

## ANIMAL DRUG AMENDMENTS OF 1968<sup>1</sup>

[As Amended Through P.L. 108–282, Enacted August 2, 2004]

[Currency: This publication is a compilation of the text of Public Law 90–399. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at <https://www.govinfo.gov/app/collection/comps/>]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

SEC. 108. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections shall take effect on the first day of the thirteenth calendar month which begins after the date of enactment of this Act.

(b)(1) As used in this subsection, the term “effective date” means the effective date specified in subsection (a) of this section; the term “basic Act” means the Federal Food, Drug, and Cosmetic Act; and other terms used both in this section and the basic Act shall have the same meaning as they have, or had, at the time referred to in the context, under the basic Act.

(2) Any approval, prior to the effective date, of a new animal drug or of an animal feed bearing or containing a new animal drug, whether granted by approval of a new-drug application, master file, antibiotic regulation, or food additive regulation, shall continue in effect, and shall be subject to change in accordance with the provisions of the basic Act as amended by this Act.

(3) In the case of any drug (other than a drug subject to section 512(n) of the basic Act as amended by this Act) intended for use in animals other than man which, on October 9, 1962, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the words “effectiveness” and “effective” contained in section 201(v) to the basic Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

(4) Regulations providing for fees (and advance deposits to cover fees) which on the day preceding the effective date applicable under subsection (a) of this section were in effect pursuant to section 507 of the basic Act shall, except as the Secretary may otherwise prescribe, be deemed to apply also under section 512(n) of the basic Act, and appropriations of fees (and of advance deposits to

<sup>1</sup>Public Law 90–399, which was enacted July 13, 1968. Such Public Law added section 512 to the Federal Food, Drug, and Cosmetic Act, and made related amendments. Section 108 concerned the effective date and applicability of the amendments.

cover fees) available for the purposes specified in such section 507 as in effect prior to the effective date shall also be available for the purposes specified in section 512(n), including preparatory work or proceedings prior to that date.