



National Grain and Feed Association

September 13, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Request for Comment on First Amendment Issues
Docket # 02N-0209**

Dear Sir or Madam:

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration's request for comment on First Amendment issues.

The NGFA is the U.S.-based nonprofit trade association that consists of more than 1,000 grain, feed, processing and grain-related firms comprising 5,000 facilities that handle more than two-thirds of U.S. grains and oilseeds. More than 300 NGFA member companies are involved in commercial feed manufacturing and integrated livestock and poultry feeding operations. The NGFA's membership also encompasses all other sectors of the commercial grain handling and processing industry, including country, terminal and export elevators; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and feeders; commodity futures brokers and commission merchants; and allied industries, such as railroads, barge lines, banks, grain exchanges, insurance companies, computer software firms, and engineering/design/construction companies. The NGFA also consists of 36 affiliated state and regional grain and feed associations, as well as two international affiliated associations. The NGFA also has established strategic alliances with the Pet Food Institute and the Grain Elevator and Processing Society.

The NGFA commends FDA for seeking comment on complying with First Amendment protections afforded to commercial speech in a way that is consistent with its statutory responsibility to protect public health. As responsible corporate citizens and as a key link in America's food chain, the grain, feed and processing industry has a long-cherished reputation for providing consistently safe and wholesome agricultural products that are responsive to customer needs. Indeed, the NGFA's Mission Statement commits our Association and its members to fostering an "efficient free-market environment that achieves an abundant, safe and high-quality food supply for domestic and world consumers."

02N-0209

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The NGFA will confine the majority of its remarks to issues important to commercial animal feed manufacturers and integrators. The Federal Food, Drug and Cosmetic Act defines “food” as “articles used for food or drink for man or other animals.” [21 U.S.C. § 321(f)(1)] We support and commend for FDA’s consideration the statement submitted by the Pet Food Institute with respect to issues important to commercial pet food manufacturers.

The recent history of food labeling legislation and regulation in the United States has created an unlevel playing field when it comes to the type of commercial information allowed for dietary supplements compared to animal feed and feed ingredients. For manufactured animal feed, only products (i.e., medicated feeds) that are approved under a FDA new animal drug application (NADA) or abbreviated new animal drug application (ANADA) may make health claims and claims of nutritional support. Thus, manufacturers of animal feed, even if they possess substantial and credible scientific evidence or data to substantiate the truthfulness and non-misleading nature of such claims, are not allowed to make such claims unless the product is subject to FDA preapproval under a NADA or ANADA.

Further, unlike human food, which is regulated primarily by FDA, animal feed is regulated primarily by the states. Most states implement laws and regulations requiring a manufacturer or distributor of animal feed to register the label of each product to be sold in the state. Pursuant to this requirement, the state reviews the product label and can refuse registration of any label based upon the nature of the claim. Thus, for animal feed, each state currently finds itself in the position of interpreting the law itself, which has resulted in inconsistent requirements as to the wording of structure/function claims or outright denial of product registration based upon standards that vary from state to state.

To rectify this situation – and to conform with recent court decisions admonishing FDA for infringing on commercial free speech rights embodied under the U.S. Constitution’s First Amendment – the NGFA believes that FDA should develop and issue criteria that permit truthful, non-misleading information on animal feed and pet food labels and advertising that are consistent with the commercial free-speech doctrine and do not require FDA’s preapproval through a NADA or ANADA process. The NGFA believes there is insufficient justification to subject health claims on foods or animal feed to a higher standard than those applicable to dietary supplements, and that doing so would create confusion. The NGFA also believes, consistent with the Pearson v. Shalala appellate court decision (see page three of this statement), that FDA should expressly recognize that manufacturers may utilize qualifying statements or disclaimers so that such claims accurately reflect and are consistent with the nature and caliber of substantiation associated with the product.

In advocating this position, the NGFA believes that FDA – whose Center for Veterinary Medicine has expressly, as well as frequently and consistently, stated that dietary supplements intended for use in animals are outside the realm of the Dietary Supplement Health and Education Act (DSHEA) – should devise a policy pursuant to First Amendment commercial free-speech in a manner that does not condone or legitimize claims that are unsubstantiated or misleading. Unfortunately, such claims have

Simply put, the NGFA believes the manufacturer, sponsor or distributor of such products should be able to substantiate any health or structure-and-function claims made for the product – or any qualifications or disclaimers to such claims – so that they are truthful and not misleading.

Thompson v. Western States Medical Center

In its request for comment, FDA specifically refers to the U.S. Supreme Court’s decision in Thompson v. Western States Medical Center [535 U.S. ____ (2002)] as a legal authority with which it must comply. The Thompson opinion mandates several basic principles that NGFA supports: 1) the free flow of commercial information concerning lawful activities that is truthful and not misleading; 2) when governmental interests are sufficiently demonstrated, the restrictions imposed should be no more extensive than necessary, and should not be based simply upon convenience, so that less restrictive alternatives will be pursued; and 3) the fear that people will make bad decisions if given truthful information (the paternalistic approach) is no justification for a complete advertising ban; information may be valuable or not, but it is for the consumer – not the government – to decide.

Although the regulations challenged in Thompson concerned compounded drugs, the principles set forth by the Supreme Court relate no less to the regulation of foods (including animal feed) and dietary supplements.

Pearson v. Shalala

In its effort to comply with the First Amendment, the NGFA further urges FDA to defer to the principles and authorities espoused by the U.S. Court of Appeals for the District of Columbia Circuit in Pearson v. Shalala [164 F.3d 650 (D.C. Cir. 1999)].¹

In this case, the Court of Appeals reviewed the “significant scientific agreement” standard relied upon by FDA to approve of health claims associated with dietary supplements. The appellate court ruled that this standard violated the First Amendment because it precluded the approval of less-well supported claims accompanied by a disclaimer. Specifically, the court found that the FDA had: 1) simply concluded that the evidence failed to give rise to “significant scientific agreement” because it was inconclusive; 2) never explained how the agency measured “significant” or otherwise defined the phrase; and 3) refused to consider suggested disclaimers, such as “The FDA has determined that the evidence supporting this claim is inconclusive.”

¹ The appellate court’s rulings were subsequently discussed at length and followed by the U.S. District Court for the District of Columbia in Pearson v. Shalala, 139 F. Supp. 2d 105 (D. D.C. 2001).

It is important to emphasize that under well-established case law, only truthful advertising related to lawful activities is entitled to First Amendment protection. As set forth in this decision, advertising that is “inherently misleading” may be prohibited entirely. But advertising that is only “potentially misleading” may not be completely banned if the information can be presented in a way that is not deceptive. In this case, the court accepted FDA’s arguments that the health claims at issue were at least potentially misleading because the consumer would have difficulty in independently verifying these claims, and that consumers might actually assume the government had approved such claims. Rather than an outright ban, however, the court proposed appropriate disclaimers, such as “The evidence in support of this claim is inconclusive” or “The FDA does not approve this claim.” The court stated simply that disclaimers are “constitutionally preferable to outright suppression,” i.e., more disclosure is preferred rather than less. [164 F.3d at 657 (citing Bates v. State Bar of Arizona, 433 U.S. 350, 376 (1977))].

“Conventional” Foods Vs. Dietary Supplements

An important question raised in FDA’s request for comment and discussed in the Pearson decision concerns conventional foods. The precise claims in Pearson involved dietary supplements. However, the court noted that FDA uses “the same substantive standard and procedure” to regulate health claims on conventional foods as on dietary supplements, even though it is implemented by statute for foods and by regulation for dietary supplements. [164 F.3d at 654, n.2.] Whether the impermissible restriction stems from regulatory or legislative enactment is inconsequential. Indeed, the court specifically rejected the notion of refraining from second guessing a legislative decision to restrict speech. [164 F.3d at 658 (citing Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico, 478 U.S. 328 (1986))].

Thus, under the Pearson decision, there is no basis upon which to grant greater deference to First Amendment free speech for conventional foods or animal feed than for dietary supplements. To the contrary, as noted by the court in Pearson, the government traditionally has extended an apparently greater willingness to approve health claims on conventional foods than on dietary supplements. [164 F.3d at 654, n.3].

In fact, three of the four dietary supplement health claims discussed in Pearson already had been approved for foods containing those components. Existing research had examined only the effects of consumption of foods containing the components. “The FDA logically determined that the specific effect of the component of the food constituting the dietary supplement could not be determined with certainty,” the court said. [164 F.3d at 658.] Without questioning FDA’s logic, the court simply proposed “adding a prominent disclaimer to the label along the following lines: ‘The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods.’” Id. The fourth proposed health claim involved the superiority of folic acid in dietary supplement form rather than food form. Here again, the court rejected FDA’s failure to consider a disclaimer, such as “The evidence in support of this claim is inconclusive.” [164 F.3d at 658-59.]

There are possible explanations for the disparate treatment between dietary supplements and foods, such as the greater fear of adverse effects from dietary supplements. For example, FDA's initial denial of a proposed health claim in Pearson was that consumption of the ingredient involved (folate) might have harmful effects on persons suffering from anemia. Dietary supplements generally might be more likely to include greater concentrations of that ingredient. In addition, the court found that dietary supplements are more likely to be intended and promoted to serve the particular purpose of affecting a bodily condition or treating disease. The public is more likely to view those components in foods as providing a side-benefit, and not as likely to forego alternative treatment.

In any event, there is no basis for subjecting health claims on foods or animal feed to a higher level of scrutiny or regulation than on dietary supplements. The public interest and need for information is identical. Further, applying different "free speech" standards for different products would create tremendous confusion.

Conclusion

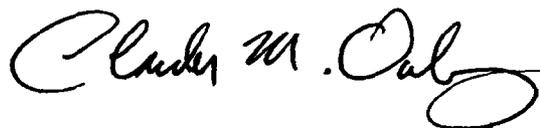
In closing, the NGFA supports FDA adopting a regulatory approach that permits manufacturers to make available to consumers truthful, non-misleading information on animal feed and pet food labels and advertising that are consistent with the commercial free-speech doctrine and do not require FDA's preapproval through a NADA or ANADA process. The NGFA does not believe there is a sufficient basis for subjecting health claims on foods or animal feed to a higher standard than imposed on dietary supplements, and that doing so would create confusion. The NGFA also believes, consistent with the Pearson decision, that FDA should expressly recognize that manufacturers may utilize qualifying statements or disclaimers so that such claims are credible and reflect – and are consistent with – the level of substantiation associated with the product.

The NGFA appreciates your consideration of its views on these important matters. If you have any questions, please contact either of us at (202) 289-0873.

Sincerely,



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