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103D CONGRESS
2D SESSION

H. R. 5056

To amend the Federal Food, Drug, and Cosmetic Act to allow licensed veterinarians to order the extra-label use of drugs in animals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 1994

Mr. STENHOLM (for himself, Mr. WAXMAN, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow licensed veterinarians to order the extra-label use of drugs in animals, 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.

This Act may be cited as the ''Animal Drug Amendments of 1994''.

SEC. 2. UNAPPROVED USES

(a) GENERAL RULE.—Section 512(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)) is

amended by adding the following new paragraphs at the end:

''(4)(A) Except as provided in subparagraph (B), if an approval of an application filed under subsection (b) is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of paragraph (1) and shall be exempt from the requirements of section 502(f) with respect to a different use or intended use of the drug, other than a use in or on animal feed, if such use or intended use—

''(i) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

''(ii) is in compliance with regulations promulgated by the Secretary that establish the conditions for such different use or intended use.

Regulations under clause (ii) may prohibit particular uses of an animal drug and shall not permit such different use of an animal drug if the labeling of another animal drug which contains the same active ingredient and which is in the same dosage form and concentration provides for such different use.

''(B) If the Secretary finds that there is a reasonable probability that a use of an animal drug authorized under subparagraph (A) may present a risk to the public health, the Secretary may—

''(i) establish a safe level for a residue of an animal drug when it is used for such different use authorized by subparagraph (A); and

''(ii) require the development of a practical, analytical method for the detection of residues of the drug above the safe level established under clause (i).

The use of an animal drug which results in residues exceeding a safe level established under clause (i) shall be considered an unsafe use of such drug under paragraph (1). Safe levels may be established under clause (i) either by regulation or order.

''(C) The Secretary may by general regulation provide access to the records of veterinarians to ascertain any use or intended use authorized under subparagraph (A) that the Secretary has determined may present a risk to the public health.

''(D) If the Secretary finds, after affording an opportunity for public comment, that a use of an animal drug authorized under subparagraph (A) presents a risk to the public health or that an analytical

method required under subparagraph (B) has not been developed and submitted to the Secretary, the Secretary may, by order, prohibit any such use.

''(5) If the approval of an application filed under section 505 is in effect, the drug under such application shall not be deemed unsafe for purposes of paragraph (1) and shall be exempt from the requirements of section 502(f) with respect to a use or intended use of the drug in animals if such use or intended use—

''(A) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

''(B) is in compliance with regulations promulgated by the Secretary that establish the conditions for the use or intended use of the drug in animals.''.

(b) OTHER AMENDMENTS.—

(1) SECTION 301.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(A) in paragraph (e), by inserting ''512(a)(4)(C),'' before ''512(j)'',

(B) by adding at the end the following:

''(u) The violation of section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).''.

(2) SECTION 512(e).—Section 512(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e) is amended in subparagraph (A), by inserting before the semicolon the following: ''or the condition of use authorized under subsection (a)(4)(A)''.

(3) SECTION 512(l).—Section 512(l)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)(1)) is amended by inserting after ''relating to experience'' the following: '', including experience with uses authorized under subsection (a)(4)(A),''.

(c) REGULATIONS.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement paragraphs (4)(A) and (5) of section 512(a) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)).

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the adoption of final regulations under subsection (c).

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