

# APPMA<sup>®</sup>

American Pet Products Manufacturers Association, Inc.

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December 18, 2006

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

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.

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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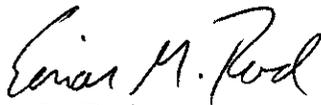
Similarly, many of the individuals identified by our members as possessing significant expertise in the area of minor species remedies have from time to time worked as consultants or advisors to various manufacturers of potential Index remedies. APPMA is concerned that the provisions of section 516.141(g) 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.

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.

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