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To: George Mitchell@OD@FDACVM

Docket No. 97N-0217

COMMENTS ON FDA AQUACULTURE DRUG APPROVALS 0573 '98 JAN 20 AM 11:44

I strongly support the Center for Veterinary Medicine's "PROPOSALS TO INCREASE THE AVAILABILITY OF APPROVED ANIMAL DRUGS FOR MINOR SPECIES AND MINOR USES." If this program can be implemented all aquaculture will be better served and hopefully the industry will no longer be subjected to "changing the rules as we go along." I believe that the current CVM leadership is genuinely interested in assisting the aquaculture industry to better address infectious disease problems.

The PRELIMINARY PROPOSALS IN DISCUSSION DRAFT are very good and will help alleviate fish health problems of aquaculture.

#### I.A. SINGLE APPROVAL MODEL

A major barrier to the private pharmaceutical industry investing in drugs for aquaculture has been the expense and time required to license drugs with little hope of recouping their investment because of the relatively small (compared to cattle, swine and poultry) potential market. That only one antibiotic (Romet-30) has been approved for fish in the past 25 years is discouraging to all of us working in aquaculture. When a drug must go through the single approval model the cost is increased tremendously because its use on each fish species and disease must be exposed to duplicate research. I believe this is unrealistic and unnecessary. Fish should be grouped into biological and life stages for drug application. Also, fingerlings and broodstock should not be held to the same drug approval criteria as production size fish that will be consumed within a year.

The fact that there are so few aquaculture licensed drugs has contributed to overuse of those that are available, thereby exacerbating the increase in drug resistance by fish pathogens and hindering therapeutic success.

#### I.B. EXTRALABEL USE

I agree that AMDUCA is not a viable answer to drug application for aquaculture in general. Although veterinarians are becoming more active in aquatic animal health they generally are not in position to properly advise aquaculturists relative to managing a disease and often must depend upon "non-veterinarians" for advice. Also, many drugs used in one animal group can not be adapted to aquaculture using the indicated label.

#### I.C. LIMITED FLEXIBILITY

We in the aquaculture industry have not seen flexibility by FDA with respect to approval of drugs for minor use. Flexibility has been expressed verbally by FDA personnel but when it comes to "fishing or cut bait" they nearly always continue to "cut bait". The approach to minor use drugs for aquaculture must be flexible, realistic, practical but still provide a safe product to the culture

97N-0217

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animal, aquaculturist, and the consumer.

#### I.D. NEED FOR SIGNIFICANT CHANGE

Approval process for minor use drugs should not be held to the same protocols for more lucrative food animals. There is no way that governmental agencies or private industry can afford the research required to push a drug through the process under current guidelines. As stated in the document, 30 years experience has shown almost no approval of new drugs.

#### IV. PROPOSALS TO INCREASE THE NUMBER OF APPROVED ANIMAL DRUGS FOR MINOR USE.

These proposals have some very good points. If the best of these can be melded into an Approval Model and implemented, aquaculture can benefit.

FDA and CVM must be commended on their efforts to assist and work with the aquaculture industry to improve availability of drugs. I have seen a significant change in attitude over the past 30 years in their willingness to discuss and work out the problems. I believe that the current proposal is another example of this attitude.

There is one final area that CVM needs to address and I do not know if it is appropriate to bring it up at this time. However, the compounds on the "LOW REGULATORY PRIORITY" list needs to be seriously examined. I understand how this list was compiled, why it is maintained and the current problems with its revision. Never-the-less as long as the list contains items such as salt, ice, onion, garlic, etc. the FDA loses credibility in the area of aquaculture. Every time I discuss this list with students or practicing aquaculturists it stimulates a chuckle. CVM and FDA will have a difficult time convincing the aquaculture industry that they are sincere in their efforts to assist the industry on drug use programs as long as these household compounds remain on the list. I have expressed this opinion before with little response, but some way needs to be found to make this list more credible for aquaculture.

Thank you for the opportunity to comment on these proposals.

Sincerely,

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