

Pool Fisheries, Inc.

1131 Brownsville Loop, Lonoke, Arkansas 72086

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Docket No. 97N-0217

To:

Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Rm 1-23, Rockville, MD 20857

From:

Dr. Eric D. Park, Aquaculture Pathologist, Pool-Risheries Irc., 1131 Brownsville Loop, Lonoke, AR 72086 (501/676-2191).

Subject:

Comments on the draft "Proposals to increase the availability of approved animal drugs for minor species and minor uses". **Docket No. 97N-0217**

PROPOSALS

- A. Modification of Extra label provisions.
- B. Removal of Disincentive.
- C. Enhancement of existing programs for data development.
- D. Incentives to pursue minor use drug approvals.
- E. Data sharing by major species NADA holders.
- F. Creation by statute of a "Minor use Animal Drug" program.
- G. Conditional drug approval for minor uses involving non-food animals...
- H. Alternate approval standard/expert review panel for minor uses involving non-food animals.
- I. International harmonization.

The aquaculture industry is, and will continue to be a relatively small and very diverse industry with respect to potential markets for pharmaceuticals. This is especially true for non-food species in aquaculture. Therefore, any step that can be taken to shorten the approval time, cost and especially lower the barriers to drug approval should be seriously considered. Consequently, I found all the proposals to be a good step in the right direction. In my opinion, all of the proposals and their components are important and should be accepted as a package.

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MELISSA POOL POOL FISHERIES AIR FREIGHT, INC SHIP DATE: 19JAN98 1131 BROWNSVILLE LOOP LONOKE AR 72086 ACTUAL WGT: 1 LBS MAN-WT (501)676-2191 (<u>501</u>)676-2191 🖁 DOCKETS MANAGEMENT BRANCH (HFA-305) FOOD AND DRUG ADMINISTRATION 12420 PARKLAWN DR RM 1-23 ROCKVILLE MD 20857 4023 0093 6615 **Fed**Exx. 4023 0093 6615 Form 0201 REF: WED **2DAY** cad # 0623586 19JAN98 cad # 8623586 19JRN98
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