



## Florida Tropical Fish Farms Association, Inc.

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September 5, 1997

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

9016 '97 SEP -8 11:52

Gentlemen,

Enclosed please find our comments re:

Docket No. 97N-0217  
Request for Comments on Development of Options to Encourage  
Animal Drug Approvals for Minor Species and Minor Uses of New  
Animal Drugs, 21 CFR Chapter 1, Fed Reg. Vol 62, No. 120, June  
23, 1997.

The Florida Tropical Fish Farms Association represents over 200  
active tropical fish producers in the state of Florida. Our  
combined farm market value exceeds \$60 million annually. Florida  
is the tropical fish production center for the U.S. and the  
international market.

It has been our pleasure to participate in the JSA Working Group  
on Quality Assurance. We are also a contributor and supporter of  
the NADA National Coordinator. Many good things have been  
accomplished through this participation.

Our industry is ornamental tropical fish, also defined as  
non-food fish. Although FDA has no great human health concerns  
about the activities of our industry, we still face the reality  
that we have no drugs approved for our industry.

The Animal Drug Availability Act offers great hope that we will  
be able to obtain drug approvals. We support and recommend the  
passage of this legislation believing that it will facilitate the  
approvals of non-food minor species animal drugs.

Thank you for the opportunity to comment.

Sincerely,

Florida Tropical Fish Farms Association

*W. Paul Norton*  
By: W. Paul Norton, President

/WPN

97N-0217

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Subject:

Request for Comments on Development of Options to Encourage  
Animal Drug Approvals for Minor Species and for Minor Use (Docket  
No. 97N-0217)

The Florida Tropical Fish Farms Association (FTFFA) wishes to  
comment on the above captioned subject as follows:

A. Scope - Criteria for the determination of a minor species or a  
minor use:

Minor species should be sub-classified into minor species that  
are intended for use as food animals and those defined as  
non-food. Companion pet animals (ornamental aquarium and  
pool fishes) should be one of the definitions of a non-food fish  
and consideration should be given to classify them as "crop  
grouping".

B. Creating Additional Statutory Authority

1. Should there be different standards for target animal safety  
and effectiveness of new animal drugs intended for use in minor  
species or for minor uses? Should there be different standards  
for human food safety for new animal drugs intended for minor  
species or for minor uses?

Comments: Yes, there should be different standards. Particularly  
for non-food, companion pet animals. There should be no concerns  
for human safety and a limited concern for environmental effects.  
Effectiveness of a compound could be determined by an expert  
review panel or existing published literature. This would  
greatly reduce the costs of drug approvals for companion pet  
animals and encourage more drug approvals.

2. If so, what should those standards be?

Comments: Companion pet animals do not present any significant  
human health concerns. The standards must surely be different  
for food and non-food fish.

3. Should the standards be the same for all minor species or  
minor uses? Why?

Comments: No, the standards should not be the same. Non-food,  
companion pet animals, should be subject to reduced stringency of

drug approvals.

4. Should products be labeled to reflect the use of different standards? If not, why not?

Comments: Yes, products should be labeled to reflect the use of different standards. Non-food, companion pet animals, drugs should be labeled "Not for use in animals intended for human consumption."

5. If the act were amended to permit FDA to approve new animal drugs for a minor species or minor use under different standards, how would appropriate doses be determined and how would residue depletion and withdrawal times for food animals be determined?

Comments: There is no concern for residue in non-food, companion pet animals. Appropriate doses could be determined through literature sources and establishing a panel of experts familiar with the drug and target animal to review the dosage levels.

6. Would sponsors and users accept conditional approvals and postmarket surveillance as a tradeoff for requiring less in the way of premarket animal safety and effectiveness studies for new animal drugs for minor species or minor uses? Should a drug approved under such a mechanism bear labeling that reflects its conditional status?

Comments: Manufacturers of drugs for non-food, companion pet animals, might consider the cost for a conditional approval too great. The idea is to encourage more drug approvals.

7. Should the act be amended to allow FDA to accept foreign reviews or approvals of new animal drugs for minor species or for minor uses? How should Congress or FDA determine whether the reviews or approvals of a particular country or countries are acceptable as a basis for approval of uses for minor species or for minor uses?

Comments: Yes, foreign reviews and approvals should be used for non-food, companion pet animals, approvals. FDA could rely upon the expert review panel in such suspect cases.

8. Should the current statutory standard for new animal drug approval for drugs intended for minor species or minor uses or any alternative standards be implemented through a primary review process external to the agency? If so, how might this process be administered? Who should pay for the external reviews?

Comments: Yes, this should solve some of the time requirements involved in FDA review process. An industry expert panel could perform much of this task. Funding should come from industry or indirectly to FDA through fees assessed.

9. Could determination of animal safety and effectiveness by

expert panels or compendia be used to support drug approvals for minor species and minor uses? If so, what information would serve as the basis for such determination? Should the determination of these panels or other information be used to issue monographs or similar standards? Who would draft monographs or similar standards and why?

Comment: Expert panels should be used. Literature and expert opinion could provide the basis for determination. A protocol for non-food, companion pet animals, could be developed with the assistance of FDA.

#### C. Administrative and Regulatory Changes:

1. Should there be different standards for manufacturing of drugs for minor species of minor use? If so, what should those standards be? Should products be labeled to reflect the use of different manufacturing standards?

Comments: Yes, there should be different standards for food and non-food companion pet animals. Approvals for non-food, companion pet animals, should not have to meet the standards for human drug or food animal drug manufacturing. Standards for target animal safety and efficacy should be the main focus for non-food, companion pet animals, drug approvals.

2. Would a strategy similar to that used by the agency to facilitate drug approvals for some aquatic species be successful if extended to other minor species?

Comments: I believe a modified version of the INAD process would be helpful to the drug approval process for non-food, companion pet animals.

#### D. Creating incentives:

1. Would economic incentives, such as tax breaks, grants, and periods of market or label exclusivity, encourage the pursuit of approvals or supplement approvals for labeling modifications for minor species of minor uses? If so, what kinds of incentives would be most effective? Would different kinds of incentives be appropriate for different classes of new animal drugs?

Comments: This is really a question to the drug manufacturers. Surely some economic considerations would appeal to them. Our main problems are the drug approval processes as they exist today. We need a mechanism to enhance the approval process on a more timely basis and at a cost that is affordable to our industry.

2. What incentives would encourage sponsors to pursue approval of a drug for a minor species or for a minor use using data in public master file? Are there concerns about data in PMF's that make new animal drug sponsors reluctant to rely of such data?

What are those concerns?

Comment: Answer same as D1 above.

3. If producer groups or their organizations were willing to conduct or otherwise fund studies to demonstrate safety and efficacy for new animal drug approvals for minor species or minor uses, would sponsors be willing to use the data from the studies to support approvals and new or revised labeling? If not, why not?

Comments: Yes, sponsors should be eager to use any available data existing for drug approvals. FDA should implement methods to provide information concerning the availability of this data.

4. Should a program similar to the U.S. Department of Agriculture's National Research Support Program #7 (NRSP-7), which currently funds studies for minor use therapeutic uses for food and fiber-producing animals, be developed for wildlife and zoo animals and/or for production uses?

Comments: The NRSP-7 programs should be expanded to include drugs for non-food, companion pet animals, and for production uses such as spawning and gender manipulation aids. The availability of these drugs is very important to our industry.

5. Could and should philanthropic, public interest, or other not-for-profit organizations be encouraged to fund research for the development of new animal drugs intended for use in minor species or for minor uses? If so, how, and by whom?

Comments: Yes, we need help and funding from any and all resources.

6. Are there mechanisms other than the new animal drug approval process and extralabel uses of animal and human drugs under the AMDUCA that could enhance drug availability for minor species and for minor uses?

Comments: We are hopeful that ADAA will provide the assistance needed for more drug approvals for non-food, companion pet animals. As a producer industry, AMDUCA does provide certain help. Low Regulatory Priority (LRP) rulings should be extended for non-food, companion pet animals, on all drugs now approved for any and all aquaculture species under the guidance of an industry expert panel.

E. Extending existing legal authority.

1. Would legislation be desirable to extend the AMDUCA to permit extralabel use of: (1) medicated feeds or (2) reproductive hormones and implants? What are the pros and cons of approval versus extralabel use under AMDUCA?

Comments: Yes, to both (1) & (2). We are a production industry of ornamental, tropical fish, referred to previously as non-food, companion pet animals. The availability of spawning and gender manipulation aids and the use of medicated feeds are very important to our industry.

Thank you for the opportunity to comment.

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