

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1423

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.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 1993

Mr. STENHOLM (for himself, Mr. ALLARD, Mr. ANDREWS of Maine, Mr. ARMEY, Mr. BAKER of Louisiana, Mr. BARRETT of Nebraska, Mr. BARTLETT of Maryland, Mr. BEREUTER, Mr. BOEHLERT, Mr. BOEHNER, Mr. BONILLA, Mr. BREWSTER, Mr. BROWDER, Mr. BROWN of California, Mr. BRYANT, Mr. BURTON of Indiana, Mr. CAMP, Mr. CHAPMAN, Mr. COLEMAN, Mr. COMBEST, Mr. CONDIT, Mr. COSTELLO, Mr. CRAMER, Mr. DOOLEY, Mr. DORNAN, Mr. DUNCAN, Mr. EMERSON, Mr. EWING, Mr. FIELDS of Texas, Mr. FRANK of Massachusetts, Mr. FROST, Mr. GALLEGLY, Mr. GIBBONS, Mr. GLICKMAN, Mr. GOODLING, Mr. GORDON, Mr. GUNDERSON, Mr. HALL of Texas, Mr. HAMILTON, Mr. HANCOCK, Mr. HANSEN, Mr. HASTERT, Mr. HASTINGS, Mr. HEFNER, Mr. HUTCHINSON, Mr. HUTTO, Mr. HYDE, Mr. INHOFE, Mr. JOHNSON of South Dakota, Mr. KLECZKA, Mr. KOLBE, Mr. KOPETSKI, Mr. KYL, Mr. LANCASTER, Mr. LEHMAN, Mr. LEWIS of Florida, Mr. LIGHTFOOT, Ms. LONG, Mr. McCLOSKEY, Mr. McCRERY, Mr. MONTGOMERY, Mr. NEAL of North Carolina, Mr. NUSSLE, Mr. OBERSTAR, Mr. OXLEY, Mr. PACKARD, Mr. PAXON, Mr. PENNY, Mr. PICKETT, Mr. POMEROY, Mr. ROTH, Mr. ROWLAND, Mr. ROYCE, Mr. SARPALIUS, Mr. SENSENBRENNER, Mr. SHAW, Mr. SHAYS, Ms. SLAUGHTER, Mr. SMITH of Michigan, Ms. SNOWE, Mr. STUMP, Mr. SWIFT, Mr. TANNER, Mr. TORRES, Mr. TOWNS, Mrs. UNSOELD, Mr. UPTON, Mrs. VUCANOVICH, Mr. WALSH, Mr. WILSON, Mr. YOUNG of Alaska, Mr. ZELIFF, and Mr. ZIMMER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

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.**

4        This act may be cited as the “Animal Medicinal Drug  
5 Use Clarification Act of 1993”.

6 **SEC. 2. FINDINGS.**

7        Congress finds that—

8            (1) the Federal Food, Drug, and Cosmetic Act  
9            currently permits the use of an animal drug, or a  
10            drug intended for human use, that is approved by  
11            the Food and Drug Administration, only in accord-  
12            ance with the specific labeling approved for the drug;

13            (2) there are not such approved animal drugs  
14            available to relieve pain and suffering, or to treat  
15            every specific disease or condition found, in each  
16            species of animal;

17            (3) it is sometimes necessary for veterinarians  
18            to use such an approved animal drug or approved  
19            drug intended for human use in a manner that is  
20            not in accordance with the label of the drug if—

21                    (A) the health of an animal is immediately  
22                    threatened; and

1 (B) suffering or death would result from  
2 failure to provide effective treatment; and

3 (4) duly licensed veterinarians possess the pro-  
4 fessional training and medical judgment to admin-  
5 ister drugs in a clinically appropriate manner that  
6 benefits animals and safeguards the public health.

7 **SEC. 3. PURPOSES.**

8 The purposes of this Act are—

9 (1) to permit veterinarians to use such an ap-  
10 proved animal drug, or approved drug intended for  
11 human use, for therapeutic purposes in animals in  
12 a manner that is not specified on the label of the  
13 drug, if a valid veterinarian-client-patient relation-  
14 ship exists; and

15 (2) to permit the Secretary of Health and  
16 Human Services to establish conditions for such use  
17 as may be necessary to protect the public health.

18 **SEC. 4. ALTERNATE USES.**

19 Section 512(a) of the Federal Food, Drug, and Cos-  
20 metic Act (21 U.S.C. 360b(a)) is amended by adding at  
21 the end the following new paragraphs:

22 “(4)(A) Except as provided in subparagraph  
23 (B), if an approval of an application filed under sub-  
24 section (b) is in effect with respect to a particular  
25 use or intended use of a new animal drug, the drug

1 shall not be deemed unsafe for the purposes of sec-  
2 tion 501(a)(5), and shall be exempt from the re-  
3 quirements of section 502(f), with respect to a dif-  
4 ferent use or intended use of the drug, if such use  
5 or intended use—

6 “(i) is by or on the lawful written or oral  
7 order of a licensed veterinarian within the con-  
8 text of a veterinarian-client-patient relationship,  
9 as defined by the Secretary; and

10 “(ii) is in compliance with regulations pro-  
11 mulgated by the Secretary under subparagraph  
12 (C).

13 “(B) Notwithstanding subparagraph (A), if the  
14 use of a new animal drug results in residues in food  
15 that the Secretary has determined to be in violation  
16 of established safe levels for such drug, such drug  
17 shall then be deemed unsafe for the purposes of sec-  
18 tion 501(a)(5), and shall be subject to the require-  
19 ments of section 502(f).

20 “(C) The Secretary shall implement final regu-  
21 lations that establish the conditions for the use or  
22 intended use of new animal drugs, as provided under  
23 this paragraph and as may be necessary to protect  
24 the public health, not later than one year after the  
25 enactment of this Act.

1           “(5)(A) If an approval of an application filed  
2           under section 505 is in effect with respect to a par-  
3           ticular use or intended use of a drug intended for  
4           human use, the drug shall not be deemed unsafe for  
5           the purposes of section 501(a)(5), and shall be ex-  
6           empt from the requirements of section 502(f), with  
7           respect to a use or intended use of the drug in  
8           nonfood producing animals, if such use or intended  
9           use—

10                   “(i) is by or on the lawful written or oral  
11                   order of a licensed veterinarian within the con-  
12                   text of a veterinarian-client-patient relationship,  
13                   as defined by the Secretary; and

14                   “(ii) is in compliance with regulations pro-  
15                   mulgated by the Secretary under subparagraph  
16                   (B).

17           “(B) The Secretary shall implement final regu-  
18           lations that establish the conditions for the use or  
19           intended use of human drugs, as provided under this  
20           paragraph and as may be necessary to protect the  
21           public health, not later than one year after the en-  
22           actment of this Act.”.

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