

Public Law 103-396  
103d Congress

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.

Oct. 22, 1994  
[S. 340]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

Animal  
Medicinal Drug  
Use Clarification  
Act of 1994.  
21 USC 301 note.

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Animal Medicinal Drug Use Clarification Act 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.

The regulations promulgated by the Secretary 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 that 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 such drug above the safe level established under clause (i).

The use of an animal drug that 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 striking “507(d) or (g),” and inserting “507(d) or (g), 512(a)(4)(C),”; and

(B) by adding at the end the following:

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

(2) SECTION 512(e).—Section 512(e)(1)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(e)(1)(A)) is amended 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 striking “relating to experience” and inserting “relating to experience, 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 the final regulations under subsection (c).

### SEC. 3. MAPLE SYRUP.

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

(1) in paragraph (1), by inserting at the end the following: “except that this paragraph does not apply to a standard of

21 USC 360b  
note.

21 USC 360b  
note.

identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g);

(2) in paragraph (2), by inserting at the end the following: “except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) and that is applicable to maple syrup.”; and

(3) in paragraph (3) by inserting at the end the following: “except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(h)(1) and that is applicable to maple syrup.”.

(b) PROCEDURE.—Section 701(e)(1) (21 U.S.C. 371(e)(1)) is amended by striking “or maple syrup (regulated under section 168.140 of title 21, Code of Federal Regulations).”.

Approved October 22, 1994.

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**LEGISLATIVE HISTORY—S. 340:**

CONGRESSIONAL RECORD, Vol. 140 (1994):

Oct. 4, considered and passed Senate.

Oct. 6, considered and passed House.