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Food and Drug Administration  
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Rockville, MD 20857

SUBJECT: Comments on the Discussion Draft "Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Use" (Docket No. 97N-0217)

FROM: Gary L. Jensen, National Program Leader-Aquaculture-USDA/CSREES

I wish to thank the Center for Veterinary Medicine (CVM) for their efforts in presenting needed options and provisions that can be significant factors to gain more needed approvals of drugs for minor species and uses, which includes diverse aquaculture species and conditions. My comments as an individual pertain to the FDA/CVM Discussion Draft "Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Use" (Docket No. 97N-0217).

As a member of the Joint Subcommittee on Aquaculture's Working Group on Quality Assurance in Aquaculture Production since November 1990, I have been involved in numerous issues and initiatives supported by industry, FDA/CVM, state and other federal agencies and academia. Many have invested much time and effort educating and seeking innovative approaches to enhance approvals of NADAs for aquaculture species. After all this we have gained a label extension for formalin and also approval for fish generically rather than for a particular species. The point is that the various options presented in this proposal ARE NEEDED to make a difference in NADAs for minor species and uses. The background and rationale associated with the different approaches are well presented and capture the frustration, complexity, needs and opportunities.

I commend FDA/CVM for this proposal and only hope that most of these are supported by FDA in their final document. We need to adopt programs and practices that have proven to be successful for other drug categories whether major species or human. There is a need for extralable use of medicated feeds and spawning hormones. The mandatory seafood HACCP inspection regulation and more emphasis on producer quality assurance programs are important safeguards to assure the proper use of approved drugs and chemicals. The consumer and regulatory environments demand the prevention of contamination of aquatic foods and to date the

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US aquaculture sector has been responsible for producing safe, wholesome products as evidenced in FDA pesticide sampling and monitoring programs and other pesticide residue studies of farm-raised aquatic products. Because of the safe track record and history for aquaculture products since 1990 there is no longer a special code for these products in current seafood pesticide residue sampling work. Spawning hormones are essential for the propagation of certain species and provisions are needed to permit the legal use of these products on only mature, adult animals.

A Minor Use Advocate is commendable, however efforts should focus on incentives rather than disincentives. NRSP-7 has been instrumental in assisting with NADAs and the impact can be enhanced with extending the eligibility of spawning hormones and non-food animals with a corresponding increase in budget justified by an expanded role. The earmarking of federal formula funds (Hatch) or competitive grant program funds (S-K) will likely face much difficulty and is not foreseeable in the near future. Increased funding in programs such as NRSP-7 which have a specific mandate to assist in drug approvals for minor species and uses should be supported. A Minor Use supplement to include groups currently excluded may be a viable option. The use of a database has merit and requires the buy-in of key stakeholders to support it and participate. It could also foster international harmonization. Data sharing can benefit the approval process and a statutory designation of minor use animal drug can direct the resources and attention needed to make a significant difference.

Incentives which have proven successful in gaining more approvals at reasonable cost for orphan human drugs should be beneficial to minor use drugs and should be a component of overall any Minor Use Animal Drug Program. A conditional approval for drugs for non-food animals seems a reasonable approach to facilitate approvals for this category. The sunset period of 5 years may not be adequate based on current experience. There should be flexibility for extension based on case-by-case circumstances. Expert Review Panels for non-food animals also seems to be a good option and worthy of further consideration. Needed expertise does exist in aquaculture sector and funding would depend on knowledge that this model will develop intended results.

The aquaculture sector has initiated international harmonization workshops involving sea lice with Canada, conducted one workshop on international harmonization of aquaculture drugs and biologics and planned a second to be held in February 1998. This effort has attracted participation of EU, FAO, WHO and others. The interest is strong but we need some examples of success and willingness of regulatory agencies to take the initiative for minor species and uses. Most of emphasis has been on major species yet forums are needed for minor species. I feel harmonization efforts can in fact greatly assist the approval process. FDA/CVM should take the initiative for harmonization to assist the US industries as efforts through CODEX and VICH appear to be complex and require many years of effort. Although these organizations need to support such initiatives to get other countries to participate.

Again, let me commend FDA/CVM for their efforts in developing this draft document and even more so for supporting these options that will make the difference that is so desperately needed for minor species and uses.