

(l) *Designated journal(s)* means journals listed in § 510.95.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989]

§ 510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Is the holder of an approved application under § 514.2 of this chapter; or

(2) Will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under § 514.2 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in part 558 of this chapter.

§ 510.45 Packaging requirements for drugs for animal use.

The packaging requirements for antibiotic drugs for veterinary use are described under § 432.1 of this chapter, except that antibiotic drugs for veterinary use need not be packaged for dispensing in containers of colorless, transparent glass.

§ 510.95 Designated journals.

The following journals are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

All Pet's Magazine (Jersey City).
 American Journal of Veterinary Research (Chicago).
 Animal Health (Journal of the Animal Health Trust) (London).
 Animal Nutrition & Health (Sausalito, CA).
 Animal Production (Edinburgh).
 Avian Diseases (Amherst).
 British Poultry Science (Edinburgh).
 Canadian Journal of Comparative Medicine and Veterinary Science (Gardenvale, Quebec).
 Canadian Veterinary Journal (Guelph, Ontario).
 Cornell Veterinarian (Ithaca).
 Experimental Parasitology (New York).
 The Feed Bag (Milwaukee).
 Feedstuffs (Minneapolis).
 Hoard's Dairyman (Fort Atkinson).
 Journal of the American Veterinary Medical Association (Chicago).
 Journal of Animal Science (Albany).
 Journal of Dairy Science (Champaign).
 Journal of Economic Entomology (Baltimore).
 Journal of Small Animal Practice (London).
 Modern Veterinary Practice (formerly North American Veterinarian) (Wheaton, IL).
 National Hog Farmer (Grundy Center, IA).
 New Zealand Veterinary Journal (Wellington).
 Poultry Science (Guelph, Ontario).
 Praktische Tierarzt (Postfach, Germany).
 Research in Veterinary Science (Chicago).
 Small Animal Clinician (Kansas City, MO).
 Veterinaermedizin (Konstanz, Germany).
 Veterinarian (London).
 Veterinarian (International) (New York).
 The Veterinary Bulletin (Farnham Royal, England).
 Veterinary Medicine (Kansas City, MO).
 Veterinary Record (Croydon, England).
 Zentralblatt Fuer Veterinaermedizin Zentr. Veterinaermed (Berlin).

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Subpart B—Specific Administrative Rulings and Decisions

§ 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 540 of this chapter provides for new animal drugs intended for

intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(D) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the warning, "Milk that has been taken from animals during treatment and within _____ hours (_____ milkings) after the latest treatment must not be used for food," the blanks to be filled in with the number of hours (not to exceed 96) and milkings that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement "Warning: Not for use in animals producing milk, since this use will result in contamination of the milk" or the statement "Warning: Milk that has been taken from animals during treatment and for — hours (— milkings) after the latest treatment must not be used for food", the first blank being filled in with the figure, which shall not be greater than 96, that the Commissioner has authorized the manufacturer of the drug to use, and the second figure shall be the first

number divided by 12. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, he may exempt the drug from bearing either of the above warning statements.

§ 510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, § 510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to establish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the