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SENATE

BILL	DATE	PAGE(S)
S.1538	SEP 12 '84 (113)	S10981-90

ACTION:

Drug Price Competition and Patent Term Restoration Act: Senate concurred in the amendments of the House to S. 1538, amending the Federal Food, Drug, and Cosmetic ~~Act, revising~~ the procedures for new drug applications, and amending title 35, United States Code, authorizing the extension of patents for certain regulated products.

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DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT

Mr. HATCH. Mr. President, I intend at this time to ask that the Chair lay before the Senate a message from the House on S. 1538, the patent law amendments of 1984.

Mr. BYRD. Mr. President, will the distinguished Senator yield?

Mr. HATCH. I am delighted to yield.

Mr. BYRD. Can the Senator or Senators give me assurance there will be no amendments to or pertaining to any aspect of the message, and that there will be no motions?

Mr. HATCH. That is certainly the intent of this side. I do not believe there are any amendments on this side or any motions contemplated.

Mr. BYRD. Mr. President, would the distinguished Senator ask unanimous consent that there be no amendments in any manner, shape, or form, and no motion except the motion to concur in the House amendments?

Mr. HATCH. I ask unanimous consent, Mr. President, that there be no further amendments to S. 1538 nor any motions permitted other than the motion that the Senator concur.

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

Mr. BYRD. I thank the distinguished Senator.

Mr. HATCH. Mr. President, I ask that the Chair lay before the Senate a message from the House of Representatives on S. 1538.

The PRESIDING OFFICER laid before the Senate the following message from the House of Representatives:

Resolved, That the bill from the Senate (S. 1538) entitled "An Act to amend the patent laws of the United States", do pass with the following amendments: Strike out all after the enacting clause and insert:

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 ingredient is an active ingredient of a listed drug or of a drug which does not meet 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)(1);

"(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 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.

The Secretary may not require that an abbreviated application contain information in addition 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 applicant 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 representative 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, 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 described in 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 a 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 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 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 and if the court decides that such patent is not invalid or not infringed, 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 forty-five days from 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 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 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), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another 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 or which refers to a change approved in a supplement to the subsection (b) application 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 or 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 Secretry 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 or 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 absorption 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 if amended by adding at the end 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 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 an 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 "505(b)" each place it occurs and inserting in lieu thereof "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 the following:

"(2) An application submitted under paragraph (1) for a drug for which the 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 and 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 will give 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 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 a 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 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 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 and if the court decides that such patent is not invalid or not infringed, 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 forty-five days from 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 regular 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 the 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 and for 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 clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the 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 and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(a). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (c) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the 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 and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the 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 and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the 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 and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and 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 clause.".

SEC. 104. Section 505 of such Act is amended by adding at the end 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—

"(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 the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had 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 amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning sixty days after 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.".

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 155A:

"§ 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 30 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 the 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 is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

"(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, or 515 is a reference to section 503, 505, 507, 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 paragraph (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 subsection (d) of section 507 became effectice 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 or described in section 505(b)(2) of such 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 commercial 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 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 there has been commercial 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—AMENDMENTS TO THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT AND THE WOOL PRODUCTS LABELING ACT OF 1939

SEC. 301. Subsection (b) of section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended by adding at the end thereof the following new paragraph:

"(5) If it is a textile fiber product processed or manufactured in the United States, it be so identified.".

SEC. 302. Subsection (e) of section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended to read as follows:

"(e) For purposes of this Act, in addition to the textile fiber products contained therein, a package of textile fiber products intended for sale to the ultimate consumer shall be misbranded unless such package has affixed to it a stamp, tag, label, or other means of identification bearing the information required by subsection (b), with respect to such contained textile fiber products, or is transparent to the extent it allows for the clear reading of the stamp, tag, label, or other means of identification on the textile fiber product, or in the case of hosiery items, this section shall not be construed as requiring the affixing of a stamp, tag, label, or other means of identification to each hosiery product contained in a package if (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a stamp, tag, label, or other means of identification bearing, with respect to the hosiery products contained therein, the information required by subsection (b), and (3) the information on the stamp, tag, label, or other means of identification affixed to such package is equally applicable with respect to each textile fiber product contained therein.".

SEC. 303. Section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended by adding at the end thereof the following new subsections:

"(i) For the purposes of this Act, a textile fiber product shall be considered to be falsely or deceptively advertised in any mail order catalog or mail order promotional material which is used in the direct sale or direct offering for sale of such textile fiber product, unless such textile fiber product description states in a clear and conspicuous manner that such textile fiber product is processed or manufactured in the United States of America, or imported, or both.

"(j) For purposes of this Act, any textile fiber product shall be misbranded if a stamp, tag, label, or other identification conforming to the requirements of this section is not on or affixed to the inside center of the neck midway between the shoulder seams or, if such product does not contain a neck, in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product, or in the case of hosiery items on the outer side of such product or package.".

SEC. 304. Paragraph (2) of section 4(a) of the Wool Products Labeling Act of 1939 (15 U.S.C. 68b(a)(2)) is amended by adding at the end thereof the following new subparagraph:

"(D) the name of the country where processed or manufactured.".

SEC. 305. Section 4 of the Wool Products Labeling Act of 1939 (15 U.S.C. 68b) is amended by adding at the end thereof the following new subsections:

"(e) For the purposes of this Act, a wool product shall be considered to be falsely or

deceptively advertised in any mail order promotional material which is used in the direct sale or direct offering for sale of such wool product, unless such wool product description states in a clear and conspicuous manner that such wool product is processed or manufactured in the United States of America, or imported, or both.

"(f) For purposes of this Act, any wool product shall be misbranded if a stamp, tag, label, or other identification conforming to the requirements of this section is not on or affixed to the inside center of the neck midway between the shoulder seams or, if such product does not contain a neck, in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product or in the case of hosiery items, on the outer side of such product or package.".

SEC. 306. Section 5 of the Wool Products Labeling Act of 1939 (15 U.S.C. 68c) is amended—

(1) by striking out "Any person" in the first paragraph and inserting in lieu thereof "(a) Any person",

(2) by striking out "Any person" in the second paragraph and inserting in lieu thereof "(b) Any person", and

(3) by inserting after subsection (b) (as designated by this section) the following new subsection:

"(c) For the purposes of subsections (a) and (b) of this section, any package of wool products intended for sale to the ultimate consumer shall also be considered a wool product and shall have affixed to it a stamp, tag, label, or other means of identification bearing the information required by section 4, with respect to the wool products contained therein, unless such package of wool products is transparent to the extent that it allows for the clear reading of the stamp, tag, label, or other means of identification affixed to the wool product, or in the case of hosiery items this section shall not be construed as requiring the affixing of a stamp, tag, label, or other means of identification to each hosiery product contained in a package if (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a stamp, tag, label, or other means of identification bearing, with repsect to the hosiery products contained therein, the information required by subsection (4), and (3) the information on the stamp, tag, label, or other means of identification affixed to such package is equally applicable with repsect to each hosiery product contained therein.".

SEC. 307. The amendments made by this title shall be effective ninety days after the date of enactment of this Act.

Amend the title so as to read: "An Act 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 extension of the patents for certain regulated products, and for other purposes.".

Mr. HATCH. Mr. President, I bring to the floor S. 1538, the Drug Price Competition and Patent Term Restoration Act of 1984. This is the successor to S. 2926, which the Senate passed on August 10, 1984. When S. 2926 was received by the House, Representative HENRY WAXMAN, the House sponsor, took up the House version, H.R. 3605, brought it into conformity with the Senate bill, with a few minor additional amendments, and substituted H.R. 3605 for the text of S. 1538; a separate Senate bill. That bill was passed by the House and is now before us.

Perhaps the most significant difference between the House and Senate bills is the change in the 5-year moratorium on abbreviated new drug application or [ANDA] filings after the approval of a new chemical entity NDA. As now modified by the House, a prospective competitor could file its ANDA after 4 years, but only if it filed a patent challenge under the statute at the same time. Nevertheless, the competitor could not get its ANDA made effective during the pendency of the litigation until 7½ years had passed from the NDA approval, the same result as under S. 2926. Still, this provision as changed offers some relief to those concerned about patent challenges during the 5 years. And I would add that nothing would prevent a prospective competitor from taking the same steps to set up an infringement action—where it could challenge the patent—as it could under current law. In no case would the ability of a generic manufacturer to challange a patent be less than it is now.

I would also note that the House added as title III of the bill a measure earlier passed by the Senate, dealing with the labeling of textiles. I am unaware of any objection to this step, and understand that Senator THURMOND, the sponsor, is willing to accept the House changes.

Finally, I would like to address the matter of the release of information submitted to FDA by manufacturers. In the debate on S. 2926, I engaged in a colloquy on the floor with Senator DECONCINI confirming that the intent of the bill is simply to continue current FDA policy and procedures in this area. I would simply like to reaffirm that colloquy to make plain that it refers to this bill—whose language is identical on this point with S. 2926—just as it did to S. 2926:

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.

Further, I would like to read at this point a letter I received today from the Food and Drug Administration confirming its current treatment of this issue. Again, it is our intent to ratify FDA's present interpretation of the extraordinary circumstances regulation.

PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, MD, September 12, 1984.

Hon. ORRIN G. HATCH,
U.S. Senate,
Washington, DC.

DEAR SENATOR HATCH: Thank you for your September 4 letter requesting comment on section 104 of S. 1538, the Drug Price Competition and Patent Term Restoration Act of 1984. Section 104 would amend section 505 of the Federal Food, Drug, and Cosmetic Act to require, unless "extraordinary circumstances" were shown, the disclosure of safety and effectiveness data if any of the following five conditions were met:

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

Section 104 essentially restates FDA's current regulations governing the disclosure of information in new drug application files where the data are no longer important to the marketing status of the drug in the United States. See, e.g., 21 C.F.R. 314.14(f).

During testimony on S. 1538, FDA Chief Counsel Tom Scarlett testified that the agency interprets the term "extraordinary circumstances" as including a situation in which safety and effectiveness data have commercial value as confidential business information, even though their submission is not required as a condition to the approval of a marketing application by FDA. As you know, that interpretation is set forth explicitly in a pending proposal to revise FDA's new drug approval regulations. Mr. Scarlett noted that the agency's interpretation of the term "extraordinary circumstances" had not been judicially tested, and suggested that clarification of the intended meaning of the term as it appeared in the bill would be useful.

In the colloquy between you and Senator DeConcini, you stated that the term "extraordinary circumstances" as used in the bill is intended to retain the applicability of exemption (b)(4) of the Freedom of Information Act, relating to confidential commercial or financial information. The proposed revision in FDA's regulations would eliminate the term "extraordinary circumstances" in 21 C.F.R. 314.14(f), and provide that safety and effectiveness data in new drug application files are subject to disclosure in the events described unless they continue to represent trade secret or confidential commercial or financial information, which is the standard for exemption under section (b)(4) of the FOIA. Thus, the understanding expressed in the colloquy about the meaning of "extraordinary circumstances" in the bill is the same as the proposed revision in FDA's regulations. That

revision, which is meant to conform the agency's disclosure standard with that of exemption (4), also reflects FDA's current interpretation of the term "extraordinary circumstances" as it now appears in the regulations.

As your letter points out, that interpretation has not often been applied in practice. For this reason, it would be difficult to specify the conditions under which safety and effectiveness data in new drug applications would continue to have commercial value as confidential information even though they no longer needed to be submitted to obtain FDA marketing approval. Under the bill language, decisions on the status of particular safety and effectiveness data would be made on a case-by-case basis, as they are at the present time.

I hope this letter is responsive to your request.

Sincerely yours,

FRANK E. YOUNG, M.D., PH.D.,
Commissioner of Food and Drugs.

Before concluding, I cannot fail to acknowledge the yeoman efforts of Representative WAXMAN as manager of the House bill in fighting off amendments which would have doomed this great compromise.

Mr. President, this is a significant day for the American consumer and the American drug industry. This is one of those rarest of measures under which everyone wins—the consumer will from this time forward reap every day the benefits of lower drug prices. The research drug companies will gain substantial new encouragement to redouble their efforts, efforts which have brought us one miracle drug after another.

Mr. THURMOND. Mr. President, I rise in strong support of S. 1538, 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 urging concurrence in the House amendment.

Mr. President, patent term restoration is important for both business and consumers. It encourages progress by making patent terms real and useful. The new approval procedures for drugs coming off patent will expedite the availability of generic drugs. This is a balanced measure which deserves our strong support.

Mr. President, I want to commend Senator HATCH and other involved parties for their hard work on this bill. I am sorry that the House was unwilling to accept my "Diabeta" amendment and hope that we can pass it on other legislation.

In addition, S. 1538 contains language pertaining to proper labeling of textile/apparel products. This is the exact language that the Senate agreed to on June 29, 1984, when S. 1538 was approved and sent to the House of Representatives for review.

I originally introduced this language as S. 1816 in an effort to strengthen domestic law as it relates to country of origin labeling requirements for textile and apparel products. While present law requires country of origin marking on textile products entering the United States, there have been increasing instances where textile and apparel products are entering the United States in violation of domestic labeling laws.

One of the major problems in the effectiveness existing law is the fact that labels are often placed in inconspicuous places. This bill would designate that the label be attached to the neck of the garment if applicable, or if the garment does not contain a neck, to the most conspicuous place on the inner side of the foreign made textile/apparel product. This will allow easy identification of the label by consumers and will help with enforcement of present textile agreements.

My bill will also require that textile/apparel products produced in this country carry origin labels. Since there is no present law which requires American-made textile and apparel products to be labeled as such, foreign textile/apparel products that are misbranded are often mistaken for American-made products.

Another provision of the bill will require that, in the case of bulk packaging of textile products, both the package, as well as the garments within be labeled as to country of origin.

The final major future of this legislation would mandate that mail order catalog sale descriptions contain country of origin information. A large portion of all textile/apparel products sold in this country are purchased through mail order catalog-type systems. Through these mail order transactions, the consumer dose not have access to country of origin information for texitle/apparel products at the actual point of purchase.

Reports have shown that U.S. consumer perfer to buy American-made textile products. My legislation will simply allow consumers to better identify the products the wish to purchase.

Mr. President, it is most important for this legislation to be approved by the full Senate and signed into law as soon as possible. The domestic textile, fiber and apparel complex employs over 2 million Americans nationwide. This industry provides more jobs than the U.S. auto and steel industries combined. Unfortunately, the U.S. textile/apparel industry is suffering through its most severe crisis in recent history. Textile/apparel imports from low-wage paying countries, such as the People's Republic of China, Taiwan, Hong Kong, have flooded our markets and displaced thousands of American workers.

In 1983, imports of textile/apparel products increased 25 percent over 1982. For the first 4 months of 1984, textile/apparel imports were up 49 percent over the same period in 1983. Last year's trade deficit for textiles and apparel was $10.6 billion—15 percent of the entire U.S. trade deficit, which totaled $69.3 billion. Finally, over the past 7 years, 413,000 textile and apparel jobs have been lost in this country. While this legislation will not correct all the problems confronting our domestic textile/apparel industry, it is a positive step toward preserving one of America's most vital and strategically important industries.

Mr. President, S. 1816 was unanimously approved by the Senate Commerce, Science, and Transportation Committee on June 13, 1984. I ask unanimous consent that a list displaying the numerous textile/apparel related associations that fully support this bill be printed in the RECORD following my remarks.

Before concluding, Mr. President, I would like to thank the 22 Members of this body who chose to cosponsor S. 1816. I would also like to especially thank Senators PACKWOOD and KASTEN, and their very capable committee staff members, for their invaluable assistance on this legislation during its review by the Commerce Committee.

In closing, Mr. President, I strongly believe that this bill is a positive step toward stabilizing the jobs of the over 2 million Americans employed in the textile, fiber, and apparel complex, and I hope that the Senate will give this legislation the strong vote of approval which it merits.

There being no objection, the list was ordered to be printed in the RECORD, as follows:

Amalgamated Clothing & Textile Workers Union.
American Apparel Manufacturers Association.
American Textile Manufacturers Institute.
American Yarn Spinners Association.
Clothing Manufacturers Association of America.
International Ladies' Garment Workers Union.
Knitted Textile Association.
Luggage & Leather Goods Manufacturers of America.
Man-Made Fiber Producers Association, Inc.
National Association of Hosiery Manufacturers.
National Association of Uniform Manufacturers.
National Cotton Council of America.
National Knitwear Manufacturers Association.
National Knitwear & Sportswear Association.
National Wool Growers Association.
Neckwear Association of America.
Northern Textile Association.
Textile Distributors Association, Inc.
Work Glove Manufacturers Association.

Mr. METZENBAUM addressed the Chair.

The PRESIDING OFFICER. The Senator from Ohio.

Mr. METZENBAUM. Mr. President, I rise to indicate my concern and my opposition to this bill, but I do not intend to fight the concurrence in the conference report.

This is a bill which has received a lot of hoopla, a lot of excitement. This is the so-called pro generic drugs bill. I think that I, as well as probably the overwhelming majority of my colleagues, support the concept of permitting the sale of generic drugs because by permitting the sale of generic drugs, we are able to bring down the price that the American consumer has to pay for pharmaceuticals.

But that is only part of the bill. The other part of the bill has to do with the price that we are paying in order to get this bill passed.

It is a fact that the Pharmaceutical Manufacturers Association has really not been enthused about helping the generic drug industry. So in order to meet their objections, there were concessions made that in fact and in reality will give the pharmaceutical manufacturers additional extended time in connection with their patented drugs.

As a matter of fact, they will have under this bill protection from competition for a period in excess of 20 years. The specific time is difficult to determine by reason of some of the details of the legislation and some of the procedures of the FDA.

The fact is that the American consumer who has to buy these patented pharmaceuticals is going to be paying more money, and in some instances they will be able to get generics, but not the same kinds of drugs. As a matter of fact, in the rush to pass this legislation, there were some last-minute changes that even those who were involved in the drafting process were not aware of. They learned about it too late.

I now hear word that some of the consumer groups and some of those who were supporting the whole concept of generic drug authorization now have tongue-in-cheek reservations and are not really sure they are for the bill. They are not quite sure whether they are for it or against it, as I understand it.

The fact is that I think many Americans will rue the day that this legislation passed. It provides some new legal concepts. It provides an extension of time in connection with the protection of those drugs on which there is an application for patenting in which the generic drugs are precluded from challenging the validity of the patent application until 7, 8, or 10 years. That certainly is not going to help the American consumer in connection with the purchase of pharmaceuticals.

I determined that I was not going to make an all-out effort to defeat this legislation because everything I have read about it in the papers and other news media would give one the impression that it is the answer to the problem of high-priced drugs. It is not and we ought not to be kidding ourselves. The generic drug lobbyists who were involved in connection with this bill were gung ho—they wanted a bill. But they were not so concerned about the price that the American people would be paying and will be paying for patented drugs.

I do not intend to hold the floor any longer. I do want it recorded that my vote is in the negative.

I ask unanimous consent that when the vote on this measure is taken, and I assume it will be without a record vote, that the Senator from Ohio's vote be recorded as being in the negative.

The PRESIDING OFFICER. The record will so show.

Mr. HATCH. Mr. President, I move that the Senate concur in the House amendments.

The PRESIDING OFFICER. The question is on agreeing to the motion of the Senator from Utah.

The motion was agreed to.

Mr. HATCH. I thank the Chair, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. HATCH. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. HATCH. Mr. President, I ask unanimous consent that I be permitted to move to reconsider the vote by which the motion was agreed to.

Mr. BYRD. Mr. President, reserving the right to object, I would suggest that the distinguished Senator include a motion to table the motion to reconsider.

Mr. HATCH. Mr. President, the distinguished Senator is correct.

Mr. President, I ask unanimous consent that it be in order to move to reconsider the vote by which the motion was agreed to and include in that a motion to table the motion to reconsider.

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

Mr. HATCH. I thank my dear friend from West Virginia.

I so move.

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

The motion to lay on the table was agreed to.

Mr. HATCH. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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