

## **COPY of Hand Delivered Comments**

January 26, 2004

### **BY HAND DELIVERY**

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

Re: Docket No. 2003N-0496 – Food Labeling: Health Claims; Dietary Guidance

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) advance notice of proposed rulemaking (ANPR) regarding health claims and dietary guidance. 68 Fed. Reg. 66040 (November 25, 2003). 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.

As AFIA understands FDA's proposal, the procedure ultimately promulgated would apply to "health claims" -- that is claims describing a relationship between a food, food component, or dietary supplement ingredient, and a reduction in the risk of a disease or health-related condition. A health claim refers to reduction in the risk of future disease; treatment of existing disease is a drug claim, and a product bearing a drug claim would still have to comply with the FDA requirements applicable to drugs. See, e.g., Whitaker v. Thompson, No. 03-5020 (D.C. Cir. Jan. 9, 2004). Moreover, the proposed procedures would not apply to statements that address the role a specific substance plays in maintaining normal healthy structures or functions of the body; such statements are "structure/function" claims and different procedures apply. To avoid being characterized as a drug, structure/function claims may not explicitly or implicitly link a substance to a disease or health related condition. 21 C.F.R. § 101.93(g).

AFIA applauds FDA for establishing a procedure for the evaluation of qualified health claims that assures consumers receive accurate and truthful information about foods and dietary supplements. The proposed "option 1" FDA sets out in the ANPR would codify the evidence-based ranking system and procedures FDA proposed in its July 2003 Consumer Health Information for Better Nutrition Initiative (Better Nutrition Initiative), 68 Fed. Reg. 41387 (July 11, 2003). Codifying the procedures of option 1, or a similar alternative, would both protect the commercial free speech rights of food and supplement sponsors, and assure that consumers receive non-misleading information about foods.

However, in AFIA's view, the ANPR does not go far enough to protect commercial free speech rights of FDA-regulated industry. FDA has not included animal feed, pet food, feed ingredients and animal dietary supplements (collectively "animal foods") in the agency's health claims initiatives. AFIA recommends 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 qualified 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 qualified claims for human foods from qualified 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 qualified health claim. The proposed qualified 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).

These and other issues are discussed further below.

### **Regulatory Background**

As has been discussed elsewhere in exhaustive detail, the Nutrition Labeling and Education Act (NLEA) created a mechanism by which human foods and dietary supplements could expressly or implicitly link the consumption of a food substance (e.g., ingredient, nutrient, or complete food) to the risk of a disease (e.g., cardiovascular disease) or a health-related condition (e.g., hypertension). See 21 U.S.C. § 343(r)(1); 21 C.F.R. § 101.14(a). Under the NLEA, a health claim must be authorized by FDA regulation based on the agency's determination that there is "significant scientific agreement" (SSA) as to the relationship between a food substance and a disease or health-

related condition. Those wishing to make health claims must petition the agency and demonstrate that SSA supports the proposed health claim. 21 C.F.R. § 101.70. If the claim is supported by SSA, and the petitioner otherwise complies with the statutory and regulatory requirements, FDA promulgates a regulation authorizing the claim and the conditions under which it could appear on a product label. See e.g., 21 C.F.R. § 101.72 (authorizing health claim describing relationship between consumption of calcium and reduction in risk of osteoporosis). The wording and placement of health claims are highly regulated.

The NLEA provisions explicitly authorizing health claims apply only to foods and to dietary supplements for human consumption. 21 U.S.C. § 343(r)(1); 21 C.F.R. § 101.14. FDA's Center for Veterinary Medicine (CVM) has stated that it has adopted the "philosophy" of the NLEA and might permit health claims on a case-by-case basis for some animal foods.<sup>1</sup> There is, however, no established framework for manufacturers to follow and those who have petitioned CVM to permit health claims for a particular animal product have found that CVM sets very restrictive standards.<sup>2</sup>

### **First Amendment Litigation**

Historically, FDA took the position that lawful health claims rose exclusively from the statutory grant of the NLEA. Only health claims authorized by procedures set forth in the NLEA and meeting the SSA standard were permissible. See 67 Fed. Reg. 78002 (Dec. 20, 2002); 21 CFR 101.14(c). However the agency's presumption in this regard was up-ended when the Court of Appeals for the District of Columbia Circuit held FDA could not constitutionally prohibit a product sponsor from making a substantiated, truthful, qualified health claim, even if the claim did meet the SSA standard of the NLEA. Pearson v. Shalala, 14 F. Supp.2d 10 (D.D.C. 1998), rev'd, 164 F.3d 650 (D. C. Cir. 1999), pet. for reh'g en banc denied, 172 F.3d 72 (D. C. Cir. 1999). Whitaker v. Thompson, 248 F.Supp.2d 1 (D.D.C. 2002), expanded upon Pearson, and held that FDA could not ban a truthful claim that was supported by good evidence, even if it was not supported by SSA or even by the preponderance of the evidence. FDA has come to recognize that Pearson cannot be

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<sup>1</sup> See Sharon Benz, Ph.D., P.A.S., Information For Consumers Food And Drug Administration Center For Veterinary Medicine, FDA's Regulation of Pet Food, available for download at: <http://www.fda.gov/cvm/index/consumer/petfoodfier.html>.

<sup>2</sup> CVM may also deem the animal product to be an unapproved food additive and require a lengthy premarket clearance application and approval process.

construed as limited solely to dietary supplements and has repeated that acknowledgement in other forums.<sup>3</sup>

The Better Nutrition Initiative and the accompanying guidance, Interim Procedures for Qualified Health Claims In the Labeling of Conventional Human Food and Human Dietary Supplements (Procedures Guidance), set out a constitutional procedure for FDA to follow that is consistent with Pearson and its progeny. What the Better Nutrition Initiative does not do is eliminate the artificial and arbitrary distinction between human foods and animal foods. As set out, the ANPR, like the Better Nutrition Initiative and the Procedures Guidance on which it is based, applies only to human foods and supplements.

### **Extending The Qualified Health Claims Rulemaking To Animal Foods**

Under Pearson and its progeny, and as FDA has acknowledged for human foods and supplements, the NLEA is not the sole vehicle for making a health claim. The Constitution protects and all of FDA (including CVM) must allow, qualified health claims that are substantiated, truthful and not misleading.

In spite of FDA's significant reforms of its health claim regulations and policies, CVM has failed to follow Pearson and Whitaker. CVM adheres to the position that animal foods may not bear qualified health claims for disease risk reduction:

When a substance, including one considered food, is intended to be used for the treatment or prevention of disease or "non-food" structure/function effect, [CVM] considers it a drug. Under the law, a new animal drug must be shown to be safe and effective for its intended use by adequate data from controlled scientific studies as part of a New Animal Drug Application [NADA] (21 CFR, Part 514). If a product on the market is not approved, it may be deemed an adulterated drug and subject to regulatory action.<sup>4</sup>

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<sup>3</sup> See Memorandum in Support of Defendant FDA's Motion to Dismiss, CSPI, etal. v. FDA, No. 03-962 (RBW) (D.D.C. Nov. 24, 2003) ("Although the Courts' holdings pertained to health claims for dietary supplements and not conventional foods, *the same First Amendment, statutory, and regulatory principles are applicable to health claims for both dietary supplements and conventional foods*") (emphasis supplied).

<sup>4</sup> See Benz, Ph.D., P.A.S., Information For Consumers Food And Drug Administration Center For Veterinary Medicine, FDA's Regulation of Pet Food, available for download at: <http://www.fda.gov/cvm/index/consumer/petfoodflier.html>.

While CVM has permitted health claims on animal foods in isolated cases, in AFIA's experience, the process is lengthy and very uncertain. There are no clear procedures to follow, no timetables for resolution, and agency determinations are usually not committed to writing. CVM rarely permits animal foods to make qualified health claims for reduction in the risk of future disease. In CVM's view, the NLEA does not apply to animal foods, and so that ends the matter, except when it decides otherwise, on an infrequent and *ad hoc* basis.

CVM should not and cannot continue to prohibit manufacturers of animal foods from making qualified health claims. In an era where FDA is moving beyond the paternalistic view that consumers cannot comprehend qualified health claim information, CVM's continuing restrictions stand as an unconstitutional and impractical holdover.

First, CVM's restrictions are not in accordance with the weight of constitutional authority. CVM may not rely upon the lack of an authorizing provision of the NLEA to justify its prohibitions upon qualified animal food health claims. The NLEA provides but one mechanism for approving certain health claims – those claims that are unqualified and supported by SSA. The United States Court of Appeals for the District of Columbia plainly held in Pearson, 164 F.3d at 655, that the First Amendment mandates FDA allow some health claims that do not meet the NLEA standards. In short, the NLEA is **not** the sole legal basis on which health claims rest.

Although Pearson and Whitaker deal with qualified health claims for human foods, these cases apply with equal force to qualified health claims for animal foods. FDA cannot ban outright qualified health claims for human foods simply because they do not comply with the NLEA. Neither may FDA automatically ban qualified health claims for animal foods.<sup>5</sup> Simply because there is no mechanism under the NLEA for animal foods to make unqualified health claims does not mean that there is no other mechanism for animal foods to make qualified health claims. The First Amendment requires that CVM allow animal foods to bear qualified health claims, irrespective of the NLEA.

Apart from the legal reasons why FDA cannot constitutionally prohibit qualified health claims on animal foods, there are compelling practical reasons as well. CVM's view has been that if a claim for an animal food, animal feed ingredient, or animal dietary supplement is of such significance, then the manufacturer can undertake the effort to obtain a NADA approval. Obtaining a NADA approval, however, is a costly prospect and unattractive business option. The typical NADA requires years of development, additional years of review within FDA, and entails millions of dollars in development and regulatory costs.

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<sup>5</sup> FDA could ban a qualified health claim as inherently misleading if FDA possessed data showing that consumers did not comprehend the qualified claim. Pearson, 164 F.3d at 656; Whitaker, 248 F. Supp.2d at 13.

Like human foods and dietary supplements, and unlike typical drugs, many of the ingredients in animal foods that could form the basis for substantiated qualified health claims are common dietary ingredients. The substances are usually vitamins, minerals, carbohydrates, fats, proteins, yeasts, enzymes, and proprietary mixes of these types of ingredients. For some of these ingredients, CVM has established by regulation that the substance is generally recognized as safe (GRAS) for consumption. Other food ingredients of natural biological origin, such as milk protein concentrates, fish oils and high lysine corn, although not specifically identified by CVM regulation as GRAS, have nevertheless been widely consumed for their nutrient properties for many years without ill effect.

Because these substances are generic and ubiquitous, they usually cannot be patented. Without the benefit of a long period of patent protection, a product sponsor who completes a NADA for a common, generic substance might only receive five years of marketing exclusivity. See 21 U.S.C. § 360b(c)(2)(F)(i). Five years is typically too short a time to recoup the millions of dollars in expenses necessary to bring the product to market under a NADA.

CVM's restrictions upon dissemination of qualified health claim information are especially problematic given the audience to whom many animal food health claims would be directed. In the case of animal foods for commercial use, specifically, animal feed, animal feed ingredients and feed supplements, qualified health claims would be targeted to a sophisticated audience -- farmers, ranchers, animal health nutritionists, and feedlot operators. These buyers understand the importance of nutrition in maintaining a food animal's health and they have the capacity (and economic incentive) to observe the product's efficacy or lack thereof in their own herds and flocks.

The parallel and often duplicative presence of State regulation creates an additional barrier for animal and pet food manufacturers and ingredient suppliers who wish to make qualified health claims. Some States go further than CVM and require that pet food and animal feed manufacturers and ingredient suppliers submit labels to state officials for approval and clearance. Some States will only permit claims on animal food labels and labeling if CVM has pre-approved the claim. In AFIA's experience, even in instances where CVM does not object to a label claim, it is often unwilling to commit to that position in writing -- which means that State officials will reject the label claim. The First Amendment applies to both federal and State restrictions upon commercial speech. FDA should educate State regulators on how the First Amendment applies to State restrictions upon animal food labeling as well.

There is broad and significant support for FDA to extend the qualified health claims rulemaking to animal foods. In May 2002 FDA issued a call for comments from interested persons on how FDA regulations, policies, and practices may violate the First Amendment to the U.S. Constitution. 67 Fed. Reg. 34942 (May 16, 2002). In the comments that were submitted, numerous

commentators addressed animal product claims.<sup>6</sup> These commentators all identified and criticized FDA's inconsistent policies that permit health claims for human foods, but prohibit the same sort of health claims for animal foods. They agreed that CVM's restrictions on health claims for animal feed, pet foods, feed ingredients, and animal dietary supplements violate the First Amendment. The qualified health claims rulemaking provides FDA with an excellent opportunity to rectify this significant, unconstitutional, and unfair restriction on animal foods.

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AFIA thanks FDA for this opportunity to comment. AFIA urges FDA to recognize the full implications of the Pearson and Whitaker decisions. There is no basis for limiting the application of those cases to human food and human dietary supplements. When the agency issues a proposed rule implementing a qualified health claims procedure, AFIA urges the agency to include animal feed, pet food, animal feed ingredients, and animal dietary supplements within the rulemaking.

Sincerely,



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<sup>6</sup> Commentators included the National Grain and Feed Association, the Pet Food Institute, Iams Company, American Pet Products Manufacturers Association, the American Feed Industries Association, and the joint comment of Julian M. Whitaker, M.D., Durk Pearson and Sandy Shaw, Pure Encapsulations, Inc., Wellness Lifestyles, Inc. Suarez Corporation Industries, Inc., Life Enhancement Products, Inc., and Life Extension Foundation. Comments may be viewed at [www.fda.gov/ohrms/dockets/dockets/02n0209/02n0209.htm](http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n0209.htm).