

# APPMA<sup>®</sup>

American Pet Products Manufacturers Association, Inc.<sup>®</sup>

January 10, 2005

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

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

Dear Dr. Beaulieu:

The American Pet Products Manufacturers Association (APPMA) is a trade association representing approximately 750 pet product manufacturers and manufacturers' representatives. Among our membership are manufacturers of pet foods, pet treats, remedies and other pet care products necessary for the health and welfare of companion animals. An important segment of our membership includes manufacturers of aquatic remedies. A national survey of pet owners conducted by APPMA shows that there are as many as 280 million pets in the United States and that 62% of American households have at least one pet. Be they furry, feathered or finned, Americans love their pets.

We are grateful to the staff of the MUMS Office at the Center for Veterinary Medicine for taking the time to speak with our members about the forthcoming rules and look forward to continuing to work with the FDA towards the accomplishment of the goals of the Act. We appreciate this opportunity to provide comments on behalf of the aquatic sector of our membership. Of particular importance to our members is Section 572 of the Act relating to the Index of Legally Marketed Unapproved New Animal Drugs.

To ensure the availability of remedies for minor species, APPMA has worked to encourage the adoption of the MUMS Act. Since 1992, APPMA has worked with the FDA to assure that aquatic remedies are available to hobbyists and to prevent the misuse of these remedies. By developing guidelines to prevent the misuse of these remedies, we have actively encouraged our members to take steps to ensure that these products are used appropriately, including changing the delivery form of many remedies so that they are not similar to human dosage forms. The products our manufacturers sell are marketed solely for use in ornamental fish, ornamental organisms and other non-food minor species.

In determining eligibility for indexing we recognize that members will need to provide certain information to the MUMS Office. It is our hope that the FDA will establish a representative submittal package that our members can readily follow. Our members acknowledge that manufacturers will be required to indicate that they follow Good Manufacturing Practices before a product may be indexed. We anticipate that a letter from the company certifying that they understand and intend to follow GMPs will be sufficient to satisfy that requirement.



The remedies manufactured by many of our members are for use in ornamental aquariums and small outdoor garden ponds. We foresee that our members would be exempt from completing an environmental assessment as part of the eligibility determination for indexing these drugs; as it is our belief that the environmental consequences of medications in small garden ponds and aquariums would be insignificant.

Our members are concerned as to how species will be designated for each product. The vast majority of aquarium tanks share a multitude of species and ornamental organisms. Our members respectfully request that in indexing these products you consider designating three groups of species for ornamental aquatic remedies. These should include ornamental marine fish and organisms, tropical ornamental fish and organisms and coldwater ornamental fish and organisms. These fish and related organisms often share the same tank and any treatment methods will affect all animals in a tank as all remedies are added directly to the water. A narrow designation of species for any given product that is included in the index will not assist consumers when they must treat an entire aquarium with many species. This straightforward species designation complies with the spirit of the MUMS Act to make these medications readily available to suffering animals.

The Act provides that recommendations for indexing will be made by a group of experts which will be nominated by industry. We would like to see the expert panels that review the indexing applications comprised of a maximum of three individuals. This will help keep the cost to manufacturers' low which is also in keeping with the intent of the Act. We hope to be able to provide you with a list of potential experts in the near future.

We look forward to continuing to work with FDA to assure that remedies that aquarium hobbyists depend on are readily available. These products have been safely and effectively used by aquarium and garden pond owners for a long time, and we are hopeful that existing literature and anecdotal information on these drugs will make up the large part of the informational requirements necessary to include these products on the index.

Thank you for your consideration.

Yours truly,

Gina Valeri  
General Counsel & Director of Legislative Affairs