104TH CONGRESS
1ST SESSION

S. 773

To amend the Federal Food, Drug, and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 9 (legislative day, MAY 1), 1995

Mrs. KASSEBAUM (for herself, Mr. GREGG, Mr. GORTON, Mr. COATS, Mr. JEFFORDS, Mr. FRIST, Mr. HARKIN, Mr. CRAIG, Mr. LUGAR, Mr. INHOFE, Mr. GRASSLEY, Mr. MCCONNELL, Mr. KYL, Mr. SANTORUM, Mr. HEFLIN, Mr. BOND, Mr. PRYOR, Mr. KERREY, Mr. BENNETT, and Mr. HELMS) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes.

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

SECTION 1. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Animal Drug Availability Act of 1995''.

(b) REFERENCE.—Whenever in this Act 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 (21 U.S.C. 321 et seq.).

SEC. 2. FINDINGS.

Congress finds that—

(1) the new animal drug approval process has been proceeding too slowly, with the result that necessary and useful drug therapies are being kept from the marketplace;

(2) the lack of drug approvals for new animal drugs places the health and well-being of animals at risk;

(3) the expense and delays caused by effectiveness testing for new animal drugs have begun to outweigh the benefits of such testing;

(4) the overreliance on field investigations to establish the effectiveness of new animal drugs is a primary reason the new animal drug approval process has become so burdensome;

(5) there are not sufficient approved animal drugs available to treat every specific disease or condition found in each species of animal;

(6) it would benefit the public health and safety to have many additional animal drugs reviewed and approved by the Food and Drug Administration;

(7) economic and regulatory incentives are necessary to encourage manufacturers of animal drugs to convert unlabeled uses of the drugs to approved, labeled uses; and

(8) it is important that the Center for Veterinary Medicine of the Food and Drug Administration promptly implement the recently developed mission, vision, and guiding principles of the Center so that the Food and Drug Administration is a global leader as a public health organization that enables the marketing of safe and effective products.

SEC. 3. EVIDENCE OF EFFECTIVENESS.

(a) ORIGINAL APPLICATIONS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by striking paragraph (3) and adding at the end the following new paragraph:

''(4)(A) As used in this subsection and subsections (c)(2)(F)(iii) and (e)(1)(C), the term 'substantial evidence' means evidence from 1 or more scientifically sound studies, including as appropriate in vitro studies, studies in laboratory animals (including a target species), bioequivalence studies, tissue residue studies, and any studies voluntarily undertaken by or for the applicant,

that taken together provide reasonable assurance that the drug will have the claimed or intended effect of the drug.

''(B) For purposes of subparagraph (A), a study shall be considered to be scientifically sound if the study is designed and conducted in a manner that is consistent with generally recognized scientific procedures and principles.''.

(b) SUPPLEMENTAL APPLICATIONS.—Section 512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amended—

(1) by striking ''reports of new clinical or field investigations (other than bioequivalence or residue studies) and'' and inserting ''substantial evidence (as defined in subsection (d)(4)) of the effectiveness of the drug involved, any studies of animal safety, or''; and

(2) by striking ''essential to'' and inserting '', required for''.

(c) MINOR SPECIES AND USES.—Section 512(d)(1) (21 U.S.C. 360b(d)(1)) is amended by adding at the end the following new sentence: ''Subparagraph (E) shall not apply to a claim for use of the drug described in subparagraph (E) in a minor species, or for a minor use of the drug, as the terms 'minor species' and 'minor use' are defined in regulations issued by the Secretary, if there is an application filed under subsection (b) for the drug, and

the application is approved, prior to the submission of the claim.''.

(d) COMBINATION DRUGS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by inserting before paragraph (4) (as added by subsection (a)) the following new paragraph:

''(3) In a case in which a new animal drug contains more than 1 active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with another animal drug, in evaluating the safety and effectiveness of the ingredients or the combination, respectively, the Secretary shall consider—

''(A) whether any of the active ingredients or any of the drugs in the combination, respectively, alters the safe concentration of another of the active ingredients or drugs in the combination, respectively, or interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively;

''(B) whether each of the active ingredients or drugs in the combination, respectively, that is claimed to have the same intended effect has been shown to contribute to the effect; and

''(C) to the extent that subparagraph (B) does not apply, whether each of the active ingredients or

drugs in the combination has an identified target population for which dosing with the active ingredients or combination represents appropriate concurrent therapy.''.

(e) WITHDRAWAL OF APPROVAL.—Section 512(e)(1)(C) (21 U.S.C. 360b(e)(1)(C)) is amended by inserting after ''substantial evidence'' the following: ''(as defined in subsection (d)(4))''.

(f) IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary shall issue proposed regulations implementing the amendments made by this section. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing the amendments.

(2) CONTENTS.—In issuing regulations implementing the amendments made by this section, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption for a new animal drug under subsection (j) of such section, that is pending or has been submit-

ted prior to the effective date of the regulations, the Secretary shall—

(A) further define the term ''substantial evidence'', as defined in subsection (d)(4) of such section, in a manner that encourages the submission of applications for production drugs that conserve food resources, of applications for veterinary prescription drugs whose use is designed to rely on the experience and training of practitioners in establishing effective doses for such drugs, and of supplemental applications, including applications seeking approval for uses of animal drugs in minor species, for minor uses of such drugs, and for permitted unlabeled uses of such drugs;

(B) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434/CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991;

(C)(i) provide for a conference prior to the submission of an application for approval of a new animal drug under such section, and prior to the submission of a request for an investiga-

tional exemption under subsection (j) of such section, to make a decision establishing a submission or an investigational requirement (which decision shall bind the Secretary and the applicant or requester unless the Secretary by order determines that a documented scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference); and

(ii) not later than 10 days after each such conference, by written order, provide a scientific justification specific to the animal drug and intended uses under consideration for requiring studies of types other than the types of studies specified in subsection (d)(4) of such section, as being essential to provide substantial evidence of effectiveness for the intended uses of the drug;

(D) define the kinds of evidence that an applicant may use to establish the contribution of each active ingredient in a new animal drug, or new animal drug used in combination with another animal drug, for the same intended effect, as described in subsection (d)(3)(B) of such section; and

(E) define the kinds of evidence that an applicant may use to establish the appropriateness of concurrent therapy represented by each active ingredient in a new animal drug, or new animal drug used in combination with another animal drug, for the same intended effect, as described in subsection (d)(3)(C) of such section.

(g) REPORT TO CONGRESS.—The Secretary shall study any efficiencies in the new animal drug approval process that are caused by the amendments made by this Act. Not later than 24 months after the date of enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a report containing the results of the study.

SEC. 4. TIMEFRAME FOR APPROVAL.

The first sentence of section 512(c)(1) (21 U.S.C. 360b(c)(1)) is amended by striking ''one hundred and eighty'' and inserting ''90''.

SEC. 5. DISPUTE RESOLUTION.

Section 512(c)(1) (21 U.S.C. 360b(c)(1)) is amended—

(1) in the first sentence—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively; and

(B) by inserting ''(A)'' after ''(1)'';

(2) in the second sentence, by striking ''If'' and inserting the following:

''(C) If''; and

(3) by inserting after subparagraph (A) (as designated by paragraph (1)(B)) the following new subparagraph:

''(B)(i) At any time prior to the issuance of the notice under subparagraph (A)(ii), the applicant may, in writing, notify the Secretary that an impasse exists in the review of the application with respect to a specifically identified issue that is preventing the issuance of an order under subparagraph (A)(i).

''(ii) On receipt of the notification from the applicant, the Secretary shall refer the disputed issue—

''(I) to an existing (as of the date of the notification) advisory committee having expertise related to the issue;

''(II) to an advisory committee convened in accordance with the procedure in section 721(b)(5)(D); or

''(III) to a special Government employee, as defined in section 202(a) of title 18, United States Code, who is acceptable to the Secretary and the applicant.

''(iii) The applicant and representatives of the Secretary may consult with the committee or employee on the matter referred. The committee or employee shall submit to the Secretary and the applicant a report containing recommendations (including a statement of reasons for the recommendations) regarding the matter not later than 60 days after the date of the referral, or not later than 90 days after the date of the referral if the committee or employee considers the additional 30 days to be necessary. Not later than 30 days after the date of receiving the report, the Secretary shall, in writing, confirm or modify the recommendations received, providing reasons and reference to data before the committee or employee for any modification.''.

SEC. 6. LIMITATION ON RESIDUES.

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

''(F) on the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;''.

SEC. 7. EXPORT OF NEW ANIMAL DRUGS.

(a) EXPORT IN ACCORDANCE WITH FOREIGN LAW.—Section 801(e)(1) (21 U.S.C. 381(e)(1)) is amended by striking the last sentence.

(b) EXPORTS OF CERTAIN UNAPPROVED PRODUCTS.—Section 802 (21 U.S.C. 382) is amended—

(1) in subsection (a)(1)(A), by striking ''or section 512'';

(2) in subsection (b)(1)—

(A) in subparagraph (A)—

(i) by striking the comma at the end of clause (ii) and inserting '', or'';

(ii) by striking ''or'' at the end of clause (iii); and

(iii) by striking clause (iv); and

(B) in subparagraph (C)—

(i) by striking ''or 512,'' and inserting a comma; and

(ii) by striking ''or 512(d) or'' and inserting ''of this Act or section'';

(3) in subsection (c)(1)(C), by striking ''505 or 512,'' and inserting ''505,''; and

(4) in subsection (d)—

(A) in paragraph (3), by striking ''505 or 512,'' and inserting ''505,''; and

(B) in paragraph (4)—

(i) by striking ''or 512(j)''; and

(ii) by striking ''505 or 512,'' and inserting ''505,''.

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