

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

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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