Immediate Disclosure
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10-20-06 3:48pm
10-25-06
D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 170

[Docket No. 2002P–0122] (formerly 02P–0122)

Conventional Foods Being Marketed as "Functional Foods"; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing on the regulation of certain conventional foods that companies are marketing as "functional foods." The purpose of the hearing is for the agency to share its current regulatory framework and rationale regarding the safety evaluation and labeling of these foods, and to solicit information and comments from interested persons on how FDA should regulate these foods under the agency's existing legal authority.

DATES: The public hearing will be held on Tuesday, December 5, 2006, from 9 a.m. to 4:30 p.m. Persons who wish to request an opportunity to make an oral presentation must submit a notice of participation by November 14, 2006. All other persons must submit a notice of participation by November 28, 2006. Persons who request an opportunity to make an oral presentation also must submit either the full text of the oral presentation, or a comprehensive outline or summary of the oral presentation, by November 28, 2006. Written or electronic comments (i.e., submissions other than notices of participation and the text, comprehensive outline, or summary of an oral presentation) may be

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submitted until January 5, 2007. The administrative record of the hearing will remain open until January 5, 2007.

ADDRESSES: The public hearing will be held at Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Harvey W. Wiley Auditorium, College Park, MD 20740 (Metro stop: College Park on the Green Line).

Submit electronic notices of participation to *http://www.cfsan.fda.gov/~comm/register.html*. Submit written notices of participation and the written full text, comprehensive outline, or summary of any oral presentation to Isabelle Howes, U.S. Department of Agriculture Graduate School, 600 Maryland Ave., SW., suite 270 Washington, DC 20024–2520. To submit a notice of participation orally, or to submit a notice of participation or the full text, comprehensive outline or summary of the oral presentation by e-mail or by fax, see **FOR FURTHER INFORMATION CONTACT**.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Instructions: All submissions and comments received must include the agency name and docket number found in brackets in the heading of this document. All submissions and comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*, approximately 30 days after the hearing.

FOR FURTHER INFORMATION CONTACT:

To submit a notice of participation orally, by fax, or by e-mail: Isabelle Howes, U.S. Department of Agriculture Graduate School, 202–314–4713, FAX: 202–479–6801, or e-mail: *isabelle_howes@grad.usda.gov.*

For all other questions about the meeting, to request onsite parking, or if you need special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1714, e-mail: *Juanita.Yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

FDA is responsible for ensuring that all foods in the American food supply (other than meat products, poultry products, and egg products that are regulated by the U.S. Department of Agriculture) are safe, secure, sanitary, wholesome, and properly labeled.

Section 201(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA or the act) (21 U.S.C. 321(f)) defines food to mean: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. The act also defines several specific types of food and substances that are added to food, including: "raw agricultural commodity" (section 201(r) (21 U.S.C. 321(r))), "food additive" (section 201(s) (21 U.S.C. 321(s))), "color additive" (section 201(t) (21 U.S.C. 321(t))), "infant

formula" (section 201(z) (21 U.S.C. 321(z))), "dietary supplement" (section 201(ff) (21 U.S.C. 321(ff))), and "processed food" (section 201(gg) (21 U.S.C. 321(gg))).

The act does not define the term "conventional food." However, the act defines a dietary supplement, in part, as a product that is "not represented for use as a conventional food" (see section 201(ff)(2)(B) (21 U.S.C. 321(ff)(2)(B))). Products such as beverages, baked goods, cheeses, milk products, cereal, grain products, pasta, fats and oils, vegetable spreads, snack foods, candy, soups, and infant formula are examples of conventional foods. The act includes provisions that relate to certain types of conventional food, such as requirements for infant formula in section 412 of the act (21 U.S.C. 350a).

In recent years, the food industry has developed and marketed foods that it refers to as "functional foods." Although there is no formal definition of what the industry means by "functional food," on March 24, 2005, the Institute of Food Technologists (IFT) issued a report entitled "Functional Foods: Opportunities and Challenges" (Ref. 1) (the IFT report) in which "functional foods" are defined as "foods and food components that provide a health benefit beyond basic nutrition (for the intended population). * * * These substances provide essential nutrients often beyond quantities necessary for normal maintenance, growth, and development, and/or other biologically active components that impart health benefits or desirable physiological effects." Examples of functional foods cited in the report include "conventional foods; fortified, enriched or enhanced foods; and dietary supplements."

Currently, FDA has neither a definition nor a specific regulatory rubric for foods being marketed as "functional foods." We regulate conventional foods

being marketed as "functional foods" under the same regulatory framework as other conventional foods. Although we are confident that the existing provisions of the act are adequate to ensure that conventional foods being marketed as "functional foods" are safe and lawful, we believe that it would be in the best interest of public health to begin a dialog with industry, consumers, and other stakeholders regarding the regulation of these products. Therefore, in this document we announce a public hearing to afford consumers, industry, and other interested parties the opportunity to provide focused comments on approaches to the regulation of conventional foods being marketed as "functional foods." As background relevant to the hearing, we describe key provisions of the act regarding the safety and labeling of conventional foods.

For the purpose of this hearing, we are not considering dietary supplements to be encompassed by the term "functional foods." Dietary supplements have their own detailed regulatory framework prescribed by Congress in the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Public Law 103–417, 108 Stat. L. 4325), which amended the FFDCA to define "dietary supplement" and to set forth requirements for the safety and labeling of dietary supplements. DSHEA specifically excludes from the definition of dietary supplement any product that is "represented for use as a conventional food or as a sole item of a meal or the diet" (Section 201(ff)(2)(B) of the act (21 U.S.C. 321(ff)(2)(B)). However, because some labeling provisions of the act with respect to dietary supplements are relevant to the issues and questions that are part of the scope of this hearing, in this document we describe some labeling provisions of the act with respect to dietary supplements.

B. Statutory and Regulatory Framework for the Safety of Food Ingredients

In 1958, Congress enacted the Food Additives Amendment (the 1958 amendment) to the act (Public Law 85–929, 72 Stat. L. 1784). The basic thrust of the 1958 amendment was to require "the processor who wants to add a new and unproven additive to accept the responsibility of * * * first proving it to be safe for ingestion by human beings" (S. Rept. 2422, 85th Cong., 2d Sess.). The 1958 amendment defined the terms "food additive" (section 201(s) of the act (21 U.S.C. 321(s))) and "unsafe food additive" (section 409(a) of the act (21 U.S.C. 348(a))), established a premarket approval process for food additives (section 409(b) through (g) (21 U.S.C. 348(b) through (g)), and amended the food adulteration provisions of the act to deem adulterated any food that is, or bears or contains, any food additive that is unsafe within the meaning of section 409 (section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C))).

Recognizing that the safety of a food additive cannot be established with absolute certainty and that safety is dependent on dietary intake and other conditions of use, Congress stated that "safety" under the 1958 amendment means a reasonable certainty that no harm will result from the intended use of an additive (S. Rept. 2422, 85th Cong., 2d Sess.). We have incorporated this safety standard into our regulation defining the terms "safe" and "safety" (21 CFR 170.3(i)). If we find an additive to be safe, based ordinarily on data submitted by the manufacturer to the agency in a food additive petition, we issue a regulation specifying the conditions under which the additive may be safely used in food.

Many substances intentionally added to food do not require a formal premarket review by FDA to assure their safety, either because their safety has been established by a long history of use in food or by virtue of the nature

of the substances, their customary or projected conditions of use, and the information generally available to scientists about the substances. In enacting the 1958 amendment, Congress addressed this category of substances by adopting, in section 201(s) of the act (21 U.S.C. 321(s)), a two-step definition of "food additive." The first step broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The second step, however, excludes from the definition of "food additive" substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through experience based on common use in food) to be safe under the conditions of their intended use. Substances that are exempted from the food additive definition under this second step are referred to as "GRAS" (generally recognized as safe). The safety standard for a GRAS substance is the same as the safety standard for a food additive, i.e., reasonable certainty of no harm under the substance's intended conditions of use (21 CFR 170.30(i)). However, for the use of a substance to be GRAS, it must not only be safe but, unlike for an approved food additive, there must also be general recognition of its safety among qualified experts.

We have established regulations governing the food additive petition process (21 CFR 171.1). We also have established regulations (21 CFR 170.35(c)) governing a voluntary process whereby an interested person may petition us to affirm, through rulemaking, that a use of a food substance is GRAS. However, more recently we have proposed to eliminate the voluntary

GRAS affirmation petition process and replace it with a voluntary notification procedure in which we respond to a notifier by letter rather than conduct rulemaking to affirm GRAS status (62 FR 18937, April 17, 1997 (the GRAS proposal)). As announced in the GRAS proposal, we are accepting GRAS notices during the interim between the proposed rule and any final rule that publishes based on the proposed rule. A summary of notices filed under the rubric of the GRAS proposal, with links to our letters responding to those notices, is available on the Internet (see *http://www.cfsan.fda.gov/~rdb/opa-gras.html*).

We have developed a number of guidance documents relevant to evaluating the safety of food ingredients, such as recommendations relating to chemical and toxicological considerations. These are available at *http://www.cfsan.fda.gov/~dms/opa-guid.html*.

C. Statutory and Regulatory Framework for the Labeling of Food

1. Provisions regarding false or misleading labeling

Under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)), a food is misbranded if its labeling is false or misleading in any particular. Under section 201(n) of the act (21 U.S.C. 321(n)), in determining whether the labeling of an article 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."

Sections 403(a)(1) and 201(n) of the act (21 U.S.C. 343(a) and 321(n)) broadly apply to the labeling of all foods, in addition to any specific labeling requirements established by or under authority of the act for certain foods or for certain statements on foods. In the absence of specific statutory or regulatory requirements for statements in the labeling of a food, we apply the standards of sections 403(a)(1) and 201(n) of the act (21 U.S.C. 343(a)(1) and 321(n)) to determine if the food is misbranded.

2. Provisions for health claims and nutrient content claims

Section 403(r) of the act (21 U.S.C. 343(r)) lays out the statutory framework for the use of labeling claims that characterize the relationship of a substance in food to a disease or health-related condition ("health claims," defined in section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)), or that characterize the level of a nutrient in a food ("nutrient content claims," defined in section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A))). We have established regulations implementing section 403(r) of the act (21 U.S.C. 343(r)) with respect to health claims (21 CFR 101.14 and subpart E) and with respect to nutrient content claims (21 CFR 101.13 and subpart D).

The definition of "health claim" identifies two basic elements for a health claim: (1) A substance (e.g, a nutrient); and (2) a disease or health-related condition (see section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) and 21 CFR 101.14(a)(1)). In determining whether a particular claim is a health claim, we evaluate, in part, whether the claim is about a substance in food (see 21 CFR 101.14(a)(2)) and whether the claim is about reducing risk for a disease or health-related condition (see *Whitaker* v. *Thompson*, 353 F.3d 947 (D.C. Cir.), cert. denied, 125 S. Ct. 310 (2004)).

There are three ways by which we exercise our oversight in determining which health claims may be used in the labeling of conventional foods and dietary supplements. First, the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535, 104 Stat. L. 2353), which amended the FFDCA, provides for us to issue regulations authorizing health claims for conventional foods and dietary supplements after our evaluation of the scientific evidence relative to the claim under the significant scientific agreement (SSA) standard (see section 403(r)(3)(B) of the act (21 U.S.C. 343(r)(3)(B)). Health claims authorized through this process are commonly referred to as "SSA claims." Second, the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115, 111 Stat. L. 2296), amended the FFDCA to provide for health claims for conventional foods based on an authoritative statement of certain scientific bodies of the United States government or of the National Academy of Sciences (now the National Academies). Such claims may be used from 120 days after submission of a health claim notification to FDA until the agency prohibits or modifies the claim by regulation or obtains a court order determining that the statutory requirements for an authoritative statement notification health claim have not been met (see section 403(r)(3)(C)–(D) of the act (21 U.S.C. 343(r)(3)(C)–(D))). We have issued guidance on the authoritative statement notification procedure (see Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body; available at *http://www.cfsan.fda.gov/~dms/hclmguid.html*) (Ref. 2). Third, as a result of court decisions interpreting the first amendment of the U.S. Constitution, we exercise enforcement discretion with respect to certain qualified health claims (QHC) where there is credible evidence to support the proposed claim, but

the strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation based on significant scientific agreement (see, e.g., *Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). For information on qualified health claims for which FDA has issued a letter of enforcement discretion, see *http://www.cfsan.fda.gov/~dms/qhc-sum.html*).

A "nutrient content claim" is a statement in food labeling that explicitly or implicitly characterizes the level of a nutrient in a food (see section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)) and 21 CFR 101.13(b)). Nutrient content claims must be authorized by regulation (see section 403(r)(2)(A)(i) and (r)(4)(A)(i) of the act (21 U.S.C. 343(r)(2)(A)(i) and (r)(4)(A)(i))), through a synonym or brand name petition process (see section 403(r)(4)(A)(ii)–(iii) of the act (21 U.S.C. 343(r)(4)(A)(ii)–(iii))), or (for conventional foods only) through an authoritative statement notification process (see section 403(r)(2)(G)–(H) of the act (21 U.S.C. 343(r)(2)(G)–(H))) before they may be used in food labeling.

3. Provisions for structure/function claims

In the DSHEA, Congress amended section 403(r) of the act (21 U.S.C. 343(r)) to authorize certain types of claims to be used in the labeling of dietary supplements without premarket review by FDA. Among the types of claims specifically authorized are statements describing the role of a nutrient or dietary ingredient intended to affect the structure or function of the body in humans and statements that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function. Under section 403(r)(6) of the act (21 U.S.C. 343(r)(6)), such statements (as well as two other types of claims not relevant to this notice) may be made in the labeling of a dietary supplement if the manufacturer of the dietary supplement

has substantiation that such statement is truthful and not misleading, and the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." A statement under section 403(r)(6) (21 U.S.C. 343(r)(6)) may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The manufacturer of a dietary supplement that bears such a statement must notify FDA, no later than 30 days after the first marketing of the dietary supplement with the statement, that the statement is being made. We have established in 21 CFR 101.93 regulations implementing section 403(r)(6) of the act (21 U.S.C. 343(r)(6)).

The act includes no provision analogous to section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) for statements made in the labeling of conventional food. However, the provision of the act that defines "drug" to include articles intended to affect the structure or function of the body contains an exception for foods, which affect the structure and function of the body by virtue of providing nutrition to sustain life and health (see section 201(g)(1)(C) of the act (21 U.S.C. 321(g)(1)(C)). As discussed in section I.A of this document, "food" is defined in section 201(f) of the act (21 U.S.C. 321(f)). Therefore, for conventional foods we regulate claims about the effect of a substance in food on the structure or function of the body under sections 201(f), 201(g), 403(a) and 201(n) of the act, as well as case law interpreting these provisions (see, e.g., *Nutrilab* v. *Schweiker*, 713 F.2d 335 (7th Cir. 1983)).

D. Nutrition and Fortification Policy

The *Dietary Guidelines for Americans*, 2005 (Dietary Guidelines) (Ref. 3), a joint publication of the Department of Health and Human Services, FDA's

parent agency, and the U.S. Department of Agriculture, forms the basis for the Federal Government's nutrition programs and policies. The Executive Summary of the *Dietary Guidelines* states: "A basic premise of the *Dietary Guidelines* is that nutrient needs should be met primarily through consuming foods. Foods provide an array of nutrients and other compounds that may have beneficial effects on health. In certain cases, fortified foods and dietary supplements may be useful sources of one or more nutrients that otherwise might be consumed in less than recommended amounts. However, dietary supplements, while recommended in some cases, cannot replace a healthful diet."

FDA's policy on food fortification is set forth in § 104.20 (21 CFR 104.20), which outlines the circumstances under which FDA considers fortification to be appropriate; e.g., to correct a nutritional deficiency recognized by the scientific community or to replace nutrients lost in storage, handling, or processing. Folic acid-fortified grain products and milk fortified with Vitamin D are examples of fortification under § 104.20.

E. Reports and Recommendations Regarding "Functional Foods"

In July 2000, the General Accounting Office (GAO; now the Government Accountability Office) issued a report (the GAO report) entitled "Improvements Needed in Overseeing the Safety of Dietary Supplements and 'Functional Foods'" (Ref. 4). The GAO report makes recommendations to the Congress (regarding statutory amendments) and to FDA (regarding the development of regulations and guidance) directed to improving Federal oversight of safety for dietary supplements and "functional foods" and to ensuring that these products provide the health benefits they claim. The GAO report recommends that Congress amend the act to require "functional food" manufacturers to

meet these requirements: Advance notification to FDA regarding ingredients that companies have determined are safe; notification to FDA regarding the use of labeling claims about effects on the structure or function of the human body (structure/function claims); and disclaimers of FDA approval on product labels containing structure/function claims. The GAO report also recommends that FDA: (1) Develop and promulgate regulations or guidance for industry on the safety-related information required on labels for "functional foods" and (2) develop and promulgate regulations or guidance for industry on the evidence needed to support structure/function claims.

In August 2000 the Functional Foods Committee of the International Life Sciences Institute (ILSI) issued a report (the ILSI report) entitled "Health Claims on Functional Foods—Proposals on Scientific Substantiation and Regulatory Systems" (Ref. 5). The ILSI report emphasizes factors to consider when conducting a clinical study in support of a health claim so as to be able to appropriately use the data collected during the study. As a basis for its proposals, the ILSI report includes information, both domestic and international, regarding recent progress in the area of health claims from a regulatory perspective and regarding recent developments with "functional foods" from a commercial perspective.

In March 2002 the Center for Science in the Public Interest (CSPI) submitted a citizen petition making several requests concerning FDA regulation of "functional foods" (the CSPI petition; Docket No. 2002P–0122; formerly 02P–0122) (Ref. 6). We describe some of CSPI's requests in more detail in section III of this document.

In March 2005 the IFT issued its report entitled "Functional Foods: Opportunities and Challenges" (Ref. 1). We describe some of IFT's recommendations in more detail in section III of this document.

II. Purpose and Scope of the Hearing

The purpose of the hearing is for the agency to share its current regulatory framework and rationale regarding the safety evaluation and labeling of conventional foods being marketed as "functional foods," and to solicit information and comments from interested persons on how FDA should regulate these foods under the agency's existing legal authority. The scope of this hearing is determined by this notice. FDA invites information and comments on the issues and questions listed in section III of this document as follows:

III. Issues and Questions for Discussion

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?

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?

- *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?

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"?

B. Food Labeling

- *Issue 3*: The CSPI petition requests that we require food companies to notify us within 30 days of marketing a conventional food bearing a structure/function claim if such food contains a "novel ingredient," and to include the disclaimer currently required on dietary supplements making structure/function claims on the label and in labeling of such foods.

Question 3. If our statutory authority permits, should we require food companies to notify us within 30 days of marketing a conventional food bearing a structure/function claim and to include the disclaimer currently required on dietary supplements making structure/function claims in labeling of such foods? If yes, what is the scientific (e.g., consumer studies) basis for your position? Under what existing legal authority could FDA require notification of these claims? Under what legal authority could FDA require inclusion of such a disclaimer with these claims?

- *Issue 4*: The IFT report recommends that companies wishing to make label claims regarding the effects of "functional foods" or ingredients convene panels of independent experts qualified to evaluate the efficacy of the functional food component under consideration. According to IFT's recommendations, the findings of these Generally Recognized as Efficacious (GRAE) panels would be submitted to FDA under a process that is similar to the notification program that we proposed for GRAS substances. If the GRAE panel report found that the proposed label claim was supported by the available scientific evidence, the agency would have 90 days to object to the use of the notified GRAE label claim, and in the absence of such objection the label claim would be permitted at the end of the 90 days.

The act limits FDA's ability to accept this recommendation with regard to certain health claims and nutrient content claims (assuming that the recommendation applies to nutrient content claims, which is unclear because the IFT report does not specify). First, the act requires health claims and nutrient content claims for conventional foods to be submitted to FDA for review through a petition process (see section 403(r)(4)(A) of the act (21 U.S.C. 343(r)(4)(A))), unless the proposed claim is based on an authoritative

statement. Second, even though claims based on an authoritative statement are submitted to FDA for review through a notification process, the act limits the "scientific bodies" that can be sources of such an authoritative statement to certain Government agencies and the National Academy of Sciences (now the National Academies) (see sections 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act (21 U.S.C. 343(r)(2)(G)(i) and (r)(3)(C)(i))). The GRAE panels recommended in the IFT report do not qualify as scientific bodies for this purpose. FDA can and does consider the findings of outside groups that do not qualify as "scientific bodies" as part of the totality of publicly available scientific evidence evaluated in support of a health claim petition, however.

In an advance notice of proposed rulemaking (ANPRM) on food labeling, including health claims (68 FR 66040 at 66044; November 25, 2003 (the 2003 ANPRM on food labeling)), we previously asked for public comment on a question about whether the evaluations of non-governmental groups should be given weight in evaluating the strength of the science supporting a health claim. In that ANPRM, we asked: "If the agency should give weight to the evaluations of these groups, how should this weight be determined?" That question is related to IFT's recommendations regarding the agency's acceptance of the findings of GRAE panels for "functional food" label claims. We are asking the question below, which is similar to the question we asked in the 2003 ANPRM on food labeling, because we would like additional input on this topic.

Question 4. Within our statutory authority, how (if at all) should FDA utilize the findings of non-governmental groups, such as the IFT recommended GRAE panels, in support of health claims, nutrient content claims, and other labeling claims about the effects of a "functional food" or ingredient, such as

structure/function claims? What is the scientific and legal basis for your position? Should FDA institute a premarket notification process for review of the scientific evidence for structure/function claims for "functional foods" and ingredients, as recommended by IFT? What is the scientific basis for your position? Under what existing legal authority could FDA institute a premarket notification process for review of the scientific evidence for "functional foods" and ingredients?

- *Issue 5*: Under *Nutrilab* v. *Schweiker* (713 F.2d 335 (7th Cir. 1983)), 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 (e.g., blocking the digestion of starch) 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. FDA's health claim regulations also require that the substance that is the subject of the claim contribute taste, aroma, nutritive value, or a technical effect recognized in FDA's food additive regulations (21 CFR 101.14(b)(3)(i)). Because we recognize that food substances may confer health benefits through a number of processes, we have provided significant flexibility in determining whether a substance possesses nutritive value. Nutritive value is defined at 21 CFR 101.14(a)(3) as a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients, or providing energy, and we have discussed this definition in many of our health claim reviews. Listings of health claims reviewed to date can be found at *http://www.cfsan.fda.gov/~dms/lab-ssa.html* (SSA claims) and *http://www.cfsan.fda.gov/~dms/qhc-sum.html* (QHCs).

The IFT report criticizes the approach of requiring that the health benefit be derived from the food's nutritive value as too restrictive to allow for claims on foods being marketed as "functional foods." Instead, the IFT report recommends that FDA permit a labeling claim for a "functional food" if the claimed benefit is based either on nutritive value or on "the provision of a physical or physiological effect that has been scientifically documented or for which a substantial body of evidence exists for plausibility" (Ref. 1).

Question 5. Given the agency's interpretation of the definition of nutritive value as reflected in 21 CFR 101.14(a)(3) and our decisions on the health claims reviewed to date, does or will the agency's interpretation of *Nutrilab* v. *Schweiker* to limit structure/function claims and health claims to those that are based on nutritive value (or other food attributes such as taste and aroma) adequately allow for claims in the labeling of "functional foods"? If no, how is the agency's approach inadequate? What is the scientific and legal basis for your position? If you favor a change in the agency's approach, do you recommend that FDA adopt the IFT report's recommendation on this issue, or some other alternative? What legal rationale would support your preferred change in approach?

- *Issue 6*: The IFT report recommends that research into "functional foods" be stimulated using incentives to the food industry, including market exclusivity for their bioactive food components and government research grants for the investigation of these components. There is currently no statutory provision for exclusivity of the use of a substance added to food (whether this be a food additive or a GRAS substance) or for the use of a health claim (whether a health claim has been authorized under NLEA or FDAMA or whether FDA has issued a letter of enforcement discretion for a QHC).

In the 2003 ANPRM on food labeling, we previously asked "How can FDA more effectively develop public-sponsored research on substance/disease relationships?" (68 FR 66040 at 66043). We are asking the question below, which is similar to the question we asked in the 2003 ANPRM on food labeling, because we would like additional input on this topic.

Question 6. Should FDA provide incentives to manufacturers to conduct further research on emerging substance/disease relationships? If yes, how? If yes, what is the scientific (e.g., consumer research) basis for your position? (For example, in the case of exclusivity, we are interested in consumer data concerning the use of a health claim on one product but not on other similar products by other manufacturers, and in how such data show that such claims are or are not misleading.) Under what existing legal authority could FDA provide such incentives?

C. Overall Framework for Foods Being Marketed as "Functional Foods"

- *Issue 7*: The FFDCA does not recognize "functional foods" as a distinct category of food, either by definition or through establishing specific requirements for "functional foods." The IFT report recommends that we establish, by regulation, a definition of, and labeling requirements for, "functional foods." The IFT report asserts that these regulations are necessary because consumer interest in the relationship between diet and health has increased the demand for these foods. According to the IFT report, this increased consumer demand is causing the food industry to add more and larger amounts of substances to food and this competitive pressure has shifted the focus of food fortification from carefully orchestrated and closely monitored interventions for addressing specific dietary deficiencies to a focus on meeting market demands.

Question 7. Can the conventional foods being marketed (now or in the future) as "functional foods" be adequately addressed through the current regulations for food additives, GRAS substances, and labeling claims? If no, how are these regulations insufficient to address these products, and what is the scientific and legal basis for your position?

IV. Notice of Hearing Under 21 CFR Part 15

By delegation from the Acting Commissioner of Food and Drugs (the Acting Commissioner) (Staff Manual Guide 1420.21, section 1(b)), the Associate Commissioner for Policy and Planning finds that it is in the public interest to permit persons to present information and views at a public hearing regarding the regulation of conventional foods marketed as "functional foods," and is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Acting Commissioner or his designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the hearing must file a notice of participation (see **ADDRESSES**, **DATES**, **FOR FURTHER INFORMATION CONTACT**, and "Notices of Participation" in section V of this document). By delegation from the Acting Commissioner (Staff Manual Guide 1420.21, section 1(b)), the Associate Commissioner for Policy and Planning has determined under § 15.20(c) that advance submissions of oral presentations are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e), and that the submission of a comprehensive outline or summary is an acceptable alternative to the submission of the full text of the oral presentation. We request that individuals and organizations with common interests consolidate their requests for oral presentation and request time for a joint

presentation through a single representative. After reviewing the notices of participation and accompanying information, we will schedule each oral presentation and notify each participant of the time allotted to the presenter and the approximate time that the presentation is scheduled to begin. If time permits, we may allow interested persons attending the hearing who did not submit a notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading of this notice.

To ensure timely handling of any mailed notices of participation, presentations, or comments, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement "Conventional Foods Being Marketed as 'Functional Foods' Public Hearing."

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to the procedures and limitations in § 10.206, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript will be available on the

Internet at *http://www.fda.gov/ohrms/dockets/default.htm*, and orders for copies of the transcript can be placed at the meeting or through the Division of Dockets Management (see **ADDRESSES**).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of these provisions as specified in §§ 10.19 and 15.30(h). In particular, § 15.21(a) states that the notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time. If the public interest requires, e.g., if a hearing is to be conducted within a short period of time, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given. If the public interest requires, the notice may also provide for submitting notices of participation at the time of the hearing. In this document, the conditions for the hearing specify that notices of participation be submitted electronically to an agency Internet site, to a contact person (outside of FDA) who will accept notices of participation by mail, telephone, fax, or e-mail, or in person on the day of the hearing (as space permits). We are using these procedures for submitting notices of participation, rather than provide for the submission of notices of participation to the Division of Dockets Management, because the hearing is to be conducted within a short period of time and these procedures are more efficient. In addition, these procedures provide more flexibility to persons who wish to participate in the hearing than would be provided if participants were required

to submit the notice of participation in writing to the Division of Dockets Management. By delegation from the Acting Commissioner (Staff Manual Guide 1420.21, section 1(f)(2)(i)), the Associate Commissioner for Policy and Planning finds under § 10.19 that no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law if notices of participation are submitted by the procedures listed in this notice rather than to the Division of Dockets Management.

V. Notice of Participation

Pre-registration by submission of a notice of participation is necessary to ensure participation. The notice of participation may be submitted electronically or by mail (see **ADDRESSES**). The notice of participation also may be submitted orally, by fax, or by E-mail (see **FOR FURTHER INFORMATION CONTACT**). We encourage you to submit your notice of participation electronically. See **DATES** for the dates by which you must submit your notice of participation. A single copy of any notice of participation is sufficient.

The notice of participation must include your name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available). If you wish to request an opportunity to make an oral presentation during the open public comment period of the hearing, your notice of participation also must include the title of your presentation, the sponsor of the oral presentation (e.g., the organization paying travel expenses or fees), if any; and the approximate amount of time requested for the presentation. Presentations will be limited to the questions and subject matter identified in section III of this document.

Under § 15.20(c), if you request an opportunity to make an oral presentation you must submit two copies of your presentation (either as the

full text of the presentation, or as a comprehensive outline or summary), except that individuals may submit one copy. See **DATES** for the dates by which you must submit your presentation. See **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** for information on where to send your presentation

Registration will be accepted on a first-come, first-served basis. Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the meeting. Depending on the number of oral presentations, we may need to limit the time allotted for each oral presentation (e.g., 5 minutes each). We request that interested persons and groups having similar interests consolidate their requests for oral presentation and present them through a single representative. If you need special accommodations due to a disability, please inform us (see **FOR FURTHER INFORMATION CONTACT**). We will also accept registration onsite; however, space is limited and registration will be closed when the maximum seating capacity is reached. Individuals and organizations that do not pre-register to make an oral presentation may have the opportunity to speak if time permits.

Persons pre-registered or wishing to register onsite should check in between 8:30 and 9:00 a.m. We encourage all participants to attend the entire day. Because the meeting will be held in a Federal building, meeting participants must present photo identification and plan adequate time to pass through the security system.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments for consideration at or after the hearing in addition to, or in place of, a request for an opportunity to make an oral presentation (see **DATES**). Submit two paper copies of any written

comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

1. Institute of Food Technologists, "Functional Foods: Opportunities and Challenges," 2005. (Available at *http://members.ift.org/IFT/Research/IFTExpertReports/functionalfoods_report.htm*. Accessed and printed on September 25, 2006.)

2. Food and Drug Administration, "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body," 1998. (Available at *http://www.cfsan.fda.gov/~dms/hclmguid.html*)

3. Department of Health and Human Services and Department of Agriculture, Executive Summary, *Dietary Guidelines for Americans*, 2005. (Available at *http://www.healthierus.gov/dietaryguidelines*. Accessed and printed on September 25, 2006.)

4. General Accounting Office, "Improvements Needed in Overseeing the Safety of Dietary Supplements and 'Functional Foods,'" 2000. (Available at *http://www.gao.gov/new.items/rc00156.pdf*. Accessed and printed on September 25, 2006.)

5. International Life Sciences Institute, "Health Claims on Functional Foods—Proposals on Scientific Substantiation and Regulatory Systems," 2000.

6. Center for Science in the Public Interest, Citizen petition 2002P–0122, Petition for Rulemaking on Functional Foods and Request to Establish an Advisory Committee, 2002.

Dated: 10/19/06
October 19, 2006.

Randall W. Lutter,
Associate Commissioner for Policy and Planning.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

BILLING CODE 4160–01–S

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