

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2508

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.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 19, 1995

Mr. ALLARD (for himself, Mr. KLUG, Mr. STENHOLM, Mr. DINGELL, Mr. GANSKE, Mr. BARRETT of Nebraska, Mr. BEREUTER, Mr. BOEHNER, Mr. BROWN of California, Mr. BRYANT of Texas, Mr. BURTON of Indiana, Mr. BUYER, Mr. CHAMBLISS, Mrs. CHENOWETH, Mr. COBLE, Mr. COMBEST, Mr. CONDIT, Mr. COOLEY, Mr. COSTELLO, Mr. CRAPO, Mrs. CUBIN, Mr. DE LA GARZA, Mr. DOOLEY, Mr. EHLERS, Mr. EMERSON, Mr. ENSIGN, Mr. EWING, Mr. GOODLATTE, Mr. GORDON, Mr. GUNDERSON, Mr. HAMILTON, Mr. HEFLEY, Mr. HOLDEN, Mr. HOSTETTLER, Mr. JOHNSON of South Dakota, Mr. KLECZKA, Mr. LAHOOD, Mrs. LINCOLN, Mr. LARGENT, Mr. LATHAM, Mr. LEACH, Mr. LEWIS of Kentucky, Mr. LIGHTFOOT, Mr. LUCAS, Mr. MCINNIS, Mr. MCINTOSH, Ms. MCKINNEY, Mr. MILLER of Florida, Mr. MINGE, Ms. MOLINARI, Mr. MYERS of Indiana, Mr. NORWOOD, Mr. PASTOR, Mr. PAXON, Mr. PETERSON of Minnesota, Mr. POMBO, Mr. POMEROY, Mr. POSHARD, Mr. ROBERTS, Mr. ROEMER, Mr. ROSE, Mr. SCHAEFER, Mr. SKEEN, Mr. SOUDER, Mr. STUMP, Mr. TAYLOR of North Carolina, Mr. THORNBERRY, Mr. THORNTON, Mrs. THURMAN, Mr. WALSH, Mr. WATTS of Oklahoma, and Mr. WHITFIELD) introduced the following bill; which was referred to the Committee on Commerce

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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.

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

12 **SEC. 2. FINDINGS.**

13 Congress finds that—

14 (1) the new animal drug approval process has  
15 been proceeding too slowly, with the result that nec-  
16 essary and useful drug therapies are being kept from  
17 the marketplace;

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

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

24 (4) the overreliance on field investigations to es-  
25 tablish the effectiveness of new animal drugs is a

1 primary reason the new animal drug approval proc-  
2 ess has become so burdensome;

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

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

9 (7) economic and regulatory incentives are nec-  
10 essary to encourage manufacturers of animal drugs  
11 to convert unlabeled uses of the drugs to approved,  
12 labeled uses; and

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

20 **SEC. 3. EVIDENCE OF EFFECTIVENESS.**

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

24 “(4)(A) As used in this subsection and subsections  
25 (c)(2)(F)(iii) and (e)(1)(C), the term ‘substantial evi-

1 dence’ means evidence from 1 or more scientifically sound  
2 studies, including as appropriate in vitro studies, studies  
3 in laboratory animals (including a target species),  
4 bioequivalence studies, and any studies voluntarily under-  
5 taken by or for the applicant, that taken together provide  
6 reasonable assurance that the drug will have the claimed  
7 or intended effect of the drug.

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

12 (b) SUPPLEMENTAL APPLICATIONS.—Section  
13 512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amend-  
14 ed—

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

21 (2) by striking “essential to” and inserting “,  
22 required for”.

23 (c) MINOR SPECIES AND USES.—Section 512(d)(1)  
24 (21 U.S.C. 360b(d)(1)) is amended by adding at the end  
25 the following new sentence: “Subparagraph (E) shall not

1 apply to a claim for use of the drug described in subpara-  
2 graph (E) in a minor species, or for a minor use of the  
3 drug, as the terms ‘minor species’ and ‘minor use’ are de-  
4 fined in regulations issued by the Secretary, if there is  
5 an application filed under subsection (b) for the drug, and  
6 the application is approved, prior to the submission of the  
7 claim.”.

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

12 “(3) In a case in which a new animal drug contains  
13 more than 1 active ingredient, or the labeling of the drug  
14 prescribes, recommends, or suggests use of the drug in  
15 combination with another animal drug, and the active in-  
16 gredients or drugs in the combination have been sepa-  
17 rately approved for particular uses and species prior to  
18 the approval of the application for the same uses and spe-  
19 cies in combination (or, in the absence of such approvals,  
20 after evaluating the safety and efficacy of the combination  
21 itself), the Secretary may only consider with respect to the  
22 combination whether any of the active ingredients or any  
23 of the drugs in the combination, respectively, at the long-  
24 est withdrawal time of any of the active ingredients or  
25 drugs in the combination, respectively, is above its safe

1 concentration, i.e. exceeds its established tolerance (as  
2 measured by its marker residue), or interferes with the  
3 methods of analysis for another of the active ingredients  
4 or drugs in the combination, respectively.”.

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 the opportunity for a  
23              conference prior to the submission of an appli-  
24              cation for approval of a new animal drug under  
25              such section, and prior to the submission of a

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

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

20 **SEC. 4. TIMEFRAME FOR APPROVAL.**

21 The first sentence of section 512(c)(1) (21 U.S.C.  
22 360b(c)(1)) is amended by striking “one hundred and  
23 eighty” and inserting “90”.

1 **SEC. 5. DISPUTE RESOLUTION.**

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

4 (1) in the first sentence—

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

7 (B) by inserting “(A)” after “(1)”;

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

10 “(C) If”; and

11 (3) by inserting after subparagraph (A) (as des-  
12 ignated by paragraph (1)(B)) the following new sub-  
13 paragraph:

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

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

22 “(I) to an existing (as of the date of the notifi-  
23 cation) advisory committee having expertise related  
24 to the issue;

1           “(II) to an advisory committee convened in ac-  
2 cordance with the procedure in section 721(b)(5)(D);  
3 or

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

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

22 **SEC. 6. LIMITATION ON RESIDUES.**

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

1           “(F) on the basis of information submitted to  
2           the Secretary as part of the application or any other  
3           information before the Secretary with respect to  
4           such drug, any use prescribed, recommended, or  
5           suggested in labeling proposed for such drug will re-  
6           sult in a residue of such drug in excess of a toler-  
7           ance found by the Secretary to be safe for such  
8           drug;”.

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

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

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

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

17           (2) in subsection (b)(1)—

18               (A) in subparagraph (A)—

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

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

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

24               (B) in subparagraph (C)—

1 (i) by striking “or 512,” and inserting  
2 a comma; and

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

5 (3) in subsection (c)(1)(C), by striking “505 or  
6 512,” and inserting “505,”; and

7 (4) in subsection (d)—

8 (A) in paragraph (3), by striking “505 or  
9 512,” and inserting “505,”; and

10 (B) in paragraph (4)—

11 (i) by striking “or 512(j)”; and

12 (ii) by striking “505 or 512,” and in-  
13 serting “505,”.

14 **SEC. 8. REPORT TO CONGRESS.**

15 The Secretary shall study any efficiencies in the new  
16 animal drug approval process that are caused by the  
17 amendments made by this Act. Not later than 24 months  
18 after the date of enactment of this Act, the Secretary shall  
19 submit to the appropriate committees of Congress a report  
20 containing the results of the study.

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