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IA#68-01, ---- 5/12/92, REVISED

Note: This revision updates information and reformats the text of the alert.

TYPE OF ALERT : Automatic Detention

PRODUCT : Chloramphenicol

PRODUCT CODE : 68-----

HARMONIZED CODE : 2933

PROBLEM : New animal drug without an approved new animal drug application (NADA) (DRAD)

COUNTRY : Multiple

MANUFACTURER : N/A

MANUFACTURER ID NO. : N/A

SHIPPER : N/A

SHIPPER ID NO. : N/A

CHARGE : "The article is subject to refusal of admission within the meaning of Section 801(a)(3) in that it appears to be a new animal drug and no new animal drug application (NADA) has been approved and/or no notice of claimed investigational exemption is on file for this drug or the drug is not from an approved foreign source as specified in the approved NADA, (Adulteration, Section 501(a)(5))."

RECOMMENDING OFFICE : Division of Import Operation and Policy (HFC-131) and CVM/HFV-236.

REASON FOR ALERT : Marketing of chloramphenicol for aquarium fish has occurred for a number of years. Like many other aquarium fish products, chloramphenicol was permitted to be marketed without formal approval, although it has never been demonstrated to be safe and effective for use in aquarium fish.

It is now recognized that a potential health risk exists due to a causal relationship between the use of chloramphenicol and the development of a usually irreversible aplastic anemia in man. The case fatality rate is approximately 70%, and those who recover experience a high incidence of acute leukemia. This irreversible aplastic anemia does not seem to be related to the frequency or level of exposure to the drug. In fact, there appears to be a significant subgroup of the population with an apparent predisposed sensitivity to

chloramphenicol. This type of blood dyscrasia has been associated with extremely low levels of exposure to the drug. An example is a rancher diagnosed as having aplastic anemia four months after he began treating his cattle with chloramphenicol. The treatment of aquarium fish with chloramphenicol presents the same health risk.

In view of the public health risk and the fact the safety and effectiveness of chloramphenicol in aquarium fish has not been established, CVM has concluded that all chloramphenicol products intended for aquarium use are New Animal Drugs (NADA's) which require approved NADA's.

FY 89-91 detention data indicated at least 6 detentions of chloramphenicol have been made. Bulk chloramphenicol is also covered under import alert #68-09 as one of the common bulk chemicals that will not be released until or unless it is to be shipped to a holder of an approved NADA.

INSTRUCTIONS : Automatically detain all entries of chloramphenicol intended for animal drug use (including those destined for use on aquarium fish) unless there is a exemption (INAD) or an approved new animal drug application (NADA) on file. Contact HFI-236/CVM FTS 8-295-8785 to check if application is current.

PRIORITIZATION :

FOI : No purging required.

KEY WORDS : Chloramphenicol, NADA, Feed.

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