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Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Docket No. 02N-0209 Request for Comment on First Amendment Issues. 67 Fed. Reg. 34942, May 16, 2002

The Pet Food Institute (PFI) appreciates the opportunity to submit comments in response to the "Request for Comment on First Amendment Issues." Founded in 1958, PFI is a trade association of dog and cat food manufacturers and those who supply goods and services to the pet food industry. PFI represents the manufacturers of 97 percent of the total dog and cat food produced in the United States.

The recent history of food labeling legislation and regulation in the United States has placed pet food manufacturers at a disadvantage with respect to what types of truthful commercial information FDA asserts they may provide to consumers on product labeling in comparison with the types and categories of information manufacturers of human foods and dietary supplements are permitted to convey. The Nutritional Labeling and Education Act of 1990 ("NLEA"), which allowed the use of health claims on food labels, was expressly limited to human foods. FDA's Center for Veterinary Medicine has taken the position that the Dietary Supplement Health and Education Act ("DSHEA") excludes dietary supplements intended for use in animals. Hence, the benefits those Acts provided to human food manufactures either expressly or arguably do not apply to pet food manufacturers.

Moreover, the requirement that pet food labels be registered in individual states in which the products are sold, in the absence of federal guidance to the states as to which kinds of labeling claims are acceptable, means that pet food manufacturers potentially face dozens of different determinations regarding the propriety of any given claim. The disparity in the treatment of human food and pet food manufacturers is most clearly illuminated by the fact that pet food manufacturers may not be able to use a truthful, properly

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substantiated and non-misleading claim in their labeling that is used for similar products for human use. PFI urges FDA to examine and address this disparity as it applies to food for humans and animals.

1. Background

In 1987, before the passage of the NLEA, FDA had stated in a Federal Register Notice (52 Fed. Reg. 28843, 28845 (1987)) that health claims could be applied to food labels and labeling in a non-misleading manner without causing the food to be considered a drug provided that certain criteria were met:

> The agency believes that, if proper criteria are followed, it is possible to use the food label to communicate more explicit health-related information. The agency acknowledges that in the past, foods labeled with information of this type could have been viewed as subject to action under 21 CFR 101.9(i) and the new drug provisions of the act. The agency's current view is that appropriate health messages would not be inconsistent with either of these provisions.

Because Section 201(f)(1) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") defines "food" as "articles used for food or drink for man or other animals," (21 U.S.C. § 321(f)(1)), FDA's pronouncement that health claims could be used in a non-misleading manner on food labeling applied to labeling for animal feed as well as human food.

When the NLEA was passed in 1990, however, the scope of its provision governing the use of health claims on food labels and labeling was expressly limited to food intended for use in humans. NLEA Sec. 3(a), codified as 21 U.S.C. § 343(r)(1). As a result, the health claim regulations at 21 C.F.R. §§ 101.72-83 apply only to labels and labeling for human foods and dietary supplements.

In 1994, Congress passed DSHEA. Unlike the NLEA, DSHEA was not expressly limited to human food, with the exception of Section 3(a), codified as 21 U.S.C. § 321(ff))(1)(E), which defined "dietary supplement" as, among other things, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake." The other parts of the definition of "dietary supplement" in 21 U.S.C. § 321(ff))(1), e.g., as "a vitamin," "a mineral," however, are not limited to use in humans. DSHEA also added Section 403(r)(6) to the FFDCA (21 U.S.C. § 343(r)(6)). Section 403(r)(6) states that, for purposes of the requirements for health claims, a statement may be made on the labeling of a nutritional supplement if:

> The statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States,

> Describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,
>
> Characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function;
>
> Or describes general well being from consumption of a nutrient or dietary ingredient.

Despite the fact that most provisions of DSHEA are not limited to dietary supplements intended for use in humans, CVM is on record as having taken the position that DSHEA in its entirety does not apply to dietary supplements for animals. *See* 61 Fed. Reg. 17706 (1996); October 26, 1998 speech by Stephen F. Sundlof, DVM, Ph.D. to PFI. As a result, it is unclear whether and to what extent the final structure/function rule published in the Federal Register on January 6, 2000 (65 Fed. Reg. 999) applies to animal feed or dietary supplements.

The system under which animal food products, including pet food, is regulated also contributes to the uncertainty pet food manufacturers face in drafting label claims. Unlike human foods, which are primarily regulated by FDA,[1] animal feed is primarily regulated by the states. Most states have a system under which a manufacturer or distributor of animal feed, including pet food, must provide for review and, in many instances, registration of the label of each product to be sold in that state. When the labels are reviewed by state regulators they can refuse registration of any label that contains a claim the regulator believes does not comply with his or her state law. Although the states would be subject to federal preemption in areas addressed by the FFDCA or FDA regulation, and generally speaking follow guidance promulgated by FDA on feed labeling issues, the states are free to interpret the law in those areas in which FDA guidance does not exist.

A pet food manufacturer therefore faces the following scenario: If the manufacturer sells the pet food product, that label must be registered in many or all of the states in which the product is to be sold. This is true whether or not the label includes either a structure/function or a health claim. Because there is no meaningful FDA guidance on the issue of structure/function claims or health claims on pet food labels, each state is free to interpret the law itself and can deny registration of the product. Alternatively, states can make inconsistent requirements as to the wording of structure/function claims. Either situation would require: 1) that a seller give up his First Amendment rights to make truthful, non-misleading label claims; or 2) that the seller produce more than one set of labels for a product and insure that specific labels go to specific states, which due to transportation and distribution issues will not be possible for many manufacturers and/or may be prohibitively expensive; or 3) the seller would be prohibited from selling a product that would be legal if truthful claims were allowed. In

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[1] FDA regulation is also controlling on the states in primary labeling areas. 21 U.S.C. § 343-1; this provision has been interpreted to have limited effect on animal feed, including pet food.

short, the current state of FDA oversight on this issue produces a risky and potentially unworkable situation for pet food manufacturers.

2. FDA must provide to pet food manufacturers the same kind of certainty human food manufacturers have with respect to these issues while still insuring that claims are not false or misleading.

Manufacturers and distributors of pet food are entitled to the same level of certainty in labeling their products that the manufacturers of human products enjoy. Indeed, in the context of the disparity between claims for conventional human foods and dietary supplements, the Agency has said: "FDA has an obligation to treat all segments of the regulated food industry with fairness." 56 Fed. Reg. 60537, 60541 (1991).

Under the current regulatory scheme, as illustrated above, pet food manufacturers may find it too risky to include in labeling the very types of truthful and non-misleading commercial speech, health-related information and health claims FDA deemed to be appropriate in food (including pet food) labeling in its August 4, 1987 Federal Register Notice (52 Fed. Reg. at 28845). FDA's failure to address this uncertainty by drafting guidance, therefore, operates as a *de facto* suppression of commercial speech.

Recent controlling case law provides that FDA must allow commercial speech if the Agency's regulatory goals can be met other than by prohibiting it. "[I]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson v. Western States Med. Center*, 535 U.S. ___, ___, 122 S.Ct. 1497, 1506 (2002). The Supreme Court explained in *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996):

> The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.

The Supreme Court has repeatedly held that the government must allow consumers to have information so they can make decisions themselves:

> [I]nformation is not in itself harmful . . . people will perceive their own best interests if only they are well enough informed . . . the best means to that end is to open the channels of communication rather than to close them.

Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976).

> Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.

Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557, 562 (1980). The Supreme Court reiterated this principle in the *Western States* decision, handed down in April 2002:

> We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.

Western States, 535 U.S. at ___, 122 S.Ct. at 1507 (*citing Virginia Bd. of Pharmacy*, 425 U.S. at 769).

Nor may FDA argue that such claims should not be allowed because they may be misleading. As the DC Circuit clearly stated in *Pearson v. Shalala*, "the States may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive." *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)). Given proper substantiation, appropriately drafted structure/function and health claims can be presented in a non-misleading manner on pet food labels just as they are on labels of human foods and dietary supplements. As the *Pearson* court explained, "It is clear, then, that when government chooses a policy of suppression over disclosure--at least where there is no showing that disclosure would not suffice to cure misleadingness--government disregards 'far less restrictive' means." *Id.* at 658.

3. Conclusion

In summary, PFI believes that existing laws and regulations allow the use of truthful and nonmisleading structure/function claims for food, including pet food; and that FDA has an obligation to confirm this interpretation. This is consistent with the First Amendment case law referenced above and is in the best interest of companion animals, their owners and the pet food industry.

We appreciate the opportunity to provide these comments.

Sincerely,

Nancy K. Cook
Vice President,
Technical and Regulatory Affairs

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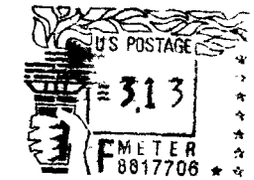

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