State of Washington
DEPARTMENT OF FISH AND WILDLIFE

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Dockets Management Branch (HFA - 305)
FDA
12420 Parklawn Drive, Room 1-23
Rockville MD 20857

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Dear Dr. Wilmot and ADAA Minor Use Working Group:

I have reviewed your committee's discussion draft, *Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses,* and wish to provide comments. I represent the interests of the Washington Department of Fish and Wildlife. Our agency operates 83 major aquaculture facilities and is responsible for technical supervision at numerous cooperative projects operated through partnerships with the state's citizens and Native American tribes. The fish we produce are primarily for release into the wild, however, a critical role of our agency is the rehabilitation of endangered and threatened species which we rear in captive brood programs. Access to approved drugs for use in fish culture is essential to reaching our agency goals of protecting the resource and providing harvest opportunities to recreational, commercial and tribal fishers.

General comments

I. Introduction , D. The Need for Significant Change, paragraph 2, 2nd line

"FDA recognizes that proposals that alter the approval process *are not without risk* and do not necessarily represent , as a matter of science, the *best way* to approve animal drugs."

I believe this statement to be inflammatory, unnecessary, and it gives people a sense of uneasiness about this reformed process. I suggest that current procedures are 'not without risk' and that improvements could be made in how all drugs are approved, both for major or minor species. It appears to me (as an observer of how drugs get approved) that there are significant factors , other than science, which influence the process of approving drugs. Anyway, I would suggest re-writing or deleting the aforementioned line.

IV. Proposals, A. Modification of Extralabel Provisions, 3rd paragraph and 4th paragraph

"There have been some concerns expressed that the extension of extra-label use of medicated

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feeds might result in the increased development of antibiotic resistance and environmental contamination.
For game birds, these are not significant issues".

First, there have been concerns raised by a variety of people that labeled use of medicated feeds, let alone ELDU, might result in increases in antibiotic resistance and environmental contamination. However, the "concerns" that have been raised are in my experience, politically motivated. Science has had little to do with these claims. Examination of the peer-reviewed literature and consultation with recognized world experts such as Dr. Peter Smith, University of Galway, Ireland, would indicate that many of the "claims" are without basis. It is curious that terrestrial animals, such as game birds, are easily dismissed as a non-issue while aquatic issues are not. I suggest familiarity with avian medicine allows the committee to make this subjective risk analysis. Giving aquaculture special consideration or constraint due to hearsay cannot be justified. I suggest that these two sentences be omitted. As you state further along in the section, the activities of aquaculture (and specifically discharges in effluent) are strictly regulated by state and federal authorities, and thus not be a primary issue with FDA.

Particular issues on which FDA seeks comment

- I think the proposed idea of modifying ELDU for in or on feed is a good one. Perhaps a 5 year period with review at that time would be a more reasonable approach than a ten year period. We need to be aggressive in moving the approval process along, both sponsor and CVM. FDA could require some demonstration on an annual basis that efforts are being made towards drug approval, and if none has been made , could terminate the ELDU.

- It should be extended to include all drugs, hormones and implants.

B. Removal of Disincentives

Particular issues on which FDA seeks comment

- I'm not well informed of resources currently available for enforcement, but I have made inquiries locally to understand effort delegated to surveillance/compliance. A little effort in this area goes a long ways towards achieving the desired outcome. The aquaculture industry, private and public, are well networked and are very aware when citations or warnings are issued. Though a minor use advocate in CVM might be helpful, I'm not sure how that would translate in changes in priorities of enforcement activities in regional offices. Bottom line, I suggest that periodic emphasis in the aquaculture arena by existing enforcement resources would achieve the required goal without additional investments in personnel by FDA. For aquaculture interests, I believe additional staff in the NADA and INAD areas would be a better investment of FDA dollars. Other ideas are good.

- Another way in which FDA could remove disincentives for sponsors would be consistent

application of the existing rules. Sponsors have no way of insulating themselves against "discretionary" decisions by FDA. Further, FDA must provide some guarantees that once they issue a position, it will remain the same for an extended period of time (i.e., years instead of months).

C. Enhancement of Existing Programs

- Dollars from Congress are scarce for major drug uses. Though desirable, I suggest it is unrealistic to expect increases for minor uses. It becomes important that coordination takes place on existing research so that duplicity is prevented. I believe if sufficient incentives are provided by FDA and Congress, private industry will sponsor new drugs. However, this is best answered by industry folks.

I. International Harmonization

Significant investments have been made outside the United States for approval of drugs used in aquaculture, particularly in Europe and Japan. The literature is quite extensive and would appear to fulfill many of the FDA approval requirements for an NADA. I would support a significant emphasis by FDA in this area, particularly for aquaculture. I would give a resounding "yes" to all questions on the last issues for comment. Time and money would be saved and natural resources protected if FDA would make a concerted effort in becoming able to accept approval packages from foreign sources.

Thank you for the opportunity to comment. I am looking forward to seeing final work products.

Sincerely,

Kevin H. Amos
Fish Health Division Manager

cc: Larry Peck, Assistant Director, WDFW
Pacific Northwest Fish Health Protection Committee

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