

CPG Sec. 625.300 Unapproved New Animal Drugs - Follow-up Action to Approved Warning Letter - Direct Reference Seizure Authority

REGULATORY ACTION GUIDANCE:

Direct reference seizure of new animal drugs without approved New Animal Drug Applications, section 501(a)(5) cases, may be submitted by the appropriate division offices within the Office of Pharmaceutical Quality Operations (OPQO) directly to the OPQO Program Director and the Office of Enforcement, provided all of the following criteria are met:

1. CVM approval has been obtained and a *Warning* letter has been issued within the previous twelve months charging a section 501(a)(5) violation for the product in question, referencing section 512(a)(1)(A).
2. There has been no change in the label, labeling, or in the product since CVM approval of the previously issued section 501(a)(5) *Warning* letter pertaining to the unapproved new animal drug product.

REMARKS:

1. Send a copy of the seizure recommendation transmittal to CVM, Case Guidance Branch (HFV-236).
2. Interstate origin of the drug or its components must be well documented.
3. Direct reference seizure authority does not extend to section 501(a)(5) violations based on the extra-label use of approved new animal drugs.

SPECIMEN CHARGE:

Article was adulterated when introduced into 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(w), 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

Issued: 4/3/91

Revised: 4/16/91, 3/95