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SENATE

BILL	DATE	PAGE(S)
S.2926	AUG 10 '84 (107-II)	S10503-13

ACTION:

Drug Price Competition and Patent Term Restoration Act: Senate passed S. 2926, amending the Federal Food, Drug, and Cosmetic Act, revising the procedures for new drug applications, amending title 35, United States Code, and authorizing the extension of the patents for certain regulated products, after agreeing to the following amendments proposed thereto:

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(1) Hatch Amendment No. 3707, of a technical and clarifying nature.

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(2) Hatch (for Thurmond) Amendment No. 3708, providing for extension of patent which encompasses within its scope a composition of matter which is a new drug product, if such new drug product is subject to the labeling requirements for oral hypoglycemic drugs of the sulfonylurea class.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENT

Mr. BAKER. Mr. President, could I inquire next of the minority leader if it is possible for him to clear for action by unanimous consent Calendar Order No. 1115, S. 2926, the drug bill.

Mr. METZENBAUM. Mr. President, reserving the right to object, and I shall not object, I wish to address myself for one moment to the minority leader.

Mr. BAKER. Mr. President, I am advised now that it may take a few additional moments to get that in shape.

I withdraw my request of the minority leader.

Mr. President, I believe now that the earlier matter may be cleared.

Let me renew my inquiry of the minority leader.

I wish now to go to Calendar No. 1115, S. 2926, if the minority leader can clear that.

Mr. BYRD. Mr. President, the matter has been cleared on this side, and there is no objection.

Mr. BAKER. I thank the minority leader.

Mr. President, I ask the Chair to lay before the Senate Calendar Order No. 1115, S. 2926.

The PRESIDING OFFICER. The bill will be stated by title.

The assistant legislative clerk read as follows:

A bill (S. 2926) to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extention of the patents for certain regulated products, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. HATCH. Mr. President, we have before us the most important pharmaceutical legislation to come before Congress in many years. This bill, S. 2926, is the final version of S. 2748, the Drug Price Competition and Patent Term Restoration Act of 1984. This is a groundbreaking compromise in the public interest. It reconciles the opposing, competitive interests of two segments of the pharmaceutical industry which have often stymied each other's attempts to improve the law. The research-based drug industry ob-

tains an extension of patents for new drug discoveries to compensate them for the time spent off-market in Food and Drug Administration review. The generic drug industry gets the ability to bring generic copies of off-patent drugs to market as soon as the patent expires, without the needless reduplication of studies and tests already in FDA's files.

The public receives the best of both worlds—cheaper drugs today and better drugs tomorow. The proliferation of new generics for some of the most important drugs on the market will save consumers an estimated $1 billion or more over the next decade. The added patent life will restore to our domestic drug companies some of the incentive for innovation which has weakened as Federal pre-market approval requirements have become more expensive and time-consuming. That incentive will produce both the investment and commitment to reseach and development that will again place the United States in unquestioned leadership in the field. And it will generate an increase in the number of important new drugs, among the most vital causes for this century's dramatic increase in the length and quality of life.

Now, those who have been following this bill know this is a vastly simplified account of the bill and its effect. It is involved and is carefully balanced at a number of points in ways only lawyers could have devised. But it is a good bill, one which I have heartily endorsed and promoted in the Senate. It is backed by a wide range of organizations including the Pharmaceutical Manufacturers' Association, the AFL-CIO and numerous individual unions, the American Association of Retired Persons, and the National Council of Senior Citizens.

As you are probably also aware, several research-based pharmaceutical companies have felt that the compromise embodied in S. 2748 was not adequate and have pressed for changes in the bill. During the past 3 months I have met with many of these companies to discuss their concerns as has Congressman HENRY WAXMAN, the bill's House sponsor, and indeed as have many members of my committee. While I believe S. 2748 enjoys overwhelming support in the Senate, it has certainly been my belief that it is preferable to accommodate requests for changes which do not disturb balances essential to the bill.

As the time remaining during this session has decreased, discussions over these concerns have intensified. Hoping that I could catalyze a final agreement among the interested parties, we met Tuesday and Wednesday and conducted many hours of intense negotiation. We discussed and placed on the table issues relating both to the abbreviated new drug application (ANDA) and patent portions of the bill.

Further negotiations ensued yesterday with Congressman WAXMAN, the House sponsor, in an attempt to develop a final position which would be satisfactory to everyone. I am pleased to report that these negotiations bore fruit and that a compromise set of amendments has been incorporated into this new bill and into the technical amendment I am proposing today. The bill, S. 2926, as amended has drawn the support of almost all of the companies opposing S. 2748, and has been accepted by Congressman WAXMAN and by the administration.

Before continuing my remarks, let me acknowledge the good offices of the many people who assisted in these negotiations, especially Mr. Joe Williams, president of Warner-Lambert and chairman of the Pharmaceutical Manufacturers Association; Mr. Jack Stafford, chief executive officer of American Home Products; Mr. Bill Haddad, president of the Generic Pharmaceutical Industry Association; Mr. William Greif, vice president of Bristol Myers; and Mr. William Ryan assistant general counsel of Johnson & Johnson. Above all, I express my appreciation for the flexibility and leadership of Chairman WAXMAN. We have enjoyed a close and amicable working relationship during the progress of this legislation through the Congress.

The elements of the compromise are:

There is to be a prospective 5-year waiting period for filing of ANDA's following approval by FDA of a new chemical entity new drug application [NDA]. For all other NDA's involving new clinical tests, there will be a 3-year period during which no ANDA approval may be made effective. This protects products whose development has taken much time and money in FDA testing and review, but which have little for no patent life left when they are finally allowed on the market.

Further, the 10-year ANDA moratorium for products approved between January 1, 1982, and the date of enactment is supplemented by a similar provision for 2 years for non-new-chemical-entity drugs.

The period of time during which an abbreviated new drug application is not to be made effective, during the pendency of a patent challenge under the statute, is extended from 18 to 30 months from the date of submission of an ANDA application containing bioequivalency data. This increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed.

Some of the complicated current restrictions on the nature of patents which can be extended are removed, with the provision that one patent on a product, not necessarily the first, can be extended but that total exclusive market life of the product cannot exceed 14 years.

The authority of the Secretary of Health and Human Services to deny a petition for filing an ANDA for a product not exactly similar to the original drug will be expanded to include cases where the proposed generic is a combination drug, one of whose active ingredients is different from those of the original combination drug. This will make sure that FDA retains the authority to prevent drugs from coming to market without proper tests to establish the unforeseen interactions that substituted active ingredients may have on each other.

The concern was raised that FDA might be forced under the bill to approve an ANDA, even if FDA had started proceedings to remove the original drug from the market but had not completed the process. Language was adopted which would remedy this loophole.

The treatment of animal drugs contained in S. 2748 is deleted in this bill.

I would also like to address a comment to one issue which arose during the discussion of the bill. The Patent Commissioner has expressed concern that he is required to verify the contents of applications for patent extension. This was not intended, and a wording change in the bill clarifies that he may rely wholly on the required information as represented by the applicant.

Mr. President, the United States waits for this bill.

Mr. THURMOND. Mr. President, I express my strong endorsement of S. 2926, the Drug Price Competition and Patent Term Restoration Act of 1984. This important compromise measure builds upon legislation which was reported by the Judiciary Committee and passed by the Senate in the 97th Congress. I was a cosponsor of that bill and its successors, and I am pleased to join the distinguished chairman of the Labor and Human Resources Committee, Senator ORRIN HATCH, in cosponsoring this measure.

Mr. President, patent term restoration makes eminently good sense and is fair to business and consumers alike. It encourages inventiveness by making the patent term a real and useful one. This bill adds an additional feature relating to approval procedures for drugs coming off patent, which will expedite the availability of generic drugs. This is a balanced package which addresses legitimate needs in a reasonable manner.

Mr. President, after a long delay, we are finally able to bring this important legislation before the Senate. I want to commend Senator HATCH for his persistence in this matter. I also want to express my congratulations to representatives of the various interested groups who worked together to resolve their differences so that the public interest would be served. Although, as with any compromise, everyone did not get everything that he wanted, this package represents a fair balance of interests.

I urge my colleagues to support S. 2926 so that we can enact patent term

restoration and ANDA provisions without further delay.

AMENDMENT NO. 3707

(Purpose: To make certain technical changes to the bills)

Mr. HATCH. Mr. President, I now send to the desk a technical amendment to S. 2926 on behalf of myself and the other cosponsors and Senator METZENBAUM.

The PRESIDING OFFICER. The amendment will be stated.

The legislative clerk read as follows:

The Senator from Utah [Mr. HATCH], for himself and Mr. METZENBAUM, Mr. DECONCINI, Mrs. HAWKINS, Mr. KENNEDY, Mr. DENTON, and Mr. THURMOND proposes amendment numbered 3707.

Mr. HATCH. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

Clause (iii) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the bill, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)", and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

Clause (iv) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the bill, redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

Clause (iii) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the bill, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)" and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

Clause (iv) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the bill, is redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clincial investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

Subsection (1) of section 505 of the Federal Food, Drug, and Cosmetic Act, as added by section 104 of the bill, is amended by striking out, beginning with ", including", all matter through "financial information".

Mr. HATCH. Mr. President, the amendment clarifies the data release provision and the 3-year moratorium for ANDA's [Abbreviated New Drug Applications]. It would protect only those new drug applications which involve new clinical investigations.

The effect on changes to existing NDA's would be to restrict coverage to only those alterations, like some changes in strength, indications, and so forth, which require considerable time and expense in FDA required clinical testing.

Mr. President, I move that the amendment be adopted.

The PRESIDING OFFICER. If there be no further debate, the question is on agreeing to the amendment of the Senator from Utah.

The amendment (No. 3707) was agreed to.

Mr. HATCH. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. BAKER. Mr. President, I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 3708

Mr. HATCH. Mr. President, at this time, I submit an amendment on behalf of Senator THURMOND and ask for its immediate consideration.

The PRESIDING OFFICER. The amendment will be stated.

The legislative clerk read as follows:

The Senator from Utah [Mr. HATCH] for Mr. THURMOND proposes an amendment numbered 3708.

Mr. HATCH. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

At the end of the bill insert the following new title:

TITLE —

SEC. —. (a) Title 35 of the United States Code is amended by adding immediately following section 155 the following new section:

"§ 155A. Patent extension.

"(a) Notwithstanding section 154 of this title, the term of any patent which encompasses within its scope a composition of matter which is a new drug product, if such new drug product is subject to the labeling requirements for oral hypoglycemic drugs of the sulfonylurea class as promulgated by the Food and Drug Administration in its final rule on March 22, 1984 (FR Doc. 84-9640) and was approved by the Food and Drug Administration for marketing after promulgation of such final rule and prior to the date of enactment of this law, shall be extended until April 21, 1992.

"(b) The patentee or licensee or authorized representative of any patent described in such subsection (a) shall, within ninety days after the date of enactment of such subsection, notify the Commissioner of Patents and Trademarks of the number of any patent so extended. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.".

(b) The table of sections for chapter 14 of title 35, United States Code is amended by adding after the item relating to section 155 the following new item:

"155A. Patent extension.".

Section 25(a) of the bill, as redesignated, is amended by striking out "9 and 10" and inserting in lieu thereof "9, 10, and 24".

Mr. HATCH. Mr. President, I would like to share with my colleagues a statement by Senator THURMOND on this amendment.

This amendment passed the Senate without objection on June 29 as an amendment to S. 1538. It would provide limited patent extension for certain oral diabetic drugs. Such relief is necessary because the FDA unduly delayed final approval for these drugs while it developed class labeling. This would restore some of the patent life lost because of the government's undue delay.

Mr. President, it is my understanding that Members of the House are willing to take this amendment, as well, so we are adding it to this bill.

Mr. METZENBAUM. Will the manger of the bill be good enough just to repeat what this amendment is? This is not the Thurmond textile amendment?

Mr. HATCH. Mr. President, this has nothing to do with textiles. This is an amendment that provides limited patent extensions for certain oral diabetic drugs. Such relief is necessary because the Food and Drug Administration unduly delayed final approval for these drugs while it developed class labeling. This would restore some of the patent life lost because of the Government's undue delay.

Mr. METZENBAUM. Mr. President, I have to say to my colleague from Utah that this amendment is not agreeable at all. I have not heard of this amendment before. This is the first time I have heard about a patent extension with respect to diabetic drugs. We have many patent extensions proposed.

Mr. HATCH. Mr. President, if the Senator will yield for just a moment.

Mr. METZENBAUM. Mr. President, I have to advise my colleague that although apparently one of my staff members saw fit to clear it, it does not reflect my views. But if he did so, I am not going to renege on that understanding. I withdraw my objection.

Mr. HATCH. I appreciate the distinguished Senator from Ohio doing that.

I might add that this is part of the package that has been considered and accepted by, I believe, Representatives in the House and the Senate. I understood that it had been cleared. I appreciate that kindness on the part of the distinguished Senator from Ohio.

Mr. METZENBAUM. Is the Senator finished with the amendment?

Mr. HATCH. I have not moved the amendment yet.

Mr. METZENBAUM. I would like to be heard on the bill when the Senator from Utah is finished.

Mr. HATCH. I am not quite through yet.

Mr. President, I move the amendment.

The PRESIDING OFFICER. Is there further debate on the amendment? If not, the question is on agreeing to the amendment of the Senator from Utah [Mr. HATCH].

The amendment (No. 3708) was agreed to.

Mr. HATCH. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. BAKER. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. HATCH. Mr. President, I yield the floor to the distinguished Senator from Ohio.

Mr. METZENBAUM. Mr. President, I spent the last couple of days on this bill, and I am frank to admit that I have grave misgivings about it. I have misgivings about it because it provides the Senate with the horns of a dilemma.

One part of the bill provides a good legislative approach to the use of generic drugs, and it breaks some new ground in that area. I support the concept of the use of generic drugs. I think it helps senior citizens as well as all people in our society if you can buy drugs that are not merely by reason of their name and the advertising but based upon the content.

But there is another part of the bill that gives me great concern; that is that portion of the bill that provides for an extension of patents under various and sundry circumstances.

I have seen a proliferation of legislation in this session of Congress calling for the extension of patents. Some brilliant lawyer or lobbyist came to the conclusion that if we went to the Congress we could get patents extended beyond their usual 17-year term. So we have seen bills having to do with pharmaceuticals and chemicals, and agriculture chemicals, specific drugs, various and sundry drugs, some described rather generally, and in each instance there was a strong case made, "Well, the FDA delayed it or whatever and there should be an extension."

This bill is not specific in that respect. It provides for a more general extension of patents. In that respect, I have grave reservations about it.

Then there are provisions of this bill that provide for specific extensions. And each day of extension, it should be pointed out, costs the American consumers literally hundreds of thousands, and in some instances millions, of dollars. When I attempted to determine how much the extension rights for the patent extensions provided in this bill were worth, I was unable to get a figure. Nobody can say whether it was $1 billion, $2 billion, $5 billion, or $50 billion. I am frank to admit I do not know the amount. But I know that it is a large amount and the drug companies will clap with enthusiasm and excitement when this bill becomes law.

Then there is another provision in this bill that breaks even further more new ground, and that is it is a totally new concept. It provides that the FDA, upon approval of a drug, may grant exclusivity, exclusive rights to use that drug for 5 years. Then if you read it closely enough, you will learn it really is not 5 years, it is closer to 6 years because of the date and the manner in which it is written.

Well, that was enough and that was sufficient reason to be concerned about the passage of this legislation. But then we learned just in the last few minutes that the language of the 5-year exclusive marketing provision which the FDA can give may also, in some way, detour or detract from the right of generic drug manufacturers and perhaps others as well to challenge the patent during that period.

I have received an iron-clad assurance from the man primarily responsible for the passage of this legislation, the distinguished and well-respected Congressperson from California HENRY WAXMAN, who said if this is a problem, he will see to it that it is taken care of in the House. I want at this point to say very publicly that one of the reasons that I have withdrawn any objection to this bill is because of the distinguished record that the Congressperson from California, Congressman WAXMAN, has had and the confidence that I have in his legislative approach.

I still have reservations. I still have concerns. I will not oppose this legislation. I am not at all certain that the Senate, when it passes it this evening, will be doing the right thing, but I will not stand in the way of the passage.

There are some fine groups, generic groups, retired senior citizens groups, Congress Watch, other groups of that kind, consumer groups, who have indicated their support. I hope they are right. I hope they are not making a mistake. I hope that they have not given away too much of the ball game to the big drug manufacturers of this country, and only time will tell whether or not I am right.

On one other subject, there are many people asking what this bill is all about; what it means; how do you interpret it. Let me say, for one, that I interpret it in only one manner. Nobody can change the language of the legislation. It speaks for itself. So notwithstanding anybody who may feel that they can interpret the language of this legislation in one way or another, I want the courts to understand that the legislation speaks for itself and the interpretation which anyone may make on the floor does not really add anything to that interpretation.

Mr. HATCH. Mr. President, I cannot overstate the importance of this bill. It will revolutionize the drug industry and the drug market. It is a boon to both consumers and producers, and I know of no group which opposes it as amended.

The support is bipartisan, and it is overwhelming.

Mr. President, I cannot tell you how much the distinguished Member of Congress, Congressman WAXMAN, has done to help bring this bill about. Without his tireless, unrelenting leadership, I do not know that we would ever have had this bill. And there has been a lot of work here in the Senate, and especially in the Labor and Human Resources Committee, as well.

I was pleased to join in the effort with Congressman WAXMAN in this bipartisan effort.

I want to thank the people in industry, the consumer groups, the people in the generic pharmaceutical industry, the people in the Pharmaceutical Manufacturers Association, and all of those who have worked with us. I want to thank the Senator from Ohio. I would like to thank the distinguished Member of Congress, Congressman WAXMAN.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill pass?

The bill (S. 2926) was passed, as amended as follows:

S. 2926

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Price Competition and Patent Term Restoration Act of 1984".

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

SEC. 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain—

"(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active in-

gredient is an active ingredient of a listed drug or of a drug which does not meet the the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(i);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which dose not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the application will give the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the respresentative of such holder designated to receive such notice.

"(ii) The notice referred to in clause (i) shall state that an application which contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. "The Secretary shall approve such a petition unless the Secretary finds—

"(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients or of the route of administration, the dosage form, or strength which differ from the listed drug; or

"(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

"(A) the methods used in; or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds deseribed under the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)(A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) if the applicant only made a certification described in subclause (I) or (II) of

paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) if the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) if the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of each patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(I) if before the expiration of such period the court decides that each such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

"(II) if before the expiration of such period the court decides that any such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) if the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period begining January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection. No application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b).

"(iii) If an application (or supplement to an application) submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application approved under subsection (b), is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of three years from the date of the approval of the application (or supplement thereto) under subsection (b).

"(IV) If an application (or supplement to an application) submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

"(A) for the same period as the withdrawal of suspension under subsection (e) or this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

"(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purposes of this subsection:

"(A) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(B) A drug shall be considered to be bioequivalent to a listed drug if—

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose of multiple doses; or

"(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorpotion of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

SEC. 102. (a)(1) Section 505(b) of such Act is amended by adding at the end thereof the following: "The applicant shall file with the

application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.".

(2) Section 505(c) of such Act is amended by inserting "(1)" after "(c)", by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and by adding at the end thereof the following:

"(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.".

(3)(A) The first sentence of section 505(d) of such Act is amended by redesignating clause (6) as clause (7) and inserting after clause (5) the following: "(6) the application failed to contain the patent information prescribed by subsection (b); or".

(B) The first sentence of section 505(e) of such Act is amended by redesignating clause (4) as clause (5) and inserting after clause (3) the following: "(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or".

(b)(1) Section 505(a) of such Act is amended by inserting "or (j)" after "subsection (b)".

(2) Section 505(c) of such Act is amended by striking out "this subsection" and inserting in lieu thereof "subsection (b)".

(3) The second sentence of section 505(e) of such Act is amended by inserting "submitted under subsection (b) or (j)" after "an application".

(4) The second sentence of section 505(e) is amended by striking out "(j)" each place it occurs in clause (1) and inserting in lieu thereof "(k)".

(5) Section 505(k)(1) of such Act (as so redesignated) is amended by striking out "pursuant to this section" and inserting in lieu thereof "under subsection (b) or (j)".

(6) Subsections (a) and (b) of section 527 of such Act are each amended by striking out "under section 505(b)" and inserting in lieu thereof "under section 505".

SEC. 103. (a) Section 505(b) of such Act is amended by inserting "(1)" after "(b)", by redesignating clauses (1) through (6) as clauses (A) through (F), respectively, and by adding at the end thereof the following:

"(2) An application submitted under paragraph (1) for a drug for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant or for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

"(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

"(i) that such patent information has not been filed,

"(ii) that such patent has expired,

"(iii) of the date on which such patent will expire, or

"(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

"(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph (b) to—

"(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.".

(b) Section 505(c) of such Act (as amended by section 102(a)(2)) is amended by adding at the end thereof the following:

"(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

"(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

"(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of each patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(i) if before the expiration of such period the court decides that each such patent is invalid or not infringed, the approval may be made effective on the date of the court decision.

"(ii) if before the expiration of such period the court decides that any such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regiar and established place of business.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in

any other application under subsection (b), is approved after the date of the enactment of this subsection no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitting before the expiration of five years from the date of the approval of the application under subsection (b).

"(iii) If an application (or supplement to an application) submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application approved under subsection (b), is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of three years from the date of the approval of the application (or supplement thereto) under subsection (b).

"(iv) If an application (or supplement to an application submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsecton which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this subsection.".

SEC. 104. Section 505 of such Act is amended by adding at the end thereof the following:

"(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown, including that the data and information represent trade secret or confidential commercial or financial information—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug, or

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon that date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amendment by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(6) During the period beginning on the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

SEC. 107(a). Clause (iii) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the Act, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)", and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

(b) Clause (iv) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the Act, is redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(c) Clause (iii) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the Act, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)", and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

(d) Clause (iv) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the act, is redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(e) Subsection (1) of section 505 of the Federal Food, Drug, and Cosmetic Act, as added by section 104 of the Act, is amended by striking out, beginning with ", including", all matter through "financial information".

TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 155:

"§ 156. Extension of patent term

"(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

"(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

"(2) the term of the patent has never been extended;

"(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

"(4) the product has been subject to a regulatory review period before its commercial marketing or use;

"(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product'.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

"(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

"(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

"(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g);

"(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

"(4) in no event shall more than one patent be extended for the same regulatory review period for any product.

"(d)(1) to obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

"(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

"(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services to determine the period of the extension under subsection (g);

"(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

"(E) such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act of the extension application and shall submit to the Secretary a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

"(B)(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

"(3) For purposes of paragraph (2)(B), the term 'due diligence' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

"(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

"(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

"(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a certificate of extension was issued or denied, the Commissioner shall extend the term of the patent for periods of up to one year until such certificate is issued or denied.

"(f) For purposes of this section:

"(1) The term 'product' means:

"(A) A human drug product.

"(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

"(3) The term 'major health or environmental effects test' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

"(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

"(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(5) The term 'informal hearing' has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

"(6) The term 'patent' means a patent issued by the United States Patent and Trademark Office.

"(g) For purposes of this section, the term 'regulatory review period' has the following meanings:

"(1)(A) In the case of a product which is a human drug product, the term means the period described in subparagraph (B) to which the limitation described in paragrapn (4) applies.

"(B) The regulatory review period for a human drug product is the sum of—

"(i) the period beginning on the date an exemption under subsection (i) of section 505 or under subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

"(ii) the period beginning on the date the application was initially submitted for the approved human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

"(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a food or color additive is the sum of—

"(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

"(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

"(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a medical device is the sum of—

"(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

"(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a

product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

"(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

"(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(B) If the patent involved was issued before the date of the enactment of this section and—

"(i) no request for an exemption described in paragraph (1)(B) was submitted.

"(ii) no major health or environmental effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

"(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted.

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (b) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

"(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.".

(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end thereof the following:

"156. Extension of patent term.".

SEC. 202. Section 271 of title 35, United States Code is amended by adding at the end the following:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

"(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commerical manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

"(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under the paragraph (1).

"(4) For an act of infringement described in paragraph (2)—

"(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

"(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

"(C) damages or other monetary relief may be awarded against an infringer only if ther has been commerical manufacture, use, or sale of an approved drug.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.".

SEC. 203. Section 282 of title 35, United States Code, is amended by adding at the end the following: "Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

"(1) by the applicant for the extension, or

"(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.".

TITLE III—SEPARABILITY CLAUSE

SEC. 301. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of this Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

TITLE IV—MISCELLANEOUS PATENT EXTENSIONS

SEC. 401. (a) Title 35 of the United States Code is amended by adding immediately following section 155 the following new section:

"§155A. Patent extension.

"(a) Notwithstanding section 154 of this title, the term of any patent which encompasses within its scope a composition of matter which is a new drug product, if such new drug product is subject to the labeling requirements for oral hypoglycemic drugs of the sulfonylurea class as promulgated by the Food and Drug Administration in its final rule of March 22, 1984 (FR Doc. 84-9640) and was approved by the Food and Drug Administration for marketing after promulgation of such final rule and prior to the date of enactment of this law, shall be extended until April 21, 1992.

"(b) The patentee or licensee or authorized representative of any patent described in such subsection (a) shall, within ninety days after the date of enactment of such subsection, notify the Commissioner of Patents and Trademarks of the number of any patent so extended. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.".

(b) The table of sections for chapter 14 of title 35, United States Code is amended by adding after the item relating to section 155 the following new item:

"155A. Patent extension.".

SEC. 402. Section 25(a) of the bill, as redesignated, is amended by striking out "9 and 10" and inserting in lieu thereof "9, 10, and 24".

Mr. METZENBAUM addressed the Chair.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

Mr. METZENBAUM. Mr. President, I would like the RECORD to reflect the fact that the Senator from Ohio voted in the negative.

Mr. BAKER. Mr. President, I move to reconsider the vote by which the bill was passed.

Mr. HATCH. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. DECONCINI. I would like to engage in a colloquy with my friend, Senator HATCH. I understand that S. 2926, as amended, statutorily codifies FDA's current regulation and practice with reference to standards for the release of trade secret, confidential commercial and financial information contained in NDA files, is that correct?

Mr. HATCH. Yes, the bill carries over from the existing regulation the provision that information is releasable—if other requirements are met—unless extraordinary circumstances are shown. Under current practice, which will be the practice under this bill, extraordinary circumstances are present for example when the information is trade secret or confidential commercial or financial information. As one specific example, release would not be permitted if the information has never been previously released and would support the application of a competitor for approval before a foreign regulatory agency. As another example, safety and efficacy data contained in an application that was not approved will not be released if the data retains possible commercial, competitive value. In short, the provision retains the applicability of the (b)(4) exemption under the Freedom of Information Act.

Mr. DECONCINI. That is my understanding also.

Mr. BAKER addressed the Chair.

The PRESIDING OFFICER. The majority leader is recognized.

Mr. BAKER. Mr. President, I wish to express my appreciation to the distinguished Senator from Utah for work well done. The work was long, hard, and done diligently. There were moments even as recently as 30 minutes ago when I thought it would be impossible for him to get this bill cleared for passage before we go out. But he did.

I think that is remarkable. I extend to the Senator my heartiest congratulations for doing so.

Mr. President, I thank the minority leader for his willingness to consider this matter, and the Senator from Ohio for agreeing to go forward without objection.

There is one other point, Mr. President, that I would like to make. The distinguished Senator from South Carolina [Mr. THURMOND], is not here. He is necessarily absent from the floor at this point. He had originally planned to offer a textile amendment to this bill. He feels very keenly about that. Many Members know of the

great interest he has in that, and the dedication that he has for the purposes to be served. But the Senator from South Carolina in his characteristically generous way agreed not to offer that amendment, in order to facilitate the passage of this bill.

I wish to acknowledge that at the conclusion of this RECORD.

Mr. President, as well I am told that in addition to myself, the distinguished Senator from Ohio [Mr. METZENBAUM], had indicated to the President pro tempore that in his absence we would offer that amendment. We were released from the obligation. I thank the Senator for doing so.

Senator GORTON, and others, had indicated their objection. They all were withdrawn. I thank all Members for making it possible for us to proceed in this manner at this time.

Mr. HATCH addressed the Chair.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, I would express my gratitude to the distinguished majority and minority leaders of this great body, and for the cooperation they have given to me and to other Members to try to get this bill passed this evening. It is historic. It is important.

I want to personally express my personal gratitude to both of them, and to everybody else who has worked to make this possible.