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FDA's Dockets Management Branch (HFA-305)
12420 Parklawn Dr.
Rm 1-23
Rockville MD 20857

re: Comments to Docket No. 97N-0217

Dear Sirs

It is with great pleasure that I submit the following comments to the above referenced docket no. My comments are slanted towards this issue with regards to aquaculture since this is the business I am in and can relate these issues to. My comments may conflict with the general sentiment of other commentary's from other industries. As a general comment, I find that the proposals as a whole are a step in the right direction. Specifically the recognition that the use of drugs in aquaculture is a serious problem for our industry to come into compliance with, and one that the FDA is becoming more helpful in finding realistic solutions to. The proposals are definitely a step in the right direction, but in some cases go to far and in some cases do not go far enough. With that I offer my specific comments to specific proposals.

1. With respect to the "Modification of Extralabel Provisions" asking whether or not to amend the FD&C to remove the prohibition of extralabel use of medicated feeds in minor species. In an earlier section, the report indicates that "extralabel use is not the answer". Thus time and resources should not be spent on trying to amend the corresponding regulations to allow this treatment, when at best it is a short term solution to the problem and one which probably has an end to the program as a majority of the industry comes into compliance with minor species drug use through other means currently available or proposed in this document.
2. With respect to "Removal of Disincentives", I am opposed to some of the alternatives listed. First of all, increased specific enforcement is not the answer to remove disincentives by drug companies to become involved in minor uses approvals. The FDA has a current mechanism in place to handle this in a much more cost effective manner than hiring additional personnel for enforcement activities. The FDA has a mandatory HACCP program for all processed seafood, including processed aquaculture species. In the FDA's "Fish & Fisheries Hazards & Control Guide" all aquaculturally reared species listed in Table 1 are identified that chemical and drugs are potential hazards. The FDA has created an unlevel playing field in the aquaculture industry by requiring only those aquaculture species which are processed prior to reaching the end user to comply with the HACCP process. Aquaculturally

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reared fish which are sold directly to the consumer alive still poses as great a potential hazard from Chemical and Drugs used during the culture cycle, yet they have no complimentary system to come into compliance with the drug laws as do those fish which are processed. Rather than spending time and resources to increase enforcement measures, a more fair system is to create a self regulated system similar to the HACCP for processed aquaculture fish for the live fish sales component of the industry and to use this system as the HACCP does for processed fish to bring everyone in compliance with the drug use laws.

3. With respect to "Enhancement of Existing Programs for Data Development" certainly the National Sea Grant Program should be included in the list of potential programs available for funding these programs. Additionally, certain state programs under existing State Dept. of Agriculture may have funds for species that are unimportant in other states but contribute significantly to that states aquaculture industry. The proposal fails to look at how some of these existing state programs, where available, may be leveraged through matching funds to enhance the existing programs for data development.
4. With respect to "Establish New Programs Based on the NRSP-7 Model" the FDA asks for specific comments on a new model program that supplements existing NRSP-7 programs. The question should be why not compliment the existing NRSP-7 program, why create a new program when it probably would be much more cost effective to build upon an existing program. It makes more sense to change the research support program of NRSP-7 to allow minor use group research rather than excluding it as is currently the case and building upon the infrastructure already in place in that program.
5. With respect to "Incentives to Pursue Minor Use Drug Approvals", I am generally opposed to extension of the protection against generic versions of approved drugs from 3 to 7 years. Generally this will continue to develop and extend a monopoly a specific drug sponsor will have over the industry. Unless this recommendation includes methods to hold the price level of approved drugs under control, it will severely restrict or reduce the purchase of approved drugs from sponsors. As prices continue to increase, farmers will seek out lower priced un-approved versions of approved drugs, which would further increase prices on approved versions of the drug as a sponsor's market share shrank.

I believe the better method is through the use of the tax credit option which also would apply to the farmers themselves who expend time and resources in the gathering of critical data leading to a NADA.

Of all the arguements for releive of minor animal drug usage, time and again the proposal indicates the greatest problem being the time and cost of sponsors going through the process of obtaining approval for minor drug use. Only two short sentences in this section (2) "Negotiation of a shorter timeframe for the review of a major product indicates any willingness by FDA to make the process less costly and thus increase the attractiveness to enter into the approval process by sponsors. In this section only major products is addressed and then very scantily. I would like to see alternatives to the lengthy approval process explored further, in conjunction with tax credits and data gathering and sharing from other species to reduce the cost to drug

companies to encourage further involvement in this process. This in general is lacking in this proposal.

6. With respect to “Data Sharing by Major Species NADA Holders”, a major component is missing, in that the document looks only towards sharing data by other major species, but of far more critical need by the aquaculture industry is the data sharing between like species within aquaculture and even species groupings for purposes of INAD’s and NADA’s. It seems so redundant that a separate INAD needs to be generated as well as a separate NADA for a rainbow trout being treated with drug A and a brown trout with drug A. Additionally, in the normal drug registration method, a sponsor does the food safety tests and the environmental safety tests and after this has shown promising, then does the clinical field trials. But they are only obligated to do one trial at one facility and then extrapolate the data out to a variety of conditions to be included on the label. But under the current INAD system, everyone using a specific drug has to have a separate INAD in terms of data collections, etc. If the concept is to promote compliance by the industry, and a model proposed here is data sharing, why cannot one representative species be chosen for a specific drug, and all like species would fall under that INAD and as long as an individual grower who wants to use that drug joins the INAD, why must they also collect the data? If data generated by another species for the same drug is ongoing, they should be able to continue their production operating under that INAD without the data collection responsibilities. This would greatly increase the number of private growers willing to participate in the process.

Additionally, later in the proposal the International Harmonization is discussed and identification of existing foreign new animal drug approvals or data. If species groups were used, this would greatly increase the ability of finding like species in other countries which have determined a specific drugs safety for a species, and then that information could be utilized for a whole group of similar species instead of again breaking the process down into a species by species basis.

Thank you very much for your consideration.

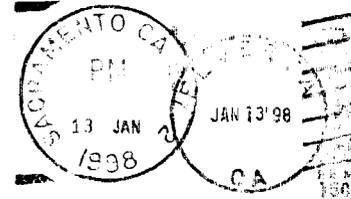
Sincerely,



Peter Struffenegger
General Production Manager

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