

Rec'd 12/7/99

November 23, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

RE: Docket No. 99D-2638, Use of Medicated Feeds for Minor Species; Draft CPG

To Whom it May Concern,

Recently I received and reviewed the new Compliance Policy Guide issued by the CVM regarding the extra label use of medicated feeds for minor species. We are shrimp growers in Texas and have been working through an INAD for pursuing approval of oxytetracycline for shrimp disease control. We have been collecting data for several years and are hopeful that FDA will approve this drug's use for shrimp in the U.S. soon.

Since the FDA approval process for new drugs in aquaculture is long and detailed, any policy changes which would make the extra label use of drugs for minor use species more flexible should be supported. It should be noted that there is a great diversity of species and disease situations which exist for "minor species" in aquaculture. Making the extra label process more accessible for minor species is a step in the right direction, however not a panacea. The FDA should increase funding and staff working on new drug approvals so that specific feed formulations and dosages can be utilized by more minor species producers. For instance a shrimp farmer cannot utilize a salmon feed which has been extra labeled because the feed formulation and approved dosage of drug will not be effective to prevent mortalities associated with specific shrimp diseases.

Please evaluate what can be done to accomplish a faster turn around time in the FDA new drug approval process. Thank you for the opportunity to comment.

Sincerely,

Fritz Jaenike

99D-2638

CPG

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RE: Docket No. 99D-2638, Use of Medicated Feeds for Minor Species; Draft CPG

Dear Sir or madam:

The National Aquaculture Council wishes to express its support for the new CPG issued by the CVM regarding extra label use of medicated feeds for minor use species. We applaud FDA CVM for recognizing that certain minor species, such as fish and shellfish, have too few approved drugs and most often can not be treated by means other than medicated feeds.

There is a pressing need to treat aquatic animals when serious medical circumstances arise to avoid their suffering and death. Therefore, the FDA policy is needed to create a viable option to medicate afflicted animals. The criteria outlined by the CPG should assure that extra-label use occurs only in appropriate circumstances and only after proper diagnosis and supervision are assured.

It should be noted that the policy, while helpful, is not a substitute for approval of new drugs for minor species. FDA resources should be enhanced so that more minor species producers can utilize specific feed formulations and dosages. The process of reviewing INADs must become a higher priority to provide accelerated approval of more and better therapeutants for the treatment of aquatic animals.

Thank you for the opportunity to comment on the new CPG.

Sincerely,

Robert L. Collette

Robert L. Collette
V.P. of Science and Technology

99D-2638

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