

# NATIONAL AQUACULTURE COUNCIL



A DIVISION OF  
NATIONAL FISHERIES INSTITUTE

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January 28, 1998

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

Re: Docket No. 97N-0217

Dear Sir:

The National Aquaculture Council, representing farmer and processors of aquacultured products wish to comment on proposals to "increase the availability of approved animal drugs for minor species and minor use."

We strongly support the following:

- (1) To modify the provisions to allow extra label use of approved medicated feeds including reproductive hormones and implants. This relief is badly needed while approved products go through the approval process. The sunset proposal is acceptable but we doubt it will be needed.
- (2) We would encourage a budgetary change to increase resources for CUM minor use enforcement. Confidence in the food derived from aquaculture must be maintained for consumer safety concerns. We concur that section 21 CFR 514.106 be amended in such terms that the addition of minor species to major species labels would not trigger a critical review of the original major species data package. While we support removal of drugs that have not been approved by FDA, we would urge caution the consideration be given to the reason and application of such use and the disruption that may result.
- (3) We would support increase appropriations for the budgets of NRSP-7 and the hatch funds. The Saltonstall/Kennedy program already support many aquaculture projects. That program has funding problems as does the NCRI program. We suggest those be dropped from further consideration.

We would suggest, rather than developing another NRSP-7 like program, that additional funding and responsibility be given to the National Aquaculture NADA Coordinator to mentor the minor use program.

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We fully support the concept of establishing a minor use database and the personnel needed to maintain it, the program is long overdue. This could provide needed data from sources outside the U.S. that could be incorporated in submission packages.

- (4) We support the intent to increase protection from three to seven years for NADA Supplements for new minor use claims and from five to ten years for new NADA's. CVM policies should be revised to (1) allow for shorter review times where major NADA's will include provisions for minor use and (2) residue depletion data should qualify as significant new data when relating to Food Safety requirements.

We certainly support any and all tax incentives to move the approval process along. The intent is to obtain more compounds to protect our animals, cost becomes a minor issue in a crisis.

- (5) If the road block to sharing data is considered to be a problem for the drug manufacturer, the FD&C Act should be amended to allow for a "hold harmless" clause that will exempt the manufacturer from liability.
- (6) We fully support amending the FD&C Act to create a category of minor use animal drugs. Once created the category could be expanded for other minor use considerations.
- (7) Conditional drug approvals should be considered for ornamental fish. The designation "non-food fish" should be re-examined in light of our citizen's petition dated July 28, 1994 and FDA's response February 1, 1995. Broodstock is a prime example of a non-food fish, that could be considered under this program.
- (8) Use of expert review panels as alternate means of approving minor use compounds for non-food fish is long overdue and we fully concur. Labeling for this use will pose no undue hardship. Experience using this mechanism may lead to an expansion of the concept beyond non-food fish applications.
- (9) If the science behind a foreign body of data is credible we strongly suggest that it be used. We would encourage CUM to develop the programs necessary to collect, identify and harmonize, where necessary, data from sources other than the U.S. AS aquaculture continues to grow harmonizing internationally must be part of our overall minor use program.

We trust these comments will be useful. Thank you for the opportunity to respond.

Sincerely,



Roy E. Martin  
Sr. Vice President of Science and Technology



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Arlington, VA 22209



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