

103D CONGRESS  
2D SESSION

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**S. 340**

**AN ACT**

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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## AN ACT

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. SHORT TITLE.**

4        This Act may be cited as the “Animal Medicinal Drug  
5        Use Clarification Act of 1994”.

1 **SEC. 2. UNAPPROVED USES.**

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

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

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

18 (ii) is in compliance with regulations promul-  
19 gated by the Secretary that establish the conditions  
20 for such different use or intended use.

21 The regulations promulgated by the Secretary under  
22 clause (ii) may prohibit particular uses of an animal drug  
23 and shall not permit such different use of an animal drug  
24 if the labeling of another animal drug that contains the  
25 same active ingredient and which is in the same dosage  
26 form and concentration provides for such different use.

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

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

8           “(ii) require the development of a practical, an-  
9 alytical method for the detection of residues of such  
10 drug above the safe level established under clause  
11 (i).

12 The use of an animal drug that results in residues exceed-  
13 ing a safe level established under clause (i) shall be consid-  
14 ered an unsafe use of such drug under paragraph (1). Safe  
15 levels may be established under clause (i) either by regula-  
16 tion or order.

17       “(C) The Secretary may by general regulation pro-  
18 vide access to the records of veterinarians to ascertain any  
19 use or intended use authorized under subparagraph (A)  
20 that the Secretary has determined may present a risk to  
21 the public health.

22       “(D) If the Secretary finds, after affording an oppor-  
23 tunity for public comment, that a use of an animal drug  
24 authorized under subparagraph (A) presents a risk to the  
25 public health or that an analytical method required under

1 subparagraph (B) has not been developed and submitted  
2 to the Secretary, the Secretary may, by order, prohibit any  
3 such use.

4 “(5) If the approval of an application filed under sec-  
5 tion 505 is in effect, the drug under such application shall  
6 not be deemed unsafe for purposes of paragraph (1) and  
7 shall be exempt from the requirements of section 502(f)  
8 with respect to a use or intended use of the drug in ani-  
9 mals if such use or intended use—

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

14 “(B) is in compliance with regulations promul-  
15 gated by the Secretary that establish the conditions  
16 for the use or intended use of the drug in animals.”.

17 (b) OTHER AMENDMENTS.—

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

21 (A) in paragraph (e), by striking “507(d)  
22 or (g),” and inserting “507(d) or (g),  
23 512(a)(4)(C),”; and

24 (B) by adding at the end the following:

1       “(u) The failure to comply with any requirements of  
2 the provisions of, or any regulations or orders of the Sec-  
3 retary, under section 512(a)(4)(A), 512(a)(4)(D), or  
4 512(a)(5).”.

5           (2) SECTION 512(e).—Section 512(e)(1)(A) of  
6 the Federal Food, Drug and Cosmetic Act (21  
7 U.S.C. 360b(e)(1)(A)) is amended by inserting be-  
8 fore the semicolon the following: “or the condition of  
9 use authorized under subsection (a)(4)(A)”.

10          (3) SECTION 512(l).—Section 512(l)(1) of the  
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 360b(l)(1)) is amended by striking “relating to expe-  
13 rience” and inserting “relating to experience, includ-  
14 ing experience with uses authorized under subsection  
15 (a)(4)(A),”.

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

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

1 **SEC. 3. MAPLE SYRUP.**

2 (a) PREEMPTION.—Section 403A(a) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)) is  
4 amended—

5 (1) in paragraph (1), by inserting at the end  
6 the following: “except that this paragraph does not  
7 apply to a standard of identity of a State or political  
8 subdivision of a State for maple syrup that is of the  
9 type required by sections 401 and 403(g),”;

10 (2) in paragraph (2), by inserting at the end  
11 the following: “except that this paragraph does not  
12 apply to a requirement of a State or political sub-  
13 division of a State that is of the type required by  
14 section 403(c) and that is applicable to maple  
15 syrup,”; and

16 (3) in paragraph (3) by inserting at the end the  
17 following: “except that this paragraph does not  
18 apply to a requirement of a State or political sub-  
19 division of a State that is of the type required by  
20 section 403(h)(1) and that is applicable to maple  
21 syrup,”.

22 (b) PROCEDURE.—Section 701(e)(1) (21 U.S.C.  
23 371(e)(1)) is amended by striking “or maple syrup (regu-

1 lated under section 168.140 of title 21, Code of Federal  
2 Regulations).”.

Passed the Senate October 4 (legislative day, Sep-  
tember 12), 1994.

Attest:

*Secretary.*