

CPG Sec. 608.500 Illegal Sales of Veterinary Prescription Drugs Direct Reference Authority for 'Warning' Letter Issuance

BACKGROUND:

All veterinary drugs must bear adequate directions for lay use to comply with Section 502(f)(1) of the act. Since certain drugs intended for animal use are toxic or have other potential for harmful effect or because the method of use is not safe for lay use except under the supervision of a licensed veterinarian, adequate directions for lay use cannot be prepared. However, these veterinary drug products are exempt from Section 502(f)(1) if all the conditions stated in section 503(f)(2)(A) of the Federal Food, Drug and Cosmetic Act (Pub. L. 100-670, Sec. 105, 102 Stat. 3971, 1988) and 21 CFR 201.105 are met. Among other things, the labeling for this class of veterinary drugs must bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." Furthermore, in order to qualify for the exemption, a veterinary prescription (Rx) drug must either be (1) in the possession of a person who is regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or order of a licensed veterinarian for use in the course of his/her professional practice, or (2) in the possession of a licensed veterinarian for use in the course of his/her professional practice.

Serious consequences to the public health and to animal health may result from illegal sales and use of veterinary Rx drugs. Misuse of veterinary Rx drugs in food-producing animals may result in unsafe residues in edible products from the treated animals and/or injury to the treated animals or users. These drugs must be used in accordance with the directions and supervision of licensed veterinarians within the course of their professional practice, which involves diagnosis of the disease condition and knowledge of the animals to be treated, to be exempt from Section 502(f)(1).

REGULATORY ACTION GUIDANCE:

Compliance Program 7371.002 provides guidance on conducting investigations of the illegal sale of veterinary Rx drugs. The initial step in obtaining correction of the illegal sales of veterinary Rx drugs is consideration of the issuance of a *warning* letter. When all of the following criteria are met *warning* letters may be issued directly by the appropriate division within the Office of Pharmaceutical Quality Operations for the illegal sales of veterinary Rx drugs:

1. Investigations to document the illegal sales of veterinary Rx drugs have been conducted in accordance with CP 7371.002, Part III, and
2. Investigation has revealed that illegal sales of the veterinary Rx drugs are a sales practice and not a one-time occurrence. Illegal sale of one or more drugs on more than one occasion is required, and
3. The drug or drugs are listed in Attachment A of CP 7371.002 and are labeled with the veterinary Rx legend, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," and

4. The drug or drugs are veterinary Rx drug(s) which are approved and listed in 21 CFR Parts 520-529* for the specific sponsor(s) identified in the regulation(s), and which bear the approved sponsor's labeling, and
5. No prescription or other order from a licensed veterinarian for the sale or use of the veterinary Rx drug(s) by the purchaser is purported to exist, and
6. Interstate origin documentation of the veterinary Rx drug(s) involved is available.

Cases involving illegal sale of veterinary Rx drugs which do not meet all the criteria for direct issuance of *warning* letters may be submitted to the Center for Veterinary Medicine, Case Guidance Branch (HFV-236) for review.

SPECIMEN CHARGE:

Section Brief Description

502(f)(1) The drugs are misbranded while held for sale after shipment in interstate commerce within the meaning of Section 502(f)(1) in that the labeling fails to bear adequate directions for use. They are not exempt from such requirements since they are veterinary drugs which, because of toxicity or other potentiality for harmful effect, or the method of their use, are not safe for use except under the supervision of a licensed veterinarian. The drugs fail to comply with the conditions prescribed by 21 U.S.C. 353(f)(2)(A) and 21 CFR 201.105 for exemption from Section 502(f)(1) in that they were sold without a valid prescription or other order of a licensed veterinarian based upon a legitimate veterinarian/ client-patient relationship.

Material between asterisks is new or revised

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