

CPG Sec. 654.300 Chloramphenicol as an Unapproved New Animal Drug - Direct Reference Seizure Authority

BACKGROUND:

Chloramphenicol is a potent, broad spectrum antibiotic drug. The drug, when used in humans, is associated with many toxic effects and, therefore, is used only in life-threatening situations when less toxic drugs are not effective. The principal toxic effect is the development of a type of bone marrow depression (aplastic anemia) in susceptible individuals, which is usually irreversible and fatal. Since this condition only occurs in humans, an appropriate animal test model has never been developed. The onset of the condition is not dose dependent.

Chloramphenicol in various dosage forms is currently approved for use in non-food producing animals (dogs and cats) as codified in 21 CFR Part 520-529. The new animal drug applications (NADAs) for the oral solution form of chloramphenicol were revoked because of widespread illegal use in food animals. See 51 FR 1367 and 51 FR 1441 (January 13, 1986). The current labeling for the approved chloramphenicol products bears a specific warning statement that the drug is not to be used in animals raised for food production.

Chloramphenicol, for animal use, is a new animal drug. The drug must be the subject of an approved NADA for legal commercial marketing. In addition, chloramphenicol is a veterinary prescription drug and must be used by or under the direction of a licensed veterinarian. The drug must be handled in accordance with the requirements of Section 503(f) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 201.105 to meet the exemption from bearing adequate directions for use.

REGULATORY ACTION GUIDANCE:

Direct reference seizure of chloramphenicol products, which are unapproved new animal drugs, may be submitted by the appropriate division offices within the Office of Pharmaceutical Quality Operations (OPQO) to the Office of the *Chief Counsel* through the OPQO Program Director, in consultation with the Division of Enforcement, within the Office of Enforcement and Import Operations in the Office of Regulatory Affairs, provided the following criteria are met:

1. The drug contains chloramphenicol and is labeled for use in food-producing animals;
2. The drug contains chloramphenicol and is labeled for use in dogs and/or cats, however, its intended use as determined by the method of sale or promotion, is for food-producing animals and the intended use in food-producing animals is well documented by investigator observations, treatment records, and/or determination of chloramphenicol residues in treated animals;

or

3. The drug contains chloramphenicol and it is intended for an unapproved use in animals, or for the manufacturing of animal drugs, which are not approved, and no approved NADA exists for

the drug sampled, as determined by consultation with the Center for Veterinary Medicine (CVM), Case Guidance Branch (HFV-236).

REMARKS:

1. Determine by analysis or label statement that the product contains chloramphenicol.
2. If the drug is in bulk containers not bearing directions for use in animals, for direct reference seizure intended use must be clearly documented to support use in animals or to manufacture an unapproved drug.
3. Interstate origin of the drug or its components must be well documented.

SPECIMEN CHARGE:

Article was adulterated when introduced and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 351(a)(5), in that the article is a "new animal drug" within the meaning of 21 U.S.C. 321(v)(1), which is unsafe within the meaning of 21 U.S.C. 360b(a)(1)(A) since no approval of an application filed pursuant to 21 U.S.C. 360b(b) is in effect with respect to its use or intended use.

Material between asterisks is new or revised

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