

APPMA[®]

American Pet Products Manufacturers Association, Inc.[®]

October 28, 2002

Dockets Management Branch (HRA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0209

To Whom It May Concern:

The American Pet Products Manufacturers Association, Inc. (APPMA) is a trade association representing approximately 685 pet product manufacturers and manufacturers' representatives both nationally and internationally. Approximately 44% of our members are small manufacturers, *i.e.*, with gross annual sales of less than \$500,000. We also represent large manufacturers. Our industry employs more than 250,000 individuals in the manufacturing, distribution and marketing of pet products, including products essential for the health and well being of companion animals, such as pet food, treats and supplements. In addition, the pet industry which includes, not only products but veterinary services, breeding, grooming and other care, is expected to reach \$31 billion this year. Be they furry, feathered or finned, Americans love their pets.

The US Food and Drug Administration's request for comment is commendable. The Congress and the US Supreme Court have weighed in on commercial speech. It is time for FDA to do the same. Review of the vast number of public comment that has been collected in this request is a formidable task but we are confident that FDA will consider the views presented fairly and carefully. We have read several comments submitted by colleagues in the field, regulators and private citizens. We submit this comment to support the well-articulated views presented by the animal feed and pet food manufacturers and their representatives who have previously commented. Specifically, we hope that FDA will consider the importance of allowing structure/function claims on products for companion animals.

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A recent survey sponsored by Kemin Nutrisurance, a manufacturer of feed ingredients for the pet food industry, indicates that consumers care about their pet's health and are increasingly making dietary choices for their pets, based on ingredients. 67% of pet owners in 1000 telephone interviews stated that they would choose one pet food over another if it contained beneficial vitamins and nutrients. More than half of the pet owners interviewed stated that they would buy a separate vitamin or supplement for their pet. These consumers should be left to make choices based on accurate information.

The courts have spoken on First amendment protections of commercial speech. Other commenters have cited extensively Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980), and its progeny related to health claims including Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), Thompson v. Western States Med. Center, 535 U.S. ___, 122 S.Ct. 1497 (2002), et al. to support the judiciary's long-held view that the state is charged with a high burden when regulating commercial speech.

In addition, the passage of the Nutrition Labeling and Education Act (NLEA) and the Dietary Supplement Health and Education Act (DSHEA) expanded the ability of manufacturers of foods and dietary supplements to make health claims. One must conclude that both the Congress and the courts wish to preserve the First Amendment protections that apply to commercial speech for the overarching government interest of free speech. Yet, as these protections relate to products for companion animals, there is no clear guidance.

Meanwhile, pet product manufacturers continue to register products at the state level that requires submission of labels in many cases. For practical purposes, without state government review of label claims, a pet food, treat or supplement cannot be sold in the United States. Yet the review conducted at the state level can result in disparate determinations of label appropriateness for sale in a given state. Some states require pre-market approval of products with claims while neighboring states may not. Manufacturers seeking broad distribution, or even national sales, struggle to satisfy individual state requirements. In fact, without clear federal guidance on claims related to health benefits, manufacturers are at a loss as to compliance. We believe that both manufacturers and the states require clear federal guidance on acceptable health claims.

We are left with a regulatory scheme that is virtually impossible with which to comply in a heavily competitive climate where consumers are demanding more information to help them make educated choices about their pet's health and welfare. Therefore, we encourage FDA to provide a level regulatory environment in which pet product

manufacturers do not face impossible compliance choices that the manufacturers of human food and dietary supplements do not face. FDA should follow the direction set by legislators and judges on commercial speech related to health claims on product labeling. Structure/function claims should be permitted on pet products that conform to current law requiring truthful labeling. In conclusion, we believe that the only logical way to achieve this goal is to permit all manufacturers to label products in a truthful and nonmisleading manner that will benefit not only consumers but their pets as well.

We respectfully submit our views.

Sincerely yours,

A handwritten signature in cursive script that reads "Gina Valeri". The signature is written in black ink and is positioned above the typed name and title.

Gina Valeri
Director of Legislative Affairs & General Counsel