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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 2002P-0122

Dear Sir or Madam:

In response to the Food and Drug Administration's (FDA's or the agency's) request for comments on conventional foods being marketed as "functional foods" (Notice),<sup>1</sup> Hyman, Phelps & McNamara, P.C. submits these comments on behalf of food and dietary supplement clients. Before responding individually to FDA's discussion questions, we present more detailed analysis of FDA's interpretation of Nutrilab v. Schweiker<sup>2</sup> and the existing statutory requirements for notification of structure/function claims for dietary supplements.

**I. DISCUSSION**

FDA's Notice defines "functional food" for the purposes of its request for comments as excluding dietary supplements but including "conventional" foods (meaning foods other than dietary supplements) that make claims relating to the food's intended effect on the structure of any function of the body (structure/function claims).<sup>3</sup> Since 1938, the Federal

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<sup>1</sup> 71 Fed. Reg. 62,400 (Oct. 25, 2006).

<sup>2</sup> Nutrilab v. Schweiker, 713 F.2d 335 (7th Cir. 1983).

<sup>3</sup> 71 Fed. Reg. at 62,401.

Food, Drug, and Cosmetic Act (FDC Act) has recognized and authorized structure/function claims for all foods through the definition of the term “drug,” which reads, in part, as follows: “The term ‘drug’ means . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals.”<sup>4</sup>

In the Notice, FDA states that “we are confident that the existing provisions of the [FDC Act] are adequate to ensure that conventional foods being marketed as ‘functional foods’ are safe and lawful.”<sup>5</sup> We agree with FDA that the current provisions of the FDC Act and FDA’s regulations adequately assure the safety of conventional food ingredients. We also agree that the current provisions of the FDC Act and FDA regulations that govern structure/function claims for conventional foods, as well as case law interpreting these provisions,<sup>6</sup> appropriately regulate structure/function claims for conventional foods. However, we do not agree with FDA’s interpretation of Nutrilab, and view this as the appropriate time for FDA to abandon its long-held and incorrect interpretation.

Finally, there is no public health need for any form of notification of structure/function claims for conventional foods. We remind the agency that it has still not responded to issues regarding FDA’s misinterpretation of the notification requirements for dietary supplements, issues which this firm raised in a petition to FDA in 2000.

**A. FDA is not Authorized to Require Structure/Function Claims for Conventional Foods to Be Based on Nutritive Value**

The Nutrilab decision confirms that the FDC Act definition of the term “food” in 21 U.S.C. § 321(f) includes not only articles used for taste, aroma, or nutritive value, but also other articles such as coffee and prune juice that have physiological effects that do not derive from taste, aroma, or nutritive value, and that are consumed for those effects.

When the statute defines “food” as “articles used for food,” it means that the statutory definition of “food” includes articles used by people in the ordinary way most people use food – primarily for taste, aroma, or nutritive value. To hold as did the district court that articles used as food are articles used solely

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<sup>4</sup> 21 U.S.C. § 321(g)(1).

<sup>5</sup> 71 Fed. Reg. at 62,401.

<sup>6</sup> See, e.g., Nutrilab, 713 F.2d 335.

for taste, aroma or nutritive value is unduly restrictive since some products such as coffee or prune juice are undoubtedly food but may be consumed on occasion for reasons other than taste, aroma, or nutritive value.<sup>7</sup>

FDA has historically ignored the Court of Appeals' explicitly broad reading of the definition of "food" and erroneously applied the district court's incorrect interpretation, which the Court of Appeals rejected. FDA's historic misinterpretation of the "food" definition and the resulting limitation of structure/function claims for conventional foods to claims that derive from taste, aroma, or nutritive value are reflected in the Notice, where FDA states the following:

Under Nutrilab v. Schweiker, structure/function claims on the label or in labeling of conventional food make the product a drug if they promote the product for a structure/function effect . . . that is unrelated to the product's "food" attributes of taste, aroma, and nutritive value. FDA has interpreted this court decision to limit structure/function claims for conventional foods to claims about effects that derive from the taste, aroma, or nutritive value of the food or food ingredient that is the subject of the claim.<sup>8</sup>

In issuing a final rule for the labeling of dietary supplements, FDA set out its "nutritive value" position for conventional foods, using the physiological effects of cranberries as an example, as follows:

[A] claim that cranberry products help to maintain urinary tract health may be permissible on both cranberry products in conventional food form and dietary supplement form if it is truthful, not misleading, and derives from the nutritional value of cranberries. If the effect derives from the nutritive

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<sup>7</sup> Id. at 338 (emphasis added). See also Am. Health Prods. Co. v. Hayes, 574 F. Supp. 1498, 1507 (S.D.N.Y. 1983), aff'd, 744 F.2d 912 (2d Cir. 1984) ("[I]f an article affects bodily structure or function by way of its consumption as a food, the parenthetical [*i.e.*, the "(other than food)"] provision of 21 U.S.C. § 321(g)(1)(C)] precludes its regulation as a drug notwithstanding a manufacturer's representations as to physiological effect. . . . The presence of the parenthetical in part (C) suggests that Congress did not want to inhibit the dissemination of useful information concerning a food's physiological properties by subjecting foods to drug regulation on the basis of representations in this regard.").

<sup>8</sup> 71 Fed. Reg. at 62,404 (citation omitted).

value of cranberries, the claim would describe an effect of a food on the structure or function of the body and thus fall under one exception to the definition of the term “drug” found in 201(g)(1)(C) of the [FDC Act]. The claim is not a health claim because no disease is mentioned explicitly or implicitly (see section 403(r)(1)(B) of the [FDC Act]).<sup>9</sup>

The illogical result that FDA here suggests is that a claim that is a legal structure/function claim for a cranberry-based dietary supplement is an illegal claim for a conventional food, unless the claim derives from the “nutritive value” of the cranberries when marketed as conventional foods. FDA admits that the claim “maintaining urinary tract health” is not a “drug” claim as the term “drug” is defined under the FDC Act, but asserts only that cranberries marketed with this claim would be drugs under the FDC Act if the physiological effect on urinary tract health were the result of something other than “nutritive value.” This interpretation is not consistent with the FDC Act definitions of “food” and “drug.”<sup>10</sup>

The FDA’s definition of “nutritive value” only exacerbates this problem. In its health claim regulations, FDA defines “nutritive value” to mean “a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.”<sup>11</sup> The core of the definition, “a value in sustaining human existence,” is arguably inclusive enough to include any substance that provides the slightest benefit to human health or wellbeing. On the other hand, should FDA choose to focus on the definition’s examples of what constitutes “a value in sustaining human existence,” the agency would recognize only a much smaller subset of substances as providing nutritive value.

The general lack of structure/function claims on cranberry products marketed as conventional foods reflects both the lack of clarity surrounding the exact meaning of “nutritive value” and the huge stakes for the conventional food marketers should FDA disagree with respect to truthful structure/function claims. FDA has repeatedly issued

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<sup>9</sup> 62 Fed. Reg. 49,859, 49,860 (Sept. 23, 1997).

<sup>10</sup> 21 U.S.C. § 321(f)-(g).

<sup>11</sup> 21 C.F.R. § 101.14(a)(3).

warning letters to conventional food manufacturers questioning structure/function claims for conventional foods that FDA has not objected to when made for dietary supplements.<sup>12</sup>

FDA should abandon this misreading of Nutrilab and permit conventional foods to make the breadth of structure/function claims that the FDC Act, as interpreted by the Court of Appeals in Nutrilab, allows. This approach would also allow FDA to address the shortcomings of the agency's "nutritive value" approach from a scientific perspective as identified by the Institute of Food Technologists (IFT) March 2005 Expert Report. As the IFT has recommended, FDA should permit substantiated structure/function claims based on any physical or physiological effect that a food might have.

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FDA has issued warning letters regarding:

- beverages that made structure/function claims relating to the ability of echinacea to help stimulate the body's production of interferon. Letter to Hansen Beverage Company, June 4, 2001, at [http://www.fda.gov/foi/warning\\_letters/g1317d.pdf](http://www.fda.gov/foi/warning_letters/g1317d.pdf).
- cereals that made structure/function claims relating to ginseng for mental concentration, physical vitality and energy, and its adaptogen and anti-oxidant qualities and ginkgo to sustain memory. Letter to US Mills, Inc., June 5, 2001, at [http://www.fda.gov/foi/warning\\_letters/g1320d.pdf](http://www.fda.gov/foi/warning_letters/g1320d.pdf).
- various beverages that made structure/function claims relating to the ability of various ingredients to eliminate fat and build muscle mass, to promote calm and focused thoughts, or to sharpen the mind. Letter to South Beach Beverage Company, February 1, 2000, at [http://www.fda.gov/foi/warning\\_letters/m3436n.pdf](http://www.fda.gov/foi/warning_letters/m3436n.pdf).
- beverages that made structure/function claims relating to the ability of various ingredients to provide brain boosting power to enhance memory and circulation, or to increase energy. Letter to Langers Juice Company, September 28, 1999, at [http://www.fda.gov/foi/warning\\_letters/m2978n.pdf](http://www.fda.gov/foi/warning_letters/m2978n.pdf).

FDA has also issued a courtesy letter regarding a beverage mix containing soy that made structure/function claims relating to the effects of soy on the cardiovascular system, cellular growth, hormone balance, and on well-being in women during certain times of life. Letter to J.R. Carlson Laboratories, Inc., December 30, 1999, at <http://www.fda.gov/ohrms/dockets/dailys/00/feb00/021100/let0323.pdf>.

**B. Notification for Functional Food Ingredients and Structure/Function Claims for Conventional Foods**

FDA has requested comments on two possible notification requirements for functional foods.<sup>13</sup> First, FDA questioned whether the agency should require premarket notification for ingredients added to functional foods.<sup>14</sup> FDA then inquired whether it should require a company marketing a conventional food bearing a structure/function claim to notify the agency within 30 days of beginning to market the food.<sup>15</sup> FDA does not have authority to impose any form of claim notification on functional foods, and we recommend that FDA not seek such authority.

The safety of functional foods and functional food ingredients is ensured by FDA's statutory authority with regard to food additives, which FDA has used to effectively create a premarket notification/approval system for food ingredients. No ingredient can be added to a functional food unless it is an approved food or color additive, is subject to a prior sanction, or is generally recognized as safe (GRAS). While some food ingredients are approved through the food additive petition process, there is no requirement for a manufacturer of a conventional food to notify FDA prior to using a novel food ingredient that the manufacturer has found to be GRAS. Nonetheless, FDA has put in place a procedure for GRAS premarket notifications, which allows manufacturers of conventional foods to notify FDA of the company's GRAS self-affirmation prior to marketing the new GRAS ingredients. The current statutory requirements and GRAS notification procedures have adequately assured the safety of foods and food ingredients, even where no notification is required. Therefore, there is no public health need for the agency to seek authority to require premarket notification for novel ingredients added to functional foods.

The Dietary Supplement Health and Education Act amended the FDC Act to require that a dietary supplement manufacturer notify FDA within 30 days of beginning to market a dietary supplement bearing certain limited types of structure/function claims, and that the

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<sup>13</sup> 71 Fed. Reg. at 62,403-04.

<sup>14</sup> Id. at 62,404.

<sup>15</sup> Id.

labels of such products bear an FDA disclaimer.<sup>16</sup> In issuing the final rule implementing the notification provision, FDA stated for the first time that notification and the FDA disclaimer would be required for all dietary supplement structure/function claims that were truthful and non-misleading, without limitation.<sup>17</sup> Immediately following FDA's issuance of the final rule, this firm filed a petition for reconsideration to which the agency has not yet responded.<sup>18</sup> Therefore, the question of which types of claims for dietary supplements require notification and the FDA disclaimer is still an open legal issue that the agency never resolved.

Regardless of the interpretation of the provision regarding notification for dietary supplement structure/function claims, no existing provision in the FDC Act authorizes FDA to require a conventional food manufacturer to notify the agency when the manufacture begins marketing a food bearing a structure/function claim. As current statutory and regulatory requirements for conventional foods are adequate to assure that structure/function claims for such foods are truthful and not misleading, no new legislative authority is needed at this time.

## II. FDA ISSUES AND QUESTIONS FOR DISCUSSION

The following issues and questions (text in bold) are quoted from FDA's Notice.<sup>19</sup> An answer is provided for each of FDA's numbered questions.

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<sup>16</sup> 21 U.S.C. § 343(r)(6) (“If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.”).

<sup>17</sup> 65 Fed. Reg. 1000, 1033-34 (Jan. 6, 2000).

<sup>18</sup> Hyman, Phelps & McNamara, P.C., Petition for Reconsideration and for Stay of Action (Feb. 4, 2000), at <http://www.fda.gov/ohrms/dockets/98fr/980044prc1.pdf>.

<sup>19</sup> 71 Fed. Reg. at 62,403-05.

## **A. Food Ingredients**

**Issue 1: The CSPI petition requests that we require food companies to notify us regarding the use of “novel ingredients” prior to marketing foods containing such ingredients. The CSPI petition does not define the term “novel ingredients.” For the purpose of this hearing, we are using the term “functional food” to mean conventional foods that are being marketed as “functional foods,” and we are using the term “ingredients” to mean “functional food” ingredients that may have a purported health benefit and that may be the subject of a label statement about this purported health benefit, whether or not the ingredient is new to the food supply.**

**Question 1a. Is there a need for a regulatory definition and a distinct regulatory approach to the evaluation of the safety of ingredients added to “functional foods”? If yes, what would be included in this new definition and approach that is not adequately addressed under the existing definition of food additive or the provisions in the definition for GRAS substances, and what is the scientific and legal basis for your position? Under what legal authority could FDA create this new definition and distinct regulatory approach?**

Answer 1a. No. We agree with FDA that the current statutory and regulatory scheme adequately assure the safety and lawfulness of foods, including “functional foods” as defined in the Notice. The safety of functional foods and functional food ingredients is ensured by FDA’s statutory authority with regard to food additives, which FDA has used to effectively create a premarket notification/approval system for food ingredients. No ingredient can be added to a functional food unless it is an approved food or color additive, subject to a prior sanction, or GRAS. While some food ingredients are approved through the food additive petition process, there is no requirement for a manufacturer of a conventional food to contact FDA prior to using a novel food ingredient that the manufacturer has found to be GRAS. Nonetheless, FDA has put in place a procedure for GRAS premarket notifications, which allows manufacturers of conventional foods to notify FDA of the company’s GRAS self-affirmation prior to marketing the new GRAS ingredients. The current statutory requirements and GRAS notification procedures have adequately assured the safety of foods and food ingredients, even where no notification is required. Therefore, there is no public health need for the agency to seek authority to require premarket notification for novel ingredients added to functional foods.

**Question 1b. Should companies that market ingredients for addition to “functional foods” be required to notify us prior to introducing the ingredients into interstate commerce? If yes, what is the scientific and legal basis for your position?**

Answer 1b. No – see answer to question 1a.

**Issue 2: Generally, food additives have been used in conventional foods for their technical effects on the food, not for their effects on the body. Now, the interest in various uses of certain ingredients in conventional foods is due to the marketing of these conventional foods as “functional foods” with claims about health benefits.**

**Question 2a. What types of data and information would be appropriate to demonstrate that ingredients added to conventional foods being marketed as “functional foods” meet the safety standard of “reasonable certainty of no harm”? What is the scientific and legal basis for your position?**

Answer 2a. Pursuant to existing statutory authority for “food additives,” FDA has established detailed data and information requirements that apply to all food additives that are added to conventional foods. Food ingredients that are GRAS based on scientific procedures require “the same quantity and quality of scientific evidence [of safety] as is required to obtain approval of a food additive.”<sup>20</sup> As FDA has pointed out in its Notice, these requirements adequately assure ingredient safety, and there is no need for additional requirements for food additives used in “functional foods.”

**Question 2b. How could we partner with interested stakeholders regarding the development of appropriate recommendations or other information regarding the safety assessment of ingredients added to “functional foods”?**

Answer 2b. Since existing requirements are adequate, no partnering is necessary.

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<sup>20</sup> 21 C.F.R. § 170.30(b).

