98TH CONGRESS
2D SESSION

H. R. 3605

[Report No. 98-857, Part I]

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 1983

Mr. WAXMAN (for himself, Mr. MADIGAN, Mr. WYDEN, Mr. SIKORSKI, Mr. WIRTH, Mr. LELAND, Mr. MARKEY, Mr. SWIFT, Mr. BRYANT, and Mr. WEISS) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 21, 1984

Additional sponsors: Mr. GORE, Ms. KAPTUR, Mr. OWENS, Mr. MARTINEZ, Mr. BEDELL, and Mr. SYNAR

JUNE 21, 1984

Reported with amendments, referred to the Committee on the Judiciary for a period ending not later than August 1, 1984, for consideration of such portions of the amendment as fall within that committee's jurisdiction pursuant to clause 1(m) of rule X, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

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 Act of 1983".~~

~~SEC. 2. Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following new sentence: "Clause (1) of the previous sentence shall not apply in the case of an application for a drug for which a previous application has been approved in accordance with subsection (c), if the drug with respect to which such subsequent application is filed meets appropriate standards of identity, strength, quality, purity, stability, bioavailability, and bioequivalence in relation to the drug approved in the previous application.".~~

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 has given 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 commerical 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 that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients of the drug or of the route of administration, the dosage form, or strength which differ from the listed drug.

"(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 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 eighteen 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, or

"(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.

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 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 and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using such drug for any known therapeutic purposes 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 four years from the date of the approval of the application under subsection (b) unless the Secretary determines that an

adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under 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 ap-

proved 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 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 is 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 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 "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 listed under subsection (j)(6) for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not con-

ducted 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 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 eighteen-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, or

"(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.

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 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 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 and if the holder of the approved application

certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using for any known therapeutic purposes such drug, 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 four years from the date of the approval of the application previously approved under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.".

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 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.".

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)(A) in the case of a patent which claims the product or a method of using the product—

"(i) the product is not claimed in another patent having an earlier issuance date or which was previously extended, and

"(ii) the product and the use approved for the product in the applicable regulatory review period are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended; or

"(B) in the case of a patent which claims the product, the product is also claimed in a patent which has an earlier issuance date or which was previously extended and which does not identically disclose or describe the product and—

"(i) the holder of the patent to be extended has never been and will not become the holder of the patent which has an earlier issuance date or which was previously extended, and

"(ii) the holder of the patent which has an earlier issuance date or which was previously extended has never been and will not become the holder of the patent to be extended;

"(5)(A) in the case of a patent which claims a method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product—

"(i) no other patent has been issued which claims the product or a method of using the product and no other patent which claims a method of

using the product may be issued for any known therapeutic purposes; and

"(ii) no other method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product is claimed in a patent having an earlier issuance date;

"(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—

"(i) the holder of the patent for the method of manufacturing the product (I) is not the holder of a patent claiming the product or a method of using the product, (II) is not owned or controlled by a holder of a patent claiming the product or a method of using the product or by a person who owns or controls a holder of such a patent, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent; and

"(ii) no other method of manufacturing the product primarily using recombinant DNA technology is claimed in a patent having an earlier issuance.

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

"(7)(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; and

"(8) the patent does not claim another product or a method of using or manufacturing another product which product received permission for commercial marketing or use under such provision of law before the filing of an application for extension.

The product referred to in paragraphs (4), (5), (6), and (7) is hereinafter in this section referred to as the 'approved product'. For purposes of paragraphs (4)(B) (5)(B), the holder of a patent is any person who is the owner of record of the

patent or is the exclusive licensee of the owner of record of the patent.

"(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); and

"(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.

"(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 regula-

tory review period occurred for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product;

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

"(C) the identity of every other patent known to the patent owner which claims or identically discloses or describes the approved product or a method of using or manufacturing the approved product;

"(D) the identity of all other products which have received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are claimed in any of the patents identified in subparagraph (C);

"(E) 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 or the Secretary of Agriculture to de-

termine the period of the extension under subsection (g);

"(F) 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

"(G) 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—

"(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

"(ii) the Secretary of Health and Human Services if the patent claims any other 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 who is so notified a copy of the application. Not later than thirty days after the receipt of an application from the Com-

missioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(E) 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 making the determination 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 making the determination shall, in accordance with regulations promulgated by such 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 of Health and Human Services 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 making a determination under clause (i) 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 making the determination to hold an informal hearing on the determination. If such a request is made within such period, such 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 who is holding the hearing 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, such 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 information 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 determination is made 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 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 'drug product' means the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Virus-Serum-Toxin 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.

"(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151–158).

"(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 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 drug product is the sum of—

"(i) the period beginning on the date—

"(I) an exemption under subsection (i) of section 505, subsection (d) of section 507, or subsection (j) of section 512, or

"(II) the authority to prepare an experimental drug product under the Virus-Serum-Toxin Act,

became effective for the approved drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, 507, or 512 or the Virus-Serum-Toxin Act, and

"(ii) the period beginning on the date the application was initially submitted for the approved drug product under section 351, subsection (b) of such section 505, section 507, section 512, or the Virus-Serum-Toxin Act and ending on the date such application was approved under such section or Act.

"(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 request was submitted for the preparation of an experimental drug product described in paragraph (1)(B),

"(iii) 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

"(iv) no clinical investigation described in paragraph (3) was begun or product devel-

opment 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 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.".

Amend the title so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35,

United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.".