Public Law 100-670
100th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to authorize abbreviated new animal drug applications and to amend title 35, United States Code, to authorize the extension of the patents for animal drug products.

Nov. 16, 1988
[S. 2843]

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

Generic Animal Drug and Patent Term Restoration Act.
Safety.
Consumer protection.
21 USC 301 note.

SECTION 1. SHORT TITLE AND REFERENCE TO ACT.

(a) SHORT TITLE.—This Act may be cited as the "Generic Animal Drug and Patent Term Restoration Act".

(b) REFERENCE.—

(1) Whenever in title I (other than in section 107(b)) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

(2) Whenever in title II an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of title 35 of the United States Code.

TITLE I—NEW ANIMAL DRUG APPLICATIONS

SEC. 101. ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.

(a) GENERAL RULE.—Section 512(b) (21 U.S.C. 360b) is amended—

(1) by inserting "(1)" after "(b)",

(2) by redesignating clauses (1) through (8) as clauses (A) through (H), respectively, and

(3) by adding at the end the following:

"(2) Any person may file with the Secretary an abbreviated application for the approval of a new animal drug. An abbreviated application shall contain the information required by subsection (n).".

(b) APPLICATION REQUIREMENTS.—Section 512 is amended by striking out subsection (n) and inserting in lieu thereof the following: Labeling.

"(n)(1) An abbreviated application for a new animal drug shall contain—

"(A)(i) except as provided in clause (ii), information to show that the conditions of use or similar limitations (whether in the labeling or published pursuant to subsection (i)) prescribed, recommended, or suggested in the labeling proposed for the new animal drug have been previously approved for a new animal

drug listed under paragraph (4) (hereinafter in this subsection referred to as an 'approved new animal drug'), and

"(ii) information to show that the withdrawal period at which residues of the new animal drug will be consistent with the tolerances established for the approved new animal drug is the same as the withdrawal period previously established for the approved new animal drug or, if the withdrawal period is proposed to be different, information showing that the residues of the new animal drug at the proposed different withdrawal period will be consistent with the tolerances established for the approved new animal drug;

"(B)(i) information to show that the active ingredients of the new animal drug are the same as those of the approved new animal drug, and

"(ii) if the approved new animal drug has more than one active ingredient, and if one of the active ingredients of the new animal drug is different from one of the active ingredients of the approved new animal drug and the application is filed pursuant to the approval of a petition filed under paragraph (3)—

"(I) information to show that the other active ingredients of the new animal drug are the same as the active ingredients of the approved new animal drug,

"(II) information to show either that the different active ingredient is an active ingredient of another approved new animal drug or of an animal drug which does not meet the requirements of section 201(w), and

"(III) such other information respecting the different active ingredients as the Secretary may require;

"(C)(i) if the approved new animal drug is permitted to be used with one or more animal drugs in animal feed, information to show that the proposed uses of the new animal drug with other animal drugs in animal feed are the same as the uses of the approved new animal drug, and

"(ii) if the approved new animal drug is permitted to be used with one or more other animal drugs in animal feed, and one of the other animal drugs proposed for use with the new animal drug in animal feed is different from one of the other animal drugs permitted to be used in animal feed with the approved new animal drug, and the application is filed pursuant to the approval of a petition filed under paragraph (3)—

"(I) information to show either that the different animal drug proposed for use with the approved new animal drug in animal feed is an approved new animal drug permitted to be used in animal feed or does not meet the requirements of section 201(w) when used with another animal drug in animal feed,

"(II) information to show that other animal drugs proposed for use with the new animal drug in animal feed are the same as the other animal drugs permitted to be used with the approved new animal drug, and

"(III) such other information respecting the different animal drug or combination with respect to which the petition was filed as the Secretary may require,

"(D) information to show that the route of administration, the dosage form, and the strength of the new animal drug are the same as those of the approved new animal drug or, if the route

of administration, the dosage form, or the strength of the new animal drug is different and the application is filed pursuant to the approval of a petition filed under paragraph (3), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(E) information to show that the new animal drug is bioequivalent to the approved new animal drug, except that if the application is filed pursuant to the approval of a petition filed under paragraph (3) for the purposes described in subparagraph (B) or (C), information to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

"(F) information to show that the labeling proposed for the new animal drug is the same as the labeling approved for the approved new animal drug except for changes required because of differences approved under a petition filed under paragraph (3), because of a different withdrawal period, or because the new animal drug and the approved new animal drug are produced or distributed by different manufacturers;

"(G) the items specified in clauses (B) through (F) of subsection (b)(1);

"(H) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the approved new animal drug or which claims a use for such approved new animal drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b)(1) or (c)(3)—

"(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 animal drug for which the application is filed; and

"(I) if with respect to the approved new animal drug information was filed under subsection (b)(1) or (c)(3) for a method of use patent which does not claim a use for which the applicant is seeking approval of an application under subsection (c)(2), 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 subparagraphs (A) through (H).

"(2)(A) An applicant who makes a certification described in paragraph (1)(G)(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 (c)(1) 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, which contains data from bioequivalence studies, has been filed 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.

"(C) If an application is amended to include a certification described in paragraph (1)(G)(iv), the notice required by subparagraph (B) shall be given when the amended application is filed.

"(3) If a person wants to submit an abbreviated application for a new animal drug—

"(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or

"(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,

such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve a petition for a new animal drug unless the Secretary finds that—

"(C) investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed which differ from the approved new animal drug, or

"(D) investigations must be conducted to show the safety for human consumption of any residues in food resulting from the proposed active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed for the new animal drug which is different from the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug.

The Secretary shall approve or disapprove a petition submitted under this paragraph within 90 days of the date the petition is submitted.

Public information.

"(4)(A)(i) Within 60 days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public a list in alphabetical order of the official and proprietary name of each new animal drug which has been approved for safety and effectiveness before the date of the enactment of this subsection.

"(ii) Every 30 days after the publication of the first list under clause (i) the Secretary shall revise the list to include each new animal drug which has been approved for safety and effectiveness under subsection (c) during the 30 day period.

"(iii) When patent information submitted under subsection (b)(1) or (c)(3) respecting a new animal 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 new animal drug approved for safety and effectiveness before the date of the enactment of this subsection or approved for safety and effectiveness under subsection (c) 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 new animal drug was withdrawn or suspended under subsection (c)(2)(G) or for grounds described in subsection (e) 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 (c)(2)(G) or (e), 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. Federal Register, publication.

"(5) If an application contains the information required by clauses (A), (G), and (H) of subsection (b)(1) and such information—

"(A) is relied on by the applicant for the approval of the application, and

"(B) is not information derived either from investigations, studies, or tests conducted by or for the applicant or for which the applicant had obtained a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted,

such application shall be considered to be an application filed under subsection (b)(2).

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

(c) APPLICATION APPROVAL.—Section 512(c) is amended (1) by inserting "(1)" after "(c)", by redesignating clauses (1) and (2) as clauses (A) and (B), and by adding at the end the following: 21 USC 360b.

"(2)(A) Subject to subparagraph (C), the Secretary shall approve an abbreviated application for a drug unless the Secretary finds—

"(i) 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;

"(ii) the conditions of use prescribed, recommended, or suggested in the proposed labeling are not reasonably certain to be followed in practice or, except as provided subparagraph (B), information submitted with the application is insufficient to show that each of the proposed conditions of use or similar limitations (whether in the labeling or published pursuant to subsection (i)) have been previously approved for the approved new animal drug referred to in the application;

"(iii) information submitted with the application is insufficient to show that the active ingredients are the same as those of the approved new animal drug referred to in the application;

"(iv)(I) if the application is for a drug whose active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is the same as the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug referred to in the application, information submitted in the application is insufficient to show that the active ingredients, route of administration, dosage form, strength, or

use with other animal drugs in animal feed is the same as that of the approved new animal drug, or

"(II) if the application is for a drug whose active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is different from that of the approved new animal drug referred to in the application, no petition to file an application for the drug with the different active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed was approved under subsection (n)(3);

"(v) if the application was filed pursuant to the approval of a petition under subsection (n)(3), the application did not contain the information required by the Secretary respecting the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed which is not the same;

"(vi) information submitted in the application is insufficient to show that the drug is bioequivalent to the approved new animal drug referred to in the application, or if the application is filed under a petition approved pursuant to subsection (n)(3), information submitted in the application is insufficient to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

"(vii) 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 approved new animal drug referred to in the application except for changes required because of differences approved under a petition filed under subsection (n)(3), because of a different withdrawal period, or because the drug and the approved new animal drug are produced or distributed by different manufacturers;

"(viii) 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, (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, or (III) in the case of a drug for food producing animals, the inactive ingredients of the drug or its composition may be unsafe with respect to human food safety;

"(ix) the approval under subsection (b)(1) of the approved new animal drug referred to in the application filed under subsection (b)(2) has been withdrawn or suspended for grounds described in paragraph (1) of subsection (e), the Secretary has published a notice of a hearing to withdraw approval of the approved new animal drug for such grounds, the approval under this paragraph of the new animal drug for which the application under subsection (b)(2) was filed has been withdrawn or suspended under subparagraph (G) for such grounds, or the Secretary has determined that the approved new animal

drug has been withdrawn from sale for safety or effectiveness reasons;

"(x) the application does not meet any other requirement of subsection (n); or

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

"(B) If the Secretary finds that a new animal drug for which an application is submitted under subsection (b)(2) is bioequivalent to the approved new animal drug referred to in such application and that residues of the new animal drug are consistent with the tolerances established for such approved new animal drug but at a withdrawal period which is different than the withdrawal period approved for such approved new animal drug, the Secretary may establish, on the basis of information submitted, such different withdrawal period as the withdrawal period for the new animal drug for purposes of the approval of such application for such drug.

"(C) Within 180 days of the initial receipt of an application under subsection (b)(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.

"(D) The approval of an application filed under subsection (b)(2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in clause (i) or (ii) of subsection (n)(1)(G) or in both such clauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in clause (iii) of subsection (n)(1)(G), the approval may be made effective on the date certified under clause (iii).

"(iii) If the applicant made a certification described in clause (iv) of subsection (n)(1)(G), 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 45 days from the date the notice provided under subsection (n)(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 30 month period beginning on the date of the receipt of the notice provided under subsection (n)(2)(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 if before the expiration of such period— Courts, U.S.

"(I) 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) 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) 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 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 45 days from

the date the notice made under subsection (n)(2)(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 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 clause (iv) of subsection (n)(1)(G) and is for a drug for which a previous application has been filed under this subsection containing such a certification, the application shall be made effective not earlier than 180 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 subclause (III) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

"(E) 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 30 days after such notice, such hearing shall commence not more than 90 days after the expiration of such 30 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 90 days after the date fixed by the Secretary for filing final briefs.

"(F)(i) If an application submitted under subsection (b)(1) 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)(1), is approved after the date of the enactment of this paragraph, no application may be submitted under subsection (b)(2) which refers to the drug for which the subsection (b)(1) application was submitted before the expiration of 5 years from the date of the approval of the application under subsection (b)(1), except that such an application may be submitted under subsection (b)(2) after the expiration of 4 years from the date of the approval of the subsection (b)(1) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (n)(1)(G). 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 48 months after the date of the approval of the subsection (b) application, the 30 month period referred to in subparagraph (C)(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.

"(ii) If an application submitted under subsection (b)(1) 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 such subsection, is approved after the date of enactment of this paragraph and if such application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food producing animals, human

food safety studies (other than bioequivalence or residue 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)(2) for the conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of 3 years from the date of the approval of the application under subsection (b)(1) for such drug.

"(iii) If a supplement to an application approved under subsection (b)(1) is approved after the date of enactment of this paragraph and the supplement contains reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food producing animals, human food safety studies (other than bioequivalence or residue 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)(2) for a change approved in the supplement effective before the expiration of 3 years from the date of the approval of the supplement.

"(iv) An applicant under subsection (b)(1) who comes within the provisions of clause (i) of this subparagraph as a result of an application which seeks approval for a use solely in non-food producing animals, may elect, within 10 days of receiving such approval, to waive clause (i) of this subparagraph, in which event the limitation on approval of applications submitted under subsection (b)(2) set forth in clause (ii) of this subparagraph shall be applicable to the subsection (b)(1) application.

"(v) If an application (including any supplement to a new animal drug application) submitted under subsection (b)(1) for a new animal drug for a food-producing animal use, which includes an active ingredient (including any ester or salt of the active ingredient) which has been the subject of a waiver under subparagraph (B)(iv) is approved after the date of enactment of this paragraph, and if the application contains reports of clinical or field investigations or human food safety studies (other than bioequivalence or residue studies) essential to the new approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application (including any supplement to such application) submitted under subsection (b)(2) for the new conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of five years from the date of approval of the application under subsection (b)(1) for such drug. The provisions of this paragraph shall apply only to the first approval for a food-producing animal use for the same applicant after the waiver under subparagraph (B)(iv).

"(G) If an approved application submitted under subsection (b)(2) for a new animal drug refers to a drug the approval of which was withdrawn or suspended for grounds described in paragraph (1) or (2) of subsection (e) or was withdrawn or suspended under this subparagraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this paragraph shall be withdrawn or suspended—

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

"(ii) if the approved new animal 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.

"(H) For purposes of this paragraph:

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

"(ii) A new animal drug shall be considered to be bioequivalent to the approved new animal drug referred to in its application under subsection (n) 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 approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses;

"(II) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the approved new animal 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 drug concentrations in use, and is considered scientifically insignificant for the drug in attaining the intended purposes of its use and preserving human food safety; or

"(III) in any case in which the Secretary determines that the measurement of the rate and extent of absorption or excretion of the new animal drug in biological fluids is inappropriate or impractical, an appropriate acute pharmacological effects test or other test of the new animal drug and, when deemed scientifically necessary, of the approved new animal drug referred to in the application in the species to be tested or in an appropriate animal model does not show a significant difference between the new animal drug and such approved new animal drug when administered at the same dose under similar experimental conditions.

If the approved new animal drug referred to in the application for a new animal drug under subsection (n) is approved for use in more than one animal species, the bioequivalency information described in subclause (I), (II), and (III) shall be obtained for one species, or if the Secretary deems appropriate based on scientific principles, shall be obtained for more than one species. The Secretary may prescribe the dose to be used in determining bioequivalency under subclause (I), (II), or (III). To assure that the residues of the new animal drug will be consistent with the established tolerances for the approved new animal drug referred to in the application under subsection (b)(2) upon the expiration of the withdrawal period contained in the application for the new animal drug, the Secretary shall require bioequivalency data or residue depletion studies of the new animal drug or such other data or studies as the Secretary considers appropriate based on scientific principles. If the Secretary requires one or more residue studies under the preceding

sentence, the Secretary may not require that the assay methodology used to determine the withdrawal period of the new animal drug be more rigorous than the methodology used to determine the withdrawal period for the approved new animal drug referred to in the application. If such studies are required and if the approved new animal drug, referred to in the application for the new animal drug for which such studies are required, is approved for use in more than one animal species, such studies shall be conducted for one species, or if the Secretary deems appropriate based on scientific principles, shall be conducted for more than one species.".

SEC. 102. PATENT INFORMATION.

(a) SECTION 512(b).—Section 512(b)(1) 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 new animal drug for which the applicant filed 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.". 21 USC 360b. Public information.

(b) OTHER SECTIONS.—

(1) Section 512(c) is amended by adding at the end the following: 21 USC 360b.

"(3) If the patent information described in subsection (b)(1) could not be filed with the submission of an application under subsection (b)(1) because the application was filed before the patent information was required under subsection (b)(1) 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 new animal drug for which the application was filed 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)(1) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than 30 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)(1) 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 30 days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.". Public information.

(2) The first sentence of section 512(d)(1) is amended by redesignating subparagraphs (G) and (H) as subparagraphs (H) and (I), respectively and by inserting after subparagraph (F) the following: 21 USC 360b.

"(G) the application failed to contain the patent information prescribed by subsection (b)(1);".

21 USC 360b. (3) The second sentence of section 512(d)(1) is amended by striking out "(H)" and inserting in lieu thereof "(G)".

21 USC 360b. (4) The first sentence of section 512(e)(1) is amended by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively, and by inserting after subparagraph (C) the following:

"(D) the patent information prescribed by subsection (c)(3) was not filed within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information;".

21 USC 360b note.

SEC. 103. REGULATIONS.

(a) GENERAL RULE.—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 512 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101 through 103 of this title, within one year of the date of enactment of this Act.

(b) TRANSITION.—During the period beginning 60 days after the date of enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new animal drug applications may be submitted in accordance with the provisions of section 314.55 and part 320 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 512(c) of the Federal Food, Drug, and Cosmetic Act before the date of enactment of this Act. If any such provision of section 314.55 or part 320 is inconsistent with the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (as amended by this title), the Secretary shall consider the application under the applicable requirements of section 512 (as so amended).

SEC. 104. SAFETY AND EFFECTIVENESS DATA.

Section 512 (as amended by section 101(b) of this title) is amended by adding at the end the following:

Public information. "(p)(1) Safety and effectiveness data and information which has been submitted in an application filed under subsection (b)(1) 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—

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

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

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

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

"(E) upon the effective date of the approval of the first application filed under subsection (b)(2) which refers to such drug or upon the date upon which the approval of an application filed under subsection (b)(2) which refers to such drug could be made effective if such an application had been filed.

"(2) Any request for data and information pursuant to paragraph (1) shall include a verified statement by the person making the

request that any data or information received under such paragraph shall not be disclosed by such person to any other person—

"(A) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, outside the United States, the drug identified in the application filed under subsection (b)(1), and

"(B) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by such person to the Secretary, which meets the requirements of this paragraph.".

SEC. 105. VETERINARY PRESCRIPTION DRUGS.

Section 503 (21 U.S.C. 353) is amended by adding at the end thereof the following new subsection:

"(c)(1)(A) A drug intended for use by animals other than man which—

"(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

"(ii) is limited by an approved application under subsection (b) of section 512 to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

"(B) For purposes of subparagraph (A), an order is lawful if the order—

"(i) is a prescription or other order authorized by law,

"(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

"(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

"(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale. Fraud.

"(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

"(A) shall be exempt from the requirements of section 502, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

"(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

"(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

"(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

"(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512 from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

Fraud.

"(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.'. A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.".

21 USC 360b note.

SEC. 106. DRUGS PRIMARILY MANUFACTURED USING BIOTECHNOLOGY.

Notwithstanding section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services may not approve an abbreviated application submitted under such section for a new animal drug which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques.

SEC. 107. CONFORMING AMENDMENTS.

(a) BATCH CERTIFICATION.—

(1) Section 201(w) (21 U.S.C. 321(w)) is amended by striking out "; or" at the end of paragraph (2) and inserting in lieu thereof a period and by striking out paragraph (3).

(2) Section 512(a)(1) (21 U.S.C. 360b(a)(1)) is amended by inserting "and" at the end of subparagraph (A), by striking out ", and" at the end of subparagraph (B) and inserting in lieu thereof a period, and by striking out subparagraph (C).

(b) TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting "or 512" after "505".

21 USC 360b note.

SEC. 108. EFFECTIVE DATE.

The Secretary of Health and Human Services may not make an approval of an application submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2)) effective before January 1, 1991.

TITLE II—PATENT TERMS

SEC. 201. EXTENSION OF PATENT TERM.

35 USC 156.

(a) SECTION 156(a)(5).—Section 156(a)(5) is amended—

(1) by inserting "or (C)" after "subparagraph (B)" in subparagraph (A),

(2) by striking out "or" at the end of subparagraph (A), and

(3) by striking out the period at the end of subparagraph (B) and inserting "; or" and the following:

Marketing.

"(C) for purposes of subparagraph (A), in the case of a patent which—

"(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

"(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.".

(b) SECTION 156(b).—Section 156(b) is amended to read as follows: 35 USC 156.

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

"(1) in the case of a patent which claims a product, be limited to any use approved for the product—

"(A) before the expiration of the term of the patent—

"(i) under the provision of law under which the applicable regulatory review occurred, or

"(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

"(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

"(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 product—

"(A) before the expiration of the term of the patent—

"(i) under any provision of law under which an applicable regulatory review occurred, and

"(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

"(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; 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—

"(A) the approved product, or

"(B) the product if it has been subject to a regulatory review period described in paragraphs (1), (4), or (5) of subsection (g).

As used in this subsection, the term 'product' includes an approved product.".

(c) SECTION 156(c)(2).—Section 156(c)(2) is amended by striking out "and (3)(B)(i)" and inserting in lieu thereof "(3)(B)(i), (4)(B)(i), and (5)(B)(i)".

(d) SECTION 156(d)(1)(C).—Section 156(d)(1)(C) is amended by inserting "or the Secretary of Agriculture" after "Services".

(e) SECTION 156(d)(2)(A).—Section 156(d)(2)(A) is amended to read as follows:

"(2)(A) Within 60 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 manufac-

turing 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 30 days after the receipt of an application from the Commissioner, the Secretary receiving the application 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.".

Federal Register, publication.

35 USC 156.

(f) SECTION 156(d)(2)(B).—Section 156(d)(2)(B) is amended to read as follows:

"(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 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 making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Commissioner of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the office of the Assistant Secretary for Marketing and Inspection Services.

"(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 60-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 30 days after the date of the request, or at the request of the person making the request, not later than 60 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 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.".

Federal Register, publication.

Federal Register, publication.

(g) SECTION 156(f).—Section 156(f) is amended—

(1) by striking out "human" in paragraph (1)(A) and by amending paragraph (2) to read as follows:

"(2) The term 'drug product' means the active ingredient of—

"(A) 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), or

"(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.",

(2) by amending subparagraphs (B) and (C) of paragraph (4) to read as follows:

"(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).", and

(3) by adding at the end the following:

"(7) The term 'date of enactment' as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

"(8) The term 'date of enactment' as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.".

(h) SECTION 156(g).—

(1) Paragraph (1) of section 156(g) is amended— 35 USC 156.

(A) in subparagraph (A), by striking out "human drug product" and inserting in lieu thereof "new drug, antibiotic drug, or human biological product",

(B) in subparagraph (B)—

(i) by striking out "human drug product" in the matter before clause (i) and inserting in lieu thereof "new drug, antibiotic drug, or human biological product", and

(ii) by striking out "human drug product" in clauses (i) and (ii) and inserting in lieu thereof "product".

(2) Paragraph (1)(A) of section 156(g) is amended by striking out "paragraph (4)" and inserting in lieu thereof "paragraph (6)".

(3) Paragraphs (2)(A) and (3)(A) are each amended by striking out "paragraph (4)" and inserting in lieu thereof "paragraph (6)".

(4) Section 156(g) is amended by redesignating paragraph (4) as paragraph (6) and by inserting after paragraph (3) the following:

"(4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

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

"(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was

initially submitted for such animal drug product under section 512, and

"(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

"(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

"(B) The regulatory period for a veterinary biological product is the sum of—

"(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

"(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.".

35 USC 156.

(5) Paragraph (6) (as so redesignated) of section 156(g) is amended—

(A) by striking out "paragraph (1)(B) was submitted" in subparagraph (B)(i) and inserting in lieu thereof "paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted",

(B) by striking out "paragraph (2)" in subparagraph (B)(ii) and inserting in lieu thereof "paragraph (2)(B) or (4)(B)", and

(C) in subparagraph (C), by inserting before the period the following: "or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years".

(i) SECTION 271(e).—

(1) Section 271(e)(1) is amended—

(A) by inserting before the last close parenthesis the following: "which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques", and

(B) by inserting before the period the following: "or veterinary biological products".

(2) Section 271(e)(2) is amended to read as follows:

"(2) It shall be an act of infringement to submit—

"(A) 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, or

"(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is 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 or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.".

(3) Section 271(e)(4) is amended by inserting "or veterinary biological product" after "drug" each place it occurs. 35 USC 271.

Approved November 16, 1988.

LEGISLATIVE HISTORY—S. 2843 (H.R. 4982):

HOUSE REPORTS: No. 100-972, Pt. 1 (Comm. on Energy and Commerce) and Pt. 2 (Comm. on the Judiciary), both accompanying H.R. 4982.
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Oct. 6, H.R. 4982 considered and passed House.
Oct. 13, S. 2843 considered and passed Senate and House.