

103D CONGRESS  
1ST SESSION

# H. R. 1178

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 2, 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

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.

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. AMENDMENTS TO THE FEDERAL FOOD, DRUG,**  
4       **AND COSMETIC ACT.**

5       (a) Section 512(a) of the Federal Food, Drug, and  
6       Cosmetic Act (21 U.S.C. 360b(a)) is amended by adding  
7       the following new paragraphs at the end:

8       “(4) A new animal drug that is the subject of an ap-  
9       proved new animal drug application, the use or intended  
10      use of which does not conform to such approved applica-  
11      tion, shall not be deemed unsafe for the purposes of sec-  
12      tion 501(a)(5) if such use or intended use of such drug  
13      is by or upon the lawful prescription or oral order of a  
14      licensed veterinarian within the context of a veterinarian-  
15      client-patient relationship and is in compliance with regu-  
16      lations promulgated by the Secretary that establish such  
17      conditions for such use as may be necessary to protect  
18      the public health, except that such drug shall be deemed  
19      unsafe if its use results in residues in food that are above  
20      the tolerance established for the new animal drug.

21      “(5) When used in nonfood animals, a new drug for  
22      human use that is the subject of an approved new drug  
23      application shall not be deemed unsafe for the purposes  
24      of section 501(a)(5) and shall be exempt from the require-

1 ments of section 502(f) if such use or intended use of such  
2 drug in nonfood animals meets the requirements of para-  
3 graph (4).”.

4 (b) Section 503 of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 353) is amended by redesignating  
6 subsections (c) through (f) as subsections (d) through (g).

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