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December 18, 2006

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

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RE: Index of Legally Marketed Unapproved New Animal Drugs for Minor Species  
Docket No 2006N-0067

Dear Sir or Madam:

The American Pet Products Manufacturers Association (APPMA) is a trade association representing approximately 900 members of the pet industry. 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 minor species animal remedies, including remedies for nonfood aquarium and pond fish, reptiles, and other small animals. APPMA appreciates the assistance that the MUMS Office has provided in explaining aspects of the law to our members. APPMA respectfully submits the following comments regarding the proposed rules for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

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APPMA would like some clarification as to the empanelling of expert panels. Given the limited numbers of individuals identified by our members as having expertise in the area of aquarium and pond fish or with regard to reptiles, pet mammals or birds, our members have some concerns that there will be insufficient numbers of experts that are willing to commit the time and expertise involved in participating in an expert panel. To ensure that potential experts will not be dissuaded from participating we suggest adding language that would specifically state that if experts had previous interaction with the sponsor, such as advising in the development of the drug, they would not be excluded as long as they did not have an ownership or financial interest in the company sponsoring the drug. ¶

Generally APPMA's members are very pleased with the proposed Indexing rules, and believe that the FDA has made a significant contribution to animal health, while maintaining appropriate safeguards for both human and animal safety. In applying these rules, APPMA hopes that the MUMS Office will embrace the spirit of the MUMS Act, and interpret the rules in a broad, flexible manner that will encourage rather than discourage the development of animal drugs for minor species and uncommon conditions. Specifically, APPMA members would appreciate clarification that the individuals serving on Expert Panels will be permitted to base their recommendations on a broad range of materials and expertise, including published and anecdotal information, as well as new information developed in support of an indexing request.

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Similarly, many of the individuals identified by our members as possessing significant expertise in the area of minor species remedies have from time to time worked as consultants or advisors to various manufacturers of potential Index remedies. APPMA is concerned that the provisions of section 516.141(g) regarding conflicts of interest may, if applied too narrowly, limit the pool of qualified Experts available to serve on MUMS panels. APPMA believes that Experts should not automatically be disqualified from serving on MUMS panels, provided the Expert does not have a current employment relationship with or financial interest in the sponsoring Requestor.

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APPMA is also concerned that the period within which to request an informal conference following an initial determination denying a request for addition to the index may be too short to allow preparation of a proper response to the FDA's grounds for the initial decision, and therefore we suggest that the 30 day period set forth in section 516.123(b) be amended to 90 days.

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The proposed regulations provide that the expert panel will make recommendations in the written report as to which species the drug is intended for. For most terrestrial species, the intended animal target will be very clear, and will not be an issue for the expert panels. However, for aquarium drugs, because of the vast number of species that exist and because multiple species are often treated in one tank at the same time, it would add clarity and reduce inconsistent results if the regulations provide that non-food aquatic animals should be grouped by water temperature. Therefore, we suggest with regard to aquatic species that the regulations state that the panels review the crop group for aquarium and pond fish based on water temperature. We suggest the grouping of species for warm water, cool water and cold water fish be provided for in the regulations. If necessary the panel could exclude any specific species from the general grouping. This could eliminate any potential inconsistent results amongst experts. In addition, it is unclear whether there is a mechanism to address inconsistent results from panel members for similar drugs or active ingredients. ¶

Finally, APPMA expects that many of our member companies applying to have a product added to the index will be small businesses, with few employees and limited in-house regulatory expertise. APPMA would encourage the MUMS Office to extend its extremely valuable practice of explaining aspects of the indexing rules to interested parties to also applying the rules in a way that will assist small businesses to comply with the law in a commercially reasonable manner with flexibility and consideration on a case by case basis.

We appreciate this opportunity to express our thoughts regarding the proposed regulations.

Very truly yours,

Einar M. Rod  
General Counsel & Associate Vice President  
Government Affairs

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