

July 1, 2008

Dr. Steven F. Sundlof, D.V.M. Ph.D. Director Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

Dear Dr. Sundlof:

The Center for Science in the Public Interest (CSPI) requests that the Food and Drug Administration (FDA) take enforcement action to halt false and misleading "structure/function" claims for numerous food products that dishonestly claim to protect immunity, nourish the brain, support a healthy digestive system, or protect cartilage and joints. Such products are misbranded under §§ 403(a) and 201(n) of the Federal Food, Drug and Cosmetic Act (FDCA).

CSPI is requesting that the FDA: (1) issue warning letters to the companies named in this complaint letter; (2) disseminate a letter to the food industry clarifying the substantiation standard for structure/function claims for foods; and (3) establish a "safe harbor" list of permissible structure/function claims for conventional foods.

I. Background

Food manufacturers have been permitted to make claims that a food can "affect a structure or any function of the body" since 1938. Until recently, such claims for food were rare. However, as structure/function claims for dietary supplements began to proliferate, food manufacturers have increasingly sought to make such claims as well.

Dietary supplement sales soared when Congress expressly permitted structure/function claims for those products.² The FDA helped fuel this trend when the Agency established a policy of only taking enforcement action against false or misleading structure/function claims for dietary supplements if they presented a safety issue and/or were being marketed with unapproved drug claims.³ The General Accounting Office, now the Government Accountability Office

¹ FDCA § 201(g)(1)(C), 21 U.S.C. § 321(g)(1)(C).

² Dietary Supplement Health and Education Act, Pub. L. 103-417.

³ See, FDA, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body: Final Rule, 65 Fed. Reg. 999, 1003 (Jan. 14, 2000) [hereinafter Final Rule on Structure/Function Claims].

(GAO), reported that the FDA's "review of dietary supplement labels does not address whether the company has adequate evidence to support the structure/function claim in the first place."

Over the last several years, food manufacturers have increasingly begun to utilize structure/function claims to market conventional foods on the basis of health. Many companies prefer them to "health claims" that must be preapproved by the Agency and meet the "significant scientific agreement" standard, which is a much higher standard than the "competent and reliable evidence" standard the FDA has applied to structure/function claims for supplements.⁵

By definition, structure/function claims are not permitted to refer to a disease, but through clever wordsmithing, food manufacturers can imply disease prevention or treatment. The FDA catalyzed this troublesome trend by creating hairsplitting distinctions between permissible and impermissible claims (with respect to dietary supplements). For example, claims such as: "helps maintain regularity," are permitted on dietary supplement labels but, statements like "prevents and treats chronic constipation," are considered impermissible disease prevention claims.⁶

A study by the industry-funded International Food Information Council (IFIC) concluded that:

Consumers do not perceive a difference among unqualified textual health claims, structure-function claims, and dietary guidance statements with respect to scientific evidence.⁷

The FDA's own research on supplement labeling demonstrates that:

[T]here was no indication that participants differentiated at all between structure/function and health claims. ⁸

Because consumers cannot distinguish between structure/function claims and health claims, the FDA should apply the same evidentiary standards for their use. This has been a longstanding problem that FDA has largely ignored. In a report published more than seven years ago discussing, *inter alia*, conventional foods sold as functional foods, the GAO recommended that the FDA "develop and implement a strategy for identifying and taking appropriate enforcement actions against companies marketing products with unsupported structure/function claims on

⁴ Report to Congressional Committees, Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods." (GAO/RCED-000-156 July 2000) at 21 [hereinafter *GAO Report*].

⁵ FDA, Guidance for Industry, Substantiation for Supplement Claims Made under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. (Draft) 69 Fed. Reg. 64962 (Nov. 9, 2004) [hereinafter Guidance].

⁶ See, Final Rule on Structure Function Claims, supra note 3, at 1015.

⁷ *Qualified Health Claims Consumer Research Project*, March 2005 at 12, *available at* http://www.ific.org/research/qualhealthclaimsres.cfm.

⁸ GAO Report, supra note 4, at 23, quoting unnamed report of FDA research conducted in August 1999.

their labels." More recently, House and Senate Appropriations Committees have also urged the FDA to take enforcement action against false or misleading claims to maintain the integrity of the food label and retain consumer confidence in its accuracy. ¹⁰

The FDA has failed to adequately heed those recommendations. As a result, the supermarket aisles are filled with structure/function claims for foods that are basically lies. The claims discussed in this complaint illustrate the need for the FDA to take enforcement actions and notify the industry of the Agency's overall enforcement policy on this issue.

II. Examples of Misleading Structure/Function Claims that Constitute Misbranding

A. False or Misleading Claims that a Food Can Help the Immune System

Many major companies—including Dole, Kraft Foods, and General Mills—are selling foods with labels that claim that the foods contain vitamins that help maintain a healthy immune system and, implicitly, prevent illnesses ranging from the common cold to HIV-AIDS. Scientific studies indicate that the amounts of vitamins found in these foods provide little or no benefit to the immune systems of the average consumer. We urge the FDA immediately to warn Dole, Kraft, and General Mills that the Agency will seize their products unless these claims are promptly removed.

1. Description of Specific Claims

• Dole Packaged Foods' Wildly Nutritious Tropical Fruit states on its label: "Each serving of Dole Wildly Nutritious Immunity Blend provides essential vitamins and nutrients that help support a healthy immune system. Vitamin C has been shown to enhance white blood cell function, which is important to maintaining a healthy immune system. Vitamin A helps support the body's first line of immune defense: the maintenance of cells lining the airway, urinary, and digestive tracks. Vitamin A, in the form of beta carotene, plays an important role in the development of white blood cells, which help protect the body against viruses and bacteria." See Attachment A.

Each ¾-cup serving of Dole's tropical fruit contains 10 percent of the Daily Value (DV) of vitamin A and 110 per cent of the DV of vitamin C. In response to a query from CSPI about the scientific evidence that eating this fruit blend will affect the immune system of consumers, a Dole representative did not cite any specific research, but said about the fruits' vitamin C: "In the Institute of Medicine's DRI [Dietary Reference Intakes] report for vitamin C, they quote that the antioxidant functions of vitamin C helps [sic] scavenge reactive oxidants from white blood cells which are your immune cells If you keep that up, that can seriously impact your immunity Vitamin C is a water-soluble vitamin and you eat it and it goes into your body pretty quickly and it can also leave your

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⁹ *Id.* at 27.

¹⁰ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2006, S. Rep. No. 109-92 at 153 (2005), H. Rep. No. 109-102 at 83 (2005).

body pretty quickly, too. So, it's one of these vitamins you need to keep topping up on all the time Vitamin C is one of the things a lot of people don't get enough of . . ."¹¹

- Kraft Foods' Crystal Light Immunity Diet Beverage claims on its label that its "Vitamins A, C, E Helps [sic] Maintain a Healthy Immune System." Similarly, Kraft Foods' Fruit₂O Immunity Nutrient Enhanced Water Beverage claims on the label that it contains vitamin A and antioxidants C and E to help maintain the immune system." See Attachments B for labels of the products. An 8-ounce serving contains 10 percent of the DV for vitamins A and C and 20 percent of the DV for vitamin E. In response to a query from CSPI, Kraft said: "We do not expect, or claim, that consumption of Crystal Light Immunity and Fruit₂O Immunity will—in and of itself—significantly impact immune function. Consumed as part of a healthy, balanced diet, however, we believe the added Vitamins C, E and A in these products can supplement consumers' intake of these important nutrients and in so doing 'help maintain a healthy immune system,' as the labels state." ¹²
- General Mills' Green Giant Immunity Boost states on its label: "naturally rich in antioxidants, Vitamins A & C to help support a healthy immune system." See Attachment C. Each 2/3-cup serving contains 30 percent of the DV of vitamin A and 50 percent of the DV of vitamin C. General Mills stated, in response to a query from CSPI, that "it is well documented that vitamin A & vitamin C play an important role in supporting immune function . . . In the immunity boost product, General Mills carefully selected vegetables that deliver 30% of the Daily Value for vitamin A and 50% of the Daily Value of vitamin C per serving." "We used the word 'boost' to convey to consumers that eating our product will provide essential nutrients (vitamins A and C) that assist the immune function. Per USDA/HHS Dietary Guidelines for Americans 2005, dietary intake levels of vitamin A and C are of concern for adults. This product can contribute to dietary adequacy ('boost') of vitamin A and C nutrients that support immune function."

To better understand what consumers believe a structure/function claim means, CSPI recently conducted via e-mail a survey of about 1,200 fairly knowledgeable consumers. The survey participants were shown the label for Green Giant Immunity Boost frozen vegetables, which bears the claim that it is "naturally rich in antioxidants Vitamins A & C to help support a healthy immune system," and were asked what this label means. Of the 1,155 who responded, 49.1 percent said the immunity claim means that the food "helps prevent colds and the flu," 22.8

¹¹ Telephone call from the Dole Nutrition Institute to CSPI on August 31, 2007.

¹² Email from Bridget A. MacConnell to CSPI dated September 7, 2007.

¹³ Email from Pam Becker to CSPI dated September 12, 2007.

¹⁴ Email from Pam Becker to CSPI dated September 21, 2007.

percent answered that the food "helps prevent cancer," 4.2 percent said the food "helps prevent AIDS," and 32.9 percent answered that it "helps the body in some other way." See Appendix I. 15

2. Scientific Studies Show that Additional Vitamins do not Affect the Immune System of Most Consumers

Vitamins A, C, and E are important for the functioning of the immune system (and practically every other system in the body). However, supplementing the diet with those vitamins in the amounts found in foods making immunity-supporting claims has little or no impact on the immune system of healthy persons, according to the scientific research. And most studies have failed to demonstrate that contrasts in the quality of dietary intake translate into measurable differences in chronic immune function among health individuals. See Appendix II. Very high doses of antioxidants may even increase the risk of premature death.

There is no consistent evidence that vitamin A supplementation is beneficial for the immune function of adults and the elderly. ¹⁹ In fact, supplemental vitamin A might worsen respiratory illnesses, particularly among children who are not malnourished. ²⁰

The innate immunity system, the rapidly activated first line of defense against pathogens, includes mast cells, phagocytes, and natural killer cells. Adaptive immunity uses T- and B-cell lymphocytes and antibodies in an antigen-specific manner. The effect of vitamin C on innate and adaptive immunity is negligible or uncertain, according to experts in the field.²¹ As for

¹⁵ Survey conducted from January 17, 2008, to June 9, 2008, of CSPI list-serve members, who are more interested in food and health than the average person.

¹⁶ Very large doses of vitamin E might strengthen the immune system of frail elderly people, but they are not the intended market for the products at issue, as discussed later.

¹⁷ Letter to Barbara Schneeman, PhD., from Drs. Neiman, Potter, and Ulrich, June 30, 2008.

¹⁸ In a recent Cochrane Collaboration review of 47 high-dose antioxidant supplementation trials with nearly 181,000 participants, beta-carotene (mean dose of 19 mg), vitamin A (mean dose of 26,833 IU), and vitamin E (mean dose of 566 IU), singly or combined, significantly increased mortality. *Journal of the American Medical Association*, 2007; 297:842-857.

¹⁹ "There is limited research on the effects of vitamin A supplementation to adults and the elderly on their immune function; currently available data provide no consistent evidence for beneficial effects." Eduardo Villamor and Wafaie W. Fawzi: Effects of vitamin A supplementation on immune responses and correlation with clinical outcomes. *Clinical Microbiology Reviews*. 2005; 18:446-64, at 460.

²⁰ Very large doses of vitamin A have decreased measles morbidity, the severity of diarrhea, and malarial episodes in children in the developing world. But vitamin A may be counter-productive for well-nourished children and adults. "Most hospital-based studies on vitamin A supplementation and the severity of pneumonia have not shown significant overall effects. In fact, some of the hospital-based studies suggest an apparent increase in indicators of severity associated with vitamin A supplementation. A number of community-based trials have also shown an apparent increase in respiratory symptoms in relation to vitamin A supplementation, particularly among children who are not malnourished." Villamor and Fawzi, at 460.

²¹ "Whether vitamin C supplementation has an effect on counts of innate immune cells is uncertain....Lymphocyte counts do not appear to be influenced by vitamin C supplementation....Similarly, supplementation does not appear to

immunity against illness, a few studies have found that very large doses of vitamin C, far in excess of what is found in food, taken daily and prophylactically might reduce slightly the duration, but not the incidence, of respiratory infections.²²

Evidence that vitamin E affects innate or adaptive immunity is limited to the use of large amounts (233-800 mg) in older populations (that segment of the population is certainly not the focus of marketing campaigns for the products of concern and discussed below). (Kraft Foods' Crystal Light Immunity Diet Beverage contains just 6 I.U. or 4 mg of vitamin E.) As for protection against illness, some evidence suggests that large amounts (134-200 mg) can reduce the incidence, but not the severity or duration, of respiratory infections in the elderly. There are no studies showing it can do the same in children or non-elderly adults.²⁴

Combinations of supplemental vitamins A, C, and E do not appear to affect the immune system of the elderly.²⁵ And there is little evidence that combinations of these vitamins can prevent illness in healthy children or non-elderly adults.²⁶

To test whether supplemental nutrients, including vitamins A, C, and E, could prevent illness, researchers in five countries—Canada, Scotland, the Netherlands, France, and the United States—gave multivitamins or placebos to more than 2,300 healthy men and women aged 60 and

influence concentrations of circulating immunoglobulins." Aimee L. Webb and Eduardo Villamor: Update: Effects of antioxidant and non-antioxidant vitamin supplementation on immune function. *Nutrition Reviews*, 2007; 65:181-217, at 201.

²² "Several controlled studies suggest a small benefit of vitamin C supplementation at doses ranging from 1,000 to 8,000 mg/d in reducing the duration, but not the incidence, of respiratory infections; a greater benefit seems apparent in children....The potential role of vitamin C supplementation in non-respiratory infections has not been characterized in RCTs [Randomized Controlled Trials]." Webb and Villamor, at 201.

²³ "Current evidence from RCTs does not support a consistent role for vitamin E supplementation in influencing counts of innate immune cells, with the exception of increased neutrophil counts in older populations....Some studies suggest that vitamin E supplementation enhances cell-mediated adaptive immunity in older populations....The effects of supplementation on various parameters of adaptive immunity in non-elderly populations are less clear due to a lack of RCTs." Webb and Villamor, at 196.

²⁴ "Findings from the three RCTs, however, do not support a role for vitamin E supplementation in reducing the duration or severity of respiratory infections in elderly populations or smokers. Reductions in the incidence of the common cold were observed in two of the three studies conducted in elderly persons." Webb and Villamor, at 196.

²⁵ "In controlled studies among elderly populations, antioxidants provided in combination did not appear to influence the number or function of cells of the innate or adaptive arms of the immune system." Webb and Villamore, at 211.

²⁶ "One study of therapeutic antioxidant vitamin supplementation in children with acute lower respiratory infection did not demonstrate an effect on cell-mediated immunity or measures of severity or duration of respiratory illness.... Most of the studies investigating the influence of antioxidant vitamins on specific parameters of immune function have largely been conducted in adult or elderly populations who were exposed to oxidative stress or were immunologically compromised." Webb and Villamor, at 211.

older and tracked them for up to 18 months. Those taking the supplements did not have any fewer illnesses, days sick, or hospital visits than those who got the placebos.²⁷

In summary, there is little or no evidence that the nutrients that Dole, Kraft, and General Mills tout as supporting the immune system have any significant effect on innate or adaptive immunity or on the incidence, severity, or duration of illness. Further, CSPI's survey indicates that many consumers are mislead into thinking that products bearing immunity claims on the label provide a significant health benefit, such as preventing colds, cancer, and even AIDS, when that is not the case.

B. False or Misleading Claims that a Food Can Support the Digestive System

• Welch's Fiber 100% Grape Juice: The principal display panel (PDP) carries the word "fiber" in large type. The information panel states that the product provides "A good source of fiber to help support a healthy digestive system." See Attachment D.

However, juices – other than prune juice – have little or no naturally occurring fiber. To increase the fiber level, manufacturers add maltodextrin, a chain of sugars not quite long enough to be a starch. According to a 2005 report by the National Academy of Sciences, "there are no human studies to support a laxative benefit from ingestible dextrins;" ²⁸ a few small studies have produced inconsistent results.

C. False or Misleading Claims that a Food Can Support Brain Function

• Minute Maid Enhanced Juice Blend Omega-3 DHA Pomegranate Blueberry Flavored Blend of 5 Juices: The PDP states: "OMEGA-3/DHA HELP NOURISH YOUR BRAIN 5 NUTRIENTS TO SUPPORT BRAIN & BODY." See Attachment E.

At least seven observational studies have examined the association between cognitive function and the omega-3 levels in the blood or the fish consumption among older adults. Some of these studies found a link, and some did not. There are no published randomized controlled trials testing the effect of omega-3s on cognitive function in healthy adults. One trial in schoolage children failed to find an effect.²⁹

In addition, the five nutrients that are the subject of claims on the information panel do not support the underlying claim: "Vitamin C is highly concentrated in brain nerve endings." Three randomized controlled trials have tested the effect of vitamin C on cognitive function in healthy adults. None of these found an effect. ³⁰ "Antioxidant vitamin E may help shield the

²⁷ J Am Geriatr Soc 2007, 55:35; BMJ 331: 324, 2005; JAMA 288: 715, 2002; Int J Vitam Nutr Res 1993; 63:11; Ann Intern Med 2003; 138:365.

²⁸ National Academy of Sciences, Food and Nutrition Board, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (Macronutrients) (2005).

²⁹ Am J Clin Nutr. 2007 Oct; 86(4):1082-93.

³⁰ Nutr J. 2007; 6:10; Prev Med. 2005; 41(1): 253-9; Neurology. 2004; 63(9): 1705-7. Nutr J.

omega-3s in the brain from free radicals." Five randomized controlled trials have tested the effect of vitamin E on cognitive function in healthy adults. None of these found an effect. 31 "Choline and B_{12} play a role in brain and nervous system signals." Two randomized controlled trials have tested the effect of choline on cognitive function in healthy adults. One found no effect after exhaustive physical activity. 32 One found that two days of taking a large 10 g dose of choline improved serial learning, recall, and memory in men. 33 And ten randomized controlled trials have tested the effect of vitamin B-12 on cognitive function in healthy adults. Nine of these found no effect. 34 A tenth study found an effect on just one of 16 measures of cognitive function and memory. 35

Thus, claims that the juice will nourish the brain are false and misleading.

D. False or Misleading Claims that a Food Can Maintain Healthy Joints

• Minute Maid Enhanced Juice Active 750 mg Glucosamine HCL: Minute Maid Claims on the PDP that this product is designed "to help protect healthy joints." The information panel states: "Glucosamine helps protect cartilage and joints from the stress of normal daily activities." See Attachment F.

The form of glucosamine used in this beverage, glucosamine hydrochloride, does not relieve the symptoms of osteoarthritis. The most recent review of the 15 best studies of glucosamine and osteoarthritis concluded that "glucosamine hydrochloride is not effective." In the largest study of glucosamine, funded by the National Institutes of Health, glucosamine hydrochloride did not reduce pain in patients with osteoarthritis of the knee. 37

Such claims are, therefore, false and misleading.

³¹ Nutr J. 2007; 6:10; Arch Intern Med. 2006; 166(22): 2462-8; Prev Med. 2005; 41(1): 253-9; Neurology. 2004; 63(9): 1705-7; Drugs Aging. 2002; 19(10): 793-805.

³² Mil Med. 2002; 167(12): 1020-5.

³³ Life Sci. 1978; 22(17): 1555-60.

Nutr J. 2007; 6:10; Br J Nutr. 2007; 98(5): 960-8; Am J Clin Nutr. 2006; 84(2): 361-70; N Engl J Med. 2006;
 354(26): 2764-72; Prev Med. 2005; 41(1): 253-9; Am J Clin Nutr. 2005; 82(6): 1320-6; Am J Clin Nutr. 2005; 81(5): 1155-62; J Affect Disord. 2004; 81 (3): 269-73; Int J Geriatr Psychiatry. 1998; 13(9): 611-6.

³⁵ J Nutr. 2002; 132: 1345-56.

³⁶ Arthritis Rheum. 2007: 56: 2267-77.

³⁷ N Engl J Med. 2006, Feb 23; 354 (8): 795-808, available at http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3051&itool=AbstractPlus-def&uid=16495392&db=pubmed&url=http://content.nejm.org/cgi/pmidlookup?view=short&pmid=16495392&promo=ONFLNS19.

III. Recommendations

A. The FDA Should Take Enforcement Action

Dishonest structure/function claims mislead consumers with regard to serious health matters and threaten the integrity of the food label. Section 403(a)(1) of the FDCA states that "a food shall be deemed to be misbranded if its labeling is false or misleading in any particular." Section 201(n) of the FDCA provides, in pertinent part, that:

[I]n determining whether the labeling . . . is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . thereof or under such conditions of use as are customary or usual.

21 U.S.C. §343. The structure/function claims discussed here mislead consumers both expressly and by implication. We, therefore, urge the FDA to order the companies to promptly remove the dishonest claims from the labels of the products named in this complaint.

B. The FDA Should Issue an Industry-Wide Letter Clarifying the Substantiation Standard for Structure/Function Claims for Foods

The FDA should warn the food industry of its obligations to comply with the law by issuing an industry letter setting forth the substantiation standard for structure/function claims for foods. The last "Dear Manufacturer" letter the FDA issued on structure/function claims for foods in January 2007³⁸ failed to specify a substantiation standard for such claims, simply noting that they be truthful and not misleading. The FDA's failure to specify a substantiation standard has effectively granted food manufacturers carte blanche to make any claims they want.

1. The FDA should require structure/function claims for foods to meet the same standard as health claims for foods

Both FDA and food industry studies³⁹ demonstrate that consumers do not differentiate between structure/function claims for foods made pursuant to § 201(g)(1)(C) of the FDCA (which exempts structure/function claims for foods from the definition of a "drug"), and health claims for foods made pursuant to § 403(r)(3)(B) of the Act. To prevent deception, the FDA should, therefore, subject structure/function claims for conventional foods to the evidentiary

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³⁸ Dear Manufacturer Letter Regarding Food Labeling (Jan. 30, 2007), http://www.cfsan.fda.gov/~dms/flguid.html. Accessed June 5, 2008.

³⁹ *Supra*, n. 7.

standard used for health claims for foods. That standard is "significant scientific agreement," 21 U.S.C. §403 (r)(3)(B). 40

In addition, the FDA should require that structure/function claims for foods meet the "significant scientific agreement" standard to: 1) preserve order within the food industry; 2) restore integrity to the food label; 3) clarify the limited applicability to foods of FDA's regulations and draft guidance documents pertaining to dietary supplements; and 4) establish a proactive regulatory policy to ensure that all structure/function claims for foods, not just the most egregious examples named in this complaint, are scientifically valid.

2. The FDA should not apply its substantiation standards for dietary supplements to structure/function claims for conventional foods

In its 2000 regulation addressing structure/function claims for dietary supplements, ⁴¹ the FDA stated in passing that such claims must be "supported by adequate scientific evidence" noting that "[I]n response to a request for substantiation for the statement, the agency would expect manufacturers to provide a requester with contrary as well as supporting studies." ⁴² Later, in 2004, the FDA issued "Draft Guidance" on how to comply with the Agency's policy on substantiating structure/function claims for supplements. However, the FDA stated in both its *Guidance* document and the *Federal Register* notice announcing its availability that the draft policy "does not extend to substantiation issues that may exist in other sections of the Act." (emphasis added). ⁴³ Thus the FDA's "Draft Guidance" for substantiating structure/function claims for supplements does not – and for the reasons explained below – should not apply to structure/function claims for foods. ⁴⁴

⁴³ *Guidance, supra* note 5, at 2; 69 Fed. Reg. at 64963. We further note that the Guidance is in "draft" form and therefore carries little weight with regard to dietary supplements, let alone any other products regulated by the FDA.

⁴⁰ In 2002, the FDA began allowing so-called "qualified health claims" for conventional foods that were not supported by "significant scientific agreement." *See* 68 Fed. Reg. 66040 (Nov. 25, 2003), 68 Fed. Reg. 41387 (July 11, 2003), 67 Fed. Reg. 78002 (Dec. 20, 2002). Congress has urged the Agency to abandon that policy. 153 Cong. Rec. H 15765 (daily ed. Dec. 17, 2007).

⁴¹ *Supra*, n. 3. The FDA's 2000 regulation was intended only to prevent supplement manufacturers from making unapproved drug claims under the guise of structure/function claims. For example, the FDA said: "the claim that vitamin A is necessary to maintaining a healthy immune response does not imply that a specific disease or class of diseases will be prevented," but that "supports the body's antiviral capabilities" implies disease prevention. Although that regulation applies only to claims on dietary supplements, the FDA said at that time: "for consistency, the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements." Regardless, the regulation, does not address the issue of how much substantiation a food manufacturer needs to render a structure/function claim non-misleading.

⁴² Id., at 1032.

⁴⁴ We maintain that the claims discussed here are false and misleading, and constitute misbranding, even if the FDA applied the "competent and reliable scientific evidence" standard. That enforcement approach would still require companies to maintain "competent and reliable" substantiation for their claims including studies that are contrary to, as well as supportive of the claims in question. Clearly, if the FDA requested the companies to provide their substantiation, studies contrary to the claims would greatly outweigh any studies supporting the claims. However, as discussed herein, we believe the FDA should require that structure/function claims for foods meet the same significant scientific agreement standard as health claims for foods.

In its "Draft Guidance," the FDA said that its substantiation standard for dietary supplements "is consistent with the Federal Trade Commission's standard for *advertising* of supplements and other health related products . . ." (emphasis added) which requires that claims be based on "competent and reliable scientific evidence." However, advertising is not the same as labeling. Consumers expect ads to be filled with pitches and exaggerations, but they depend on food labels for accurate information about product quality and content. ⁴⁶

Thus, it would be inappropriate for the FDA to apply the FTC's advertising substantiation standard to food labeling claims. Further, the FTC's approach to supplement advertising claims, while enforced by that agency on numerous occasions over the last decade, has overall been a colossal failure; misleading claims in supplement advertising abound despite repeated attempts by the FTC to stop them. The extension of the FDA's structure/function claims substantiation policy for supplements to conventional foods would merely accelerate the spread of the dishonesty and skullduggery that has plagued the dietary supplement industry to the much larger food industry. 47

C. The FDA Should Issue a Safe Harbor List of Structure/Function Claims that are Permissible

The FDA should facilitate industry compliance with our recommended regulatory approach by establishing a "safe harbor" of permissible claims. Such a list could include claims such as: "Calcium builds strong bones" on foods with at least a specified amount of calcium, *See* 21 C.F.R. §101.54 (nutrient content claim for "good source") and that do not exceed the disqualifying levels for nutrients set forth at 21 C.F.R. §101.14 (e)(6). The list could also include approved health claims that have been reworded as structure/function claims. This would help ensure that consumers see only those structure/function claims that are scientifically sound.

⁴⁵ 69 Fed. Reg. at 64943.

⁴⁶ Korber Hats v. Federal Trade Commission, 311 F.2d. 358, 361, (1st Cir. 1962) ("Consumers accept labeling statements literally while perhaps viewing with a more jaundiced eye the vaunted claim of the advertising media.")

⁴⁷ This complaint letter does not address whether FDA acted appropriately in issuing draft guidance suggesting that structure/function claims on dietary supplement labels be regulated by the FTC substantiation standard (which was designed for advertising claims) and we urge that the "draft" guidance not be finalized. However, it is noteworthy that under the FDCA, Congress addressed structure/function claims for foods and dietary supplements in different manners, *compare*, 21 U.S.C. § 201(g)(1)(C) with 21 U.S.C. § 403 (r)(6)(A).

IV. Conclusion

For the foregoing reasons, we urge the FDA to: (1) take enforcement actions against the companies named in this letter; (2) issue an industry-wide warning letter explaining that structure/function claims for foods are subject to the significant scientific agreement standard; and (3) issue a "safe harbor" list of structure/function claims.

Sincerely,

Michael F. Jacobson, Ph.D.

Executive Director

Michael F. Jacobson

David Schardt

Senior Staff Nutritionist

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Ilene Ringel Heller

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Bruce Silverglade

Director of Legal Affairs

Appendix I: CSPI Survey on Consumers

Appendix II: Letter to Barbara Schneeman, Food and Drug Administration

Attachments A-F: Food Labels

APPENDIX I

Survey: Participants were shown the label of Green Giant Page: Immunity Boost frozen vegetables, which states "naturally rich in antioxidants Vitamins A & C to help support a healthy immune system."

1. This label means that the food (check all that apply):		
	Response Percent	Response Count
Helps prevent cancer.	22.8%	241
Helps prevent AIDS.	4.2%	44
Helps prevent colds and the flu.	49.1%	519
Helps the body in some other way.	32.9%	348
Has no special benefit.	21.8%	230
Don't know	6.5%	69
Other (please specify)		217
answered question		1057
skipped question		154

APPENDIX II

June 30, 2008

Barbara Schneeman, Ph.D.
Director, Office of Nutritional Products, Labeling, and Dietary Supplements U.S. Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Schneeman:

We, the undersigned, urge the Food and Drug Administration to address the rapidly growing problem of misleading "immunity" claims being made for foods and dietary supplements.

More and more manufacturers are claiming that their products can "maintain," "assist," "support," or even "boost" the immune systems of consumers, despite having little or no credible evidence that their products actually do that.

Some examples are:

<u>Crystal Light "Immunity" Beverage</u>. This diet drink, fortified with 10 percent of the Daily Value for vitamins A and C and 20 percent of the Daily Value for vitamin E, "helps maintain a healthy immune system," according to the label. Kraft Foods, its manufacturer, conceded in an email to the Center for Science in the Public Interest (CSPI) that "we do not expect, or claim, that consumption of *Crystal Light* Immunity will -- in and of itself -- significantly impact immune function."

Green Giant "Immunity Boost." This consists of frozen vegetables (broccoli florets, julienne carrots and red and yellow sweet pepper strips) in a garlic-herb infused extra virgin olive oil seasoning. According to an email to CSPI from General Mills, its manufacturer, "we used the word 'boost' to convey to consumers that eating our product will provide essential nutrients (vitamins A and C) that assist the immune function... This product can contribute to dietary adequacy ("boost") of vitamin A and C-- nutrients that support immune function."

<u>Dole Wildly Nutritious "Immunity Blend</u>." This mixture of frozen pineapple, mango, golden kiwi, papaya and strawberries "provides essential vitamins and nutrients that help support a healthy immune system, such as Vitamin C and Vitamin A," according to Dole.

<u>Airborne dietary supplement</u>. This mixture of 17 vitamins, minerals, and herbs, "boosts your immune system to help your body combat germs," according to its manufacturer Airborne, Inc. Consumers are instructed to "take it before entering crowded places, when you will be or have

been exposed to germs and viruses, or whenever your immune system needs a boost." There are no scientific studies of Airborne.

<u>DanActive "Immunity" probiotic dairy drink.</u> This fermented milk with a specific Lactobacillus casei strain added "helps strengthen your body's defenses," according to its manufacturer Dannon. The company's website and television commercials portray busy, healthy people of all ages striving to stay healthy by drinking the beverage. Dannon advertises that DanActive is "clinically proven" with more than 25 studies showing its effect on "the body's natural defenses." But of the 27 studies Dannon cites, only one tested whether DanActive could prevent healthy people from getting sick---and it failed to do so.

Claims that products like these can "maintain," or "support," or even "boost" the immune system mislead consumers for several reasons.

First, many, if not most, consumers associate the immune system with protection from disease. There is little or no evidence that these products can provide that protection.

The FDA sanctioned the use of an immunity structure/function claim in a background discussion of its regulations in 2000. The agency reasoned that "a statement of support for the immune system, by itself, conveys no specific reference to disease treatment or prevention," since the immune system has other important functions, such as phagocytosis, in addition to its defense against pathogens. ⁴⁸ (A specific reference to disease treatment or prevention would render the product an unapproved drug.)

The FDA and immunologists know that the immune system does more than fight disease, but for many, if not most consumers, something that "supports" or "boosts" immunity means an ability to reduce the risk of disease.

A small survey that the Center for Science in the Public Interest (CSPI) conducted recently of about 1,000 fairly knowledgeable consumers found that a significant proportion of them believe that a claim that a product "boosts immunity" means it can prevent colds, the flu, and even cancer.

When consumers buy an "immune-boosting" product like Airborne with instructions to take it right before entering a germ-infested room, they're not anticipating that the health benefit will be an enhanced phagocytosis of their aged red blood cells. Rather, they're like the schoolteacher who concocted and markets Airborne -- they want the product to help keep them from getting another cold or other illness.

The second reason these immunity claims are misleading is that it's not clear whose, if anyone's, immune system would benefit from buying these products. Companies are exploiting the fact that a minimum amount of virtually every nutrient is necessary for the proper functioning of the immune system. But that doesn't mean, once those minimum requirements are met, that eating,

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 $^{^{48}}$ [Federal Register: January 6, 2000 (Volume 65, Number 4)] [Page 999-1050] http://www.cfsan.fda.gov/~lrd/fr000106.html

for example, "Immunity Boost" broccoli, carrots, and sweet peppers as part of dinner or a vitamin-fortified diet drink will then "boost" their immune defenses.

In fact, most studies show that the amounts of nutrients found in many of the products making deceptive immunity claims have little impact on either intermediate immune markers or on clinical outcomes in the types of consumers these products are marketed to, healthy children and adults. And most studies have failed to demonstrate that contrasts in the quality of dietary intake translate into measurable differences in chronic immune function among healthy individuals. ⁴⁹

We urge the FDA to suspend its approval of immunity structure/function claims until the agency establishes that these immunity claims can be made in a way that provides meaningful information to the public, while not misleading consumers into thinking they're getting more of a health benefit than they really are.

Sincerely,

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⁴⁹ Am J Clin Nutr. 2007 Nov; 86(5): 1445-55.





























