From: <CAW@GNV.IFAS.UFL.EDU>, on 1/16/98 3:33 PM:
To: George Mitchell@OD@FDACVM

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Food and Drug Administration
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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: Craig A. Watson, Director and Research Coordinator, University of Florida, Tropical Aquaculture Laboratory, 1408 24th Street S.E., Ruskin, FL, 33570

It is with much appreciation that I submit my comments to the Center for Veterinary Medicine (CVM) concerning the above referenced discussion on improving the procedures and statutes surrounding the labeling of minor species and minor use animal drugs. Our work at the Tropical Aquaculture Laboratory is centered around providing research and extension education to the ornamental aquaculture industry, and the issues surrounding the labeling of drugs for this industry have been a major problem for us historically. Perhaps our most successful and highest impact program is in fish health management, and in response we have hired a full time veterinarian to provide diagnostic, treatment and husbandry assistance to the industry. With that said, it was with a great sense of satisfaction that I read the discussion on suggested improvements to the labeling process. Following are my comments:

1) Including the use of medicated feeds in the extra label use provisions will be extremely beneficial to our efforts. The ornamental fish industry has a history of using bath treatments in aquaria and other small tanks to administer most medications, including antibiotic treatments. We have found this to be not only uneconomical in most situations, but efficacy is questionable depending upon dosage rates, water quality and its impact on the drug's activity, and ability of the fish to absorb the drug. However, the restrictions on use of medicated feeds for extra label drug use has limited the administration of drugs in this manner. I highly support the proposed changes concerning this issue.

In the discussion, the concerns over development of antibiotic resistance is raised. In my experience, the risks of producing resistance is actually lowered by administering antibiotics in the feed. The efficacy is improved, and therefore the chances of eliminating the bacterial disease are perhaps better than if the drug is administered in a bath treatment.

The use of reproductive hormones in the feed should be allowed as well. I would also suggest that this could be expanded to steroids as well. For example, methyltestosterone in the feed can be used in ornamental fish production to increase the value of fish which display secondary, male sexual characteristics (i.e. color, finnage). However, again, the existing restrictions of extra label drug use in feeds prohibits this.

2) While the discussion on removing disincentives (and improving incentives) should best be addressed by industry representatives who will be participating in funding of labeling efforts, I support the direction of the discussion. Currently there are many disincentives to a company investing in a labeling effort when their competitors are allowed to continue to market products which are not labeled.

3) Concerning the section on funding the collection and sharing of data for drugs; this is indeed a need in the efforts to improve the situation the industry faces. Whether funds through existing federal programs can be earmarked for minor use labeling is indeed the question, but regardless, a request for funds should be made to Congress. The ability of the NRSP-7 program to effectively improve the situation is questionable in my opinion, and I encourage the continued development of the FDA/CVM alternatives proposed. Creation of a minor use data base would be extremely beneficial to all parties involved.

4) Creation of a minor use category in the statutes is essential to the efforts being discussed. The current NADA process is not appropriate for most labeling in aquaculture, especially in non-food species.

5) The creation of a conditional drug approval for minor use drugs in non-food species is much needed, and would alleviate many of the problems in the labeling process. The five year restriction may be too soon for some drugs, but should be possible for most, especially if efficacy and target species safety are the major concerns which must be met. The non-food species only restriction is appropriate, given the elimination of residue studies in the conditional approval.

6) The suggestion of creating an Expert Review Panel as an alternative approval process is perhaps the best suggestion in the entire discussion, if improving the labeling of drugs for non-food species is the concern. The United States possesses an outstanding wealth of knowledge and expertise in health care of minor species, that could be drawn upon at no cost to the federal government. Private industry in Florida has already demonstrated its commitment to funding such expertise to assist the industry, and there is no reason to expect the rest of the states to follow suit if the outcome were labeled drugs for aquaculture. There are at least 2,000 species of non-food fish in the ornamental trade, making drug approval through the normal process impossible. If the statutes can be rewritten to allow for expert review as an alternative, labeling can be easily accomplished. The expertise exists to meet the requirements as detailed in the discussion.

7) International harmonization is clearly an advantage to all concerned, and again if done as detailed in the discussion, there appears to be ample control over the quality standards necessary to accept data and other information from international sources. There are several nations, especially within the European Community, which have considerable expertise and experience in aquaculture health management and drug therapy, including intimate involvement of veterinarians with industry.

In closing, I once again would like to commend the FDA/CVM for what appears to be a sincere and thoughtful approach to improving the current situation concerning minor use drugs and minor species. The aquaculture industry of the United States has proven itself to be receptive to regulatory oversight, but the current process for developing labels for new animal drugs has proven incapable of meeting the needs of the industry. The concerns over environmental safety, human health, efficacy, and target species safety are legitimate concerns, should not be ignored, but it has become obvious that the current legislation which dictates procedures for approval needs to be changed.