

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCE.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Animal Drug Availability Act of 1995”.

6 (b) REFERENCE.—Whenever in this Act an amend-
7 ment or repeal is expressed in terms of an amendment

1 to, or repeal of, a section or other provision, the reference
2 shall be considered to be made to a section or other provi-
3 sion of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 321 et seq.).

5 **SEC. 2. FINDINGS.**

6 Congress finds that—

7 (1) the new animal drug approval process has
8 been proceeding too slowly, with the result that nec-
9 essary and useful drug therapies are being kept from
10 the marketplace;

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

14 (3) the expense and delays caused by effective-
15 ness testing for new animal drugs have begun to
16 outweigh the benefits of such testing;

17 (4) the overreliance on field investigations to es-
18 tablish the effectiveness of new animal drugs is a
19 primary reason the new animal drug approval proc-
20 ess has become so burdensome;

21 (5) there are not sufficient approved animal
22 drugs available to treat every specific disease or con-
23 dition found in each species of animal;

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

4 (7) economic and regulatory incentives are nec-
5 essary to encourage manufacturers of animal drugs
6 to convert unlabeled uses of the drugs to approved,
7 labeled uses; and

8 (8) it is important that the Center for Veteri-
9 nary Medicine of the Food and Drug Administration
10 promptly implement the recently developed mission,
11 vision, and guiding principles of the Center so that
12 the Food and Drug Administration is a global leader
13 as a public health organization that enables the mar-
14 keting of safe and effective products.

15 **SEC. 3. EVIDENCE OF EFFECTIVENESS.**

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

19 “(4)(A) As used in this subsection and subsections
20 (c)(2)(F)(iii) and (e)(1)(C), the term ‘substantial evi-
21 dence’ means evidence from 1 or more scientifically sound
22 studies, including as appropriate in vitro studies, studies
23 in laboratory animals (including a target species),
24 bioequivalence studies, tissue residue studies, and any
25 studies voluntarily undertaken by or for the applicant,

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

3 “(B) For purposes of subparagraph (A), a study shall
4 be considered to be scientifically sound if the study is de-
5 signed and conducted in a manner that is consistent with
6 generally recognized scientific procedures and principles.”.

7 (b) SUPPLEMENTAL APPLICATIONS.—Section
8 512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amend-
9 ed—

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

16 (2) by striking “essential to” and inserting “,
17 required for”.

18 (c) MINOR SPECIES AND USES.—Section 512(d)(1)
19 (21 U.S.C. 360b(d)(1)) is amended by adding at the end
20 the following new sentence: “Subparagraph (E) shall not
21 apply to a claim for use of the drug described in subpara-
22 graph (E) in a minor species, or for a minor use of the
23 drug, as the terms ‘minor species’ and ‘minor use’ are de-
24 fined in regulations issued by the Secretary, if there is
25 an application filed under subsection (b) for the drug, and

1 the application is approved, prior to the submission of the
2 claim.”.

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

7 “(3) In a case in which a new animal drug contains
8 more than 1 active ingredient, or the labeling of the drug
9 prescribes, recommends, or suggests use of the drug in
10 combination with another animal drug, in evaluating the
11 safety and effectiveness of the ingredients or the combina-
12 tion, respectively, the Secretary shall consider—

13 “(A) whether any of the active ingredients or
14 any of the drugs in the combination, respectively, al-
15 ters the safe concentration of another of the active
16 ingredients or drugs in the combination, respectively,
17 or interferes with the methods of analysis for an-
18 other of the active ingredients or drugs in the com-
19 bination, respectively;

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

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

1 drugs in the combination has an identified target
2 population for which dosing with the active ingredi-
3 ents or combination represents appropriate concu-
4 rent therapy.”.

5 (e) WITHDRAWAL OF APPROVAL.—Section
6 512(e)(1)(C) (21 U.S.C. 360b(e)(1)(C)) is amended by in-
7 serting after “substantial evidence” the following: “(as de-
8 fined in subsection (d)(4))”.

9 (f) IMPLEMENTATION.—

10 (1) IN GENERAL.—Not later than 6 months
11 after the date of enactment of this Act, the Sec-
12 retary shall issue proposed regulations implementing
13 the amendments made by this section. Not later
14 than 18 months after the date of enactment of this
15 Act, the Secretary shall issue final regulations imple-
16 menting the amendments.

17 (2) CONTENTS.—In issuing regulations imple-
18 menting the amendments made by this section, and
19 in taking an action to review an application for ap-
20 proval of a new animal drug under section 512 of
21 the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 360b), or a request for an investigational ex-
23 emption for a new animal drug under subsection (j)
24 of such section, that is pending or has been submit-

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

3 (A) further define the term “substantial
4 evidence”, as defined in subsection (d)(4) of
5 such section, in a manner that encourages the
6 submission of applications for production drugs
7 that conserve food resources, of applications for
8 veterinary prescription drugs whose use is de-
9 signed to rely on the experience and training of
10 practitioners in establishing effective doses for
11 such drugs, and of supplemental applications,
12 including applications seeking approval for uses
13 of animal drugs in minor species, for minor
14 uses of such drugs, and for permitted unlabeled
15 uses of such drugs;

16 (B) take into account the proposals con-
17 tained in the citizen petition (FDA Docket No.
18 91P-0434/CP) jointly submitted by the Amer-
19 ican Veterinary Medical Association and the
20 Animal Health Institute, dated October 21,
21 1991;

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

1 tional exemption under subsection (j) of such
2 section, to make a decision establishing a sub-
3 mission or an investigational requirement
4 (which decision shall bind the Secretary and the
5 applicant or requester unless the Secretary by
6 order determines that a documented scientific
7 requirement essential to the determination of
8 safety or effectiveness of the animal drug in-
9 volved has appeared after the conference); and

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

19 (D) define the kinds of evidence that an
20 applicant may use to establish the contribution
21 of each active ingredient in a new animal drug,
22 or new animal drug used in combination with
23 another animal drug, for the same intended ef-
24 fect, as described in subsection (d)(3)(B) of
25 such section; and

1 (E) define the kinds of evidence that an
2 applicant may use to establish the appropriate-
3 ness of concurrent therapy represented by each
4 active ingredient in a new animal drug, or new
5 animal drug used in combination with another
6 animal drug, for the same intended effect, as
7 described in subsection (d)(3)(C) of such sec-
8 tion.

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

16 **SEC. 4. TIMEFRAME FOR APPROVAL.**

17 The first sentence of section 512(c)(1) (21 U.S.C.
18 360b(c)(1)) is amended by striking “one hundred and
19 eighty” and inserting “90”.

20 **SEC. 5. DISPUTE RESOLUTION.**

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

23 (1) in the first sentence—

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

1 (B) by inserting “(A)” after “(1)”;

2 (2) in the second sentence, by striking “If” and
3 inserting the following:

4 “(C) If”; and

5 (3) by inserting after subparagraph (A) (as des-
6 igned by paragraph (1)(B)) the following new sub-
7 paragraph:

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

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

16 “(I) to an existing (as of the date of the notifi-
17 cation) advisory committee having expertise related
18 to the issue;

19 “(II) to an advisory committee convened in ac-
20 cordance with the procedure in section 721(b)(5)(D);
21 or

22 “(III) to a special Government employee, as de-
23 fined in section 202(a) of title 18, United States
24 Code, who is acceptable to the Secretary and the ap-
25 plicant.

1 “(iii) The applicant and representatives of the Sec-
2 retary may consult with the committee or employee on the
3 matter referred. The committee or employee shall submit
4 to the Secretary and the applicant a report containing rec-
5 ommendations (including a statement of reasons for the
6 recommendations) regarding the matter not later than 60
7 days after the date of the referral, or not later than 90
8 days after the date of the referral if the committee or em-
9 ployee considers the additional 30 days to be necessary.
10 Not later than 30 days after the date of receiving the re-
11 port, the Secretary shall, in writing, confirm or modify the
12 recommendations received, providing reasons and ref-
13 erence to data before the committee or employee for any
14 modification.”.

15 **SEC. 6. LIMITATION ON RESIDUES.**

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

18 “(F) on the basis of information submitted to
19 the Secretary as part of the application or any other
20 information before the Secretary with respect to
21 such drug, any use prescribed, recommended, or
22 suggested in labeling proposed for such drug will re-
23 sult in a residue of such drug in excess of a toler-
24 ance found by the Secretary to be safe for such
25 drug;”.

1 **SEC. 7. EXPORT OF NEW ANIMAL DRUGS.**

2 (a) EXPORT IN ACCORDANCE WITH FOREIGN
3 LAW.—Section 801(e)(1) (21 U.S.C. 381(e)(1)) is amend-
4 ed by striking the last sentence.

5 (b) EXPORTS OF CERTAIN UNAPPROVED PROD-
6 UCTS.—Section 802 (21 U.S.C. 382) is amended—

7 (1) in subsection (a)(1)(A), by striking “or sec-
8 tion 512”;

9 (2) in subsection (b)(1)—

10 (A) in subparagraph (A)—

11 (i) by striking the comma at the end
12 of clause (ii) and inserting “, or”;

13 (ii) by striking “or” at the end of
14 clause (iii); and

15 (iii) by striking clause (iv); and

16 (B) in subparagraph (C)—

17 (i) by striking “or 512,” and inserting
18 a comma; and

19 (ii) by striking “or 512(d) or” and in-
20 serting “of this Act or section”;

21 (3) in subsection (c)(1)(C), by striking “505 or
22 512,” and inserting “505,”; and

23 (4) in subsection (d)—

24 (A) in paragraph (3), by striking “505 or
25 512,” and inserting “505,”; and

26 (B) in paragraph (4)—

- 1 (i) by striking “or 512(j)”; and
- 2 (ii) by striking “505 or 512,” and in-
- 3 serting “505,”.

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