

SIDLEY AUSTIN BROWN & WOOD LLP

CHICAGO
DALLAS
LOS ANGELES
NEW YORK
SAN FRANCISCO

1501 K STREET, N.W.
WASHINGTON, D.C. 20005
TELEPHONE 202 736 8000
FACSIMILE 202 736 8711
www.sidley.com
FOUNDED 1866

BEIJING
GENEVA
HONG KONG
LONDON
SHANGHAI
SINGAPORE
TOKYO

WRITER'S DIRECT NUMBER
(202) 736-8684

WRITER'S E-MAIL ADDRESS
sbass@sidley.com

September 13, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0209

To Whom it May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the May 16, 2002 Notice, "Request for Comment on First Amendment Issues," 67 Fed. Reg. 34942 (2002).

NNFA is a trade association representing the interests of more than 3,000 retailers and 1,000 manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products throughout the United States. NNFA appreciates the opportunity to comment on this important issue. With the recent Thompson v. Western States Medical Center, 535 U.S. ___ (April 29, 2002), Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) and Washington Legal Foundation v. Henney, 13 F. Supp.2d 51 (D.D.C. 1998) decisions, NNFA believes that FDA's request for comments is timely. The First Amendment is critical for manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products who aim to communicate accurate health benefits of these products to consumers.

In 2001, dietary supplements represented a \$17.7 billion industry. The top 20 selling dietary supplements in 2001 included multivitamins and combination herbals, as well as the dietary ingredients glucosamine/chondroitin, essential fatty acids (fish oils, plant oils), CoQ10, echinacea, ginkgo biloba, garlic, ginseng, saw palmetto, and probiotics.¹ Americans with a variety of health concerns are seeking to actively participate in their own health maintenance by using supplements.² Thirty percent of these Americans get their information about dietary supplements from books or magazines, while another nineteen percent attain information from health food stores.³

02N-0209

C 28

¹ Nutrition Business Journal, 2002.

² "Condition-Specific Supplement Markets," Nutrition Business Journal (November 2001).

³ NNFA, Consumer Survey on Supplement Usage, August 2000.

Dockets Management Branch (HFA-305)
September 13, 2002
Page 2

As outlined by the courts, the First Amendment mandates that government schemes regulating commercial speech pass a three-part test. In brief, first the asserted government interest must be substantial; second, the government regulation must *directly* advance the governmental interest asserted; and third, there must be a reasonable fit between the government interest and the means chosen to accomplish it. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980). Government regulations that do not meet this test may be in violation of the First Amendment.

There have been three decisions in recent years applying these principles to FDA regulatory schemes, Thompson v. Western States Medical Center, Pearson v. Shalala, and Washington Legal Foundation v. Henney. Collectively, these cases establish that under the First Amendment parties may not be required to obtain government assent prior to engaging in truthful, non-misleading speech about lawful activities. "If the Government can achieve its interests in a manner that does not restrict commercial speech, or that restricts less speech, the Government must do so." Thompson v. Western Medical Center, 535 U.S. at ___.

A. **Structure/Function Claims on Dietary Supplements**

NNFA believes that the freedom to communicate information about dietary supplements is critical to the health of the American people and is protected by the First Amendment. Congress agreed with this position, stating in the preamble to the Dietary Supplement Health and Education Act of 1994 ("DSHEA") that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements" and that "there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health." 21 U.S.C. §321.

FDA's current policy on structure/function claims, set forth in the final rule "Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body,"⁴ is not consistent with the goals of DSHEA, consumer interest, or the First Amendment principles of commercial speech. The rule uses a broad definition of "disease" to identify types of statements that are unavailable as structure/function claims. 21 C.F.R. §101.93(g)(1). FDA takes the position that dietary supplements may not mention disease states even in the context of prevention or health maintenance and attempts to lay out a framework for distinguishing disease claims from structure/function claims. It is worth noting that even after 50 pages of discussion in the Federal Register, this distinction remains confused and unclear.

By attempting to restrict structure/function claims in this way, FDA effectively prevents companies from accurately reflecting scientific research on dietary supplement ingredients. For example, though a company may have scientifically valid studies showing

⁴ 65 Fed. Reg. 1000 (January 6, 2000), implementing 21 C.F.R. §§101.93(f) and (g).

Dockets Management Branch (HFA-305)
September 13, 2002
Page 3

that zinc tempers the symptoms of the common cold, claims may not mention the term "cold" even if there is no mention of diagnosis, cure or treatment of disease. Given that the common cold is a "normal physiological process" of the human condition – as are constipation or menopause⁵ – it makes no sense that it cannot be raised in a structure/function claim.

As such, the regulation prevents companies from communicating truthful and non-misleading information about the non-drug effects of dietary supplement products.⁶ Rather than facilitating the communication of health information to consumers, the regulation forces consumers to look to alternative – often conflicting – sources of information, including the internet, newspapers, and popular health books.

Ultimately, the restrictions on structure/function claims are inconsistent with the commercial speech protections of the First Amendment, which require a substantial government interest that is reasonably related to the restrictions placed on speech. FDA's interest in preventing dietary supplements from making drug claims without going through the "new drug approval" process is substantial. However, as required under Central Hudson, the restrictions on structure/function claims at present are not reasonably related to that interest.

NNFA agrees with FDA's goal in maintaining a clear distinction between dietary supplement claims and those that claim to diagnose, cure or treat disease. However, NNFA takes the position that the current interpretation of the structure/function rule should be revised to allow dietary supplement companies to communicate accurate information about prevention and health maintenance to consumers even if this means that dietary supplements mention a condition such as a cold. In addition, appropriate qualifying language or disclaimers could be allowed, where necessary, to ensure that the public receives non-misleading information about the health effects of products. See Pearson v. Shalala, 164 F.3d at 656. The Federal Trade Commission ("FTC") has already embraced this approach with respect to dietary supplements, "Dietary Supplements Advertising Guide For Industry," FTC, 1999, and consumer health would benefit if FDA followed suit.

⁵ In the preamble to the final rule, FDA states that claims regarding "mild conditions" associated with particular stages of life or normal disease physiological processes will not be considered disease claims. 65 Fed. Reg. at 1020. FDA's January 6, 2000 structure/function rule permits claims about both constipation and menopause as long as the text clarifies that use is for occasional problems and not disease indications.

⁶ The limits on structure/function claims result in some bizarre situations. For example, FDA has said that claims about the inhibition of platelet aggregation or promotion of low blood pressure are drug claims. However, the agency permits dietary supplements to bear the seemingly more aggressive statement, "supports the cardiovascular system by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation." 65 Fed. Reg. 1030.

Dockets Management Branch (HFA-305)
September 13, 2002
Page 4

B. Structure/Function Claims on Conventional Foods

NNFA also takes the position that the current arbitrary restriction on the use of structure/function claims on non-nutritive ingredients in foods stands in the way of the First Amendment goal of communicating truthful and non-misleading information to consumers. At present, structure/function claims on foods are only permitted on conventional foods when the ingredient that serves as the basis of the claim is deemed to have "nutritive value." 65 Fed. Reg. 1034.

FDA's approach arguably stems from the Federal Food Drug and Cosmetic Act ("FFDCA") definition of drug as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. (g)(1)(C)(emphasis added). The parenthetical carve out indicates that under the FFDCA foods may be positioned to affect the structure or any function of the body of man or other animals without being categorized as drugs.

Statutorily, the scope of the carve out is limited only by the definition of food. Food is defined in the FFDCA as "articles used for food or drink for man or other animals . . . and articles used for components of any such article." 21 U.S.C. (f)(1)(emphasis added). However, because of the circularity of this definition, FDA has opted to look for further guidance to a non-statutory interpretation of the FFDCA food definition, which was articulated in Nutrilab v. Schweiker, 713 F.2d 335 (7th Cir. 1983). That interpretation states that: "substances used for food are those consumed either for taste, aroma, or nutritive value."

FDA has used this reading of the statute to limit structure/function claims on foods to those relating to ingredients that provide "nutritive value."⁷ However, this restriction is non-statutory and has arbitrary results. In reality, foods consist of many ingredients such as processing aids, emulsifiers and preservatives that are not present for "taste, aroma or nutritive value." The Nutrilab definition of food thus does not adequately characterize the range of potential ingredients and its use imposes an unfounded restriction on the types of ingredients permitted as the basis of structure/function claims.

In addition, it makes no sense to allow ingredients to be present in dietary supplements with appropriate structure/function claims and not allow the same claims to be used for the same ingredients in foods provided that the relevant safety standards are met. This regulatory inconsistency is potentially misleading for consumers who read structure/function statements when an ingredient is included in a dietary supplement but do not see the information when the same ingredient appears in a food. In addition, the legitimacy of such claims for dietary supplements undermines any potential FDA argument

⁷ In its January 6, 2000 regulation, "Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body," FDA clarified that the same range of structure/function claims would be available to foods as long as the ingredients met safety standards and had nutritive value. 65 Fed. Reg. 1034.

Dockets Management Branch (HFA-305)
September 13, 2002
Page 5

that the limits on structure/function claims for foods are based on concerns about safety or consumer comprehension of the information.

Ultimately, FDA's policy that structure/function claims on foods are limited to those ingredients having "nutritive value" does not meet the Central Hudson three-part test. FDA has not offered a substantial government interest in maintaining the restriction. Further, the existence of structure/function claims for the same ingredients when present in dietary supplements would seemingly contradict any government interest in safety or preventing consumer confusion.

The potential health benefits of added ingredients in food are great. NNFA therefore asks FDA to revise its policy so that structure/function claims for which a manufacturer has substantiation are available for the full range of safe ingredients in foods.

C. Nutrient Content Claims

Lastly, NNFA believes that FDA's position on the use of the Nutrient Content Claims "contains," "with" and "provides" on dietary supplements is unduly restrictive of speech.

The Nutrition Labeling and Education Act of 1990 ("NLEA") provided for the use of claims characterizing the level of a nutrient in foods, as long as the claim had been specifically defined by FDA.⁸ In regulations pursuant to NLEA, FDA limited the use of nutrient content claims on dietary supplements, including "good source," "high" and "more," to products comprised of vitamins or minerals. FDA's action was based on its view that most supplements are comprised of vitamins and/or minerals already meeting the RDI/DRV levels required for "good source," "high" and "more" claims, and that therefore such claims would be of limited utility for making comparisons between supplements.⁹ "Food Labeling; Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs and Other Similar Nutritional Substances," 58 Fed. Reg. 33731, 33741 (1993).

While this is a reasonable approach for dietary supplements composed of vitamins or minerals, it makes no sense for the range of dietary ingredients now present in dietary supplement products. As noted above, only 10 of the 25 most popular dietary supplements on the market are vitamins or minerals; the majority of dietary supplements sought by consumers contain other dietary ingredients that do not have RDIs or DRVs

⁸ Nutrition Labeling and Education Act of 1990, 21 U.S.C. §§ 301, 321, 337, 343, 371 (1994).

⁹ According to FDA's regulations, "good source" is correlated to an RDI/DRV of 10-19%. FDA also established synonyms for the range of nutrient content claims. Thus, for example, the terms "contains," "provides" and "with" were identified as synonyms of "good source" and therefore would also require 10-19% RDI/DRV.

Dockets Management Branch (HFA-305)
September 13, 2002
Page 6

sought by consumers contain other dietary ingredients that do not have RDIs or DRVs associated with them.¹⁰ FDA's interpretation of NLEA means that these dietary supplement companies may not use claims such as "good source of," "with," "contain" or "provides" on product labels. Without the use of these claims, companies are frustrated in their ability to communicate truthful information about products to health-conscious consumers.¹¹

FDA's justification for its current rule is that, assuming dietary supplements are vitamins and/or minerals, claims such as "good source" and established synonyms are not useful in labeling. 58 Fed. Reg. at 33741. This reasoning is out of date and does not reflect the broadening of dietary supplements beyond vitamins and minerals, and the current usage patterns noted above. On these dietary supplements, "good source" claims would only be used to indicate the presence of a dietary ingredient. Moreover, it would be easy to require a disclaimer adjacent to any such claims, stating that there is no RDI/DRV for the ingredient.

FDA's restriction on the use of these nutrient content claims for dietary supplements does not constitute a substantial government interest required by Central Hudson. Instead, the provision frustrates the ability of dietary supplement companies to engage in truthful, non-misleading speech to consumers. NNFA therefore asks that FDA reconsider this position.

Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION
Mark Stowe, President
David Seckman, Executive Director

SIDLEY AUSTIN BROWN & WOOD LLP
General Counsel

By Scott Bass/amp
Scott Bass
Emily Marden

¹⁰ Nutrition Business Journal, 2002.

¹¹ NNFA recognizes that DSHEA provides for the use of percentage claims on dietary supplements (e.g., "contains X% of Echinacea"), 21 U.S.C. § 343(r)(2)(F)(i). However, these claims are generally uninformative and confusing from a marketing perspective in communicating content information to consumers.

SCOTT BASS
SIDLEY AUSTIN BROWN WOOD LLP
797 SEVENTH AVE. FLR 22
NEW YORK NY 10019

SHIP DATE: 12SEP02
ACC # 010017998
ACTUAL WGT: 1 LBS SCALE

(212)839-4750

TO: DOCKETS MANAGEMENT BRANCH
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE
ROOM 1061
ROCKVILLE MD 20852

6098 3932 8040

FedEx BILL THIRD PARTY

REF: 99910-12471-10010 L.G

PRIORITY OVERNIGHT FRI.

cad # 0689858 12SEP02

Deliver by:

TRK# 6098 3932 8040

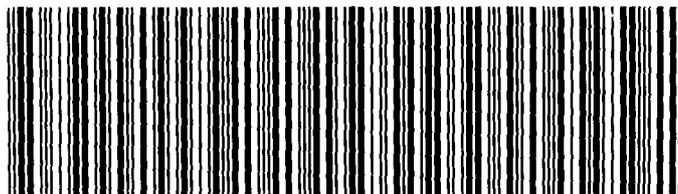
FORM
0201

13SEP02

IAD AA

20852 -MD-US

ZM GAIA



153078 NRT 4/02