

**SUMMARY OF ORAL PRESENTATION
FDA PUBLIC HEARING
DECEMBER 5, 2006**

**CONVENTIONAL FOODS BEING MARKETED AS
FUNCTIONAL FOODS**

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Pursuant to the Food and Drug Administration (FDA) Federal Register Notice of public hearing (Notice), 71 Fed. Reg. 62,400 (Oct. 25, 2006), Hyman, Phelps & McNamara, P.C. provides the following views that will be presented on behalf of food and dietary supplement clients at the December 5, 2006 public hearing.

I. OVERVIEW

FDA's Notice defines "functional food" for the purposes of this hearing 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). *Id.* at 62,401. Since 1938, the Federal 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." 21 U.S.C. § 321(g)(1).

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." 71 Fed. Reg. at 62,401. We agree with FDA that the current provisions of the FDC Act and FDA's regulations adequately assure the safety of conventional food ingredients, and that there is no need to add to or change these provisions in any way. 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, *see, e.g., Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983), appropriately regulate structure/function claims for conventional foods. However, we do not agree with FDA's historic interpretation of Nutrilab, and view this hearing and subsequent deliberations as the appropriate time for FDA to abandon its long-held, and, in our view, incorrect interpretation.

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 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.

Nutrilab, 713 F.2d at 338 (emphasis added).

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 hearing 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.

71 Fed. Reg. at 62,404 (citation omitted).

FDA should abandon this misreading of Nutrilab and permit conventional foods to make the breadth of structure/function claims that is permitted by the statute and the Court of Appeals' decision in Nutrilab. We agree with the shortcomings in the FDA's approach from a scientific perspective as identified by the Institute of Food Technologists (IFT) March 2005 Expert Report, and also agree with the IFT that, from a scientific and public health perspective, FDA should permit substantiated structure/function claims based on any physical or physiological effect that a food might have.

It appears that FDA is already considering adopting this broader and legally correct approach to structure/function claims for conventional foods. In a speech before the Food Drug Law Institute on October 31, 2006, FDA Chief Counsel Sheldon Bradshaw was quoted as stating the following:

Most importantly I think, given the FDA's interpretation of the definition of nutritive value and the agency's decision that . . . structure/function claims are limited to the nutritive value of the food, [FDA should consider] whether or not we ought to move closer to IFT's recommendation, and that is to allow conventional foods to make any sort of structure function claim at all.

FDA Will Mull Lifting Nutritive-Value Requirement for Functional Food Claims, The Tan Sheet, Nov. 6, 2006, at 8.

In summary, FDA's current statutory authority, and the regulations that FDA has promulgated pursuant to that authority, adequately assure the safety and lawfulness of

“functional foods” as defined in the Notice. To properly exercise this statutory authority, FDA should abandon its erroneous and restrictive reading of Nutrilab and permit the same breadth of structure function claims for conventional foods as is permitted for dietary supplements. Requiring that such claims be substantiated and based on any physical or physiological effects of the food would comply with statutory authority and, as pointed out by the IFT, benefit public health.

II. FDA ISSUES AND QUESTIONS FOR DISCUSSION

The following issues and questions (text in bold) are quoted from FDA’s Notice. 71 Fed. Reg. at 62,403-05. An answer is provided for each of FDA’s numbered questions.

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.

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 1a above.

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.” 21 C.F.R. § 170.30(b). 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.

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?

Answer 3. The FDCA Act does not authorize such a notification requirement. We agree with FDA that current statutory and regulatory requirements for conventional foods are adequate to assure that structure/function claims for such foods are truthful and not

misleading. Therefore, there is no need to legislate new authority to require such notification.

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?

Answer 4. We defer to the IFT, but believe that FDA has misinterpreted the IFT Expert Report. We understand that the IFT has recommended use of non-governmental

expert panels in the context of qualified health claims, and believe that such panels could be useful in this context and would help FDA with decisions concerning enforcement discretion. Since there is no authority or need for premarket review of structure/function claims (FDA's statement that the IFT has recommended such a process is incorrect) there is no need for non-governmental expert panels in this context.

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://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.cfsan.fda.gov/~dms/lab-ssa.html> (SSA claims) and <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=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”.

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?

Answer 5. FDA’s interpretation of Nutrilab is incorrect and impermissibly narrow, as explained above. The FDC Act permits structure/function claims for conventional foods that are based on properties of foods other than taste, aroma, or nutritive value. This is consistent with the IFT Expert Report recommendations. Such an approach would also encourage research and consumer awareness of the benefits of food, beyond taste, aroma, and nutritive value, and would therefore benefit public health.

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?

Answer 6. FDA should provide research grants, and request funds, and additional authority if needed, from Congress to encourage additional research into the health benefits of foods through such grants.

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?

Answer 7. Again, we defer to the IFT as to the interpretation of its own Expert Report. With the exceptions addressed above, we agree with FDA that current statutory and regulatory requirements are sufficient to address safety and labeling requirements for “functional foods.”

III. CONCLUSION

We appreciate the opportunity to participate in this hearing, and are confident that the views expressed herein are consistent with the law and the interests of public health.