

§ 500.52

adequate directions for use. Such statements include, but are not limited to:

(1) Any statement that disclaims liability when the drug is used in accordance with directions for use contained on the label or labeling.

(2) Any statement that disclaims liability when the drug is used under “abnormal” or “unforeseeable” conditions.

(3) Any statement limiting the warranty for the products to a warranty that the drug in the package contains the ingredients listed on the label.

(b) This regulation is not intended to prohibit any liability disclaimer that purports to limit the amount of damages or that sets forth the legal theory under which damages are to be recovered.

(c) Any person wishing to obtain an evaluation of an animal drug liability disclaimer under this regulation may submit it to Division of Compliance, (HFV-230), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. A supplemental NADA providing appropriately revised labeling shall be submitted for any approved new animal drug the labeling of which is not in compliance with this regulation.

[41 FR 8473, Feb. 27, 1976, as amended at 54 FR 18279, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

§ 500.52 Use of terms such as “tonic”, “tone”, “toner”, or “conditioner” in the labeling of preparations intended for use in or on animals.

(a) The use of terms such as *tonic*, *tone*, *toner*, and similar terms in the labeling of a product intended for use in or on animals implies that such product is capable of a therapeutic effect(s) and causes such a product to be a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act. The unqualified use of such terms in a product’s labeling fails to provide adequate directions and indications for use of such product and causes it to be misbranded within the meaning of section 502(a) and (f)(1) of the act. The terms *tonic*, *tone*, *toner*, and similar terms may be used in labeling only when appropriately qualified so as to fully inform the user regarding the intended use(s) of the product.

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(b) The unqualified use of the term *conditioner* and similar terms in the labeling of a product intended for use in or on animals implies that such product is capable of a therapeutic effect(s) and causes such a product to be a drug within the meaning of section 201(g) of the act. The unqualified use of such terms in a product’s labeling fails to provide adequate directions and indications for use of such product and causes it to be misbranded within the meaning of section 502(a) and (f)(1) of the act. The term *conditioner* and similar terms may be used in labeling only when appropriately qualified so as to fully inform the user regarding the intended use(s) of the product. A product labeled as a “conditioner” or with a similar term can be either a food or drug depending upon the manner in which the term is qualified in the labeling to reflect the product’s intended use.

(c) An article so qualified as to be represented as a drug must be the subject of an approved new animal drug application unless the use of the article under the conditions set forth in its labeling is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs.

§ 500.55 Exemption from certain drug-labeling requirements.

(a) Section 201.105(c) of this chapter provides that in the case of certain drugs for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law, such information may be omitted from the dispensing package. Under this proviso, the Commissioner of Food and Drugs will offer an opinion, upon written request, stating reasonable grounds therefore on a proposal to omit such information from the dispensing package.

(b) The Commissioner of Food and Drugs has considered submitted material covering a number of drug products and has offered the opinion that the following drugs when intended for those veterinary uses for which they are now generally employed by the veterinary medical profession, should be exempt from the requirements of

§201.105(c) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

Atropine sulfate. As an injectable for cattle, goats, horses, pigs, and sheep, not in excess of 15 milligrams per dosage unit; as an injectable for cats and dogs, not in excess of 0.6 milligram per dosage unit.

Barbital sodium. For oral use in cats and dogs, not in excess of 300 milligrams per dosage unit.

Epinephrine injection. 1:1,000. For cats, dogs, cattle, goats, horses, pigs, and sheep (except as provided in §500.65).

Morphine sulfate. As an injectable for dogs, not in excess of 15 milligrams per dosage unit.

Pentobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Phenobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Procaine hydrochloride injection. Containing not in excess of 2 percent procaine hydrochloride, with or without epinephrine up to a concentration of 1:50,000. For use in cats, dogs, cattle, goats, horses, pigs, and sheep.

Thyroid. For oral use in dogs, not in excess of 60 milligrams per dosage unit.

Subpart D—Requirements for Specific Animal Drugs

§ 500.65 Epinephrine injection 1:1,000 in 10-milliliter containers for emergency treatment of anaphylactoid shock in cattle, horses, sheep, and swine.

(a) Anaphylactoid reactions in cattle, horses, sheep, and swine occur occasionally from the injection of antibiotics, bacterins, and vaccines. Adequate directions for use of these antibiotics, bacterins, and vaccines can generally be written for use by the laity and thus are available to livestock producers. Epinephrine injection is effective for the treatment of anaphylactoid reactions in animals and would be of value in saving lives of animals if it were readily available at the time of administration of the causative

agents. In connection with this problem the Food and Drug Administration has obtained the views of the Advisory Committee on Veterinary Medicine, and other experts, and has concluded that adequate directions for over-the-counter sale of epinephrine injection 1:1,000 can be prepared.

(b) In view of the above, the Commissioner of Food and Drugs has concluded that it is in the public interest to make epinephrine injection 1:1,000 available for sale without a prescription provided that it is packaged in vials not exceeding 10 milliliters and its label bears, in addition to other required information, the following statements in a prominent and conspicuous manner: "For emergency use only in treating anaphylactoid shock. Usual Dosage: Cattle, horses, sheep, and swine—1 cubic centimeter per 100 pounds of body weight. Inject subcutaneously".

(c) The labeling must also bear a description of the symptoms of anaphylactoid shock including glassy eyes, increased salivation, grinding of the teeth, rapid breathing, muscular tremors, staggering gait, and collapse with death following. These symptoms may appear shortly after injection of a bacterin, vaccine, or antibiotic.

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

SOURCE: 52 FR 49586, Dec. 31, 1987, unless otherwise noted.

§ 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs) that no residue of that compound will be found in the food produced from those animals