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

(a) Part 526 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)(c)(ii) of the act.

(c) It is the position of the Food and Drug Administration that the labeling...
§ 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 after the latest treatment must not be used for food”, the blank being filled in with the figure that the Commissioner has determined by appropriate investigation is needed to insure that the milk will not carry violative 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.

[40 FR 13807, Mar. 27, 1975, as amended at 63 FR 32980, June 17, 1998; 64 FR 51241, Sept. 22, 1999]

§ 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 date of publication of § 510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to