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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

July 7, 2005

Re: Comments on MUMS Act Regulations
Docket No. 2004N-0480

Attn: Dr. Andrew Beaulieu, Director, Office of MUMS, FDA-CVM

Dear Dr. Beaulieu,

First, we would like to thank you and the FDA for allowing us to provide some input into the MUMS Act development process, and also for the great foresight that led to collaboration between government and industry to help resolve a very difficult situation—the lack of chemotherapeutant approval for numerous minor species and minor uses. We understand the difficulties of the situation and hope that our ideas will help.

Ornamental fish are a major industry in the U.S., unique as a commodity in aquaculture in that hundreds of species, comprising numerous families, are traded and sold as "ornamentals." While this diversity provides a degree of economic robustness for those involved in the trade, it also presents problems with regard to standard regulatory approaches, vís a vís the situation leading to development and passage of the MUMS Act. The species farmed by the domestic aquaculture industry comprise only a portion of the thousands of species regularly traded in the aquarium hobby, so the need for creative thinking when labeling drugs and therapeutants becomes an even greater challenge.

The University of Florida/Institute of Food and Agricultural Sciences (UF/IFAS) works closely with the ornamental aquaculture industry in Florida, as well as with wholesalers, retailers, private manufacturing companies, and fish veterinarians throughout the country. Florida's ornamental fish industry is the largest aquaculture commodity in our state, comprising approximately 180 farms, and accounts for 80-85% of all domestic ornamental production in the U.S. In Florida, a single farm will often produce a dozen or more species, with some farms producing many more. Because of the importance of this industry to our state and the nation's economy, ornamental fish health extension, research, and education programs have been a major part of the UF/IFAS mission since the late 1980s.

Chemotherapeutants and regimens in use today by veterinarians and other fish health specialists working with ornamental fish species are typically extrapolations based on: 1) scientific research for one or two food fish species (salmonids or catfish)—not on ornamentals, and/or 2) clinical experience. Clinical

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evaluation of effectiveness and target animal safety are integral components of chemotherapeutic assessment in both scenarios. For many years, these approaches have provided, overall, a good level of effectiveness and target animal safety, based on clinical experience and successful therapy for diseased fish requiring treatment.

Past discussions that have attempted to reconcile standard FDA approaches with the numbers and variety of ornamentals have centered on methods of "crop grouping." Suggestions have included groupings based on temperature, salinity preferences, and/or taxonomy, and an inherent belief that each additional species studied will allow a greater encompassment of all ornamental fish species.

Unfortunately, there are problems with each of these approaches. Temperature and salinity preferences are not necessarily good differentiating factors. Ranges given in the veterinary literature (again, based on the extrapolations mentioned above) may or may not be affected by these parameters, depending upon the chemotherapeutant (biochemical properties), the delivery method (bath or topical vs. oral vs. injectable), and the species. Close taxonomy is also not necessarily an ideal solution. Even at the family level, some major differences can be seen (e.g., in the Family: Characidae, organophosphates are toxic at recommended ranges to pacus and silver dollars, but not to common tetras).

From an economic standpoint—an important perspective that cannot be ignored— a major issue becomes one of diminishing returns. The costs incurred by a private company for FDA approval of a single chemotherapeutant for one species or one family is high, and the time table prolonged. These cost and time factors increase with each species added for a specific chemotherapeutant. Current FDA NADA protocols and current economics barely support research and development of aquaculture drugs for the major food fish groups in the U.S., including catfish (a single species commodity) and salmonids (a family commodity group). These problems act as major disincentives for private companies interested in working on approvals for aquaculture. The numbers of species that comprise the commodity group "ornamental fish" will not allow or support research and development, if approval is for only one species or even a few families within this group. The economic strength and viability of the industry is based on the very fact that it is comprised of thousands of species.

Practicality and economics necessitate an approach that is both a paradigm shift and one based on current industry and fish veterinary medicine practice. We propose allowing experts to choose two or three representative ornamental fish species, based on 1) anatomical, physiological, or sensitivity differences expected toward a given chemotherapeutant, and 2) a general knowledge of the biochemistry and interactions of the drug or chemical under study. The species selected would be those for which widely different physiological responses would be expected. Effectiveness studies would provide a range of dosage rates, and target animal safety studies would use the more sensitive species to determine overall toxicity. Once effectiveness and target animal safety studies are completed for these species, a general "ornamental fish" label would then be provided. As with other pharmaceuticals, general precautionary statements and caveats can and should be added to the label as needed, and adverse effects data should be collected and used to modify the label if indicated. There are no food safety concerns with ornamental fish, because these are not intended for human consumption. We also believe that, based on best management practices developed for ornamental aquaculture in Florida and in other states, as well as based on the final target (generally fish in closed systems, such as business or residential aquariums or ponds), minimal environmental impact will occur with ornamental chemotherapeutants.

This approach will not only provide much more scientific information than is presently available for

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fish health clinicians to base their treatment modalities, it will also make approvals reasonable and much more cost and time effective for private companies interested in working with the ornamental industry. Both of these outcomes are in keeping with the spirit and purpose of MUMS. Other major issues (such as environmental safety and user safety) can also be addressed readily.

Thanks very much for your time. If you have any questions regarding our comments, please don't hesitate to contact us.

Sincerely,

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