard to be construed so as to demand exhaustive inquiries on these matters. The statement of risks may be a summary of the opinion of experts within the Food and Drug Administration or outside the agency. Where available, references to published information respecting experience with the devices should be included. The summary of data on which there has been determined to be a need to develop

performance standards, require maintenance of records to disclose the course of development and other relevant matters, and assure access to records by appropriate officials and submission of periodic reports to disclose the course of development. These provisions will, in the Committee's view, provide the public with opportunity to participate in the process of developing proposed standards and afford the Secretary effective authority to insure that proposed standards are being developed in accordance with statutory requirements.

Fifth, the legislation authorizes the Secretary to develop a proposed performance standard if, after publication of an invitation to develop a standard, no person offers to develop a proposed standard or submits a proposed standard; the Secretary has not accepted an existing standard or an offer to develop a proposed standard; an offer to develop a standard has been accepted but the offeror is unwilling or unable to continue development; or a developed standard is unsatisfactory. (This authority is in addition to the authority for the Secretary to develop a standard in lieu of accepting an offer to do so.) The provisions for public participation in the proceeding and maintenance of records required during development of proposed standards by offerors are also applicable to the development of a standard by the Secretary under this procedure.

Establishment of a Standard.—Following development or acceptance of a proposed standard, the Secretary is to initiate proceedings making the proposed standard a mandatory, enforceable requirement for a class II device. A proposed standard is to be published as a notice of proposed rulemaking, and opportunity for comment is to be afforded. Such notices are to set forth proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by the proposed standard. Following the comment period, the Secretary is to promulgate a regulation establishing a standard for a class II device. The standard-setting proceeding can be terminated prior to promulgation of a regulation establishing a standard for a device, in which case a proceeding to reclassify the device is to be initiated. In addition, a standard can be amended or revoked by the Secretary at any time.

Because of the potential complexities and wide applicability of a proposed standard, the reported bill authorizes referral of proposed standards to expert advisory committees (which may not be classification panels) comprised of persons of diversified professional background for the purpose of making recommendations to the Secretary respecting any matter which requires scientific judgment in proposed regulations for the establishment, amendment or revocation of a standard. Membership of such panels is to include as nonvoting members one representative of consumer interests and one representative of the interests of the device manufacturing industry. A proposed regulation may be referred to an advisory committee by the Secretary on his own initiative and must be so referred upon the request of an interested party. Advisory committees are to submit reports and recommendations respecting proposed regulations within 60 days after their referral. Such reports and recommendations are to be made public.

The administrative rulemaking provisions of 5 U.S.C. 553 will apply to establishment of medical device standards for class II devices except to the extent the bill prescribes additional requirements with

The requirement to have an approved application for premarket approval with respect to these "old" devices is subject to provisions delaying the requirement for a statutory period. Second, "new" devices, i.e., devices not on the market prior to enactment and not "substantially equivalent" to "old" devices, are automatically classified into class III. Third, products which have been regulated as drugs under existing law will be classified as class III devices under the proposed legislation, with opportunity to petition for reclassification into class II or I. The form of regulation is dependent upon the regulatory status of the "drug" which is to be regulated as a "device" under the bill. In some instances, the "drug" automatically receives approval as a class III device. In other instances, premarket approval as a device is required within a certain period following enactment of the bill. Where a "drug" is subject to regulation as an investigational drug, it is to remain in that status until 90 days after the date on which regulations prescribing conditions under which devices may receive exemptions for investigational use are promulgated.

The Premarket Approval Process.—Premarket approval of a medical device is to be initiated by the filing of an application with the Secretary. The bill specifies that the application is to contain reports of investigations of the safety and effectiveness of the device; a statement of its components and principles; a description of the methods, facilities and controls used for its manufacture; a reference to any performance standard that would be applicable to the device if it were a class II device; a sample of the device, where practicable, and if submission of a sample is not practicable, the location of a sample; specimens of labeling; and such other information as the Secretary, with the concurrence of the appropriate classification panel, may require. In many instances, this information would be gained during investigation of a device under an approved application for investigational use under new section 520(g) of the Act, described elsewhere in this report.

An application for premarket approval must contain full reports of all information known or which reasonably should be known to the applicant concerning the safety and effectiveness of the device, including any information concerning its adverse effects on health.

The application is to be referred to the appropriate classification panel for study and submission of a report respecting approval of the application. The Secretary is to approve or disapprove the application within 180 days of its receipt unless a greater period of time is agreed upon by the Secretary and the applicant. With respect to a device on the market prior to the date of enactment, the Secretary may extend the period within which he must take action only if he determines that continued availability of the device subject to the application is necessary for the protection of the public health. Approval is to be denied if the Secretary finds a lack of showing of reasonable safety or effectiveness of the device, nonconformance with good manufacturing practices, false or misleading proposed labeling for the device, or lack of conformance to a standard compliance with which is a requisite to approval.

As noted above, action on the application must be taken by the Secretary within 180 days of its receipt. Of course, "receipt" of

cedure. Approval of the protocol does not constitute approval of the device; rather it constitutes the first of two steps leading toward approval of the device for marketing.

The second step requires submission of a notice of completion of the PDP to the Secretary. Such notice is to include a determination by the person for whom the PDP was approved that there is no reason bearing on safety or effectiveness why the notice should not be approved, data on which such determination is based, and the results of any preclinical or clinical trials required by the protocol. Within 90 days after the notice of completion is submitted, the Secretary is required to either issue an order declaring it completed, or, after affording opportunity for an informal hearing, issue an order declaring it not completed. The Secretary may issue an order declaring a PDP not completed only if he finds failure to comply with the requirements of the protocol, that the results of trials differ substantially from those required by the protocol, or that there is a lack of showing of safety and effectiveness of the device.

An order declaring a PDP completed has the same effect as an order approving an application for premarket approval. In the case of a device on the market on the date of the order, the device may continue to be marketed; in the case of a device not on the market on the date of the order, it may, by virtue of the order, be marketed.

The proposed legislation authorizes the Secretary to revoke an approved PDP or approval of a notice of completion after affording an opportunity for an informal hearing to the person having the approved protocol or for whom the notice is effective. Revocation of a PDP is authorized upon a determination that the person for whom it was approved has failed substantially to comply with its requirements, that the results of trials differ so substantially from required results that further trials cannot be justified, or that trial results or new information fail to demonstrate that the device tested under the PDP does not present an unreasonable risk to health and safety. Revocation of approval of a device provided by a notice declaring a PDP completed is authorized upon the same grounds as are provided for withdrawal of approval of an application for premarket approval.

The Committee anticipates that the product development protocol will be of great assistance to the rapid development of innovative devices because it should be less expensive than the conventional two-step investigation and premarket approval procedure. In particular, this procedure should be of great assistance to small device manufacturers who have been responsible for a host of innovative and important devices which are used in limited circumstances and thus are not financially attractive to larger manufacturers. The Committee would stress, however, that the requirements for proof of safety and effectiveness are no less stringent under the PDP procedures than they are under the procedure requiring an application for premarket approval.

Administrative Review of Actions with Respect to Premarket Approval.—The proposed bill authorizes two types of administrative review of orders approving, denying, or withdrawing approval of an application for premarket approval, or revoking an approved protocol, declaring a protocol not completed or revoking the approval of a device provided by notice of completion of a PDP.

Devices classified into class I will not be required to conform to performance standards or undergo premarket clearance, but will be subject to regulation under general controls.

The Committee recognizes that certain devices which would be classified into class I may not require extensive regulation in order to assure the protection of the public health, and thus has authorized the Secretary to exempt a class I device from the requirements of sections 510 (registration), 519 (records and reports), and 520(f) (good manufacturing practices requirements) if he determines that such controls are not necessary.

Performance Standards.—The proposed legislation specifies that devices which cannot be classified into class I because general controls are insufficient to provide reasonable assurance of safety and effectiveness, and for which sufficient information exists to establish a performance standard to provide such assurance are to be classified into class II. Devices placed in class II will be subject to performance standards, promulgated under new section 514 as well as to general controls unless the applicability of such controls is negated by a performance standard.

Premarket Approval.—The Committee has given much consideration to the criteria to be applied in determining whether a device should be subject to premarket approval. The challenge has been to develop statutory language that assures that devices will undergo the intensive testing and review provided by premarket approval when necessary to protect the public without mandating premarket approval in instances where it is not justified in view of alternative regulatory mechanisms. For devices other than implantables, which the Committee has determined should be treated specifically by the legislation because of their importance to health and potential for harm, the bill adopts a two-pronged test to determine whether a device should be required to undergo premarket approval.

The first criterion screens out devices which can be adequately regulated by general controls or standards: Premarket approval is required for a device if it cannot be classified into class I or II because insufficient information exists to determine the adequacy of general controls or standards to provide reasonable assurance of safety or effectiveness.

The second requirement provides that premarket approval is to be required only for devices which either are for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, or which present a potential unreasonable risk of illness or injury. This requirement will assure that premarket approval does not become a routine requisite for all devices, while still providing the Secretary with ample latitude to classify a device into class III in instances in which its use poses public health concerns.

The Committee intends that the phrase "use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health" be construed broadly where necessary. Such uses as prevention of pregnancy, application to the body of energy and substitution of a device for a major body function are uses of substantial importance that would justify a device's classification into

safety and effectiveness would not necessarily fall under the automatic classification scheme.

The proposed bill contains provisions designed to insure that manufacturers do not intentionally or unintentionally circumvent the automatic classification of "new" devices. These provisions, included in amendments to section 510 of the Act, would require all persons to advise the Secretary ninety days before they intend to begin marketing a device as to whether the device has been classified under section 513. This provision will enable the Secretary to assure that "new" devices are not marketed until they comply wtih premarket approval requirements or are reclassified into class I or II.

Implantable Devices.—The proposed legislation contains special provisions with respect to the classification of devices which are intended to be implanted in the human body. The Committee received considerable testimony documenting hundreds of incidences of death or injury associated with defective heart pacemakers, intrauterine devices, and intraocular lenses, among others. The testimony also indicated that many of these incidents could have been avoided had the devices undergone adequate scientific testing and made free of defect. On the other hand, the Committee recognizes that there are many relatively simple implantable medical devices which, while important to health, have presented no health hazards during years of use. For this reason, the Committee rejected a proposal to place all implantable devices into class III and instead adopted an approach designed to assure adequate premarket testing of implantable devices presenting potential health problems without requiring premarket approval in situations where it is unnecessary.

The proposed legislation gives special instructions to classification panels and to the Secretary with respect to implantable devices on the market prior to the date of enactment of the bill and requires premarket approval of "new" implantable devices which were not marketed before the date of enactment.

The bill in effect creates a presumption that devices intended to be implanted in the human body which are on the market prior to the date of enactment are to be classified into class III. It requires that with respect to an implantable device which has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of the bill, or which is substantially equivalent to a device so introduced or delivered, classification panels shall recommend classification into class III unless they determine that such classification is not necessary to provide reasonable assurance of safety and effectiveness of the device. If panels do not recommend that such devices be classified into class III, their recommendations are to set forth the reasons for not so recommending. Further, the legislation instructs the Secretary to classify such devices into class III unless he determines that such classification is not necessary to provide reasonable assurance of safety and effectiveness. A proposed regulation classifying such a device into class I or class II is to be accompanied by a statement of the Secretary's reasons for not classifying the device into class III.

The proposed bill requires that all devices intended to be implanted in the human body which are not on the market before the date of enact-

Further, the transitional provisions provide that any device which has been regulated as an antibiotic drug shall remain regulated as an antibiotic drug until it has been classified as a class I device, or, if classified as a class II or III device, until the requirements of the proposed legislation for such devices are met.

THE CLASSIFICATION PROCESS

Classification Panels.—In the Committee's view, it is important that the Secretary of Health, Education, and Welfare have the benefit of the scientific knowledge and experience of national experts in implementing his authority under the proposed legislation. At no time is this input more essential than in the classification process, which will determine the extent to which a device must be regulated to assure its safety and effectiveness.

Thus, the proposed legislation requires the Secretary to establish panels of experts, organized according to medical and scientific specialties, to review medical devices on the market before the date of enactment and those intended for marketing in the future and to submit recommendations to the Secretary for the classification of such devices. Such panels are also to advise the Secretary with respect to reclassification of devices, withdrawal of approval of premarket approval applications, product development protocol proposals, and proposals to ban certain devices. To encourage thorough and scientific evaluation on the parts of the panels as well as to facilitate review by the Secretary and oversight activities by the Congress and the general public, the proposed legislation requires each panel to maintain a transcript of its proceedings, from which proprietary information would be deleted prior to disclosure to the public.

The Committee is aware of the existence of some fourteen classification panels which the Secretary has established to make recommendations respecting classification of devices in anticipation of the enactment of medical device legislation. These panels have now made preliminary classification decisions for many of the products subject to classification under the bill, employing criteria which, although not identical to, are compatible with those prescribed in the proposed bill. For this reason, the proposed legislation authorizes the Secretary to use existing panels to facilitate the classification process if he determines that the composition of such panels conforms to the provisions of the proposed legislation. Once the proposed bill is enacted, each existing panel should be reconvened to reconsider its previous decisions in light of the statutory classification criteria and other requirements of the legislation. In determining whether to affirm or change its earlier classification decision, and in support of its recommendation to the Secretary with respect to the classification of a device, a panel may use information obtained, findings developed, and judgments reached prior to enactment of the bill.

The proposed legislation exempts classification panels from section 14 of the Federal Advisory Committee Act (which requires that all advisory committees established by acts of Congress terminate not later than two years after their establishment unless their duration is otherwise provided for by law) in recognition of the fact that they

sections 510, 519, or 520(f) are not to apply to the device. Finally, the Secretary may establish priorities for the application of requirements of performance standards and premarket approval to those devices he classifies into class II or class III.

Reclassification.—The proposed bill also provides for the reclassification of medical devices, either upon the Secretary's own initiative or upon petition by an interested person, based on new information respecting any such device. The Secretary is authorized to consult with the classification panel to which a device subject to a proposed reclassification was last referred prior to acting to reclassify, and if recommendations are received from the panel, they must be published. In instances in which the Secretary reclassifies a device from class III to class II, he may require that such regulation not take effect until the effective date of a performace standard established under section 514 for such device. Also, as described above, the Secretary is authorized to reclassify "new" devices (except implantable devices) automatically classified into class III and devices regulated as drugs prior to the date of enactment of the proposed legislation.

As discussed in more detail earlier in this report, opportunity to petition for reclassification of a class II device is to be afforded by the Secretary upon his notice initiating the standard-setting process. Further, opportunity to seek reclassification of a class III device is to be afforded upon publication of a proposed regulation requiring premarket approval. In both instances, the Secretary, after consultation with the appropriate classification panel, is to either publish a notice denying the petition for reclassification or initiate a proceeding reclassifying the device.

The Committee anticipates that the authority to reclassify devices on the market prior to the date of enactment of the bill would usually be invoked only in instances in which a long period has elapsed after initial classification of a device by the Secretary. The Committee does not anticipate that the Secretary will publish notice of petitions to change a device's classification unless he agrees with the petition's request or determines that public comment on a petition is desirable.

EFFECTS OF CLASSIFICATION

Class I Devices.—Upon classification into class I, a device will not be required to conform to a performance standard or have an approved application for premarket approval, but will remain subject to general controls (implementation of some of which are, as noted earlier in the report, dependent upon the promulgation of regulations), except that the Secretary is authorized to exempt class I devices from requirements respecting registration, records and reports, and good manufacturing practices.

Class II Devices.—If a device is classified into class II, it will be required to conform to an applicable performance standard only after promulgation of a regulation establishing the standard, and only upon such date as the Secretary makes the standard applicable to a class II device, which usually will be at least one year after the promulgation of the regulation. If the Secretary reclassifies a class III device into

receive such exemptions. These are to include submission of an application to the Secretary and the maintenance of such records and the making of such reports as are necessary to insure compliance with conditions to the receipt of the exemption and to enable the Secretary to review the progress of the investigation. Such procedures and conditions may vary, depending upon the scope and duration of clinical testing to be conducted, the number of human subjects to be involved in the testing, the need to permit changes to be made in the device subject to the testing, and whether the device is being tested for the purpose of developing data to support its commercial distribution. In instances in which proposed investigations do not include testing involving human subjects, the Committee would anticipate that such procedures and conditions would be addressed principally to adequate recordkeeping, reporting, and assurances that a device is not diverted into human use.

The bill contains special requirements with respect to exemptions for devices intended to be tested using human subjects.

First, the Committee believes it to be appropriate in most instances to rely upon qualified investigational review committees, rather than governmental officials, to supervise the clinical testing of devices. Such committees, which are comprised of persons with diversified backgrounds who are competent to judge the acceptability of proposed research, are now required, under the provisions of section 474 of the Public Health Service Act, to be utilized to supervise research which involves human subjects, sponsored by the Department of Health, Education, and Welfare. Such committees are also required to be used to review and approve most proposed clinical studies on investigational drugs, pursuant to regulations of the Food and Drug Administration. Thus, the bill provides, as one condition to approval of an exemption of a device for investigational use involving human subjects, that the person seeking the exemption submit a plan for proposed clinical testing and a report of any prior investigations of the device to a local institutional review committee, established in accordance with regulations, for review. If no such committee exists, or if the process of review by a committee is determined to be inadequate, then the plan and report are to be submitted to the Secretary. If an institutional review committee is to be utilized to supervise the research, the report and summary of the plan are to be submitted promptly to the Secretary.

Second, the bill requires that, if the device is to be distributed to other investigators for testing, the person applying for the exemption must obtain a signed agreement from each investigator (which must be submitted to the Secretary) that testing involving human subjects will be under the investigator's personal supervision and that informed consent will be obtained from each human subject. The Committee does not intend that this requirement impose a strict criminal or civil liability upon the sponsor of an investigation for the failure of an investigator to abide by the signed agreements or for the failure of an investigator to adhere to informed consent requirements unless the sponsor has reason to believe that the investigator is not complying with such requirements. However, the Committee does intend that sponsors should seek to insure that their investigators comply with such requirements.

are not generally available in finished form for dispensing on prescription or for commercial distribution and which are not generally available to other health professionals. It applies only to devices intended for use by a patient named in an order by a health professional or which are intended to be used solely by a particular physician, dentist, or other specially qualified person or a person under his professional supervision.

Such devices are not exempt from otherwise applicable provisions of the proposed legislation, such as provisions with respect to investigational use, banning, restriction, adulteration or misbranding. Thus, the Secretary may act when a practitioner's use of a custom device is repeated to such an extent that the practitioner is in effect conducting unsupervised experiments or is otherwise using a device in violation of the act. On the other hand, since some practitioners must use devices with customized features as a regular part of their practice (e.g., each dental patient requiring dentures must have a set that is unique to a certain extent), the Committee rejected an across-the-board rule that the custom device exemption is inapplicable where an individual practitioner uses custom devices as a course of conduct.

STATE AND LOCAL REQUIREMENTS

The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened. For this reason, the reported bill contains special provisions (new section 521 of the Act) governing regulation of devices by States and localities. First, the reported bill prescribes a general rule that no State or political subdivision thereof may establish or continue in effect any requirement with respect to a device for human use which is different from, or in addition to, any requirement made applicable to such a device under the proposed legislation or existing provisions of the Federal Food, Drug, and Cosmetic Act.

In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the requirement that intrauterine devices are subject to premarket clearance in California.

Because there are some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill's general prohibition on non-Federal regulation. Under this provision, the Secretary may authorize imposition of a State or local requirement on a device if he finds (1) that the requirement is more stringent than a requirement under the Federal Food, Drug, and Cosmetic Act or (2) that it is required by compelling local conditions and compliance with

Nevertheless, recognizing the limited resources available to physically inspect manufacturing establishments, the Committee has adopted a provision whereby the requirement for inspection every two years extends only to establishments engaged in the manufacture of class II or III devices. In according a statutory priority to the inspection of class II and III device manufacturing facilities, the Committee does not intend that the Secretary be relieved of his responsibility to inspect class I manufacturing establishments as often as is feasible.

ADMINISTRATIVE RESTRAINT

The public is sometimes unnecessarily exposed to products that violate the Act during the time period between discovery of a violation by an inspector and the completion of a legal action resulting in seizure of a product or an injunction prohibiting a violation by a firm or individual. The Act provides no authority to detain temporarily products suspected or known to be defective.

Such temporary detention authority was recommended by the General Accounting Office in a 1972 report following review of 91 seizures of products in violation of the Act. The GAO found that, on an average, only 69 percent of the total supply of a product identified by inspectors for seizure was actually removed from the market; the remaining 31 percent apparently was sold prior to court action.

Thus, the Committee has adopted a provision (new section 304(g) of the Act) which would authorize an officer or employee of the Secretary (*i.e.*, an inspector of the Food and Drug Administration) to order that a medical device which he has reason to believe is adulterated or misbranded be temporarily detained. The period of detention may not exceed twenty days unless the Secretary or his designee determines that a greater period is necessary in order to institute an action to seize the product or obtain an injunction, in which case he may authorize a detention for a period not to exceed thirty days.

In order to minimize the possibility that inspectors would order the detention of a device when it was not warranted, the bill requires that before a device may be ordered detained, the Secretary or his designee must approve the order. The Committee would expect that the officials designated by the Secretary to approve detention orders hold responsible positions and recommends that the District Directors of the various Food and Drug Administration field offices be the persons so designated.

The proposed bill provides that a detention order may require labeling or marking of a detained device for the purpose of identifying it. It also authorizes any person whose device has been detained to appeal such detention and requires the Secretary, after affording an opportunity for an informal hearing, to confirm or revoke the detention within five days after the date of the appeal.

The reported bill requires that a detained device not be moved unless released by the Secretary or until expiration of the detention order (whichever occurs first), except that if the device is not in final form for marketing it may be moved at the discretion of the manufacturer for the purpose of completing the work required to put it in final form. Of course, the manufacturer of a device subject to a deten-

petitor. No one may market a class III device without first obtaining for the device his own approved application for premarket approval demonstrating that his device is safe and effective. Thus, an approved application for premarket approval is, in effect, a private license to market the device.

On the other hand, devices classified into class I or II are subject to public regulations. Any class I device that conforms to general controls and any class II device that complies with such controls as well as with an applicable performance standard may be marketed without individual approval by the Secretary.

An analogous situation exists with respect to drugs. Under section 505 of the Act a new drug is regulated by private license acquired by a new drug application rather than by public regulations. No one may market a new drug without first obtaining his own approved new drug application. For this reason alone, the Secretary has concluded that the safety and effectiveness data for new drugs fall within the trade secret exemption and regulations preclude disclosure of such data unless the applicant previously has made the information public, the drug has been disapproved or withdrawn from the market, or the drug has reached the stage where it may be marketed without submission of such data to the agency for approval. In contrast to new drugs, antibiotic drugs are regulated by public regulations. Anyone who meets the requirements of the regulations may lawfully market an antibiotic drug. Accordingly, the Secretary has concluded that the safety and effectiveness data for antibiotic drugs do not fall within the trade secrets exemption, and regulations require that such information be made available for public disclosure.

Because premarket approval of a device under the proposed legislation follows the same individual product license approach as premarket approval of new drugs, the economic value of safety and effectiveness data for medical devices subject to premarket approval may be similar to that of such data contained in new drug applications. Accordingly, it is the view of the Committee that the release of information for devices which are classified into class III should be handled in the same manner as for new drugs. Similarly, where a device is classified in class II and thus is subject to standards, which are public regulations, the release of information should be handled in the same way as it is for antibiotic drugs.

The Committee recognizes that the Secretary will not be able to determine the confidentiality of safety and effectiveness data submitted for devices until he makes a final decision on classification. Therefore, safety and effectiveness data and information submitted to a panel, except for material that has been previously disclosed to the public, should be considered confidential until a decision on final classification is reached. Upon final classification by the Secretary, data and information which fall within the confidentiality provisions of the law or which consist of data demonstrating the safety or effectiveness of a device classified in class III should be held as confidential. Safety and effectiveness data and information for those devices classified in either class II or class I should be made available to the public promptly, unless the person who submitted it demonstrates that the data and information should remain confidential. The Committee

Under existing law any contractor who uses such information to his own advantage or reveals it to persons other than HEW employees would be subject to prosecution for violating the provisions of section 301(j) of the Act.

Release of Summaries of Safety and Effectiveness Information.— The Committee recognizes that the best interests of government, industry and the public are served by proper public scrutiny of actions of the Food and Drug Administration. Public scrutiny of the implementation of this legislation would normally be difficult, since some decisions with respect to class III devices will be based upon trade secret information.

For this reason, the Committee has included a provision (new section 520(h) of the Act) which would require the Secretary to promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device, which was the basis for major decisions made by him with respect to such a device, be released to the public. Such summaries are required to include information respecting any adverse effects of the device on health.

This requirement is applicable in the following circumstances:

(1) Upon issuance of an order approving, denying approval of, or withdrawing approval of an application for premarket approval; or upon the making of a recommendation by an advisory committee of experts to which was referred a petition to review such orders.

(2) Upon issuance of an order revoking an approved product development protocol for a device, declaring a protocol completed or not completed, or revoking the approval of a device for which a notice of completion was in effect; or upon the making of a recommendation by an advisory committee of experts to which was referred a petition to review such orders.

(3) Upon issuance of an order approving an application for investigational use for a device which has been banned, or an order disapproving or withdrawing approval of such application.

In addition the Secretary is required to promulgate regulations under which each advisory committee to which was referred a petition for administrative review of actions taken with respect to a class III device shall make available to the public a detailed summary of information submitted to the Committee respecting the safety and effectiveness of the device which was the basis for its recommendation to the Secretary. Such information is to include any information respecting adverse effects on health of the device.

This provision further requires that such safety and effectiveness information is to be made available subject to the confidentiality requirements of new section 520(c) and may not be used to establish the safety or effectiveness of another device by a person other than the person who submitted the information made available.

In the Committee's view, this provision, coupled with requirements that the proceedings of advisory panels and committees be transcribed and requirements that classification panels and the Secretary set forth reasons for recommendations and decisions, will help assure effective public scrutiny and Congressional oversight.

and time consuming, and thus are, in the Committee's view, wholly unsatisfactory to the prompt and efficient implementation of the proposed legislation. On the other hand, mere written submissions would not serve as an effective means of presenting opposing views under the circumstances described above.

Thus, the Committee has provided for a so-called "informal hearing", designed to balance the need for oral presentation of differing views with the need to avoid procedural delays in taking action on matters essential to health. An informal hearing is to include the following:

(1) Designation by the Secretary of a presiding officer who is an officer or employee of the Department of Health, Education, and Welfare but who has not participated in any action which is the subject of the hearing and who is not responsible to any officer or employee of the Department who has so participated.

(2) The right of each party to the hearing to be advised and accompanied by an attorney at all times during the hearing.

(3) Reasonable notice to each party prior to the hearing of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed to be taken and a general summary of the information to be presented by the Secretary in support of such action.

(4) The right of the parties to the hearing to hear a full and complete statement of the action which is the subject of the hearing together with information and actions supporting the action.

(5) The right of the parties to the hearing to conduct reasonable questioning and to present any oral or written information relevant to the action which is the subject of the hearing.

(6) The preparation by the presiding officer of a written report of the hearing, to which shall be attached all written material presented at the hearing, with opportunity for participants in the hearing to review and correct or supplement the report.

(7) Authorization for the Secretary to require that the hearing be transcribed and the right for a party to the hearing to have it transcribed at his own expense.

The informal hearing will be of critical importance to manufacturers and investigators of medical devices, as well as consumers. In the Committee's view, the informal hearing will assure procedural due process and allow a full and effective opportunity for presentation of information and rebuttal of opposing information sufficient to facilitate judicial review and to guide future decisions. On the other hand, the provisions assure that formal trial tactics may not be used to delay necessary action. For example, reasonable questioning, as opposed to cross-examination of witnesses, is available to the parties. Thus, formal rules of cross-examination are not to be followed, but reasonable inquiry is assured by authorizing the questioning of individuals.

JUDICIAL REVIEW

The reported bill provides special procedures respecting judicial review of actions by the Secretary under the proposed legislation that have immediate and substantial impact. Proposed new section 517 of the Act authorizes judicial review of the following regulations and orders:

the Committee has, consistent with recent judicial decisions, expressly defined the extent of the record to be examined by the reviewing court to be the administrative record of the contested proceeding.

In order to assure development of a complete record for judicial review, several provisions of the proposed legislation require that the Secretary make certain findings when he takes actions under the bill. For example, under proposed section 514(g)(2) of the Act, a notice of proposed rulemaking establishing a performance standard for a device must set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device. A final regulation promulgating a standard must also include findings on such matters (proposed section 514(g)(3)(A) of the Act). Similar findings must be proposed and made final in regulations under proposed section 515(b) requiring premarket approval for devices. Moreover, under proposed new section 517, each regulation or order issued under specified sections of the Act must contain a statement of the reasons for its issuance and the basis, in whatever proceedings that led to its issuance, for its issuance. This requirement applies to all regulations or orders issued under new sections 513, 514, 515, 516, 518, 519, 520, and 521 of the Federal Food, Drug, and Cosmetic Act, whether or not reviewable under section 517.

The proposed legislation provides a procedure for presentation of additional data, views, and arguments to the Secretary after a petition for judicial review has been filed. Under this provision, if a petitioner applies to the reviewing court for leave to adduce new information with respect to the matter being reviewed and demonstrates to the court that such information is material and that there are reasonable grounds for the petitioner's failure to adduce the information during the administrative proceeding, the court may order the Secretary to provide opportunity for the oral presentation of such information, and for any written submissions by the petitioner. If the court orders the Secretary to receive this additional information, the Secretary is authorized to modify his findings or make new findings based on such additional information. Any modified or new findings shall be filed with the court along with any recommendation for the modification or setting aside of the contested action.

The reported bill specifies that the reviewing court is to review a contested action in accordance with chapter 7 of title 5, United States Code and to grant appropriate relief, including interim relief, where necessary. Under relevant provisions of the Administrative Procedure Act, the Secretary is authorized to postpone the effective date of a contested action pending judicial review if justice so requires, and the reviewing court is authorized to postpone the effective date of the Secretary's action or preserve status or rights pending review to the extent necessary to prevent irreparable injury. In determining whether irreparable injury would be prevented by such postponement, the Committee would expect the court to weigh heavily the effect of a stay of the Secretary's action on consumers, particularly in instances involving actions removing unsafe, ineffective or deceptive products from the market.

ment protocols all are intended in part to encourage the continued viability of smaller device manufacturers.

In addition, the Committee has taken the unusual action of requiring that the Secretary establish an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Act (section 10 of the bill). The Committee does not intend that the office be a hollow shell. Rather, it expects the office to have sufficient resources and staff to provide a meaningful and effective vehicle for technical advice and other assistance.

PROVISIONS RESPECTING THE EXPORT OF DEVICES AND DRUGS

Under existing law (section 801(d) of the Act) a food, drug, device, or cosmetic that does not conform to provisions of the Act may be exported if four requirements are met: it accords to the specifications of the foreign purchaser, is not in conflict with the laws of the foreign country to which it is intended for export, is labeled as intended for export, and is not sold or offered for sale in domestic commerce. Existing law prohibits the export of a new animal drug or animal feed medicated with a new animal drug that is unsafe within the meaning of section 512 of the Act. Moreover, existing provisions of the Act authorizing the export of drugs do not apply to unapproved "new drugs". The provisions of existing section 801(d) are, however, applicable to antibiotic drugs.

In the Committee's view it is appropriate, under certain circumstances, to authorize the export of new drugs, new animal drugs, and medicated feed bearing a new animal drug, which have not yet been approved for use in the United States. Because of the limitations of present law, U.S. manufacturers of such drugs or feed which have been approved for use in foreign countries have constructed facilities and trained personnel in such countries in order to market their products. Authorizing the export of such drugs and feed, consistent with public health considerations, will encourage the development of domestic facilities with consequent benefits to employment and balance of trade payments.

Thus, the proposed legislation would authorize the export of a new drug that has not been approved to a country with an appropriate health agency that has reviewed and approved the drug as safe for its intended use. This authorization is conditioned upon requirements in existing law that such articles accord to foreign specifications, are not in conflict with the laws of the foreign country, are labeled as intended for export, and are not sold or offered for sale in domestic commerce. In addition, the exporter of any such unapproved drug must submit a notice to the Secretary annually which identifies the new drug intended for export during the prospective twelve month period beginning thirty days after the date of notice, identifies the countries to which such drug is to be exported and demonstrates that the drug has been reviewed and approved for use by the appropriate health agency of the foreign country.

The proposed legislation also authorizes the export of unapproved new drugs to countries which do not have appropriate health agen-

Agency Report

The following letter from the Department of Health, Education, and Welfare, dated February 5, 1976, setting forth that agency's views on the bill, H.R. 11124, was received by the Committee.

Department of Health, Education, and Welfare

February 5, 1976.

Hon. Harley O. Staggers,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

Dear Mr. Chairman: There is before your Committee, as reported by the Subcommittee on Public Health and Environment on November 13, 1975, H.R. 11124, the "Medical Device Amendments of 1975." The reported bill is a clean bill in lieu of H.R. 5545 as amended by the Subcommittee.

The Department of Health, Education, and Welfare supported legislation similar to H.R. 11124 in the Ninety-third Congress and has long endorsed the need for modernizing the authority of the Food and Drug Administration (FDA) over medical devices. We also presented testimony generally favorable to H.R. 5545 at hearings before the Subcommittee on July 28, 1975. Provided that it is amended to meet a few continuing concerns outlined in an analysis which we will shortly forward to your attention, the Department vigorously supports H.R. 11124 as a balanced response to this need.

If H.R. 11124 were enacted, FDA would use both existing resources and a substantial part of the $17 million requested increase for the Agency in the President's 1977 budget to implement a strengthened medical device regulation program.

A number of changes made in the Subcommittee simplified and thus improved administrative proceedings under the bill. We favor, among other changes, the amended investigational device provisions, the transitional provisions for projects formerly categorized as "drugs," the substitution of "questioning" for "cross-examination" at informal hearings, the provisions requiring FDA to make public a detailed summary of safety and effectiveness information respecting certain devices, the exemption of class I, General Control devices, from the biennial inspection provision, and the understanding that the restricted device provisions apply both as to effectiveness as well as safety of a device.

In each of the areas where H.R. 11124 would strengthen FDA's current authority, the Agency has been operating under serious handicaps because of lack of legislative authority to enable the Agency to keep pace with the burgeoning growth in the introduction of complex new medical equipment for use on or in humans.

We understand that certain industry representatives are urging your Committee to use H.R. 11124 as a vehicle for amending the criminal liability provisions of the Federal Food, Drug, and Cosmetic Act with respect to all products subject to the Act, not just medical devices.

sumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."

The same reasoning was more recently echoed by Chief Justice Burger in his opinion for the Court in the *Park* case.

FDA believes strongly that the strict liability standard is an indispensable adjunct to its efforts to enforce the Act. The dimensions of the agency's enforcement responsibilities are dramatized by a glance at the food industry as an example. There are approximately 60,000 food factories and warehouses in the United States and fewer than 1000 FDA inspectors (many of whom are assigned full-time to other duties). Inspections must, of necessity, be sporadic. It is clear therefore that the purity of the nation's food supply rests, in the first instance, in the hands of food producers and processors.

Since the civil remedies available to FDA (seizure and injunction actions) are essentially retrospective in effect, regulated firms can, and often do, simply sit back and wait for FDA to act. It is far cheaper to risk the loss of a few hundred or thousand dollars as a result of an occasional seizure or injunction than to regularly allocate the resources necessary to fully comply with the requirements of the Federal Food, Drug, and Cosmetic Act. The primary impetus to self-regulation is the fear that criminal prosecution may result from failure to take every precaution to ensure that violations—and their potentially harmful consequences to health—will not occur.

Program Oversight

Because the proposed legislation would establish a new authority with which the Secretary of Health, Education, and Welfare, through the Food and Drug Administration, is to regulate the safety and effectiveness of medical devices for human use, the Committee has conducted no oversight activities with respect to medical device regulation. As discussed earlier in this report, existing authority permits the seizure of adulterated or misbranded medical devices and also has been interpreted by the courts to include the regulation of certain medical devices as drugs. The Committee's principal oversight activities with respect to these aspects of existing law have been conducted by the Subcommittee on Health and the Environment in connection with its consideration of the new legislative authority. Legislative hearings were conducted by the Subcommittee in October of 1973 and July of 1975, and its findings are discussed in detail in this report.

Oversight hearings with respect to the need for regulation of intrauterine devices were conducted by the Subcommittee on Intergovernmental Relations and Human Resources of the Government Operations Committee in May and June of 1973, and the Committee considered those hearings in the development of this legislation. The Committee has not received oversight reports from its own Subcommittee on Oversight and Investigations.

Inflation Impact Statement

No line-item authorization is included for the implementation of the proposed legislation. The Committee anticipates that the annual cost to the Federal government in budgetary outlays in order to im-

SECTION-BY-SECTION ANALYSIS

Section 1 of the bill provides that the bill may be cited as the "Medical Device Amendments of 1976" and that the bill's amendments (except as noted in section 3) are to the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as the "Act"). This section also contains a table of contents.

Section 2 of the bill amends chapter V of the Act to add new sections 513 (classification of devices intended for human use), 514 (performance standards), 515 (premarket approval), 516 (banned devices), 517 (judicial review), 518 (notification and other remedies), 519 (records and reports on devices), 520 (general provisions respecting control of devices intended for human use), and 521 (State and local requirements respecting devices).

New section 513 governs the classification of medical devices intended for human use.

New sec. 513(a) establishes a system of classification of devices. The classes are as follows:

Class I—General Controls—devices (a) for which controls with respect to adulteration; misbranding; registration; banning; defect notification; repair, replacement, or refund; records and reports; and requirements for good manufacturing practices (referred to as "general controls" hereafter) are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (b) for which insufficient information exists to determine that general controls are sufficient to assure their safety or effectiveness or to establish a performance standard to provide such assurance, but are not represented to be for use of substantial importance to health and do not present a potential unreasonable risk of illness or injury.

Class II—Performance Standards—devices for which general controls are insufficient to provide reasonable assurance of safety and effectiveness, for which there is sufficient information to establish performance standards to provide such assurance, and for which it is thus necessary to establish performance standards to provide reasonable assurance of safety and effectiveness.

Class III—Premarket Approval—devices for which insufficient information exists to assure that general controls and performance standards will provide reasonable assurance of safety and effectiveness and (a) are represented to be for a use of substantial importance to health, or (b) present a potential unreasonable risk of illness or injury, and for which it is therefore necessary to require such devices to be subject to premarket approval.

This subsection also provides that the safety and effectiveness of a device are to be determined with respect to the persons for whose use the device is represented or intended; with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the

vices be classified in class III, such recommendations are to set forth the reasons for not recommending the classification into such class.

Panels are required to submit to the Secretary within one year of the date funds are first appropriated to carry out the Act their recommendations with respect to all devices introduced or delivered for introduction into interstate commerce for commercial distribution on or before enactment of the bill.

New sec. 513(d) requires the Secretary, upon receipt of panel recommendations for classifying a device, to publish the recommendations and a proposed regulation classifying the device. After providing opportunity for comment, the Secretary is required to classify the device by regulation. A regulation classifying a device into class I is to prescribe which if any of the requirements of section 510, 519 or 520(f) shall not apply to the device.

Any device which is intended to be implanted in the human body and which has been introduced or delivered for introduction into interstate commerce for commercial distribution on or before the date of enactment of the bill is required to be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation classifying such a device in a class other than class III is to be accompanied by a statement of the reasons of the Secretary for not classifying the device in such class. The Secretary is authorized to establish priorities which he shall use at his discretion in establishing performance standards under section 514 and requiring premarket approval under section 515.

New sec. 513(e) prescribes procedures whereby the Secretary may change the classification of a device. It provides that, based upon new information respecting a device, the Secretary may change the classification of a device and revoke any regulation or requirement in effect under section 514 or 515 with respect to the device. The Secretary is authorized to secure from the appropriate classification panel recommendations respecting any proposed changes in a device's classification. Regulations changing the classification of a device from class III to class II may provide that such action not take effect until the effective date of a performance standard applicable to the device.

New sec. 513(f) provides that any device not introduced or delivered for introduction into interstate commerce before the date of enactment of the bill is classified into class III unless the device is (1)(a) within a type of device so introduced or delivered for introduction before such date and which is to be classified pursuant to section 513(b) or (b) was not so introduced or delivered on or before such date but has subsequently been classified into class I or II and (2) is substantially equivalent to another device within such type. Except with respect to devices intended to be implanted in the human body, such devices may be reclassified, either through regular procedures under section 513(d) or by petition of a device manufacturer, which must be acted upon within 180 days after the petition is filed. The Secretary may not reclassify a device described above which is intended to be implanted in the human body before there is in effect for the device a premarket approval application under section 515. Thus, all such implantable devices must undergo premarket approval.

data on the basis of which the Secretary has found a need to initiate the proceeding to develop a standard, and an identification of any existing standards which may be relevant to the proceeding. The Secretary is to require that any offeror to develop a proposed standard submit to him relevant information with respect to the offeror's qualifications to develop a standard. This information is to include information, with respect to the offeror's financial stability, expertise, and experience, and any potential conflicts of interest, including financial interest in a device for which the proposed standard is to be developed. This information is to be made available to the public only if required under the provisions of section 552 of title 5, United States Code (relevant provisions of the Freedom of Information Act). Further, this subsection provides that if the Secretary determines that a standard can be developed by any Federal agency, including an agency within the Department of Health, Education, and Welfare (which includes the Food and Drug Administration) then in lieu of accepting any offer to develop a standard, the Food and Drug Administration or other Federal agency may develop such a standard.

New sec. 514(d) authorizes the Secretary to accept appropriate existing standards issued, adopted, or developed by a Federal agency or other qualified entity in lieu of accepting an offer to develop a proposed standard. Further, it provides that if the Secretary does not accept a standard which has been submitted pursuant to the provisions of section 514(c), he is to publish the reasons therefor.

New sec. 514(e) requires the Secretary, unless the Secretary or another Federal entity is developing a standard or the Secretary has accepted an existing standard, to accept at least one offer to develop a proposed standard for a device if he finds the offeror to be qualified, technically competent, and that the offeror will comply with appropriate procedures. Qualifications of an offeror are to be determined upon the basis of financial stability, expertise, experience, and any potential conflicts of interest, including financial interest in the device for which a standard is to be developed. The Secretary is to publish the names and addresses of persons whose offers are accepted and the terms of offers. He may contribute to the cost of development. He is required to prescribe regulations governing development of proposed performance standards pertaining to supporting data, opportunity of interested persons to participate in development of standards, maintenance of records and access to records relative to expenditure of Federal funds, and submission of periodic reports. Finally, this subsection requires that if the Secretary does not accept an offer pursuant to subsection (c) to develop a standard, he shall publish the reasons therefor.

New sec. 514(f) also authorizes the Secretary to develop a standard if no person has submitted an offer, if an offer has not been accepted, or if he determines, after accepting an offer or offers, that the offeror or offerors are unable or unwilling to continue development of a standard or a standard which has been developed is unsatisfactory.

New sec. 514(g) provides that after a publication of a section 514(c) notice inviting submission of a proposed standard or inviting an offer to develop a proposed standard, the Secretary must either publish, in a notice of proposed rulemaking, the proposed standard which has been developed or accepted or issue a notice terminating the pro-

with the premarket approval requirements. Any other device classified in class III must comply with such requirements only after a regulation has been promulgated under subsection (b) to make such requirements applicable to the device.

New sec. 515(b) directs the Secretary to require, by regulation, premarket approval of a class III device which was introduced or delivered for introduction into interstate commerce before the date of enactment (or which is of a type so introduced or delivered and substantially equivalent to another device within such type).

A proceeding for promulgation of a regulation by the Secretary requiring premarket approval is to be initiated by publication of a notice in the Federal Register. The notice is to contain the proposed regulation, proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to undergo premarket approval, opportunity for comment, and opportunity to request a change in classification based upon new information. If a request for reclassification is received, the Secretary must, after consultation with the appropriate classification panel, either promulgate the regulation or terminate the proceeding, in which case he shall initiate a proceeding under section 513(e) to reclassify the device. If the request is denied, the Secretary is either to promulgate the regulation or terminate the proceeding, in which case he shall initiate a section 513(e) proceeding unless the device has been banned under section 516. The Secretary is authorized to amend or revoke any regulation requiring premarket approval.

New sec. 515(c) authorizes any person to file an application for premarket approval for a class III device and requires that applications must contain appropriate reports of investigations of the safety and effectiveness of the device, descriptions of its manufacture, construction, and processing, references to applicable performance standards, samples as required by the Secretary, specimens of labeling, and other relevant information. An application is to be referred to the appropriate classification panel for a report and recommendation respecting its approval.

New sec. 515(d) requires the Secretary to approve or deny approval of a premarket approval application within 180 days from its receipt, unless the period is extended by agreement between the Secretary and the applicant in cases in which the continued availability of the device is necessary for the public health. (This requirement is subject to the "transitional" provisions of section 520, which require, in certain limited instances, that applications be approved or denied within 120 days). An order approving an application may require as a condition to approval that the sale and distribution of the device be restricted under the provisions of section 520(e).

The Secretary is required to deny approval of an application if (1) there is a lack of showing of reasonable assurance that the device is safe and effective, (2) the methods used in and the facilities and controls used for the manufacture of the device do not conform to good manufacturing practices required under section 520(f), (3) the labeling of the device is false or misleading, or (4) the device does not conform to an appropriate performance standard compliance with which is a condition to approval of the application. Denial of approval is,

progress reports and records of trials conducted. Proposed PDPs are to be approved or disapproved within 120 days of submission unless the Secretary and the person who submitted the PDP agree upon an additional period.

After provision of opportunity for an informal hearing, the Secretary may issue an order revoking a PDP if he finds (1) substantial failure to comply with the requirements of the PDP, (2) that the results of the trials under the PDP differ so substantially from the results required that further trials cannot be justified, or (3) that trial results or new information cannot demonstrate that the device tested under the PDP does not present unreasonable risk to health and safety.

Following approval of a PDP, the person for whom the PDP was approved may submit to the Secretary a notice of completion, containing information concerning safety and effectiveness of the device and results of trials required by the PDP. Within 90 days of receipt of such notice, the Secretary must either declare the PDP completed or declare it not completed. An order declaring a PDP not completed may take effect only after an informal hearing. A proposed PDP may be declared not completed only if the Secretary finds (1) substantial failure to comply with its requirements, (2) substantial difference between trial results and results required by the PDP, or (3) a lack of showing of reasonable assurance of safety and effectiveness of the device.

The Secretary is authorized to issue an order revoking approval of a device provided by a notice of completion which has become effective, on the basis of findings identical to those required for withdrawal of an approved application for premarket approval under section 515 (e). Persons whose PDPs have been revoked or declared not completed, and persons subject to orders revoking approval of a device provided by a notice of completion may seek review under the provisions of section 515(g).

New sec. 515(g) authorizes two means of review of orders approving, denying approval of, or withdrawing approval of, applications for premarket approval and orders revoking a PDP, declaring a PDP not to be completed, or revoking approval of a device after a notice of completion of a PDP has become effective. These means of review are mutually exclusive and the petitioner may select the type of review, except that the Secretary may deny a petition for an adjudicative hearing if he finds the petition to be without good cause. The first method is an adjudicative hearing on such order. In this case, at the request of the petitioner, the Secretary or the presiding officer, a member of the panel designated by it which considered the subject under dispute shall appear and testify at the hearing. Following the hearing and after consideration of the hearing record, the Secretary is to either affirm or reverse the disputed order. The second method of administrative review is referral by the Secretary of contested orders respecting premarket clearance or PDPs to an advisory committee of experts qualified in the subject matter to be referred to it (which may not be section 513 classification panels) for independent study and submission of a report and recommendation. The report and recommendation of the advisory committee are to be promptly supplied to the petitioner

New sec. 517(a) authorizes judicial review of the actions described above in the United States Court of Appeals for the District of Columbia or for the circuit wherein the person adversely affected by the order resides or does business, and requires the Secretary to file with the court the record of proceedings on which he based the regulation or order.

New sec. 517(b) authorizes the court to require the Secretary, upon request of the petitioner, to provide additional opportunity for oral and written submissions to him and authorizes the Secretary to make new or modified findings based on such submissions and file new findings and recommendations for modifying or setting aside of the contested regulation or order.

New sec. 517(c) authorizes the court to review petitions in accordance with chapter 7 of title 5, United States Code (relating to judicial review) and requires that the following actions not be affirmed if found to be unsupported by substantial evidence on the record taken as a whole:

(1) A regulation under section 514 establishing, amending or revoking a performance standard.

(2) A regulation under section 516 making a device a banned device (except for a proposed regulation made effective upon its publication pursuant to section 516(b)).

(3) An order issued after the administrative review authorized under section 515(g).

New sec. 517(d) provides that the judgment of the court of appeals with respect to contested regulations or orders shall be final, subject to review by the United States Supreme Court.

New sec. 517(e) specifies that the remedies authorized by section 517 do not foreclose other remedies authorized by law.

New sec. 517(f) requires that each regulation and order issued under section 513, 514, 515, 516, 518, 519, 520 or 521 contain a statement of the reasons for its issuance and the basis for its issuance in the record of proceedings held in connection with its issuance, in order to facilitate judicial review.

New section 518 authorizes the Secretary to require notification and repair, replacement, or refund in appropriate circumstances in connection with medical devices.

New sec. 518(a) authorizes the Secretary, upon his determination that a device presents an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate the unreasonable risk, and that no other more practicable means are available to eliminate such risk, to issue an order requiring notification of the risk to all health professionals who prescribe or use the device and to any other person who should properly receive notification in order to eliminate the risk. Orders shall require that persons exposed to the risk be notified unless the Secretary determines that such notification would pose a greater danger to health than lack of notification, in which case the order shall require that the health professionals who prescribe or use use the device notify individuals treated with the device of the risk presented and of any action which may be taken to eliminate or reduce such risk. The Secretary is to consult with persons who are to give notice under an order requiring notification prior to its issuance.

vide information required by regulations of the Secretary to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. This subsection further requires (1) that regulations shall not impose requirements which are unduly burdensome, taking into account the cost of complying with them and the need for protection of public health; (2) that regulations which prescribe the procedure for making requests for information require that each request state the reason or purpose for such request and identify the report or information requested; (3) that regulations which require submission of a report or information to the Secretary shall state the reason or purpose for such submission and identify such report or information; and (4) that regulations may not require that the identity of any patients be disclosed unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify information submitted under the Act. Manufacturers, importers, or distributors of class I devices may not be required to maintain or submit for such devices records or reports not in their possession or submit records on a periodic basis, unless such information is necessary to determine if such a device should be reclassified or is adulterated or misbranded. In prescribing regulations with respect to records and reports, the Secretary is required to have due regard for the professional ethics of the medical profession and the interest of patients. The prohibitions designed to protect the identity of patients, are to continue in effect irrespective of whether a person ceases to be a patient.

New sec. 519(b) exempts from the section 519(a) requirements licensed practitioners who manufacture or import devices solely for use in their professional practices, persons who manufacture or import devices solely for their own use in research or teaching, and other classes of persons that the Secretary may exempt upon a finding that the requirements are unnecessary to assure that a device is not adulterated or misbranded or otherwise to assure its safety and effectiveness.

New *section 520* establishes general provisions respecting control of devices.

New sec. 520(a) provides that any requirement of sections 501 (adulteration), 502 (misbranding), 510 (registration), and 519 (records and reports) which is applicable to a device shall continue to apply until the applicability is changed through action taken under section 514 (performance standards) or 515 (premarket approval), and that any such requirement made inconsistent by action under section 514 or 515 shall not apply.

New sec. 520(b) authorizes "custom devices" to deviate from otherwise applicable section 514 or 515 requirements in order to comply with an order of a physician, dentist, or other specially qualified person if (1) the device is not generally available in finished form for purchase or dispensing on prescription, and is not offered for commercial distribution, and (2) the device (a) is either intended for use by a patient named in an order or intended solely for use by a physician, dentist, or other specially qualified person in the course of his practice, and (b) is not generally available to other physicians, dentists, or other designated persons.

New sec. 520(c) requires that any trade secret obtained by the Secretary in connection with section 513, 514, 515, 516, 518, 519, 704 or

proving the petition) are sufficient to assure that the device is safe, effective, and otherwise in compliance with the Act. Petitioners for a variance or exemption are afforded an opportunity for an informal hearing after issuance of an order with respect to the petition.

New sec. 520(g) authorizes exemptions for devices intended for investigational use from otherwise applicable provisions of the Act. This section requires that within 120 days following the date of enactment of the bill, the Secretary shall prescribe by regulation procedures and conditions under which devices intended for human use may be granted exemptions from the requirements of section 502, 510, 514, 515, 516, 519, 706, 520(e) or 520(f), or any combination of such requirements, in order to permit the investigational use of such devices by qualified experts. Such conditions are to include (1) submission of an application to the Secretary; (2) the establishment and maintenance of such records and the making of such reports as will enable the Secretary to assure compliance with applicable conditions, review the progress of the investigation and evaluate the safety and effectiveness of the device; and (3) such other requirements as may be necessary for the protection of public health and safety. Procedures and conditions permitting investigational use may vary depending upon (1) the scope and duration of clinical testing to be conducted, (2) the number of human subjects involved in the testing, (3) the need to permit changes to be made in the device during testing, and (4) whether such testing is for the purpose of developing data to obtain approval for commercial distribution of the device.

If a device is to be the subject of testing involving human subjects, the procedures and conditions authorizing investigational use must include (1) submission of a plan for the proposed clinical testing and a report of prior investigations of the device to the local institutional review committee which is to supervise the testing, or to the Secretary if no such committee exists or the Secretary determines that the process of review by such committee is inadequate, in which case the person applying for the exemption must submit a summary of the plan and a report of prior investigations of the device to the Secretary; (2) prompt notification to the Secretary of approval by an institutional review committee of the clinical testing plan submitted to it; (3) in instances in which a device is to be distributed to investigators for testing the obtaining of signed agreements from each such investigator that any testing involving human subjects will be under the investigator's supervision and in accordance with requirements respecting informed consent; and (4) assurance that informed consent will be obtained from each human subject (or his representative) unless the investigator determines in writing that a life-threatening situation involving the proposed subject of such testing exists, that such situation necessitates the use of the device, it is not feasible to obtain informed consent from the subject, and that there is not sufficient time to obtain such consent from the subject's representative. Such determination must be concurred in by a licensed physician not involved in the testing of the subject unless immediate use of the device is required to save the subject's life and there is not sufficient time to obtain such concurrence.

Applications for exemptions for devices for investigational use shall, except in the case of applications seeking exemption from section 516 (relating to banned devices), be deemed approved on the

such requirements are necessary to assure the protection of the public health.

New sec. 520(k) authorizes the Secretary to enter into contracts for research, testing, and demonstrations respecting devices and authorizes the Secretary to obtain devices for such purposes without regard to sections 3648 and 3709 of the Revised Statutes (relating to advanced payment and procurement).

New sec. 520(l) prescribes "transitional" provisions for devices in various stages of regulation by the Food and Drug Administration as new drugs or antibiotic drugs upon the date of enactment of the bill. It provides that the following devices are automatically classified into class III unless the Secretary has classified them into class I or class II pursuant to a petition described below:

(1) A device for which on the date of enactment of the bill an approved new drug application was in effect under section 505(b) of the Act,

(2) A device for which such new drug application was filed on or before the enactment date and with respect to which no order under section 505(c) or section 505(d) of the Act had been issued on such date,

(3) A device for which an exemption for investigational use under section 505(i) was in effect on the enactment date,

(4) A device which is substantially equivalent to a device described in paragraph (1), (2) or (3) above,

(5) A device which, prior to the date of enactment of the bill, the Secretary has declared to be a "new drug" subject to section 505 of the Act, or

(6) A device with respect to which on the enactment date, there is pending in a United States court an injunction proceeding under section 302 of the Act, a criminal proceeding under section 303 of the Act, or a seizure action under section 304 of the Act, alleging the commission of a prohibited act under section 301 of the Act, which enforces a requirement of section 505 of the Act, or alleging a violation of section 505(a) of the Act.

This subsection authorizes the manufacturer or importer of any device classified into class III under the requirements described above to petition the Secretary for the issuance of an order classifying such device into class I or II. The Secretary is required to notify the petitioner of any deficiencies in the petition which prevent him from making a decision on it within 30 days after the filing of the petition. Within 180 days after the filing of such petition, and after affording opportunity for an informal hearing and consulting with the appropriate classification panel, the Secretary is required to either deny the petition or order reclassification of the device which is the subject of the petition into class I or class II in accordance with the criteria prescribed by section 513.

This subsection further provides that any device which is subject to an approved new drug application is to be considered a device with an approved application under section 515 on the date of enactment of the bill and that the requirements applicable to the device under section 505 of the Act prior to the enactment date shall continue to apply to the device until changed by the Secretary. In the case

(b) if classified into class II, until the effective date of the performance standard applicable to the device under section 514; and

(c) if classified into class III, until the date on which the device is required to have in effect an approved application for premarket approval under section 515.

New Section 521 governs the relationship between Federal requirements under the Act as amended by the bill and State and local requirements.

New sec. 521(a) provides that no State or political subdivision thereof may establish or continue in effect a requirement relating to the safety or effectiveness of a device or any requirement applicable to a device different from, or in addition to, any requirement applicable to the device under this Act as amended by the bill.

New sec. 521(b) provides that upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for oral hearing, exempt the requirement of a State or political subdivision applicable to a device intended for human use from the provisions of section 521(a) if (1) the requirement is more stringent than a requirement under the bill which would be applicable to the device if an exemption were not in effect, or (2) the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any requirement under the bill.

Section 3 of the bill includes conforming amendments to existing provisions of the Act and the Federal Trade Commission Act.

Sec. 3(a)(1) of the bill amends section 201(h) of the Act and section 15(d) of the Federal Trade Commission Act to substitute a new and expanded definition of "device" in such laws.

Sec. 3(a)(2) of the bill adds a new section 201(y) to the Act to define "informal hearing" as a hearing which is not subject to sections 554, 556 or 557 of Title 5, United States Code (applicable provisions of the Administrative Procedure Act), and which provides for (1) designation of the presiding officer by the Secretary from officers and employees of the Department of Health, Education, and Welfare who have not participated in any action which is the subject of the hearing and who are not directly responsible to an officer or employee who has so participated; (2) the right of each party to the hearing to be at all times advised and accompanied by an attorney; (3) reasonable notice to each party to the hearing prior to the hearing, including a comprehensive statement of the basis for the action taken or proposed to be taken by the Secretary which is the subject of the hearing and a general summary of information which will be presented by the Secretary at the hearing; (4) the right of the parties to the hearing to hear a full and complete statement of the action of the Secretary which is the subject of the hearing, to conduct reasonable questioning, and to present any written or oral information relevant to the action of the hearing; (5) the preparation by the presiding officer of the hearing of a written report of the hearing and the right of participants in the hearing to review and correct or supplement such report; and (6) authorization for the Secretary to require the hearing to be transcribed and for a party to the hearing to have the hearing transcribed at such

(2) a restricted device unless all advertisements and other descriptive matter with respect to it (a) bear the device's established name as defined in section 502(e) of the Act, (b) include a brief statement of the intended uses of the device, relevant warnings, precautions, side effects and contraindications, and (c) in instances in which the Secretary finds necessary to protect the public health, include a description of the components of the device or its formula showing its ingredients to the extent required in regulations issued after opportunity for hearing. This provision further provides that, except in extraordinary circumstances, no regulation shall require prior approval of the content of any advertisement and specifies that no advertisement with respect to the matters required under this new paragraph or covered by regulations issued under it, shall be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (relating to the dissemination of false advertisements). Further, the new paragraph is rendered inapplicable to printed matter determined by the Secretary to be labeling under section 201(m) of the Act.

(3) a device subject to a performance standard established under section 514, unless it bears such labeling as is prescribed in the standard.

(4) a device for which there was failure or refusal to comply with a requirement prescribed under section 518 (relating to notification, repair, replacement and refund of the purchase price of devices which present risk of substantial harm to public health), or to furnish information required by or under section 519 (relating to records and reports on devices).

Sec. 3(f) of the bill amends Sec. 801(d) of the Act to revise the conditions under which certain drugs and devices may be exported. Under existing law, a food, drug, device, or cosmetic which does not conform to provisions of the Act may be exported if three requirements are met: it accords to the specifications of the foreign purchaser, it is not in conflict with the laws of the foreign country to which it is intended for export, and it is labeled as intended for export. Existing law makes these provisions inapplicable to an article sold or offered for sale in domestic commerce. Existing law also prohibits the export of a new animal drug or animal feed medicated with a new animal drug which is unsafe within the meaning of section 512 of the Act. Moreover, existing provisions of the Act authorizing the export of drugs do not apply to "new drugs" since the Act's restriction against introduction of unapproved new drugs into interstate commerce is under the provisions of section 301(d), and not the adulteration or misbranding provisions affected by existing section 801(d). The provisions of existing section 801(d) are applicable to antibiotic drugs, since antibiotic drugs fall within the definition of "drug" as defined in section 201(g) of the Act.

New sec. 801(d)(1) restates the provisions of existing law which exempt from the adulteration and misbranding sections of the Act and which consequently permit the export of foods, drugs, devices, or cosmetics intended for export that (1) conform to the foreign purchasers' specifications, (2) are not in conflict with the laws of the countries to which export is intended, (3) are labeled on the outside of

not contrary to public health and safety of persons within the United States; and (3) (a) if the appropriate health agency of the country to which such drug or feed is to be exported has reviewed and authorized or approved such drug or feed as safe for its intended use (including investigational use), or (b) if there is no such agency, the Secretary determines that exportation is not contrary to public health and safety.

New sec. 801(d)(5) modifies existing law, which has the effect of prohibiting the export of a new drug for which an application is not in effect under section 505 of the Act. This paragraph provides that such drugs may be exported if, in addition to satisfying the requirements of section 801(d)(1), one of the following alternative conditions is met. First, if the country to which the drug is intended for export has an appropriate health agency to review the drug and authorize or approve it as safe for its intended use (including investigational use) within that country and (1) such agency has so reviewed and authorized or approved the drug, and (2) the Secretary has been provided notification as required by new section 801(d)(6), the drug may be exported to that country. Alternatively, if the country to which such drug is intended for export does not have an appropriate health agency to review and approve the drug, it may be exported to such country only if the Secretary determines upon application and after provision to the applicant of opportunity for an informal hearing on the application, that the exportation of the drug is not contrary to public health and safety.

New sec. 801(d)(6) provides that each person required to register under section 510 of the Act (which, as amended by the bill, requires persons who manufacture drugs or devices to register with the Secretary and provide a listing of drugs and devices manufactured by them) who proposes to export to a country which has an appropriate health agency to review the drug or device and authorize or approve it as safe for its intended use (including investigational use) within that country, submit to the Secretary annually, in accordance with regulations, a notice which may be amended in accordance with regulations to (1) identify each device not in compliance with section 514 or 515 or banned under section 516, each antibiotic drug not in compliance with section 507, and each new drug not in compliance with section 505 intended for export during the prospective 12-month period beginning thirty days after the date of the notice, (2) identify the countries to which each such device or drug will be exported, and (3) demonstrate to the satisfaction of the Secretary that such device or drug is in compliance with section 801(d)(1), has been reviewed by the appropriate health agency of the country to which it is being exported and that such agency has authorized or approved it as safe for its intended use.

New sec. 801(d)(7) authorizes the Secretary, after providing notice and opportunity for an informal hearing, to issue an order prohibiting the introduction or delivery for introduction into interstate commerce for export of any device not in compliance with section 514 or 515 or banned under section 516, any antibiotic drug not in compliance with section 507, any new drug not in compliance with section 505, or any new animal drug or animal feed containing a new animal drug which is unsafe within the meaning of section 512 and which is the sub-

ance with regulations or, if not in final form for shipment, in order to complete work required to put them in such form. A conforming change to section 301 is made to make violations of the administrative detention provisions a prohibited act.

Section 8 of the bill adds two new sections, 707 and 708 to the Act. New section 707 authorizes the Secretary to provide trade secrets and other confidential information to persons under contract with the Secretary and requires security precautions as a condition to receipt of such information. New section 708 establishes a presumption of existence of connection with interstate commerce required to establish jurisdiction in actions to enforce the Act with respect to devices.

Section 9 of the bill amends section 706 of the Act (relating to color additives) to render a color additive in a device to be subject to the provisions of that section if the color additive comes into contact with the body of man or other animals for a significant period of time, and authorizes the Secretary to designate, by regulation, the uses of color additives in or on devices which are subject to section 706. This section also makes necessary conforming changes in sections 501 and 502.

Section 10 of the bill requires the Secretary to establish within the Department of Health, Education, and Welfare, an office to provide technical and other nonfinancial assistance to small manufacturers of devices to assist them in complying with requirements of the Act.

94TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 94–1090

MEDICAL DEVICE AMENDMENTS OF 1976

MAY 6, 1976.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 510]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 510) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety and effectiveness of medical devices, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment to the text of the bill insert the following:

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. (a) This Act may be cited as the "Medical Device Amendments of 1976".

(b) Whenever in this Act (other than in section 3(a)(1)(B)) an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

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Sec. 2. Regulation of medical devices.
"Sec. 513. Classification of devices intended for human use.
"(a) Device classes.
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"(d) Classification.
"(e) Classification changes.
"(f) Initial classification of certain devices.
"(g) Information.
"(h) Definitions.

Sec. 7. Administrative restraint.
Sec. 8. Confidential information; presumption.
Sec. 9. Color additives.
Sec. 10. Assistance for small manufacturers of devices.

REGULATION OF MEDICAL DEVICES

SEC. 2. Chapter V is amended by adding after section 512 the following new sections:

"CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

"Device Classes

"SEC. 513. (a)(1) There are established the following classes of devices intended for human use:

"(A) CLASS I, GENERAL CONTROLS.—

"(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

"(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but because it—

"(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

"(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

"(B) CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.

"(C) CLASS III, PREMARKET APPROVAL.—A device which because—

"(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

"(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences,and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

"(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

"(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

"Classification Panel Organization and Operation

"(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

"(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs

"(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

"(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 515(b)(1) the Secretary may establish priorities which, in his discretion, shall be used in applying sections 514 and 515, as appropriate, to such devices.

"Classification Changes

"(e) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (1) change such device's classification, and (2) revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

"Initial Classification of Certain Devices

"(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

"(A) the device—

"(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

"(ii) is substantially equivalent to another device within such type, or

"(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II.

"Information

"(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

"Definitions

"(h) For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

"(1) a reference to 'general controls' is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

"(2) a reference to 'class I', 'class II', or 'class III' is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

"(3) a reference to a 'panel under section 513' is a reference to a panel established or authorized to be used under this section.

"PERFORMANCE STANDARDS

"Provisions of Standards

"SEC. 514. (a)(1) The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 513(e) but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

"(2) A performance standard established under this section for a device—

"(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

"(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

"(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

"(iii) provisions for the measurement of the performance characteristics of the device,

"(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under

"(B) *offer, within sixty days after the date of publication of the notice, to develop such a proposed standard.*

"(2) *A notice published pursuant to paragraph (1) for an offer for the development of a proposed performance standard for a device—*

"(A) *shall specify a period within which the standard is to be developed, which period may be extended by the Secretary for good cause shown; and*

"(B) *shall include—*

"(i) *a description or other designation of the device,*

"(ii) *a statement of the nature of the risk or risks associated with the use of the device and intended to be controlled by a performance standard,*

"(iii) *a summary of the data on which the Secretary has found a need for initiation of the proceeding to develop a performance standard, and*

"(iv) *identification of any existing performance standard known to the Secretary which may be relevant to the proceeding.*

"(3) *The Secretary shall by regulation require that an offeror of an offer to develop a proposed performance standard submit (and if the offeror is a business entity, require that appropriate directors, officers, and employees of, and consultants to, the business entity submit) to the Secretary such information concerning the offeror as the Secretary determines is relevant with respect to the offeror's qualifications to develop a proposed performance standard for a device, including information respecting the offeror's financial stability, expertise, and experience, and any potential conflicts of interest, including financial interest in the device for which the proposed standard is to be developed, current industrial or commercial affiliates of the offeror, current sources of financial support for research, and business entities in which the offeror has a financial interest, which may be relevant with respect to the offeror's qualifications. Such information submitted by an offeror may not be made public by the Secretary unless required by section 552 of title 5, United States Code, except that in the case of information submitted by an offeror whose offer has been accepted, the Secretary shall make such information (other than information which because of subsection (b)(4) of section 552, title 5, United States Code, is exempt from disclosure pursuant to subsection (a) of such section) public at the time the offer is accepted.*

"(4) *If the Secretary determines that a performance standard can be developed by any Federal agency (including an agency within the Department of Health, Education, and Welfare), the Secretary may—*

"(A) *if such determination is made with respect to an agency within such Department, develop such a standard in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to this subsection, or*

"(B) *if such determination is made with respect to any other agency, authorize such agency to develop such a standard in lieu of accepting any such offer.*

In making such a determination respecting a Federal agency, the Secretary shall take into account the personnel and expertise within such

the cost of construction (except minor remodeling) or the acquisition of land or buildings. Payments to an offeror under this paragraph may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

"(4) The Secretary shall prescribe regulations governing the development of proposed standards by persons whose offers are accepted under paragraph (1). Such regulations shall, notwithstanding subsection (b)(A) of section 553 of title 5, United States Code, be promulgated in accordance with the requirements of that section for notice and opportunity for participation and shall—

"(A) require that performance standards proposed for promulgation be supported by such test data or other documents or materials as the Secretary may reasonably require to be obtained;

"(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity;

"(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information submitted by any person in connection with such development, including comments and information with respect to the need for such performance standards, and (iii) such other matters as may be relevant to the evaluation of such performance standards;

"(D) provide that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and other records, relevant to the expenditure of any funds contributed by the Secretary under paragraph (3); and

"(E) require the submission of such periodic reports as the Secretary may require to disclose the course of the development of performance standards proposed for promulgation.

"(5) If an offer is made pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such offer, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

"Development of Standard by Secretary After Publication of Subsection (c) Notice

"(f) If the Secretary has published a notice pursuant to subsection (c) and—

"(1) no person makes an offer or submits a standard pursuant to the notice;

"(2) the Secretary has not accepted an existing performance standard under subsection (d) or accepted an offer to develop a proposed performance standard pursuant to the notice; or

"(3) the Secretary has accepted an offer or offers to develop a proposed performance standard, but determines thereafter that—

"(A) the offeror under each such offer is unwilling or unable to continue the development of the performance standard which was the subject of the offer or offers, or

which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

"(4) (A) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (2) and (3)(B) of this subsection, amend or revoke a performance standard.

"(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines, after affording all interested persons an opportunity for an informal hearing, that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

"(5)(A) The Secretary—

"(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

"(ii) shall, upon the request of an interested person unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation, to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative

"(B) *If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).*

"(3) *After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.*

"(4) *The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.*

"*Application for Premarket Approval*

"(c)(1) *Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—*

"(A) *full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;*

"(B) *a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;*

"(C) *a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;*

"(D) *an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;*

"(E) *such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;*

"(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

"(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

"Withdrawal of Approval of Application

"(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the applications if the Secretary finds—

"(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(C) that the application contained or was accompanied by an untrue statement of a material fact;

"(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

"(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

"(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

"(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

"(vi) if appropriate, specimens of the labeling proposed to be used for such device,

"(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and

"(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

"(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protcol is final agency action subject to judicial review under chapter 7 of title 5, United States Code.

"(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

"(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

"(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

"(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

"(i) such person has failed substantially to comply with the requirements of the protocol,

"(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

"(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

"(B) After the receipt of notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol

ing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

"(2)(A) Upon petition for review of—

"(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

"(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

"JUDICIAL REVIEW

"Application of Section

"SEC. 517. (a) Not later than thirty days after—

"(1) the promulgation of a regulation under section 513 classifying a device in class I or changing the classification of a device to class I or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,

"(2) the promulgation of a regulation under section 514 establishing, amending, or revoking a performance standard for a device,

"(3) the issuance of an order under section 514(b)(2) or 515(b)(2)(B) denying a request for reclassification of a device,

"(4) the promulgation of a regulation under paragraph (3) of section 515(b) requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 515(g)(1) or 515(g)(2)(C),

"(5) the promulgation of a regulation under section 516 (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

"(6) the issuance of an order under section 520(f)(2), or

"(7) an order under section 520(g)(4) disapproving an application for an exemption of a device for investigational use or an order under section 520(g)(5) withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28, United States Code. For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

"Additional Data, Views, and Arguments

"(b) If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data,

is available under the provisions of this Act (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

"Repair, Replacement, or Refund

"(b)(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

"(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

"(ii) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it exists at the time of its design and manufacture,

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

"(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the pro-

order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

"*Effect on Other Liability*

"(*d*) *Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.*

"*RECORDS AND REPORTS ON DEVICES*

"*General Rule*

"*SEC. 519.* (*a*) *Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—*

"(*1*) *shall not impose requirements unduly burdensome to a device manufacturer, importer, or distributor taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this Act;*

"(*2*) *which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;*

"(*3*) *which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;*

"(*4*) *may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act; and*

"(*5*) *may not require a manufacturer, importer, or distributor of a class I device to—*

"(*A*) *maintain for such a device records respecting information not in the possession of the manufacture, importer, or distributor, or*

"(*B*) *to submit for such a device to the Secretary any report or information—*

"(*i*) *not in the possession of the manufacturer, importer, or distributor, or*

ing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

"(A) (i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

"(ii) in intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

"(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

"Trade Secrets

"(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device under section 513 from class III to class II or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

"Notices and Findings

"(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

"(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

"(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

"Restricted devices

"(e)(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

"(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

"(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

"(i) the date the petition was submitted to the Secretary under subparagraph (A), or

"(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

"(C) The Secretary may approve—

"(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

"(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

"(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

"(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1) (A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

"(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

"(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which

"(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

"(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

"(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

"(ii) to the Secretary, if—

"(I) no such committee exists, or

"(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

"(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

"(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

"(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

"(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall be deemed approved on the thirtieth day after the submission of the ap-

"(3) *Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.*

"*Proceedings of Advisory Panels and Committees*

"(i) *Each panel under section 513 and each advisory committee established under section 514(g)(5)(B) or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.*

"*Traceability Requirements*

"(j) *No regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.*

"*Research and Development*

"(k) *The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).*

"*Transitional Provisions for Devices Considered as New Drugs or Antibiotic Drugs*

"(l)(1) *Any device intended for human use—*

"(A) *for which on the date of enactment of the Medical Device Amendments of 1976 (hereinafter in this subsection referred to as the 'enactment date') an approval of an application submitted under section 505(b) was in effect;*

"(B) *for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;*

"(C) *for which on the enactment date an exemption under subsection (i) of such section was in effect;*

"(D) *which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;*

"(E) *which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or*

"(F) *with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which en-*

"(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginmay agree upon), the Secretary shall act on such petition or applicaor application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

"(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

"(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

"(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

"(4) Any device intended for human use which on the enactment date was subject to the requirements of section 507 shall be subject to such requirements as follows:

"(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

"(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 514.

"(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required to have in effect an approved application under section 515.

"(*d*) *The term 'device' (except when used in subsection (a) of this section) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—*

"(*1*) *recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,*

"(*2*) *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*

"(*3*) *intended to affect the structure or any function of the body of man or other animals, and*

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.".

(*2*) *Section 201 is amended by adding at the end the following:*

"(*y*) *The term 'informal hearing' means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:*

"(*1*) *The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department of Health, Education, and Welfare who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.*

"(*2*) *Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.*

"(*3*) *Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.*

"(*4*) *At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.*

"(*5*) *The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.*

"(*6*) *The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.*"

Amendments to Section 301

(*b*) (*1*) *Section 301 is amended by adding at the end the following new paragraphs:*

"(2)(A) *In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).*

"(B) *In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—*

"(i) *on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or*

"(ii) *on the ninetieth day after the date of the promulgation of such regulation,*

whichever occurs later.

"(g) *If it is a banned device.*

"(h) *If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).*

"(i) *If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.".*

Amendments to Section 502

(e)(1) *Section 502 is amended by adding at the end the following new paragraphs:*

"(q) *In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).*

"(r) *In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph*

(3) Subsections (b), (c), and (d) are amended by inserting "or a device or devices" after "drugs" each time it occurs.

(4) Subsection (e) is amended by adding at the end the following: "The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.".

(5) Subsection (g) is amended by inserting "or devices" after "drugs" each time such term occurs in paragraphs (1), (2), and *(3) of such subsection.*

(6) Subsection (h) is amended by inserting after "704 and" the following: "every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III".

(7) The first sentence of subsection (i) is amended by inserting ", or a device or devices," after "drug or drugs"; and the second sentence of such subsection is amended by inserting "shall require such establishment to provide the information required by subsection (j) in the case of a device or devices and" immediately before "shall include" and by inserting "or devices" after "drugs".

(8) Subsection (j) is amended—

(A) in the matter preceding subparagraph (A) of paragraph (1), by striking out "a list of all drugs (by established name" and inserting in lieu thereof "a list of all drugs and a list of all devices and a brief statement of the basis for believing each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name", and by striking out "drugs filed" and inserting in lieu thereof "drugs or devices filed";

(B) in paragraph (1)(A), by striking out "such list" and inserting in lieu thereof "the applicable list"; by inserting "or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515," after "512,", and by inserting "or device" after "such drug" each time it appears;

(C) in paragraph (1)(B), by striking out "drug contained in such list" before clause (i) and inserting in lieu thereof "drug or device contained in an applicable list";

(D) by amending clause (i) of paragraph (1)(B) to read as follows—

> *"(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or";*

(E) by amending clause (ii) of paragraph (1)(B) to read as follows:

> *"(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;";*

lished name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(4) Such section is amended by adding after subparagraph (3) (as so redesignated) the following:

"(4) As used in subparagraph (2), the term 'established name' with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device."

(b) Section 508 is amended (1) in subsections (a) and (e) by adding "or device" after "drug" each time it appears; (2) in subsection (b) by adding after "all supplements thereto," the following: "and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)"; (3) in subsection (c) (2) by adding "or device" after "single drug", and by adding "or to two or more devices which are substantially equivalent in design and purpose" after "purity,"; (4) in subsection (c) (3) by adding "or device" after "useful drug", and after "drug or drugs" each time it appears; and (5) in subsection (d) by adding "or devices" after "drugs".

INSPECTIONS RELATING TO DEVICES

SEC. 6. (a) The second sentence of subsection (a) of section 704 (21 U.S.C. 374) is amended by inserting "or restricted devices" after "prescription drugs" both times it appears.

(b) The third sentence of such subsection is amended to read as follows: "No inspection authorized by the preceding sentence shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j), section 507 (d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j))."

(c)(1) Paragraph (1) of the sixth sentence of such subsection is amended by inserting "or devices" after "drugs" each time it occurs.

(2) Paragraph (2) of that sentence is amended by inserting ", or prescribe or use devices, as the case may be," after "administer drugs"; and by inserting ", or manufacture or process devices," after "process drugs".

(3) Paragraph (3) of that sentence is amended by inserting ", or manufacture or process devices," after "process drugs".

tion 304(g) or the removal or alteration of any mark or label required by the order to identify the device as detained.".

CONFIDENTIAL INFORMATION; PRESUMPTION

SEC. 8. Chapter 7 is amended by adding at the end the following new sections:

"CONFIDENTIAL INFORMATION

"SEC. 708. The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Departmeni if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

"PRESUMPTION

"SEC. 709. In any action to enforce the requirements of this Act respecting a device the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.".

COLOR ADDITIVES

SEC. 9. (a) Section 706 is amended (1) by inserting "or device" after "drug" each time it occurs, (2) by inserting "or devices" after "drugs" each time it occurs, and (3) by adding at the end of subsection (a) the following new sentences: "A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.".

(b)(1) Section 501(a) is amended (A) by inserting "(3) if its" in lieu of "(3) if it is a drug and its"; (2) by inserting "(4) if (A) it bears or contains" in lieu of "(4) if (A) it is a drug which bears or contains"; and (3) by inserting "or devices" after "drugs" in subclause (B) of clause (4).

(2) Section 502(m) is amended by striking out "in or on drugs".

ASSISTACE FOR SMALL MANUFACTURERS OF DEVICES

SEC. 10. The Secretary of Health, Education, and Welfare shall establish within the Department of Health, Education, and Welfare an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and Senate at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 510) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act (hereinafter "the Act") to assure the safety and effectiveness of medical devices submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment struck out all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which is a substitute for the Senate bill and the House amendment.

The Senate bill and the House amendment were similar in scope and identical in purpose: to assure the reasonable safety and effectiveness of medical devices intended for human use.

Because a more extensive legislative history accompanied the House amendment, the conferees agreed to use the House amendment as the basis for the conference substitute with changes to reflect certain policies embodied in the Senate bill. Thus, except as specifically set forth below, the conference substitute conforms to the House amendment.

Classification of Medical Devices

Both the Senate bill and the House amendment provided for the classification of all medical devices intended for human use into one of three categories based on the extent of regulation necessary to assure safety and effectiveness. Both measures mandated the establishment of panels of experts to make recommendations to the Secretary of Health, Education, and Welfare with respect to the classification of devices. However, there were significant differences between the two measures with respect to criteria for classification and classification procedures.

SENATE BILL

Under the Senate bill all medical devices were subject to regulation following their classification into one of three categories based on the safety and effectiveness of such devices.

The categories were (1) devices subject to scientific review, (2) devices subject to performance standards, and (3) devices exempted from scientific review and performance standards.

Under the Senate bill, classification panels were to recommend classification of all medical devices—those on the market on or before the date of enactment as well as those marketed after enactment—based upon certain statutory criteria.

The Senate bill authorized the Secretary to promulgate a performance standard for any device which was initially classified into the performance standard category if he found that (1) such action would be appropriate to assure effectiveness or to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of the device and (2) other means available to him might not be appropriate to reduce such risk of illness or injury.

Exempt Devices

Finally, those devices which were determined to be safe and effective when used in conjunction with instructions for usage and warnings of limitation, which were adequate for the persons for whom the device was represented or intended for use, and which presented a minimum risk were to be exempt from requirements for scientific review or performance standards.

Such devices would, however, be subject to existing requirements prohibiting devices which are adulterated or misbranded as well as new requirements relating to provision of certain information to the Secretary upon request; registration; banned devices; notification; repair, replacement, or refund; and good manufacturing practices.

HOUSE AMENDMENT

Under the House amendment all medical devices were subject to regulation based upon their classification into one of three categories in accordance with statutory criteria. The classes were class I, general controls; class II, performance standards; and class III, premarket approval.

General Controls

Under the House amendment, devices for which controls relating to adulteration; misbranding; registration; misbranding; notification and repair replacement or refund; records and reports; and good manufacturing practices were sufficient to provide reasonable assurance of safety and effectiveness or for which insufficient information existed to determine that general controls were sufficient but which are not represented to be for a use of substantial importance in supporting, sustaining, or preventing impairment of human life or health and which do not present a potential unreasonable risk of illness or injury were to be classified into class I and subject to general controls. Class I devices were, with the exception noted below, to be subject to existing requirements prohibiting devices which are adulterated or misbranded as well as new requirements respecting registration; banned devices; records and reports; notification; repair, replacement, or refund; and good manufacturing practices. The House amendment required that the recommendation of a classification panel for the classification of a device in class I include a recommendation as to whether the device should be exempted from requirements relating to registration, records and reports, or good manufacturing practices. Further, the House amendment required that a regulation classifying a device into class I prescribe which, if any, of such requirements would not apply to the device.

Implantable Devices

The House amendment contained special provisions for the regulation of devices intended to be implanted in the human body.

It required that with respect to an implantable device which had been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of the bill, or which was substantially equivalent to a device so introduced or delivered, classification panels were to recommend classification into class III unless they determined that such classification was not necessary to provide reasonable assurance of safety and effectiveness of the device. In addition, the House amendment required that if panels did not recommend that such devices be classified into class III, their recommendations were to set forth the reasons for not so recommending. Further, the House amendment instructed the Secretary to classify such devices into class III unless he determined that such classification was not necessary to provide reaonable assurance of safety and effectiveness. A proposed regulation classifying such a device into class I or class II was to be accompanied by a statement of the Secretary's reasons for not classifying the device into class III. Reclassification was not available to a "new" implantable device before the device had in effect an approved application for premarket approval.

CONFERENCE SUBSTITUTE

Under the conference substitute, three classes of devices intended for human use are established. The extent of regulation under each class to provide reasonable assurance of safety and effectiveness varies with each class as follows:

Class I, General Controls

This class consists of devices for which general controls (that is, controls relating to adulteration; misbranding; registration; banned devices; notification and repair, replacement or refund; records and reports; and good manufacturing practices) are sufficient to provide reasonable assurance of safety and effectiveness or for which insufficient information exists to determine that general controls are sufficient for such purpose but which are not represented to be for a use in supporting or sustaining life or preventing impairment of health, and which do not present a potential unreasonable risk of illness or injury.

Class II, Performance Standards

This class consists of devices for which general controls are determined to be insufficient to provide reasonable assurance of safety and effectiveness and for which there is determined to be sufficient information to establish a performance standard to provide reasonable assurance of safety and effectiveness is to be classified into class II and made subject to performance standards.

Class III, Premarket Approval

This class consists of devices which cannot be classified as a class I or II device because insufficient information exists with which to determine the adequacy of general controls or standards to provide reason-

A panel recommendation must contain a summary of reasons for the recommendation, a summary of the data on which the recommendation is based, an identification of the risks to health (if any) presented by the "new" device and, to the extent practicable, a recommendation for the assignment of a priority for the application of performance standards or premarket approval requirements to a device recommended to be classified in class II or class III. The recommendation of a classification panel for the classification of a device in class I is to include a recommendation as to whether the device should be exempted from the requirements relating to registration, records and reports, or good manufacturing practices.

Following receipt of a panel's recommendation with respect to a "new" device, the Secretary is required to by order approve or deny the petition within 90 days from the date he receives the panel's recommendation. An order classifying a device into class I shall prescribe which, if any, of the requirements with respect to registration, records and reports, and good manufacturing practices shall not apply to the device. Any order which makes any such requirement inapplicable to a class I device must be accompanied by a statement of the reasons of the Secretary for making such a requirement inapplicable.

Special Requirements for Devices Which are Intended to be Implanted or are Life Supporting or Life Sustaining

Under the conference substitute, a classification panel is to recommend that any "old" device which is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life be classified into class III unless the panel determines that classification in class III is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If a panel does not recommend that such device be classified into class III, its recommendation is to set forth the reasons for not so recommending. A proposed regulation classifying such device into class I or class II is to be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying the device into class III, and an identification of the risks to health (if any) presented by the device.

In the case of a petition for reclassification of a "new" device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, a classification panel is to recommend that the petition be denied unless the panel determines that classification in class III is not necessary to provide reasonable assurance of the device's safety and effectiveness and sets forth its reasons for not so recommending. If the Secretary approves such a petition and orders the classification of such a device into class I or class II, any such order shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

Intent of the Conferees

The conferees expressed their intention with respect to three aspects of the conference substitute as it relates to the classification of devices. First, the conferees intend that only in highly unusual circumstances

Opportunity To Request Reclassification of a Device After Publication of a Notice of Proposed Rulemaking Requiring Premarket Approval

The House amendment included a provision, for which there was no comparable provision in the Senate bill, which required that a notice of proposed rulemaking requiring premarket approval of a class III device contain an opportunity to request a change in the classification of the device based on new information relevant to such classification.

The conference substitute adopts the House provision, except that it requires that any request for a change in classification must be submitted within 15 days of the publication of the notice and acted upon within 60 days of such publication.

Nonvoting Representatives of Consumer and Industry Interests as Members of Advisory Committee to Review Actions of the Secretary

Both the Senate bill and the House amendment contained provisions authorizing administrative review of decisions of the Secretary with respect to premarket approval or scientific review, and product development protocols. Both authorized review of such decisions by expert advisory committees as an option to review under the provisions of section 554 of title 5, United States Code.

Under the House amendment, each such committee was to include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

The Senate bill contained no comparable provision.

Under the conference agreement, the membership of such advisory committees is not required to include such representatives.

Requirements for Notification of Patients of Risks or Hazards Presented by Devices

Both the Senate bill and the House amendment included provisions requiring notification to persons of risks or hazards presented by devices.

Under the House amendment, if the Secretary determined that (1) a device intended for human use which was introduced into interstate commerce presented an unreasonable risk of substantial harm to the public health, and (2) notification was necessary to eliminate the risk and no more practicable means was available under the Act to eliminate the risk, he was authorized to issue an order requiring adequate notification to all persons who should receive notification in order to eliminate the risk.

Notification was to be provided only after the Secretary consulted with the persons who were to give notice. All health professionals who prescribed or used the device presenting the risk were required to be notified, and all persons exposed to the risk were to be notified unless the Secretary determined that notification by the Secretary or by a manufacturer, importer, distributor, or retailer presented a greater danger to the health of such persons than no such notice. In such instances, the Secretary was to require health professionals who pre-

custom devices which, in order to comply with the order of a physician, dentist or other specially qualified person, necessarily deviated from such requirements. This provision was applicable only to devices which were not generally available in finished form for dispensing on prescription or for commercial distribution and which were not generally available to other health professionals. It applied only to devices which were (1) intended for use by a patient named in an order by a physician, dentist, or other specially qualified person or (2) intended to be used solely by a physician, dentist, or other specially qualified person or a person under his professional supervision in the course of his professional practice.

The Senate bill exempted from otherwise applicable performance standards or requirements for scientific review custom devices ordered by a physician or other specially qualified person to be made in a special way for individual patients. Under the Senate bill, any such device was required to comply with all aspects of any performance standard except those specifically ordered to be changed.

The exemption was to apply only to devices ordered for individual patients. The Senate bill also required that custom devices not be used as a course of conduct and not be generally available in finished form for dispensing on prescription and not be made available through commercial channels.

The conference substitute conforms to the House amendment, except that the provisions with respect to the individuals (patients or health professionals) for whom the device is intended for use are clarified. Thus, the exemption is made applicable only to devices which are (1) intended for use by *an individual* patient named in an order by *an individual* physician, dentist or other specially qualified person and *to be made in a specific form for such patient* or (2) *intended to meet the special needs of* such physician, dentist, or other specially qualified person in the course of his professional practice.

Restriction on the Use of Devices

Both the Senate bill and the House amendment contained provisions authorizing the Secretary to limit the sale or distribution of devices.

The House amendment authorized the Secretary to require that the sale or distribution of a device be restricted if he determined that, because of its potentiality for harmful effect or the collateral measures necessary to its use, there could not otherwise be reasonable assurance of its safety and effectiveness. Under the House amendment, such a device could have been restricted to the extent that it could be sold or distributed only upon the oral or written authorization of a practitioner licensed by law to administer or use the device, or upon such other conditions as the Secretary might prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience could have been imposed.

The Senate bill authorized the Secretary to require that the sale or distribution of a device be restricted if (1) because of its potentiality for harmful effect or the collateral measures necessary to its use, the device was not safe for use except under the supervision of a practitioner licensed by law to administer or use the device or (2) the conditions of an approved application for scientific review limited

tion would operate to stay the requirement for premarket approval for a period of 120 days, or until the date of denial of the petition or application, whichever occurred first.

Finally, the transitional provisions of the House amendment provided that any device which had been regulated as an antibiotic drug prior to the date of enactment would remain regulated as an antibiotic drug until it had been classified as a class I device, or, if classified as a class II or III device, until the requirements of the proposed legislation for such devices were met.

The Senate bill contained no comparable provisions.

The conference substitute conforms to the House amendment, except that the provisions with respect to a device that has been declared by the Secretary to be a new drug and is therefore required to have an approved application for premarket approval in effect on the date of enactment are modified. Under the conference substitute, two provisions apply to a device which has been declared to be a new drug after March 31, 1976. First, the requirement to have in effect an application for premarket approval is not made applicable until 18 months after the date of enactment of the conference substitute unless the device is exempt from such requirements by virtue of having in effect an exemption for investigational use under new section 520(g) of the Act. Secondly, the conference substitute authorizes the Secretary, during the period beginning 180 days after the date of enactment and ending 18 months after such date, to restrict the use of the device to investigational use in accordance with requirements applicable under new section 520(g). The conference substitute requires that, if the Secretary restricts such a device to investigational use, the requirements made applicable under section 520(g) be made applicable in such a manner that the device is made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

This new provision applies solely to the intraocular lens, which, on April 6, 1976, the Commissioner of Food and Drugs declared to be a new drug under section 505 of the Federal Food, Drug and Cosmetic Act.

In the event that no petition for reclassification or application for premarket approval is submitted with respect to the intraocular lens or if such petition or application is denied, the conferees direct the Secretary's attention to the statutory admonition that any requirements for exemption for investigational use provide that such a device shall be made reasonably available to physicians meeting appropriate qualifications.

The conferees intend that, if the Secretary chooses to require the investigational use of the intraocular lens, he establish experience and training requirements such that all qualified ophthalmologists who meet such requirements and agree to adhere to the protocol for the investigation would be eligible to participate in the investigation. In establishing these requirements, the Secretary is expected to consult with appropriate organizations representing ophthalmologists and manufacturers of intraocular lenses as well as qualified scientific experts who do not have an interest in the device.

In the event that the Secretary exercises his authority to place the intraocular lens in investigational status, it is anticipated that there will be a reasonable notification period during which efforts will be

PROVISIONS RESPECTING THE EXPORT OF DEVICES AND DRUGS

Under existing law (section 801(d) of the Act) a food, drug, device, or cosmetic that does not conform to provisions of the Act may be exported if four requirements are met: it accords to the specifications of the foreign purchaser, it is not in conflict with the laws of the foreign country to which it is intended for export, it is labeled as intended for export, and it is not sold or offered for sale in domestic commerce. Further existing law prohibits the export of a new animal drug or animal feed medicated with a new animal drug that is unsafe within the meaning of section 512 of the Act. Existing provisions of the Act authorizing the export of drugs do not apply to unapproved "new drugs." The provisions of existing section 801(d) are, however, applicable to antibiotic drugs.

Provisions of the House amendment would have changed existing law to authorize the export of unapproved new drugs and of devices not in compliance with applicable provisions of new section 514 (relating to performance standards), new section 515 (relating to premarket approval), or which were banned under new section 516 to countries with appropriate health agencies that had reviewed and approved the articles as safe for their intended uses. This authorization was conditioned upon compliance with the requirements of existing law, described above. In addition, the exporters of such unapproved articles would have been required to submit annually a notice to the Secretary which identified such articles intended for export during the prospective 12-month period beginning 30 days after the date of notice, identified the countries to which such articles were to be exported and demonstrated that the articles had been reviewed and approved for use by the appropriate health agencies of the foreign countries to which they were intended for export.

The House amendment also authorized the export of unapproved new drugs and unapproved devices to countries without appropriate health agencies. However, approval was to be contingent upon application to the Secretary, opportunity for informal hearing, and a determination by the Secretary that the export of the article to such country was not contrary to public health and safety.

Further, the House amendment authorized the export of an unapproved new animal drug or animal feed containing a new animal drug, if, after submission of an application, the Secretary determined, after notice and opportunity for informal hearing, that (1) such drug or feed met the four requirements of existing law described above, (2) the export of the drug or feed was not contrary to the health and safety of persons within the United States, and (3) the appropriate health agency of the country to which the drug or feed was to be exported had authorized or approved it for its intended use, or, if there was no such agency, its export was not contrary to public health and safety.

Further, the House amendment authorized the Secretary, after providing notice and opportunity for an informal hearing, to issue an order prohibiting the export of any device which did not comply with requirements of new sections 514 or 515, or which was banned under new section 516; any antibiotic drug for which a regulation or release was not in effect under existing section 507; any new drug not in compliance with existing section 505; or any new animal drug or new animal feed bearing or containing a new animal drug, which had not

MEDICAL DEVICE AMENDMENTS OF 1976

(signed May 28, 1976)

Study Papers

Part I: Summary of Major Provisions

Part II: First Concerns Upon Enactment

Part III: Introduction of New Products

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May 28, 1976

MEDICAL DEVICE AMENDMENTS OF 1976

Study Papers

Part I: Summary of Major Provisions

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Thus, in vitro diagnostic products fall within that definition as well as products traditionally considered to be devices. The definition describes those products presently on the market or to be introduced in the future which are subject to Federal requirements for medical devices. These requirements include provisions of existing law, such as adulteration and misbranding; amended provisions of existing law; and numerous provisions of the Amendments which are drawn exclusively for devices. For those products previously regulated as "drugs", the Amendments set forth transitional provisions to resolve questions of interpretation and application of the new law.

It is important to note that the definition includes within the term device any "component, part, or accessory" of a device. It is also clear from legislative history that the Amendments are to be applied taking into account related statutes. Thus, certain medical devices are subject to regulation under the Radiation Control for Health and Safety Act, the Atomic Energy Act or the biologics provisions of the Public Health Service Act (Sections 351 and 352). If present regulatory mechanisms under these statutes are adequate to assure the safety and effectiveness of a device, the Congress has cautioned that duplicative regulations under authority of the Amendments should not be promulgated.

The statutory definition of "device" includes both animal devices as well as devices intended for human use. However, the major new authorities in the Amendments are specific to devices intended for human use. For example, classification under Section 513 is limited to devices intended for human use and standards and premarket clearance requirements are applicable only to devices classified, i.e., human use devices. Further, Sections 518 (Notification), 519 (Records and Reports) and 520 (General Provisions Respecting Control of Devices) are similarly limited to devices intended for human use. Although animal devices are generally outside the scope of the new law, legislative history notes that labeling a device for veterinary use would be unacceptable where human use is an obvious or likely prospect.

Classification of Medical Devices

(Introduction)

Classification of products is the means under the Amendments by which it is determined the extent of regulatory controls which may be lawfully applied to a specific device or class or type of device. Thus, Section 513 requires that all devices intended for human use be classified into one or more of three statutory classes for purposes of control. The three classes, in ascending order of restrictiveness are: Class I, General Controls; Class II, Performance Standards, and Class III, Premarket Approval.

Device classes are nonexclusive, i.e., a device may be assigned to more than one class or possibly all three. Thus, devices in the standards and/or premarket clearance categories are subject to all general controls that are not inconsistent with any standard eventually promulgated or device application eventually approved and an

Class I is a baseline requirement of the Amendments. As noted above, all medical devices are subject to the enumerated controls even though they may be assigned to a higher classification unless such controls are inconsistent with standards and premarket clearance requirements.

(Class II - Performance Standards - Section 513(a)(1)(B))

In general, for classification in Class II, a finding must be made that general controls are insufficient to provide a reasonable assurance of safety and effectiveness, that standards would be sufficient, and that there is sufficient information available about the device to establish a standard.

(Class III - Premarket Approval - Section 513(a)(1)(C))

Class III is the highest order of classification. Devices in this classification will be required eventually to undergo premarket approval according to requirements of the Amendments and implementing regulations. Devices in this class will be those for which not enough is known to determine if general controls would provide a reasonable assurance of safe and effective performance and not enough is known to establish a performance standard. Further, a device will not be assigned to Class III unless: (1) it is intended for a use in supporting or sustaining human life or is of substantial importance in preventing impairment of human health, or (2) it presents a potential unreasonable risk of illness or injury. The criteria just described are the criteria that will be the rules by which devices are eventually classified in premarket clearance. As will be discussed below, new devices will be automatically placed in a premarket clearance category unless and until a petition to reclassify the device is approved.

(General Classification Procedure - Section 513(c))

Through a rulemaking procedure in the Federal Register, the FDA will publish proposed recommendations for classification of all medical devices. After opportunity for public comment, regulations will be published which will assign each device or class of device to one or more classifications. Manufacturers will not be required to take any action at that time. Depending upon a device's classification, however, it would be prudent to consider the available evidence on safety and effectiveness.

Recommendations for classification will be derived from device classification panels established under Section 513(b) of the Amendments. Membership on these panels must be balanced in terms of individual expertise and each panel must include a nonvoting representative of both industry and consumer interests. For devices on the market the day the law is passed, the panels are required to respond with their classification recommendations to FDA within one year of the date that funds are appropriated to implement the new law.

When one compares the differences between the criteria used for classifying the critical device and those used for classifying the noncritical device (as opposed to comparing the type of supporting data required), it is difficult to find any legal difference between them. Critical devices must be subject to premarket clearance requirements unless general controls and standards are sufficient to provide a reasonable assurance of safety and effectiveness. Noncritical devices will be subject to general controls and/or standards and not to premarket clearance if general controls and/or standards are sufficient to provide reasonable assurance of safety and effectiveness. In some senses, these criteria seem the same, that is, a device is to be subject only to the level of regulation required to assure safety and effectiveness. As a practical matter, however, it is likely that the difference in emphasis between the two sets of criteria will result in more critical devices being placed in the premarket clearance class than would be the case if the noncritical approach were applied to them. Certainly, when FDA and the panels are directed to place critical devices into premarket clearance unless they are willing to bear the burden of showing that premarket clearance is not necessary, they will tend to take the easier approach and leave them in premarket clearance. Thus, it is more than likely that more devices will be placed in the premarket clearance class than may be clearly required by the criteria set forth in the Amendments.

A manufacturer or importer of a device placed in the premarket clearance category may petition the FDA for reclassification to Classes I or II (Section 513(f)(2)). Within 30 days after filing, the agency must notify the petitioner of any deficiencies in the document which would prevent the making of a decision on the petition. Petitions found to be complete are referred to the appropriate classification panel for approval or denial within 90 days. In making a recommendation to the FDA, the panel must provide: (1) a summary of the reasons for its recommendation; (2) a summary of the data upon which the recommendation is based and (3) an identification of the risks to health (if any) presented by the device. If the petition concerns a "critical" device, the classification panel is required to recommend denial unless premarket approval is not necessary to assure safety and effectiveness. Finally, after the panel has acted, the FDA has 90 additional days to act on the recommendation and either approve or deny the petition after opportunity for comment by interested persons. The maximum allowable time limit from filing of the petition to final agency action is a total of 210 days (Section 513(f)(2)(C)).

(Notice of Device Introduction - Section 510(k))

Section 510(k) of the Amendments requires all persons who must register their establishments (manufacturers) to give the FDA at least a 90 day advance notice when proposing to begin the introduction or delivery of a device for commercial distribution. Several interpretations have been suggested concerning <u>when</u> the section becomes effective and to <u>which</u> device introductions it will apply.

(Certain Exemptions for General Control Devices - Section 513(c)(2)(B))

Where a panel recommends a Class I classification, the recommendation must also include a finding on whether the device should be exempted in whole or part from Sections 510 (registration and listing), 519 (records and reports) and 520(f)(good manufacturing practice requirements). In publishing a final classification regulation, the FDA is required to detail the reasons for any exemption granted (Section 513(d)(2)(A)).

General Controls

(Adulteration - (Section 501))

The Amendments add substantial force to existing Sections 501 (adulterated drugs and devices) and 502 (misbranded drugs and devices). New Section 501(e) deems a device to be adulterated if it is subject to an established performance standard and does not comply with such standard in all respects. New Section 501(f) is directed to devices in Class III. Generally, these devices are adulterated if requirements for an approved premarket approval application or a notice of completion of product development protocol are not complied with. Also regarded as adulterated are banned devices (Section 501(g)), devices in violation of good manufacturing practice requirements (Section 501(h)) and devices failing to comply with an investigational use exemption (Section 501(i)).

(Misbranding - (Section 502))

Severol new provisions are also added to Section 502. Similar to drug provisions, new Section 502(e)(2) requires the use of established device names on product labels in type size at least half as large as the proprietary name used. FDA is given authority to set the official name of a device which would then become its established name. Also regarded as misbranded are devices produced in unregistered facilities, those devices not listed with the FDA, and devices not in compliance with a uniform system of identification as applicable (amended Section 502(o)). New Section 502(q) finds restricted devices as misbranded for failure to meet labeling requirements of Section 502(r) unless advertisements and descriptive literature meet certain minimum requirements for disclosure of product information. Restricted devices are devices upon which FDA places special restrictions such as limitations to prescription sale only.

Additional new provisions in Section 502 would deem misbranded any device subject to a standard unless the labeling meets applicable requirements in the standard (new Section 502(s)). Finally, under new Section 502(t), misbranding occurs where a device fails to comply with Section 518 (notification and other remedies) or where there is a failure to refusal to comply with Section 519 (records and reports).

(Banned Devices (Section 516(b) - Special Effective Date)

A proposed regulation to ban a device may be made effective upon publication in the Federal Register if the deception or risk of illness or injury is unreasonable, direct and a substantial danger to the health of individuals. Note that deception, no matter how substantial, is not sufficient to warrant the imposition of a special effective date unless substantial danger to health is also involved. The FDA must notify manufacturers of its decisions to ban beforehand but is not required to afford an informal hearing until after publication. In this case, the product is required to be removed from the market on the date of publication of the proposed regulation. Judicial review of a proposed regulation under this section is not available to the affected manufacturer (Section 517(a)(5)). Even though the product is off the market, the proceedings must be continued by FDA. After opportunity for an informal hearing, the proposed regulation will either be affirmed, modified or revoked. At that time, appeal to the courts would be permitted.

(Notification - Section 518(a))

New Section 518(a) provides that the FDA may order a notification of risks associated with the use of a device where there is an unreasonable risk of substantial harm to the public health. Note the similarity between the risk criteria in this section and that in the banned device provision. Notification is authorized when it is necessary to eliminate the unreasonable risk and no more practicable means under the FD&C Act is available to meet the situation. Legislative history indicates that "substantial harm to the public health" may include widespread nonserious harm to a large number of persons as well as serious harm to a few individuals.

After consulting with the persons best suited to provide the notice, the FDA will require notice to all health professionals who prescribe or use the device and may require notice to any other person including manufacturers, importers, distributors, retailers and device users. Where a device user is subject to the risk, such persons must be notified by the responsible party unless the FDA determines that the information would present a greater danger to health than the absence of notification. If the FDA makes this determination, then the order must require that the health professional involved provide for the notification of those patients treated with the device.

(Repair, Replacement or Refund - Section 518(b))

New Section 518(b) provides authority under some circumstances to require repair of a device; to replace a nonconforming device with one which meets the requirements of the law; or to refund the purchase price (less depreciation for user possession over one year). Manufacturers, importers and distributors or any combination of them may be affected by the order. To invoke this remedy, the FDA must afford an informal hearing and make four findings. It must be

A provision closely related to GMP provisions is new Section 520(j) on traceability. The section provides that no regulation promulgated under the Act (this includes, but is not limited to, GMP regulations) may require traceability for a type or class of device unless it is necessary to assure the protection of the public health. However, legislative history indicates that the Congress expects FDA to establish categories of products for the purpose of defining the degree of distribution traceability needed to protect the public health.

(Custom Devices - Section 520(b))

According to new Section 520(b) an individual physician, dentist (or other specially qualified person designated by regulation) may order a device which deviates from an otherwise applicable performance standard or approved premarket review application/product development protocol. To qualify as a custom device, the product may not be generally available in finished form for purchase or offered for commercial distribution. Further, the device must be intended and made in specific form for an individual patient named in an individual practitioner's order, or the device must be intended to meet the special needs of the practitioner in the course of his professional practice. Also, custom devices may not be generally available to or used by other practitioners.

(Restricted Devices - Section 520(e))

Section 520(e) provides that the FDA may, by regulation, restrict the sale, distribution or use of certain devices. Restricted devices are those which require the written or oral authorization of a practitioner licensed by law to administer or use the device and/or are subject to such other conditions as the FDA may prescribe. The FDA may find that restrictions on sale, distribution or use are necessary when a device has potential for harmful effect or because the collateral measures for use are such that there cannot be a reasonable assurance of safety or effectiveness. No restriction may limit the use of a device to persons with specific training or experience unless the limitation is required for safe and effective use. Further, no restriction may exclude a physician from using a device solely because he is not board eligible or board certified in a medical specialty.

(Administrative Restraint - Section 304(g))

The Amendments add new section 304(g) to the Act. It authorizes an FDA inspector, during an inspection, to temporarily detain a device suspected to be adulterated or misbranded. The period of detention may not exceed twenty days unless FDA determines that a longer period (up to thirty days) is needed for a seizure or injunctive action. Detention orders by an inspector must be approved by a higher FDA official. Legislative history suggests that the District Director of an FDA field office would be the designated official.

Offers to develop a standard by a party outside of government are subject to certain restrictions. FDA regulations will provide that offerors disclose: (1) industrial or commercial affiliations, (2) sources of research support, (3) financial interests in businesses and (4) additional information relevant to potential conflicts of interest. However, this information will not be made public unless required by the Freedom of Information Act (FOI). If the offer is accepted by FDA, the agency is obliged to disclose the information unless it is exempt from disclosure under FOI.

The Amendments indicate a certain preference for offers to develop a standard from within government. If the agency determines that any Federal agency, including itself, has the capability and resources to develop a standard, FDA may authorize development in lieu of accepting any other offer from outside government (Section 514(c)(4)).

Step Three: The FDA may evaluate and accept as proposed standards either existing standards or those under development and reject any offer to develop a standard (Section 514(d)). Acceptance of such standards leads to publication of the submission in the Federal Register as a proposed regulatory standard.

Step Four: Even though FDA initially decides not to develop its own standard, it may change its mind and do so where any of three conditions occur after the published invitation (Section 514(f)). These conditions are: (1) no offers to submit or develop a standard are received; (2) existing standards or offers to develop are rejected; or (3) a standards offer previously accepted proves to be unsatisfactory.

Step Five: After steps one through four are satisfied, the FDA may publish the work product from whatever source as a proposed standard or publish a notice that the proceeding is terminated together with the reasons for termination (Section 514(g)). If the proceeding is terminated, the FDA must initiate a procedure to reclassify the device.

Step Six: After time for comment on any proposed standard, the FDA may publish a final standard in the Federal Register or, if warranted, terminate the proceeding and move to reclassify the device (Section 514(g)(3)(A)). The performance standard will take effect one year from date of publication, unless FDA determines that an earlier effective date is necessary to protect the public health or safety (Section 514(g)(3)(B)). The effective date may also be shortened for a device reclassified from premarket approval to standards where the reclassification is contingent upon a standard being promulgated.

Section 514 also makes provision for amending or revoking performance standards either at the initiative of FDA or by petition of interested parties (Section 514(g)(4)(A). Proposed standards, amendments to standards, or proposals to revoke standards will be referred to advisory committees of experts on scientific matters if FDA refers the matter on its own or receives a petition which is not without good cause. A proposed amendment to a performance standard may be made effective on an interim basis prior to final action on the proposal, but manufacturers cannot be compelled to comply with the amendment during the interim period.

The application is to be referred to the appropriate classification panel for study and submission of a report respecting approval of the application (Section 515(c)(2)). The FDA is to approve or disapprove the application within 180 days of its receipt unless a greater period of time is agreed upon by the FDA and the applicant (Section 515(d)). However, with respect to a Class III device on the market on the day the Amendments were passed, no agreement to extend review time may be made unless FDA finds that continued availability of the device is necessary for the protection of the public health. Approval is to be denied if the FDA finds a lack of showing of reasonable safety or effectiveness of the device, nonconformance with good manufacturing practices, false or misleading proposed labeling for the device, or lack of conformance to a standard compliance with which is a requisite to approval.

Approval of an application may be conditioned on restrictions on the sale or distribution of a device authorized under new section 520(e) of the Act.

(Product Development Protocol (Section 515(f))

A PDP for a Class III device may be submitted to the FDA for approval in lieu of a device application. It is to contain a description of the device to be developed under the protocol, a description of any preclinical or clinical trials to be conducted on the device, including results to be expected from them, and any other relevant information. A protocol must be approved or disapproved within 120 days of receipt.

Approval of a PDP for a device is contingent upon the FDA's determination that the procedure is appropriate in lieu of the requirements to submit an application for premarket approval. The FDA cannot require that a device undergo development through the PDP procedure. Approval of the protocol does not constitute approval of the device; rather it constitutes the first of two steps leading toward approval of the device for marketing.

The second step requires submission of a notice of completion of the PDP to the FDA. Such notice is to include: a determination by the person for whom the PDP was approved that there is no reason bearing on safety or effectiveness why the notice should not be approved; data on which such determination is based; and the results of any preclinical or clinical trials required by the protocol. Within 90 days after the notice of completion is submitted, the FDA is required to either issue an order declaring it completed, or, after affording opportunity for an informal hearing, issue an order declaring it not completed. The FDA may issue an order declaring a PDP not completed only if it finds failure to comply with the requirements of the protocol, that the results of trials differ substantially from those required by the protocol, or that there is a lack of showing of safety and effectiveness of the device.

An order declaring a PDP completed has the same effect as an order approving an application for premarket approval.

Protection of Trade Secrets

The Amendments attempt to strike a balance between adequate protection of trade secrets and confidential information with certain provisions which allow for public disclosure of product information outside of the agency. Procedures for Class III devices are analogous to existing provisions for release of information on new drugs. Less protection would be afforded to devices in Classes I and II.

The Amendments extend the basic trade secret protection of existing law at Section 301(j) of the Act to any information acquired by the FDA under new or revised Sections 510, 513, 514, 516, 518, 519, 520, 706, or 707.

New section 520(c) in the Amendments superimposes additional limitations on the FDA not to disclose, through certain classification actions, information which is basically protected by the Freedom of Information Act. Information submitted to FDA under sections 513, 514, 515, 516, 518, 519, 704, 520(f) and 520(g) is afforded this special protection. The FDA may not publish such information as part of the public rulemaking process for reclassification of a device from Class III to Class II or publish it as the basis for establishment or amendment of a performance standard for a device reclassified from Class III to Class II.

The Amendments recognize that the agency will have to provide confidential information (otherwise exempt from disclosure) to certain contractors engaged to carry out services for the agency. New Section 707 allows such disclosure but obligates the contractor to take security precautions as required in a regulation to be adopted by the agency.

Release of detailed summaries of safety and effectiveness information submitted to the agency is required by new Section 520(h). Such summaries must also contain information concerning adverse effects on health with respect to a device. By regulation, the FDA is required to develop the content of summaries for each of the following actions:

(1) Issuance of an order approving, denying approval of, or withdrawing approval of an application for premarket approval or upon advisory committee recommendations thereon.

(2) Upon issuance of an order revoking an approved product development protocol, declaration of approval or nonapproval of a protocol, revoking the approval of a protocol, revoking the approval of a protocol previously declared completed, or upon advisory committee recommendations thereon.

(3) Upon issuance of an order approving an investigational use exemption for a previously banned device, or an order disapproving or withdrawing approval of such exemption.

(1) different from or in addition to device requirements under the Federal Act.

(2) related to the safety or effectiveness of a device or other matters concerning devices addressed in the Federal law.

Exemptions from the general rule are authorized. A state or locality may petition for an exemption according to regulations and after notice and opportunity for an oral hearing. Exemptions are authorized for imposition of state or local requirements on devices if the FDA finds that:

(1) the requirement would be more stringent than a requirement under Federal law, or

(2) the requirement is necessitated by compelling local conditions and compliance with the requirement would not be in violation of applicable provisions of the Federal law.

Export of Devices - Section 801

Under existing law, devices which do not conform to the Federal Food, Drug and Cosmetic Act (i.e., devices which are adulterated or misbranded) may be exported if: (1) they accord to the specifications of the foreign purchaser; (2) they are not in conflict with laws of the country of destination; (3) they are labeled on the shipping package for export; and (4) they are not sold or offered for sale in domestic commerce (Section 801(d)). The former requirements apply to any device intended for export which would otherwise be adulterated or misbranded. However, the new law couples these conditions with additional conditions for export of devices which do not comply with an applicable performance standard or a requirement relating to premarket approval. Under Section 801(d)(2), such noncomplying devices may be exported if the FDA determines that exportation is not contrary to public health and safety and has the approval of the country of destination.

Other Provisions

A number of provisions which run to narrow classes of devices have not been discussed in this summary. Nevertheless, they are important requirements for affected manufacturers. Section 520(l) on transitional provisions requires study by manufacturers whose products have been heretofore regulated as new drugs or antibiotic drugs and by manufacturers of products substantially equivalent to those articles. Similarly, manufacturers whose products come in contact with the human body for a significant period of time should review the changes in Section 706 with respect to color additive certification.

MEDICAL DEVICE AMENDMENTS OF 1976

Study Papers

Part II: First Concerns Upon Enactment

MEDICAL DEVICE AMENDMENTS OF 1976
Study Papers
Part II: First Concerns Upon Enactment

Introduction

The Medical Device Amendments of 1976, P.L. 94-____ establishes numerous regulatory controls which are or will become applicable to all medical devices. Certain of these controls are effective at enactment through the terms of the statute, i.e. no regulations are required to implement them. Other provisions are "enabling" sections which require regulations before compliance may be required. Additionally, other provisions will not be immediately effective because there are certain prerequisites in the statute which must be satisfied beforehand.

The following discussion provides an explanation of first concerns under the new law as well as additional concerns after various defined or undefined periods of time.

A. Provisions which are applicable upon enactment.

1. Prohibitions against adulterated devices: Section 501 of the Federal Food, Drug and Cosmetic Act already prohibited the introduction into interstate commerce of any medical device that consists of a filthy, putrid, or decomposed substance or that is prepared, packed or held under insanitary conditions. Adulterated products are subject to FDA seizure and other enforcement actions.

   The concept of adulteration is expanded for devices under the new law. Immediately upon enactment, devices would be adulterated if their containers are composed of poisonous or deleterious substances or if the device bears or contains, for purposes of coloring only, an unsafe color additive.

2. Prohibitions against misbranded devices: Section 502 of the Act prohibits the introduction into interstate commerce of a medical device whose labeling is false or misleading in any particular, does not bear certain information, or is dangerous to health.

   The new law amends Section 502 to require that the established name of a device, if it has one, appear on the label. The established name of a device is its "official" name designated by FDA. Until the official name is designated, the common or usual name of the device will meet the label requirement for an established name.

5. Repair, replacement, or refund: As in the case of hazard notification, the authority to require repair, replacement, or refund is a wholly new, supplementary power to regulate or control faulty products. Immediately upon enactment, the FDA is vested with authority under Section 518(b) to issue an order (on the basis of appropriate findings) directing a manufacturer, importer, or distributor (or any combination of such persons) to submit a plan to the agency to repair, replace, or refund the purchase price of a device which is found to present an unreasonable risk of substantial harm to the public health. This authority is meant to be exercised in addition to hazard notification when the agency determines that the notification alone will not be enough to reduce the risk.

   Note: (With respect to the three controls just reviewed, i.e. authority to ban, hazard notification, and repair, replacement or refund, it is highly unlikely that the FDA -- in the absence of extremely hazardous situations -- would exercise such authority immediately following enactment in view of the procedural steps which must be taken. But, the fact remains that without any required delay and without the need to promulgate implementing regulations, FDA is vested with significant new authority under Sections 516 and 518.)

6. Transitional provisions for devices regulated as new drugs or antibiotic drugs: The medical device law, immediately upon enactment, expands the definition of "device". As a result, several products currently being regulated as drugs and antibiotic drugs will fall within the new definition of device. Consequently, the medical device law provides certain transitional provisions (section 520(l)) designed to place articles which are devices under the new definition but which are presently being regulated as new drugs into comparable regulatory status as devices. Under Section 520(l), all such products are automatically classified into Class III (premarket approval) and are accorded treatment consistent with their previous status as drugs. Therefore, on the date of enactment, a product which is a device under the new definition, but which was the subject of an approved new drug application (NDA), is considered to be a device with an approved application for premarket approval. In instances where a new drug application has been filed but for which no order has been issued, the new drug application will be considered as an application for premarket approval, and FDA will have to respond to it within 180 days as set forth in Section 515. The law provides for an opportunity to petition for reclassification to Classes I or II where the device is assigned to Class III by virtue of the former provisions.

10. Classification of new devices: Immediately upon enactment under new Section 513(f), a new device, i.e. one that is not within a type or class and substantially equivalent to a device on the market before enactment, is in Class III and may not be marketed without an approved premarket application. However, manufacturers or importers of such new devices may petition the FDA for reclassification as a Class I or II device. If the petition is approved, the device may be introduced to the market subject to the requirements of Class I or II, as appropriate. The FDA may utilize up to 210 days from the petition filing date to reach a decision on the petition.

11. Application for premarket approval: According to Section 515(c) any person, immediately upon enactment, may file an application for premarket approval of a device. Even though no regulations are required to implement Section 515(c), it is likely that the FDA will issue certain interpretations to assist manufacturers in submitting applications.

12. Small manufacturer assistance: Immediately after enactment, the FDA is required, by statute, to establish an identifiable office to provide technical and other nonfinancial assistance to small manufacturers to help them comply with the new law. Indications are that the FDA will announce the location of, and access to, this office in a Federal Register notice shortly after enactment of the new law.

13. Provisions for export of adulterated or misbranded devices: Essentially unchanged from existing law and thus immediately applicable are provisions of Section 801(d) which permit the export of medical devices which are considered adulterated or misbranded. Such devices may be exported if four conditions are met. These conditions are that: (1) the device accords to specifications of the foreign purchaser, (2) the device is not in conflict with the laws of the country of destination, (3) the device is labeled on the shipping package for export and (4) the device is not sold or offered for sale in domestic commerce.

14. Other provisions: Sections 520(c) (affording protection of trade secrets), 520(j) (limiting the FDA in its application of traceability requirements) and 709 (presumption of interstate commerce) become effective without further action immediately upon enactment.

The immediate use of new inspection authority by FDA is somewhat limited by other provisions of the law. Clearly, Sections 519 and 520(g) require implementing regulations to describe the nature and type of records which must be kept. Also, the place of manufacture of a restricted device (and inspection of such) cannot be known until the FDA publishes a regulation declaring a device to be a restricted device under new Section 520(e). Even though these limitations exist, it is most likely that the agency will move rapidly to identify the records appropriate to Sections 519 and 520(g) and identify certain devices as restricted devices under Section 520(e).

Until Sections 519, 520(g) and 520(e) are officially implemented through the Federal Register process, the FDA cannot specify, with legal certainty, the exact records to which it has access. During the interim period, manufacturers may, nevertheless, be requested to furnish access to records during an inspection. In such cases, each manufacturer must exercise their own judgment on whether or not to provide access to records.

7. Administrative restraint authority: The new law amends Section 304 of the Act (penalties) by adding a wholly new authority to detain a product encountered during a factory inspection which the inspector has reason to believe may be adulterated or misbranded. The provision will not be operative until such time as the FDA prescribes regulations outlining the appropriate use of this authority.

8. Custom devices: Under Section 520(b), the FDA has immediate authority without issuance of regulations to exempt certain devices from otherwise applicable requirements. Such products are referred to as custom devices. This section will not have immediate effect because it only applies to those devices which must comply with an established performance standard or requirement for an approved premarket application. Since no standards have been promulgated under the new law and only a few devices are required to have premarket approval in effect at enactment, the custom device provision will become useful only after the passage of time.

9. Export of devices subject to a performance standard or premarket approval application: In addition to the general authority which allows for export of misbranded or adulterated devices, new Section 801(d)(2) will permit export of those devices which are not in compliance with an applicable performance standard or requirement for an approved premarket application. Such devices may be exported if two conditions (in addition to Section 801(d)(1)) are satisfied. Noncomplying devices may be exported if the FDA determines that exportation is not contrary to public health and safety and has the approval of the country of destination.

MEDICAL DEVICE AMENDMENTS OF 1976

Study Papers

Part III: New Product Introduction

MEDICAL DEVICE AMENDMENTS OF 1976
Study Papers
Part III: New Product Introduction

Introduction

The Medical Device Amendments of 1976 (Amendments) contain express provisions for manufacturers to observe when considering the introduction of a new product to the market. Statutory requirements and certain regulations will be applicable before, at, and after introduction of the product. The purpose of these guidelines is to acquaint manufacturers with the required actions which will apply to new product introduction.

The date of enactment of the new law, May 28, 1976, permanently changes the practices and procedures which have been part of new product introduction by a manufacturer. Whereas new products have been able to enter the market without significant restriction under the pre-existing Federal Food, Drug and Cosmetic Act, the Amendments will henceforth give the FDA substantial authority to oversee and regulate the procedure.

One concept must be borne in mind while reviewing the following discussions. That concept is the distinction between "old", "me-too", and "new" devices. These terms are not utilized in the law, but are adopted here to facilitate reference to the following types of products:

- Old Device - A medical device or diagnostic product on the market prior to the enactment day - May 28, 1976.

- Me-too Device - A medical device or diagnostic product first marketed after the enactment date which is of the same type and substantially equivalent to a product on the market before the enactment date.

- New Device - A medical device or diagnostic product first marketed after the enactment date which is not of the same type nor substantially equivolent to a product on the market before the enactment date.

Medical Device Defined

In the most fundamental sense, a new product will not be subject to controls for medical devices unless it falls within the statutory definition of "device" at Section 201(h) of the Federal Food, Drug and Cosmetic Act (Act). The definition specifically references generic classes of products such as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent and other similar articles including their components, parts and accessories. To distinguish devices from drugs, the definition states that a device does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals. Also, a device is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

2. New Devices

A new device is any device introduced after enactment which is not of the same type nor substantially equivalent to a device already on the market before enactment. Further, a new device is any device which is not substantially equivalent to other devices introduced after enactment which have been classified in general controls (Class I) or performance standards (Class II).

The Amendments give special attention to new devices intended to be implanted in the human body or those which are purported or represented for a use in supporting or sustaining human life. To generally identify such devices, legislative history provides some guidance. Congress has indicated that devices which do not remain in the human body for a period of thirty days or more should not be considered as implants for purposes of the law. Further, legislative history identifies as life sustaining/life supporting, those devices which are essential to the restoration or continuation of a bodily function important to life.

Implants and life sustaining/life supporting devices must be distinguished from other new devices because special classification rules apply to these types of products. The classification rules and implications thereof are discussed in the following section.

Classification of New Products

(Information on Device Classification)

Section 513 of the Amendments provides for the classification of devices on the market before enactment and those introduced thereafter. Section 513(g) is a useful provision to obtain information on the classification of any device. The section requires the FDA, within 60 days of a written request, to respond with basic classification information about a device. The FDA will provide any person with a written statement of the classification of a specific device (if any) and the requirements of the Act applicable to that device. It should be noted, however, that the agency may be conservative when responding to inquiries on new devices or modified products, i.e., opting for a higher classification than anticipated by the manufacturer.

(Notice of Device Introduction)

Section 510(k) of the Amendments requires all persons who must register their establishments (manufacturers) to give the FDA at least a 90 day advance notice when proposing to begin the introduction or delivery of a device for commercial distribution. Several interpretations have been suggested concerning when the section becomes effective and to which device introductions it will apply.

(General Rule)

All devices which were not introduced to the market or in commercial distribution before the enactment date (except those which are of the same type and substantially equivalent to old devices) are legally presumed to be in Class III (premarket approval) according to Section 513(f)(initial classification of certain devices). However, there are a number of rules in Section 513(f) and other sections which suspend premarket approval requirements or allow for a lower classification provided certain express conditions are satisfied. Some conditions are stated in the law while others require findings and judgment on the part of classification panels and the FDA. All such conditions are summarized in the succeeding paragraphs.

(Classification of Me-Too Devices)

A new product intended for introduction to the market after the enactment date which is substantially equivalent to one on the market before that date bears the same classification as its pre-enactment counterpart. As noted earlier in these guidelines, the basis for substantial equivalency is not adequately defined. Experience with device introduction under the new law should, within a reasonable time, shape a test for substantial equivalency. Interpretative regulations, if published by FDA, will also provide guidance on the determination.

Devices classified by the substantially equivalent route will be regulated in the identical manner as their pre-enactment counterparts. Particular attention should be paid to post-enactment devices classified in Class III because they are substantially equivalent to pre-enactment Class III devices. These later introductions to the market will share all or part of the statutory grace period afforded to pre-enactment Class III devices before the FDA can require premarket approval or notice of completion of a product development protocol. Under the statutory grace period the FDA cannot require an approved application until 30 months after the publication of a regulation first classifying a pre-enactment device in Class III. Further, a regulation which requires the submission of an application (Section 515(b)) can't require such submission until 90 days after its effective date (Section 501(f)(2)). Thus, if a pre-enactment device is classified in Class III as of September 1, 1976, it would have until February 28, 1979 to secure premarket approval. A me-too Class III device would share the full 30 months if introduced before September 1, 1976. If introduced after such date, for example on January 1, 1977, the me-too device would have 26 months to secure premarket approval.

There is also a parallel rule for classification of devices under Section 513(f) which are introduced after enactment and are substantially equivalent to other devices introduced after enactment which have been classified in Classes I or II. For example, a new prosthetic device unlike any pre-enactment prosthetic device might be introduced after enactment. Even though the product employs new technology, the classification panel and the FDA could, in response to a reclassification petition, classify the device in Class I or II. Later, a similar device might be introduced to the market by a competitor. The later market entry, if substantially equivalent to the first device, would receive the same classification (Class I or II) as the former.

The special rules for classification petitions involving new implants and new life sustaining/life supporting devices will make it more difficult for such devices to be introduced without premarket approval.

(Judicial Review of Classification Decisions)

The Amendments, at Section 517, provide for specific judicial review of final classification orders affecting a new product. Petitions for judicial review may be filed from an adverse classification decision under Section 513(f)(2). As described above, Section 513(f)(2) allows a manufacturer or importer to petition the FDA to classify a "new" device (including implants, life sustaining/life supporting devices) in Classes I or II. If the administrative petition is denied, or the manufacturer or importer does not agree with an approved petition assigning Classes I or II, he may appeal the decision (Section 517(a)(1)). Appeals are to be filed with the U.S. Court of Appeals for the District of Columbia or the Federal appellate circuit where the manufacturer resides or has his principal place of business.

Considerations Before Introduction of a New Product

(Introduction)

The most important consideration before introducing a new product is a thorough understanding of how the device will be classified for regulatory purposes. Classification determines whether the product must receive premarket approval from the FDA before introduction or whether it must comply with a performance standard upon introduction (if one exists). Further, special implications, from both a legal and business perspective, flow from introducing a new product which is substantially equivalent to a pre-enactment device. It may be argued, in the legal sense, that substantially equivalent new products cannot be represented or claimed for uses or performance characteristics significantly different or markedly better than their pre-enactment counterparts. Under a narrow interpretation of "substantially equivalent" the FDA could regard additional manufacturer claims for safety or effectiveness as sufficient to make the product a "new" device. If this narrow view becomes prevalent, there may be sound business reasons to pursue premarket approval. By completing premarket approval for a new product, a manufacturer would enjoy certain protection for the claims approved by the FDA. For example, a competitor's device represented for the same general use as the approved product could not (at the risk of enforcement action) assert the same product claims as those made for the approved device. In effect, devices receiving premarket approval are the only devices legally entitled to make those claims reviewed and approved by the FDA. Devices so approved would enjoy a market advantage unless or until a competitor makes a similar effort to secure premarket approval using its own investigations and data to support an application.

(Established Name)

Section 502(e) will require a device to be identified by an "established name" if one exists or is designated by the agency. The established name of a device, as defined in Section 502(e)(4), is its applicable official name designated under Section 508 or a name recognized in the official compendia or if neither exists, the common or usual name of the device.

(Uniform Identification)

Similar to provisions of Section 510 for new drugs, devices may be required to be identified under a uniform system of identification. Thus, if such a list exists, the labeling of a new product will have to meet the requirements for identification.

Considerations After Introduction of a New Product

(Device Listing)

The first requirement likely to be encountered after introduction of a new product is the device listing requirements under Section 510. Reports to FDA are required in June or December if a new product has been introduced (or if a product has been discontinued) in the preceding six month period. New products not previously listed under Section 510(k) would be required to make the submissions detailed in Section 510 and any implementing regulations in force. Special listing requirements apply under Section 510 if the device is a restricted device.

(Reclassification)

Introduction: Any device on the market (new or otherwise) may be reclassified to a higher or lower class based on new information about the device. Reclassification may be sought by any interested party or the FDA itself. If reclassification is accomplished, any applicable performance standard or premarket approval requirement will be revoked. However, for devices changed from premarket approval to performance standards, the reclassification order may delay the effective date of the change until a standard is promulgated.

Class II Devices: New products classified in standards where no standard is in force may be reclassified at the outset of the procedure to develop a standard. The Amendments recognize that extended time may elapse between classification and the development of a standard. Accordingly, any person may make such a request within 15 days of Federal Register notice of opportunity to request reclassification based upon new information. The agency has 60 days from publication to act upon such requests. It may deny the request or find merit and publish a notice of intent to reclassify the device. Specific right of judicial appeal is available for denied requests.

PREMARKET CLEARANCE, HOW AND WHEN PRODUCTS GET THERE AND WHAT MUST BE DONE ABOUT THEM

My assignment this afternoon is to cover most of the provisions in the new device law relating to premarket clearance requirements. Excluded from coverage, however, are those topics assigned other speakers such as provisions defining effectiveness, sections on requirements for the testing and evaluation of devices, and the product development protocol rules. Joel Hoffmann, Joe Radzius, and Martin Kennedy will discuss these subjects. My topics will include: classification procedure, criteria for classification, transitional provisions, and general requirements concerning device applications.

As you know, the device legislation was signed into law on May 28. The basic bill involved was H.R. 11124 (S. 510), the so-called Rogers device bill, as modified by the Senate-House conferees earlier this month. At the conference, some changes were made in that bill in response to requests from the Senate conferees. The basic structure and major provisions of H.R. 11124 were retained, however.

All devices on the market on the day the law is passed ("enactment day") as well as all devices developed after that day are to be classified into one of three regulatory classes. Devices on the market as of enactment day are to be made subject to classification recommendations by advisory panels within one year after an appropriation to implement the law. The regulatory classes are: first, general controls; second, general controls plus performance standards; and third, general controls plus premarket clearance and, in some cases, performance standards as well. I express the classification categories in those terms because it is important to remember that even after a device is made subject to a standard, it must comply with those general controls that are not inconsistent with the standard and devices made subject to a premarket approval application must comply with those general controls that are not inconsistent with the application as well as any standards made applicable. For the purpose of simplicity, I will hereafter refer to the classes as "general controls", "standards", and "premarket clearance".

General controls consist of: general prohibitions against the marketing of mislabeled or unsafe devices; requirements that manufacturers be registered and their products be listed with the Food and Drug Administration; provisions authorizing the FDA to administratively remove a device from the market without court or formal Agency hearing in some circumstances; provisions authorizing the Agency to require notification of purchasers of unreasonable and substantial risks associated with devices as well as to require the repair or replacement of such devices or the refunding of purchase money paid for them; a section requiring the maintaining of records and the filing of reports to FDA on experience with devices; a provision authorizing the Agency to restrict the distribution and use of certain devices; a mandate for adherence to regulations setting forth current good manufacturing practices; and a section conferring substantial government authority over restricted device advertising. These provisions represent extensive controls over the industry. Certainly, for the majority of devices, they should be the only controls necessary.

The second regulatory class, standards, involves the promulgation of performance standards for devices in addition to the controls enumerated above. Once a standard has been established, manufacturers will know in advance of further marketing of the product what many of the performance characteristics a device must be.

The third class, the one with which I will be concerned during the rest of my presentation, is premarket clearance. Devices in this class cannot be marketed unless FDA approves detailed applications filed by their manufacturers. The application must contain full reports on available safety and effectiveness data, detailed descriptions of the manufacturing process, labeling and other data. The major difference between standards and premarket approval is that in the case of the former, once a standard has been established, any manufacturer may produce and distribute a device conforming to the standard without having to obtain advance approval from FDA; whereas no manufacturer may distribute a device in the premarket approval class unless he has submitted his own comprehensive device application and has received specific approval of his application from FDA.

Presented by: Rodney R. Munsey, Vice President, Medical Devices and Diagnostic Products, Pharmaceutical Manufacturers Association, at the AAMI "Clinical Evaluation of Medical Devices" Conference, International Inn, Washington, D.C., April 28, 1976. (NOTE: The text has been slightly modified because the Medical Device Amendments of 1976 became effective on May 28, 1976.)

merely put manufacturers on notice that at some time in the future a device application would be required. The preliminary classification did not require that the product come off the market or that the manufacturer take any action. Although for reasons I will mention in a minute, it would be prudent to begin gathering safety and effectiveness data at that time. Before the actual imposition of the order requiring a device application, that is what I call the final classification order, opportunity must be given manufacturers and others to request reclassification. After such opportunity is given, if the classification is not changed, the manufacturer is given 90 days to submit a device application. At the conclusion of the 90-day period, the manufacturer, if he has not submitted an application for approval, must have either secured an investigational exemption for the device or have voluntarily removed the device from the market. Otherwise, he would be subject to criminal or civil action brought by the Food and Drug Administration. Because any necessary clinical data could not be generated, analyzed, compiled and submitted within 90 days, manufacturers should give careful study to the effectiveness and safety data available as soon as a device is placed in a premarket clearance class as a result of recommended classification or preliminary classification.

As mentioned earlier, the classification process works out substantially differently for new devices. No three-step classification system is involved. They are automatically placed in the premarket clearance class and cannot be marketed until either an application for government approval is approved by FDA or a petition filed with the FDA requesting reclassification into general controls or standards is granted.

The bill permits manufacturers or any other person at any time to petition for a reclassification of a device. FDA may consult with the appropriate classification panel before making its decision on any petition filed and cannot deny such petition without affording the petitioner an opportunity for an informal hearing. FDA is given six months to rule on a petition.

If any manufacturer or other interested person has doubts whether a device is a me-too device or is a new device, or for any other reason is unsure of the classification of a particular device, he may request necessary information from FDA and FDA must respond to his request and provide a written statement of the classification within 60 days.

Under the bill, a manufacturer must, in accordance with regulations, report to FDA 90 days before introduction that he intends to market a device not previously marketed by him. If FDA does not object, that is, FDA agrees that the device is an old or me-too device, the product may be commercially distributed 90 days thereafter. Suppose FDA and a manufacturer disagree as to whether a particular device qualifies? The safe course for any agency is to rule that it is a new device subject to premarket approval. In such case, the product may be marketed on the 90th day by a manufacturer only at his peril. FDA could go to court against the manufacturer claiming that the device is a new device and, therefore, in the premarket clearance class and because it is not subject to an approved application, it cannot be marketed. In many situations, a manufacturer would not want to run that risk. He might, therefore, file a petition for reclassification. FDA would have 30 days to notify a manufacturer of any deficiencies in the petition. As mentioned earlier, FDA would then have six months to make a decision on whether the device should be reclassified. A real potential for delays and bottlenecks exists. It could be three quarters of a year or longer before a manufacturer would be able to find out whether a product he thinks is an old or me-too device is, in fact, such a device, and that does not include time which could be consumed by court appeal. If many of these situations develop, a complete halt to the introduction of devices after the enactment day could take place.

So much for the procedure used for classification. What is the criteria that panels and FDA must use to decide whether old, me-too, or new devices should be made subject to premarket clearance? The same criteria that applies to old devices and me-too's applies to decide whether new devices should be reclassified into standards or general controls. In order to answer this question, we must again divide all devices into two classes. This time the two classes are: first, those that are either implantable devices or devices used in supporting or sustaining human life; or second, those which involve none of the three uses just mentioned. I will call implants, life-supporting and life-sustaining devices "critical" devices. All others will be described as "noncritical" devices.

With regard to critical devices, they are to be placed in the premarket clearance class unless FDA determines that premarket clearance is not necessary to provide reasonable assurance of their safety and effectiveness. Any order reclassifying a device out of the premarket clearance class must be accompanied by a full statement with supporting documentation and data and identification of risk (if any) and the

to be devices would be considered drugs. With regard to devices which have never been painted with the drug brush, the transitional provisions apply as follows.

With regard to old devices and me-too devices, general controls are made effective on the enactment day of the law. A classification into the standards class has no immediate effect. No requirement for compliance with standards can be made effective in most cases until one year has passed after the standard has been actually promulgated. In any event, step 1, the recommended classification, step 2, the preliminary classification, and step 3, the final classification, in themselves have no effect on whether an old or me-too device may be continued on the market or not.

Concerning old and me-too devices which have been placed in the premarket clearance class as a result of step 2, the preliminary classification, FDA cannot require a new device application until at least 30 months after that preliminary classification. Thus, the product may continue on the market if the manufacturer complies with general controls for at least 30 months plus the time required by FDA to receive recommended classifications and promulgate preliminary classification. We probably are talking about three, four, or more years for most old and me-too devices. Manufacturers of old devices and me-too devices who come on the market after the enactment day have only the same grace period as that afforded devices on the market on the enactment day.

If the old or me-too device continues to be in the premarket clearance class after step 3, the final classification, FDA must permit a manufacturer at least 90 days to submit a device application. Thus, even if the final classification order was placed into effect 15 months after the preliminary classification order, a manufacturer would have to be permitted at least 15 more months to submit an application (30 months after preliminary classification), or if the final order was not promulgated until 35 months after the preliminary classification, a manufacturer would have to be allowed that 35 months plus 90 days to file an application (90 days after final classification). If a manufacturer did not submit the application within the permitted time periods, he would have to withdraw his product from the market. If the manufacturer filed the application within the permitted time limits, he could leave the product on the market until such time as FDA acted upon the application.

Concerning new devices that have never been considered as drugs by FDA, they are, of course, automatically in the premarket clearance class and cannot be marketed at all until either an application is approved or a petition is granted to reclassify the device into standards and/or general controls.

There are special transitional provisions concerning those devices which FDA considered to be drugs before the enactment day. There are different provisions governing these drug-devices depending upon which of the following categories they are in: those that had been made subject to approve new drug applications; those that were subject to pending new drug applications on the enactment day; those subject to an investigational new drug exemption on the enactment day; those of the same type and substantially equivalent to the products in the above named categories; drug-devices declared to be new drugs by FDA or subject to pending regulatory proceedings where the drug-device status of the product was at issue; and devices containing antibiotics.

Time does not permit me to discuss all of the applicable transitional provisions of these products. Certainly during the question and answer period following my remarks I will be pleased to respond to any questions you may have on the subject.

The remainder of my remarks will be concerned with the general requirements applicable to premarket clearance devices. I will not discuss the proving of effectiveness or approaches to the testing and evaluation of medical devices.

The premarket approval provisions in the proposed legislation bear a close resemblance to the existing premarket approval requirements relating to new drugs. The application for approval must contain full reports of all information known to the applicant relating to safety and effectiveness. Also included must be a full statement of the components, properties, and principles of operation of the device and a full description of all manufacturing procedures and other quality control procedures. Samples of the products must be submitted and an identifying reference to any performance standard which might be applicable. Of course, specimens of labeling intended to be used must be submitted as well as "such other information relative to the subject matter of the application" as FDA and the appropriate panel may require. Theoretically, FDA must rule on the application within six months unless the parties agree that additional time should be required. Additional time may not be granted for ruling on an application for an old

KEY PEOPLE IN THE BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS

TITLE and NAME	TELEPHONE NO.	MAILING SYMBOL
Director David M. Link (Acting)	301-427-7163	HFK-1
Assistant Director for Program Operations Robert W. Sauer	301-427-7167	HFK-10
Laboratory Director Wiley W. Tolson (Acting)	202-447-8368	HFK-50
Division Directors		
Division of Compliance Larry R. Pilot	301-427-7212	HFK-100
Division of Diagnostic Products Standards and Research Eloise Eavenson, Ph.D. (Acting)	301-427-7178	HFK-200
Division of Medical Device Standards & Research Robert J. Cangelosi (Acting)	301-427-7182	HFK-300
Division of Classification & Scientific Evaluation Carl W. Bruch, Ph.D. (Acting)	301-427-7230	HFK-400
Branch Chiefs		
Regulatory Operations Branch Harry E. Butts	301-427-7218	HFK-110
Regulations Policy & Voluntary Compliance Branch Timothy C. Sottek	301-427-7194	HFK-120
Biological Science Branch Robert S. Kennedy, Ph.D.	301-427-7234	HFK-440
Biomedical Engineering Branch Glenn A. Rahmoeller	301-427-7226	HFK-450
Medical Review Branch Joseph B. Davis, M.D.	301-427-7238	HFK-460
Physical Science Branch Richard A. Hawkins, Ph.D.	301-427-7238	HFK-470

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General Hospital William Dierksheide, Ph.D.	301-427-7234	HFK-440
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Diagnostic Products Eloise Eavenson, Ph.D.	301-427-7178	HFK-200
Clinical Chemistry Subcommittee Charles Furfine, Ph.D.	301-427-7175	HFK-200
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Immunology Subcommittee Joseph Hackett, Ph.D.	301-427-7187	HFK-200
Microbiology Subcommittee Roberta Dresser	301-427-7175	HFK-200
Statistics Subcommittee Henry T. Lee	301-427-7175	HFK-200
Toxicology Subcommittee Nabeeh Mourad, Ph.D.	301-427-7175	HFK-200

will set forth in detail the requirements of the Amendments applicable to manufacturers, distributors, and importers and other persons who handle medical devices. Notices and proposed regulations will include the requirements applicable to device establishment and product registration, new product notification, classification, performance standards, premarket approval, defect reporting and other recordkeeping and reporting requirements, good manufacturing practice, and exemptions for investigational use. Persons whose activities are subject to the Amendments should regularly consult the FEDERAL REGISTER to be aware of notices and proposed regulations that concern them. Such persons should also comply with the requirements imposed directly by the Amendments that do not depend on issuance of regulations. These statutory requirements, which will be further defined in future notices and proposed regulations, include:

1. The duty to notify the FDA 90 days before a person begins the introduction or delivery for introduction into interstate commerce for commercial distribution of a device for human use (section 510(k) of the act). Such notification should be addressed to the Registration and Device Listing Staff (HFK-124), Division of Compliance, Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, and should be marked "510(k) Notification".

2. The duty to submit an application for premarket approval, and not to market such device prior to receiving approval, for any device marketed after enactment of the Amendments that is not substantially equivalent to a device in commercial distribution prior to enactment, unless the new device has been reclassified into the regulatory categories that only require compliance with general controls (class I), or with general controls and a performance standard (class II) (sections 501(f), 513(f), and 515 of the act). Such applications should be addressed to the Division of Classification and Scientific Evaluation (HFK-400), Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, and should be marked "Premarket Approval Application."

3. The duty to comply with special transitional provisions (section 520(l) of the act) applicable to products formerly considered drugs that are to be regulated as devices because of the new definition of "device." Petitions for reclassification or applications for premarket approval of such products should be addressed to the Division of Classification and Scientific Evaluation (HFK-400), Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, and should be marked "Reclassification Petition" or "Premarket Approval Application," as the case may be.

4. The duty to comply with the new disclosure requirements for advertising of restricted devices (section 502(r) of the act).

5. The duty to permit duly authorized FDA representatives to inspect records concerning restricted devices, which supplements the authority of these representatives to inspect facilities, equipment, materials, containers, and labels and to collect samples of all devices (section 704 of the act, as amended).

Restricted devices include all prescription devices as now defined in 21 CFR 801.109 (21 CFR 201.109 prior to recodification published in the FEDERAL REGISTER of February 13, 1976 (41 FR 6896)). (See House Report No. 94-853, Medical Device Amendments, February 29, 1976, at 24-25.)

Additional notices and proposed regulations will be published in future issues of the FEDERAL REGISTER covering these and other aspects of the Amendments.

Dated: May 28, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76-16308 Filed 6-4-76;8:45 am]

[Docket No. 76N-0205]

REQUIREMENTS UNDER THE 1976 MEDICAL DEVICE AMENDMENTS

Open Public Meetings

The Food and Drug Administration (FDA) announces a series of open public meetings to discuss requirements that manufacturers and others affected by the Federal Food, Drug, and Cosmetic Act must immediately meet under the Medical Device Amendments of 1976. There will be 10 public meetings. Each meeting will be held from 9 a.m. to 1 p.m. The dates, locations, and contact persons for each meeting are as follows:

1. Boston—Monday, June 21, 1976. Meeting place: Statler Hilton Hotel, Park Square, Boston, MA, (617) 426-2000. Contact person: Robert Hallisey, (617) 223-3178, FDA, 585 Commercial St., Boston, MA 02109.

2. New York—Tuesday, June 22, 1976. Meeting place: New York Sheraton, 870 Seventh Ave., New York, NY, (212) 247-8000. Contact person: Alex Cossin, (212) 965-5708, FDA, 850 Third Ave., Brooklyn, NY 11232.

3. Philadelphia—Wednesday, June 23, 1976. Meeting place: Holiday Inn, City Ave. and Monument Rd. (Schuylkill Expressway and I-76), Philadelphia, PA, (215) 877-4900. Contact person: Wardsworth Gray, (215) 597-4390, FDA, Second and Chestnut Sts., Rm. 900, Philadelphia, PA 19106.

4. Kansas City—Thursday, June 24, 1976. Meeting place: Hilton Inn, 610 Washington St., Kansas City, MO (816) 421-1800. Contact person: Dwight Ringhausen, (816) 374-3817, FDA, 1009 Cherry St., Kansas City, MO 64106.

5. Dallas—Friday, June 25, 1976. Meeting place: Royal Coach Inn, 3800 W. Northwest Highway, Dallas, TX, (214) 357-9561. Contact person: Jerry Henderson, (214) 749-2735, FDA, 3032 Bryan St., Dallas, TX 75204.

6. Chicago—Monday, June 28, 1976. Meeting place: Sheraton-Chicago Hotel, 505 N. Michigan Ave., Chicago, IL, (312) 944-4100. Contact person: Marie Ekvall, (312) 353-1046, FDA, 175 W. Jackson Blvd., Chicago, IL 60607.

7. Seattle—Tuesday, June 29, 1976. Meeting place: Federal Building, South Auditorium, 915 Second Ave., 4th Floor, Seattle, WA. Contact person: Jeannie Wilson, (206) 442-7028, FDA, 909 1st Ave., Rm. 5003, Seattle, WA 98104.

8. Los Angeles—Wednesday, June 30, 1976. Meeting place: Hyatt-Regency Hotel, 711 S. Hope St., Los Angeles, CA, (213) 683-1234. Contact person: Ted Smolenski, (213) 688-3785, FDA, 1521 W. Piço Blvd., Los Angeles, CA 90015.

9. Denver—Thursday, July 1, 1976. Meeting place: Denver Airport Hilton Inn, I-70 and Peoria St. Exit, Denver, CO, (303) 373-5730. Contact person: Michael Quinn, (303) 327-4915, FDA, 721 19th St., Denver, CO 80202.

10. Atlanta—Friday, July 2, 1976. Meeting place: Academy of Medicine, 875 W. Peachtree St. NE, Atlanta, GA 30309. Contact person: Robert Creasy, (404) 526-3218, FDA, 880 W. Peachtree St. NW., Atlanta, GA 30309.

The meetings will consist of presentations by FDA personnel on the 1976 Medical Device Amendments, followed by questions and answers. Those planning to attend are requested to notify the appropriate FDA contact person listed above to enable the agency to assure that adequate space will be available.

Copies of the Federal Food, Drug, and Cosmetic Act, including the Amendments, may be obtained by writing to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, HFK-120, 8757 Georgia Ave., Silver Spring, MD 20910.

Dated: May 28, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76-16307 Filed 6-4-76;8:45 am]

National Institute of Education

EDUCATION DIVISION

Statement of Organization, Functions, and Delegations of Authority

The Functional Statement for the Finance and Productivity Group as published in the FEDERAL REGISTER (40 FR 37071, August 25, 1975) will be amended by the deletion of Section 12.20, K., 5. and by changing the title in Section 12.-20, K., 1. from School Finance and Management Division to School Finance and Organization Division.

Dated: May 24, 1976.

JOHN OTTINA,
Assistant Secretary for Administration and Management.

[FR Doc.76-16227 Filed 6-3-76;8:45 am]

TOOLS FOR COMPLIANCE

The publications, visuals, and other informational materials listed in this booklet are designed to help the medical device and in vitro diagnostic product industries and affiliated professional organizations understand compliance requirements of the laws and regulations of the Food and Drug Administration.

With the implementation of the 1976 Medical Device Amendments, additional materials will be forthcoming. Therefore, an updated version of this booklet will be made available to you next year.

Tools for Compliance is provided to you as an aid for developing devices and diagnostic products that meet federal requirements. If you need FDA information materials that are not listed here, we will help you locate the materials needed. Please write or call us at:

Food and Drug Administration
8757 Georgia Ave.
HFK-123
Silver Spring, MD 20910
301-427-7190

Sincerely yours,

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*TITLE 21, CODE OF FEDERAL REGULATIONS--FOOD AND DRUGS

Title 21, Code of Federal Regulations is six volumes of all FDA regulations up to April of the current year. The 1974 paperback edition may be purchased as singles or as a set as follows:

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Price: Revising-price not available.

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Contains articles on scientific and technical material with a list of all scientific published articles by FDA scientists since the previous issue. Issued twice monthly. To receive a copy and be placed on the mailing list for additional copies, write to Technical Editing Group (HFF-38), Bureau of Foods, Food and Drug Administration, 200 C St., S.W., Washington, D.C. 20204, 50-60 pages. (prefer to send to a firm name rather than individual.)

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News and reports covering drugs, devices, and diagnostics of interest to physicians and allied health professionals. Individuals may be placed on a mailing list by request. Write to: Dr. Eric Martin (HFG-25), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

ANNUAL REPORT 1975

A preprint copy. Excerpts on activities of Bureau of Medical Devices and Diagnostic Products from FDA's report. Covers all program areas.

ADMINISTRATIVE PRACTICES AND PROCEDURES (FEDERAL REGISTER, Sept. 3, 1975)

Spells out proposed rules governing all administrative practices and procedures of the Food and Drug Administration.

FOOD AND DRUG ADMINISTRATION PRESS CONFERENCE ON IUDs AND SUPPORTING DOCUMENTS (1974)

The findings and conclusions of the FDA Ad Hoc Advisory Committee On Obstetrics and Gynecology which were made public on December 20, 1974.

*REGULATION OF MEDICAL DEVICES (INTRAUTERINE CONTRACEPTIVE DEVICES) HEARINGS BEFORE SUBCOMMITTEE

Statements, papers, and studies presented at the Hearings held on May 30, 31, 1973, June 1, 12, and 13, 1973, concerning safety and efficacy of IUDs.
Stock No.: 5270-01971. Price: $3.65

*REGULATIONS FOR THE ADMINISTRATION AND ENFORCEMENT OF THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968

Contains regulations enforced by the Bureau of Radiological Health, for electronic and radiological products. Includes, records and reports, notification of defects, performance standards, etc.
Stock No.: 1712-00213. Price: 60¢.

FINAL REPORT TO THE SECRETARY ON HEARING AID HEALTH CARE

Specific recommendations of an Interdepartmental Task Force for improving the quality of hearing aid health care. Available by writing: National Technical Information Service (NTIS), U.S. Department of Commerce, Springfield, VA 22161; Accession No. PB 245601; Price: Paperback $10.25 (domestic), $12.75 (foreign); Microfiche: $2.25 (dosmetic) and $3.25 (foreign).

CASE STUDIES INVOLVING IN VITRO DIAGNOSTIC PRODUCTS

Case studies which describe actual situations which led to recalls or other penalties for the anonymous firms. Takes a look at causes of problems and suggests solutions to avoid them. Available by writing: Publications Staff, Scientific Apparatus Makers Association, 1140 Connecticut Ave., Washington, D.C. 20036. Price: $5.00.

ETHYLENE OXIDE STERILIZATION: A GUIDE FOR HOSPITAL PERSONNEL

A fact sheet of FDA guidelines for safe use of ethylene oxide sterilization of devices.

MEDICAL DEVICE AMENDMENTS OF 1975 (H.R. 11124)

The Rogers Bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices. The basis for 1976 legislation.

MEDICAL DEVICE AMENDMENTS OF 1976 (To accompany H.R. 11124)

A Report by the Committee on Interstate and Foreign Commerce which elaborates on and spells out H.R. 11124.

MEDICAL DEVICE CLASSIFICATION PANEL REPORTS

Outline the classification process. Name panel membership and consultants. Show the tentative classification of all devices relevant to that particular panel. Published panel reports to date include: Cardiovascular Panel, Radiology Panel, Anesthesiology Panel, Gastro-Urology Panel, Ob-Gyn Panel and Ear, Nose and Throat Panel. Reports are available from the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20852.

§CONTRACT REPORTS

Titles of contracts, as well as periodic and final reports are available upon request. (FOI)

§TRANSCRIPTS

Transcripts of committee, advisory, panel, or special meetings are available upon request. (FOI)

MEDICAL DEVICE AND DIAGNOSTIC PRODUCTS STANDARDS SURVEY

A comprehensive listing of current national and international standard's promulgation activities in the areas of medical devices and diagnostic products. The surveys include: voluntary and regulatory standards, tentative and recommended standards, recommended practices, purchasing specifications, policy statements and glossaries of technical terms. International Survey - each January; National Survey - each July.

1976 MEDICAL DEVICE AMENDMENTS

The law enacted on May 28, 1976.

VIDEOTAPES--FILMS--SLIDES

"DRUGS AND MICROBES"

62 color slides with taped narration, produced by the Division of Industry Liaison, Bureau of Drugs, Food and Drug Administration

Stresses nonsterile drugs and is designed primarily for in-plant training of employees, to make them aware that they have an important part to play in preventing microbial contamination. It deals with such matters as personnel hygiene, cleaning of equipment and facilities, and handling of the product during processing. It also gives the employee a simple introduction to some of the characteristics of microorganisms. In-plant training of operating employees will take an added significance with the increased emphasis in the revised GMP's on employee understanding of microbiological factors.

Available for purchase from the National Audiovisual Center, National Archives and Records Services, Washington, D.C. 20409. Price: $10.00

"GOOD DRUG MANUFACTURING PRACTICES: NO MARGIN FOR ERROR"

16mm. color, 25 minutes, sound.

Dramatic portrayal of carelessness and errors which result in the production and distribution of a subpotent, mislabeled, and contaminated drug. For all drug industry personnel. Not intended for general public. Not cleared for television. Available free for short-term (2 weeks) loan from any FDA District Office or: Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Available for purchase through: Precision Film Laboratories, 630 Ninth Avenue, New York, New York 10036. Price: $82.50(FOB New York City) Spanish version narrated by Carlos Montalban, available by purchase. Price: $82.50 from Precision Film Laboratories. Inquiries about versions in German, Swedish, and other languages should be directed to Division of Industry Liaison, Bureau of Drugs.

IMPORTANT INFORMATION YOU SHOULD KNOW

HOW TO COMMENT ON PROPOSED REGULATIONS

Regulations issued by FDA are first published in the FEDERAL REGISTER as proposals for public comment. (For obtaining the FEDERAL REGISTER, see page 4) A deadline for receiving comments accompanies each proposal, along with the address and other pertinent information for interested parties.

Comments are solicited from all interested parties. All opinions are welcome and considered in the process of preparing a final regulation. Responses range in complexity from an opinion jotted on a postcard to lengthy memoranda or briefs in support of positions. All responses are filed and available to public view in the Office of the Food and Drug Administration's Hearing Clerk.

Of particular interest to decision-makers are any new data and scientific findings pertaining directly to the subject of the proposal.

Comments should be addressed to: The Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20852. (Five copies are preferred.)

HOW TO PETITION FDA

Any member of the public, individually or with group support, can petition FDA to make or change a regulation. The petitioner addresses the Commissioner, clearly sets forth the problem or circumstances he feels requires action, and then proposed specifically what the new regulations should include.

For those interested in learning more about the authority, structure, functions, and membership of each committee, a free 153-page paperback titled "Food and Drug Administration Public Advisory Committees" is available from: Richard Schmidt, Committee Management Office (HFS-20), Room 7-83, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island
Food and Drug Administration
585 Commercial St.
Boston, Massachusetts 02109
Phone: 617/223-5066

Suburban New York City
Food and Drug Administration
850 Third Avenue
Brooklyn, NY 11232
Phone: 212/965-5050

New York State (Northern part)
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202
Phone: 716/842-6906

Illinois
Food and Drug Administration
433 West Van Buren St.
Chicago, IL 60607
Phone: 312/353-7379

Ohio
Food and Drug Administration
1141 Central Parkway
Cincinnati, Ohio 45202
Phone: 513/684-3503

Texas, Oklahoma, New Mexico
Food and Drug Administration
3032 Bryan St.
Dallas, Texas 75204
Phone: 214/749-2735

Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota
Food and Drug Administration
721 19th St., Room 513
U.S. Customhouse
Denver, CO 80202
Phone: 303/837-4915

Michigan, Indiana
Food and Drug Administration
1560 E. Jefferson Avenue
Detroit, MI 48207
Phone: 313/226-6260

Kansas, Nebraska, Iowa, Missouri
Food and Drug Administration
1009 Cherry St.
Kansas City, MO 64106
Phone: 816/374-5521

Southern California, Arizona
Food and Drug Administration
1521 W. Pico Blvd.
Los Angeles, CA 90015
Phone: 213/688-3776

Minnesota, Wisconsin
Food and Drug Administration
240 Hennepin Ave.
Minneapolis, Minnesota 55401
Phone: 612/725-2121

Tennessee, Kentucky
Food and Drug Administration
297 Plus Park Blvd.
Nashville, Tennessee 37127
Phone: 615/749-7222

New Jersey
Food and Drug Administration
20 Evergreen Place
East Orange, NJ 07018
Phone: 201/645-3023

Louisiana, Arkansas
Food and Drug Administration
423 Canal St., Room 222
New Orleans, LA 70130
Phone: 504/527-2401

Florida
Food and Drug Administration
P.O. Box 118
Orlando, FL 32802
Phone: 904/377-2281

Pennsylvania, Delaware
Food and Drug Administration
2nd and Chestnut Streets, Room 1204
Philadelphia, PA 19106
Phone: 215/597-4173

KEY PEOPLE IN THE FDA

TITLE and NAME	TELEPHONE NO.	MAILING SYMBOL
Commissioner of Food and Drugs Alexander M. Schmidt, M.D.	301-443-2410	HF-1
Deputy Commissioner of Food and Drugs Sherwin Gardner	301-443-2400	HF-2
General Counsel - Chief Counsel Richard A. Merrill	301-443-4370	GCF-1
Associate Commissioner for Medical Affairs John Jennings, M.D.	301-443-4121	HFM-1
Associate Commissioner for Compliance Sam D. Fine	301-443-1594	HFC-1
Associate Commissioner for Science Mark Novitch, M.D. (Acting)	301-443-3216	HFS-1
Associate Commissioner for Administration Gerald F. Meyer	301-443-3370	HFA-1
Assistant Commissioner for Planning & Evaluation Gerald L. Barkdoll	301-443-4230	HFP-1
Assistant Commissioner for Public Affairs John T. Walden	301-443-4177	HFI-1
Assistant Commissioner for Professional and Consumer Programs William V. Whitehorn, M.D.	301-443-1547	HFG-1
Executive Director of Regional Operations Joseph P. Hile	301-443-6230	HFO-1
Director, Bureau of Drugs J. Richard Crout, M.D.	301-443-2984	HFD-1
Director, Bureau of Foods (includes Cosmetics) Howard R. Roberts, PhD (Acting)*	201-245-1057	HFF-1
Director, Bureau of Biologics Harry M. Meyer, Jr.**	301-496-3556	HFB-1
Director, Bureau of Radiological Health John C. Villforth	301-443-4690	HFX-1
Director, Bureau of Veterinary Medicine C.D. VanHouweling, D.V.M.	301-443-3450	HFV-1

DIRECTING INQUIRIES TO THE BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS

Persons with general inquiries or questions concerning the 1976 Amendments should contact:

Regulations Policy and Voluntary Compliance Branch (HFK-120)
Division of Compliance
Bureau of Medical Devices and Diagnostic Products
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910
(301) 427-7190 or (301) 427-7194

Persons with questions regarding registration or new device notification should contact:

Registration and Device Listing Staff (HFK-124)
Division of Compliance
Bureau of Medical Devices and Diagnostic Products
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910
(301) 427-7190

Persons with inquiries or applications for premarket approval or petitions for reclassification should contact:

Division of Classification and Scientific Evaluation (HFK-400)
Bureau of Medical Devices and Diagnostic Products
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910
(301) 427-7230

Small manufacturers interested in obtaining technical and non-financial support in complying with the 1976 Amendments should contact:

Small Manufacturers Assistance and Industry Services Section (HFK-123)
Bureau of Medical Devices and Diagnostic Products
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910
(301) 427-7190



The Organization Chart of the Bureau of Medical Devices and Diagnostic Products on the following page will also be a useful guide for contacting persons in the Bureau.

CLASSIFICATION PANEL EXECUTIVE SECRETARIES

TITLE and NAME	TELEPHONE NO.	MAILING SYMBOL
Anesthesiology Franklyn K. Coombs	301-427-7226	HFK-450
Cardiovascular Glenn Rahmoeller	301-427-7226	HFK-450
Dental Darryl Singleton, D.D.S.	301-427-7238	HFK-460
Ear, Nose & Throat Harry Sauberman	301-427-7226	HFK-450
Gastro-Urology Thomas Anderson, M.D.	301-427-7238	HFK-460
General and Plastic Surgery Mark Parrish, Ph.D.	301-427-7238	HFK-470
General Hospital William Dierksheide, Ph.D.	301-427-7234	HFK-440
Neurology J. Randy Veale	301-427-7226	HFK-450
Ob-Gyn Lillian Yin, Ph.D.	301-427-7238	HFK-470
Ophthalmic Richard Hawkins, Ph.D.	301-427-7238	HFK-470
Orthopedic Robert S. Kennedy, Ph.D.	301-427-7234	HFK-440
Physiatry Johnsie Bailey	301-427-7234	HFK-440
Radiology Leroy L. Hamilton, Ph.D.	301-427-7226	HFK-450
Diagnostic Products Eloise Eavenson, Ph.D.	301-427-7178	HFK-200

(5) Owner/Operator - This business trading name of the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

(6) Registration Number - Unique number assigned by FDA to each establishment.

2. **SPECIFIC INSTRUCTIONS FOR COMPLETION OF FORM** (Numbers in parenthesis refer to the field number on the FD-2891.)

a. (1) FDA Use Only - Est. Reg. Number. Leave this space blank. FDA will assign a unique seven digit registration number to each establishment.

b. Section A. The purpose of this section is to obtain specific information on the registering establishment.

(2) Establishment Name. Enter name of establishment involved in registration activity and limit entry to 40 characters (abbreviate only if necessary).

(3) Record Date. Enter month, day, and year form is completed. All entries must be numeric and two characters each.

Example, March 1, 1977 -	Mo	Day	Yr.
	03	01	77

(4) Number and Street. Enter number and street at which the registering establishment is physically located. Do not use Postal Box or Rural Route numbers. Limit entry to 40 characters.

(5) City. Enter city name in which establishment is located. Limit entry to 20 characters.

(6) State. Enter two character state code of the U.S. Postal Service for the state, territory, or possession.

(7) Zip. Enter U.S. Postal zip code.

(8) Foreign Country. Enter foreign country name or abbreviation. Limit entry to 14 characters.

(9) Other Registries. If establishment is registered under another FDA registry, enter a mark in the space provided for each appropriate registry from the list below:

1 Blood or Blood Products
3 Drugs
6 Cosmetics

(10) Establishment Type. Select from the following descriptions appropriate code or codes that reflect device activity of establishment. Enter a mark in the space provided adjacent to the code(s).

D Initial Distributor of Imported Devices
M Manufacturer
R Repackager or Relabeler

c. Section B. The purpose of this section is to obtain information about the Owner/Operator.

(11) Owner/Operator. Enter the business trading name of the corporation, subsidiary, affiliated company, partnership, or proprietor that is Owner/Operator of registering establishment. Limit entry to 40 characters (abbreviate only if necessary).

(12) FDA Use Only. Leave this space blank.

(13) Number and Street. Enter number and street of Owner/Operator's business address. Limit entry to 40 characters.

(14) City. Enter the city name in which the Owner/Operator is located. Limit entry to 20 characters.

(15) State. Enter the two character state code of the U.S. Postal Service for the state, territory or possession.

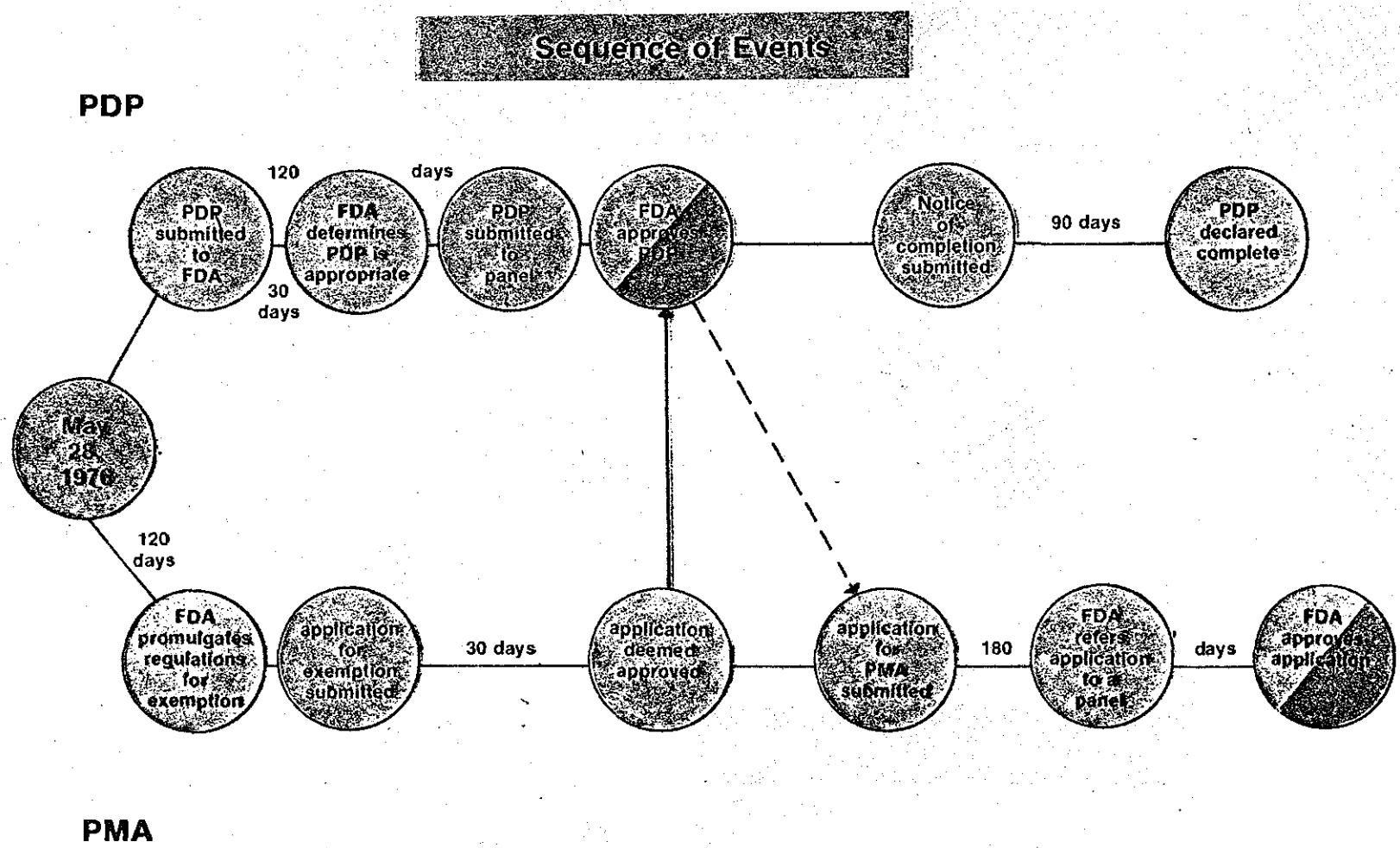
(16) Zip Code. Enter the U.S. Postal zip code.

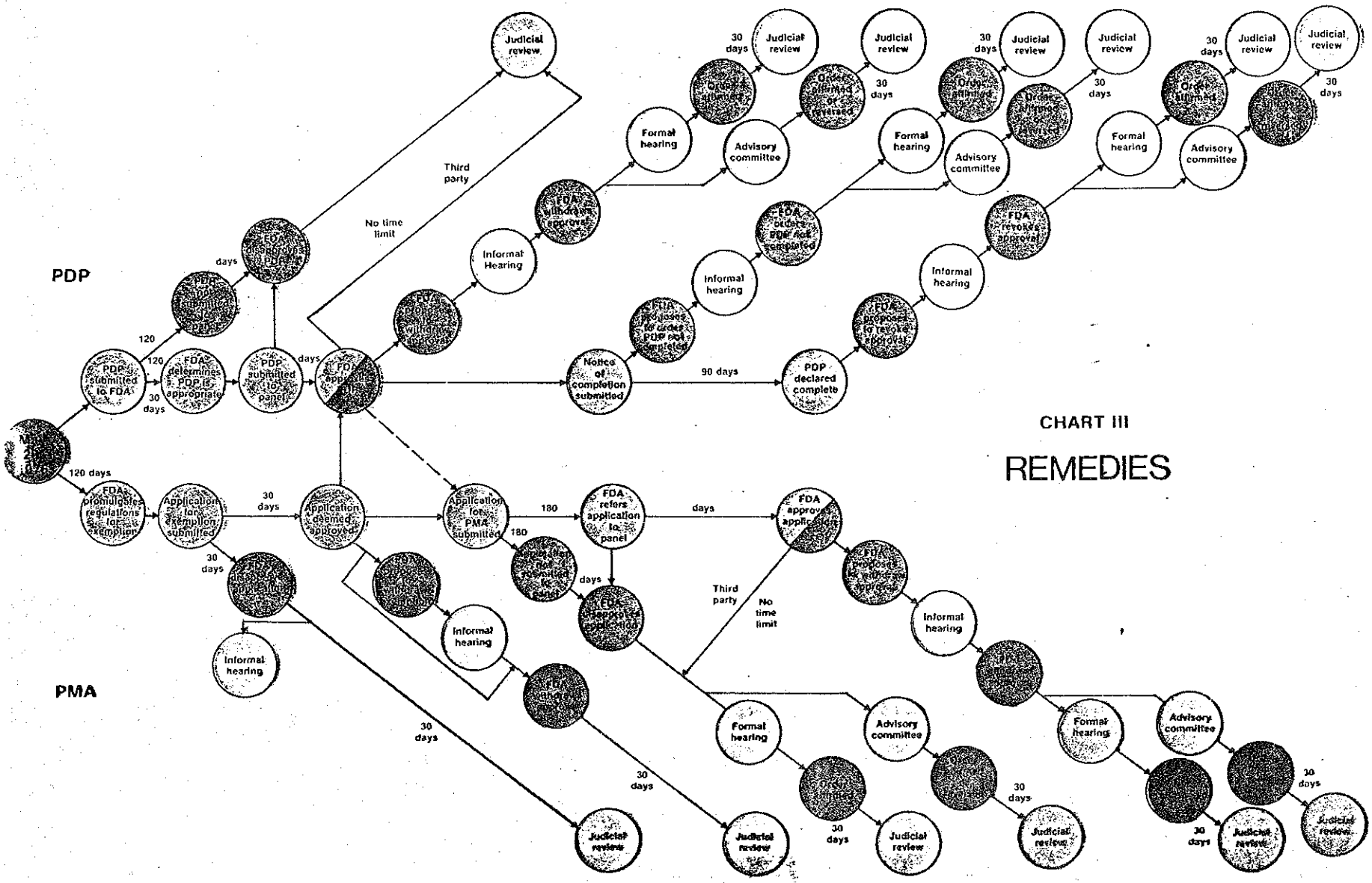
(17) Foreign Country. Enter name or abbreviation of foreign country. Limit entry to 14 characters.

(18) Device Estimate. Enter estimated number of unique devices for which the Owner/Operator is responsible. Devices having variations in physical characteristics such as size, package, shape, or color should be counted as one device provided that the variation does not change the device function or intended use. For example, a syringe manufacturer makes a particular syringe in 10 ml, 20 ml and 30 ml sizes. Each syringe is constructed of the same material and has in its labeling the same warnings and instructions for use. The manufacturer will count these syringes as one device. This figure is needed to

CHART I

Sequence of Events




PDP
PMA
CHART III
REMEDIES
PDP submitted to FDA
FDA determines PDP is appropriate
PDP submitted to panel
FDA approves PDP
FDA withdraws approval
Informal Hearing
Formal hearing
Advisory committee
Order affirmed
Order affirmed or reversed
Judicial review
No time limit
Third party
Notice of completion submitted
FDA rejects for cites PDP not completed
Informal hearing
FDA orders PDP not completed
PDP declared complete
FDA proposed to revoke approval
FDA revokes approval
FDA promulgates regulations for risk evaluation
Application for exemption submitted
Application deemed approved
Application for PMA submitted
FDA refers application to panel
FDA approves application
Informal hearing
120 days
30 days
180
90 days
days

