

VIA ELECTRONIC DOCKET TRANSMISSION

July 6, 2004

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

Re: Docket Nos. 1994P-0390 and 1995P-0241 – Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of Comment Period

Dear Sir or Madam:

The American Feed Industry Association (AFIA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition's (CFSAN) Federal Register notice requesting comments on health and nutrient content claims and dietary guidance. 69 Fed. Reg. 24541 (May 4, 2004). AFIA is the national, not-for-profit trade association for animal feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers, and other firms that supply goods and services to the animal feed and pet food industries. AFIA's nearly 600 corporate members manufacture 75 percent of the nation's primary commercial feed. AFIA offers these comments on their behalf.

FDA has reopened the comment period on various issues associated with the agency's regulation of health claims and nutrient content claims for human foods and human dietary supplements. AFIA supports this reopening of the comment period. Improving the flow of accurate and useful health information will, AFIA believes, empower consumers to make better decisions about their own health and health care. However, in reopening the comment period, FDA has not gone far enough. AFIA urges FDA to include animal feed, pet food, feed ingredients and animal dietary supplements (collectively "animal foods") in this rulemaking.

AFIA has raised its concerns before. On January 26, 2004, AFIA filed comments with FDA to Docket No. 2003N-0496 – Food Labeling: Health Claims; Dietary Guidance, 68 Fed. Reg. 66040 (November 25, 2003). In that advance notice of proposed rulemaking (ANPR), FDA proposed a regulatory framework for qualified health claims. AFIA supported the procedures FDA outlined in the ANPR, which would both protect the commercial free speech rights of food and supplement

sponsors, and assure that consumers receive non-misleading information about foods. However, the ANPR excluded animal foods. In its comment to the qualified health claims ANPR, AFIA asked that FDA remedy this constitutional shortcoming:

- ?? The proposed rule should address the First Amendment commercial free speech rights of manufacturers and distributors of both human foods and animal foods.
- ?? FDA should expand the scope and applicability of the health claims proposed in the ANPR to include animal foods when it issues a proposed rule.

Extending the proposed rule to include animal foods is proper and justified for many reasons:

- ?? In fairness, FDA should not continue to prohibit for animal foods what it allows for human foods.
- ?? Constitutionally, FDA has no basis for distinguishing claims for human foods from claims for animal foods.
- ?? Because the costs are very high, and the substances themselves are usually generic and not patentable, there is no economic incentive for an animal food manufacturer to obtain FDA approval of a new animal drug application (NADA) in order to make a health claim. The proposed health claim procedures provide a much better way for this valuable information to reach producers of animals raised for food production and owners of animals kept as companions (including pets).

AFIA attaches its January 26 comment and includes that comment in these dockets for FDA's consideration as the agency proceeds with this rulemaking.

As AFIA set out in its previous comment, the Nutrition Labeling and Education Act (NLEA) provides but one mechanism for FDA pre-approval of certain health claims – those claims that are unqualified (usually) and supported by significant scientific agreement. The NLEA is not, however, the sole vehicle via which human foods and supplements may bear health claims. The United States Court of Appeals for the District of Columbia plainly held in Pearson v. Shalala, 164 F.3d 650, 655 (D. C. Cir. 1999), pet. for reh'g en banc denied, 172 F.3d 72 (D. C. Cir. 1999), that the First Amendment mandates FDA allow other health claims, even if they do not meet the NLEA standards.

Thus, FDA may not rely upon the lack of an authorizing provision of the NLEA to justify its prohibitions upon animal food health claims. Simply because there is no mechanism under the NLEA for animal foods to make health claims does not mean that there is no other claim mechanism available to animal foods. Under Pearson and its progeny, FDA cannot ban outright health claims

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for human foods simply because they do not comply with the NLEA. The First Amendment requires that FDA allow animal foods to bear health claims, irrespective of the NLEA.

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AFIA thanks FDA for this opportunity to comment. AFIA urges FDA to recognize the full implications of Pearson and its progeny. There is no basis for limiting the application of those cases to human food and human dietary supplements. When the agency amends its health claims regulations, AFIA urges the agency to include animal feed, pet food, animal feed ingredients, and animal dietary supplements within the revised rules.

Sincerely,



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Attachment

cc: Stephen F. Sundlof, Director Center for Veterinary Medicine