

# KEO FISH FARM

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

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To Whom It May Concern:

On behalf of Keo Fish Farms, Inc., I wish to comment on the "Development of Options to Encourage Animal Drug Approvals for Minor Species and Minor Uses"; Docket No. 97N-0217.

On creating additional statutory authority, I do believe that there should be less stringent standards for target animal safety and effectiveness of new animal drugs intended for use in minor species or for minor uses. Also, there should be less stringent standards for human food safety for new animal drugs intended for minor species and for minor uses. This is just common sense and these standards should be linked to the per capita consumption of each minor species as a food item. Thus, different minor species should have different standards but these differing standards would be reflected on product labels. Appropriate dosages, residue depletion and withdrawal times would be determined as previously but a consumption value would enter into such calculations.

Sponsors and users would accept conditional approvals and postmarket surveillance as a tradeoff for requiring less in the way of premarket target animal safety and effectiveness studies. Such drugs should bear labeling that reflects its conditional status.

FDA should accept foreign reviews or approvals of new animal drugs for minor species or for minor uses. Some scientific protocol would have to be established to grade foreign reviews or approvals. This primary review process could be accomplished by a panel of industry and government participants external to the agency. FDA should pay for these reviews, but industry would have to support increased funding for FDA to do so. Any monographs or similar standards issued should be drafted by FDA.

In regards to administrative and regulatory changes, there should be different standards for manufacturing of drugs for minor species or minor uses as determined by the above panel and products should be labeled to reflect the use of different manufacturing standards.

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A strategy similar to that used by the agency to facilitate drug approvals for some aquatic species would be successful, but it needs to be expanded upon and simplified.

Economic incentives might encourage the pursuit of approvals for minor species but they would have to be significant. Large grants would probably be the most effective. Different kinds of incentives would be appropriate.

Liability issues are the biggest problems with public master files. If companies could somehow be protected from litigation via labeling then sponsors would be more willing to use such data.

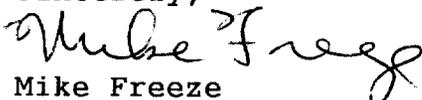
Philanthropic, public interests, or other not-for-profit organizations should be encouraged to fund research for the development of new animal drugs for use in minor species or for minor uses by a cooperative FDA and industry effort.

Groupings of similar species such as channel catfish, blue catfish and black bullhead catfish (usually at the family level in fishes) and defining certain life stages as non-food such as eggs, fry and fingerlings in fish would greatly enhance drug availability for minor species and minor uses.

Legislation to extend the AMDUCA to permit the extralabel use of medicated feeds and reproductive hormones and implants is highly desirable.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in cursive script that reads "Mike Freeze".

Mike Freeze  
Keo Fish Farms, Inc.

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