

103D CONGRESS  
2D SESSION

# S. 340

To amend the Federal Food, Drug, and Cosmetic Act to clarify the application of the Act with respect to alternate uses of new animal drugs and new drugs intended for human use, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 4 (legislative day, JANUARY 5), 1993

Mr. HEFLIN (for himself, Mr. PRESSLER, Mr. SHELBY, Mr. DASCHLE, Mr. CONRAD, Mr. CAMPBELL, Mr. BROWN, Mr. DECONCINI, Mrs. KASSEBAUM, Mr. DANFORTH, Mr. MACK, Mr. COATS, Mr. DORGAN, Mr. ROTH, Mr. HOLLINGS, Mr. WARNER, Mr. WOFFORD, Mr. FEINGOLD, Mr. INOUE, Mr. CHAFEE, Mr. McCONNELL, Mr. BOREN, Mr. PRYOR, Mr. KEMPTHORNE, Mr. CRAIG, Mr. EXON, Mr. REID, Mr. NICKLES, Mr. COCHRAN, Mr. JOHNSTON, Mr. BOND, Mr. GRASSLEY, Mr. DODD, Mr. D'AMATO, Mr. SASSER, Mr. MOYNIHAN, Mr. GORTON, Mr. BRYAN, Mr. BINGAMAN, Mr. JEFFORDS, Mr. FAIRCLOTH, Mr. THURMOND, Mr. COHEN, Mr. FORD, Mr. BURNS, Mr. LOTT, Mr. MITCHELL, Mr. WALLOP, Mr. HARKIN, Mrs. MURRAY, Mr. GLENN, Mr. GRAHAM, Mr. DOLE, Mr. KERREY, Mr. PACKWOOD, Mr. HATCH, Mr. LEVIN, Mr. BUMPERS, Mr. BENNETT, Mr. SPECTER, Mr. HELMS, Mr. BRADLEY, Mr. LUGAR, Mr. BYRD, Mr. GREGG, Mr. DOMENICI, Mr. AKAKA, Mr. RIEGLE, Mr. LIEBERMAN, and Mr. DURENBERGER) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

OCTOBER 4 (legislative day, SEPTEMBER 12), 1994

Committee discharged

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify the application of the Act with respect to alternate uses of new animal drugs and new drugs intended for human use, 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. FINDINGS AND PURPOSES.**

4        (a) FINDINGS.—Congress finds that—

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

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

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

18                (A) the health of an animal is immediately  
19                threatened; and

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

22            (4) veterinarians possess the professional train-  
23            ing and medical judgment to administer drugs in a  
24            clinically-appropriate manner that benefits animals  
25            and safeguards the public health.

1 (b) PURPOSES.—The purposes of this Act are—

2 (1) to permit veterinarians to use such an ap-  
3 proved animal drug, or approved drug intended for  
4 human use, for therapeutic purposes in animals in  
5 a manner that is not specified on the label of the  
6 drug, if a valid veterinarian-client-patient relation-  
7 ship exists; and

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

11 **SEC. 2. ALTERNATE USES.**

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

15 “(4) If an approval of an application filed under sub-  
16 section (b) is in effect with respect to a particular use or  
17 intended use of a new animal drug, the drug shall not be  
18 deemed unsafe for the purposes of section 501(a)(5), and  
19 shall be exempt from the regulations of section 502(f),  
20 with respect to a different use or intended use of the drug,  
21 if such use or intended use—

22 “(A) is by or on the lawful written or oral order  
23 of a licensed veterinarian within the context of a vet-  
24 erinarian-client-patient relationship; and

1           “(B) is in compliance with regulations promul-  
2           gated by the Secretary that establish such conditions  
3           for such use or intended use as may be necessary to  
4           protect the public health.

5           “(5) If an approval of an application filed under sec-  
6           tion 505 is in effect with respect to a particular use or  
7           intended use of a drug intended for human use, the drug  
8           shall not be deemed unsafe for the purposes of section  
9           501(a)(5), and shall be exempt from the requirements of  
10          section 502(f), with respect to a use or intended use of  
11          the drug in non-food producing animals, if such use or  
12          intended use complies with the requirements specified in  
13          subparagraph (A) or (B) of paragraph (4).”.

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