



Michael D. Maves, MD, MBA, Executive Vice President, CEO

January 5, 2007

Division of Dockets Management
[HFA-305]
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Conventional Foods Being Marketed as “Functional Foods”
[Docket No. 2002P-0122]**

Good nutrition is vital to good health. Unfortunately, many Americans have poor dietary habits, consume unhealthy foods, are overweight or obese, and are at increased risk for serious diseases such as type 2 diabetes and atherosclerosis. Thus, among other initiatives to improve the diets of our citizens, informing and educating consumers about foods that promote good health, and about foods that are unhealthy, should be a high priority.

In this regard, the Food and Drug Administration (FDA) is to be commended for soliciting public comments on conventional foods being marketed as “functional foods” (Fed. Reg. October 25, 2006; 71(206):62400-62407). The American Medical Association (AMA) is pleased to offer its views on this important subject. Generally, the FDA must ensure that the foods we eat are safe, and that food labeling is accurate, balanced, and based on sound science so that consumers are not confused or misled. The AMA makes the following specific recommendations:

1. A class of foods called “functional foods” should not be established.
2. Ingredients that are added to conventional foods must be proven – unequivocally – to be safe prior to marketing of the food product.
3. Health claims for conventional foods should be required to satisfy the “significant scientific agreement” standard.
4. Structure/function claims for conventional foods should be limited to those that are based on taste, aroma, or nutritive value.
5. The labels of conventional foods that contain amounts of ingredients that increase the risk of a disease should be required to contain precautionary information.

A class of foods called “functional foods” should not be established.

The Federal Food, Drug and Cosmetic Act (FDC Act, 21 U.S.C. 301 et seq.) has no specific provision for the establishment of a class of foods called “functional foods.” The AMA does not believe such a class of foods is needed and it should not be established by the FDA via regulation.

Many of the conventional foods that Americans currently consume in their diets could be considered “functional.” For example, fruits and vegetables are associated with a reduced risk of chronic diseases, such as stroke, type 2 diabetes, and certain cancers; fat-free and low-fat milk products are rich in calcium and can reduce the risk of low bone mass; whole grain food products are rich in fiber that can reduce the risk of coronary artery disease; and foods fortified with folic acid can reduce neural tube defects in the offspring of pregnant women. Although none of these conventional foods are designated by label as “functional foods,” most Americans understand the valuable health benefits of these foods.

If the FDA were to establish a new class of foods as “functional foods,” consumers could easily be confused and misled into believing such food products are better than conventional foods lacking such a designation. This may likely be the case even if conventional foods lacking such a designation were, in reality, more important to a good diet than so-called “functional foods.” Furthermore, the addition of micronutrients, phytochemicals, and other food compounds, beyond the amounts found naturally in plant and animal foods, increases the risk of consumers ingesting potentially harmful levels of these nutrients and compounds, particularly with the consumption of multiple “functional food” products each day. Therefore, rather than creating a new class of foods called “functional foods,” the FDA would be better served by judiciously regulating the claims on conventional foods. When consumers are accurately informed about healthy – and unhealthy – foods, consumers can make informed choices about the foods they eat without confusion.

Ingredients that are added to conventional foods must be proven – unequivocally – to be safe prior to marketing of the food product.

The most important obligation of the FDA regarding the food supply is to ensure that the foods consumed in the United States – regardless of origin – are safe. This obligation certainly is applicable within the context of food companies adding an ingredient(s) to conventional foods to “make them functional.” Thus, the AMA urges that the FDA require pre-market notification and evidence of safety prior to introducing food products containing such an added ingredient(s) into the marketplace.

The AMA suggests two possible ways this can be accomplished under current law. One approach would be to subject such ingredients to the food additive regulations (21 CFR 170). While the AMA agrees with the FDA’s comment that these regulations have traditionally been applied to ingredients added to conventional foods for their “technical

effects” on the food, the AMA believes the FDA has the legal authority to expand this to any ingredient added to a conventional food that “becomes a component or otherwise affects the characteristics of the conventional food” [see the definition of a food additive in the FDC Act at 21 U.S.C. 321(s)].

An alternative approach might be feasible if the added ingredient will be the subject of a health claim. Under these circumstances, the FDA could apply a benefit-risk calculus to determine if the conventional food with the added ingredient meets the “significant scientific agreement” standard for the health claim pursuant to 21 U.S.C. 343(r)(3)(B) of the FDC Act. Prior to marketing the food product with the added ingredient that will be the subject of the health claim, the company would be required to submit the necessary scientific evidence for review by the FDA to obtain approval for the health claim and to show the food product with the added ingredient will be safe for consumption. In other words, in order to market the product, the benefit-risk calculus would clearly have to be positive.

Health claims for conventional foods should be required to satisfy the “significant scientific agreement” standard.

The AMA reaffirms its strong view that health claims on conventional foods should be based on a single standard of scientific evidence, which should be the “significant scientific agreement” standard as mandated by law [see 21 U.S.C. 343(r)(3)(B) of the FDC Act]. When consumers see a health claim on a food product, they have the right to expect the claim to be scientifically valid and unlikely to change over time. This can only occur if the standard of scientific evidence to support the claim is both strong and consistent. The “significant scientific standard,” as comprehensively discussed in the FDA’s 1999 *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, satisfies this goal.

The AMA continues to vigorously oppose the use of so-called “qualified health claims” on conventional foods. There is no basis for the FDA to allow the use of “qualified” health claims in the labeling of conventional foods. Federal law requires [unqualified] health claims for conventional foods that are based on “significant scientific agreement.” The *Pearson v. Shalala* court decision does not apply to conventional foods, and even if it did apply, recent scientific research has shown that disclaimers cannot remedy possible deceptiveness of “qualified” health claims.

The AMA urges the FDA to rescind its approval of all “qualified” health claims for conventional foods, and to prohibit the use of such claims in the future. We have previously provided detailed reasons for our objection to the use of such claims in correspondence to the FDA on February 21, 2003 [to Docket No. 02N-0515], May 23, 2003 [to Docket No. 03N-0069], and December 16, 2005 [to Docket No. 2005N-0413]. A copy of the AMA’s most recent letter to the FDA on “qualified health claims” for conventional foods is enclosed.

Structure/function claims for conventional foods should be limited to those based on taste, aroma, or nutritive value.

The AMA agrees with the FDA that the FDC Act has no provision for structure/function claims for conventional foods. The AMA also agrees with FDA's interpretation of *Nutrilab v. Schweiker* that structure/function claims for conventional foods should be limited to claims about effects that derive from the taste, aroma, or nutritive value [as defined in 21 CFR 101.14(a)(3)] of the food or food ingredient that is the subject of the claim.

The AMA opposes the expansion of structure/function claims on conventional foods to "provision of a physical or physiological effect," as proposed by the Institute of Food Technologists, unless the FDC Act is amended to allow such claims. The AMA could support such an amendment to current federal law only if a company were required to obtain pre-market approval for a structure/function claim from the FDA after submission of scientific evidence that satisfies the "significant scientific agreement" standard. Consistent with our views on health claims, the AMA believes that if broader use of structure/function claims is allowed on conventional food labels, consumers have the right to expect that a claim is scientifically valid and unlikely to change. This can only occur if the standard of scientific evidence to support the claim is both strong and consistent.

The FDC Act currently allows structure/function claims on dietary supplements pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Public Law 103-417, 108 Stat. L. 4325). As communicated to both the Congress and the FDA on numerous occasions, the AMA believes DSHEA fails to provide the FDA with adequate authority to regulate dietary supplements. For example, while DSHEA requires manufacturers to be able to substantiate the truthfulness of structure/function claims, manufacturers are not required to provide this data to the FDA, and published data to support structure/function claims is very limited. Rather, the law only requires the manufacturer to include a disclaimer on the product label, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease." All of the burden then falls upon the FDA to prove that such a claim is inappropriate. This is an unacceptable situation. Of particular relevance, the FDA should not apply DSHEA – and all of its limitations – to regulate structure/function claims on conventional foods.

The labels of conventional foods that contain amounts of ingredients that increase the risk of a disease should be required to contain precautionary information.

Federal law requires conventional food product labels to contain information about the amounts of certain nutrients per serving [see 21 U.S.C. 343(q)(1)], and the FDA has implemented this provision of the law through its food labeling regulations [21 CFR 101]. Food product labels are required to contain a standardized "nutrition facts panel" listing the amounts of these nutrients per serving and as a percentage of the Daily Value (%DV) for a 2,000 calorie diet.

Some of the nutrients that must be included in the “nutrition facts panel,” including saturated fat, cholesterol, *trans* fat, and sodium, are known to increase the risk for certain diseases. For example, saturated fat, cholesterol and *trans* fat increase the risk of developing coronary artery disease, and sodium increases the risk of developing hypertension.

It often is assumed that consumers easily understand the “nutrition facts panel” (e.g., which food products are high in saturated fat, cholesterol, *trans* fat, or sodium) and can make appropriate judgments about which foods to purchase and consume. However, this assumption may be false (e.g., see Rothman RL et al. Patient understanding of food labels: The role of literacy and numeracy. *Am J Prev Med* 2006;31(5):391-398). Thus, the AMA encourages the FDA to be more proactive in requiring food labels to contain precautionary information when the food product contains amounts of ingredients that increase the risk of developing a disease, or when the food product is problematic for individuals with certain diseases.

The AMA believes that the FDC Act gives the FDA broad legal authority to define “misbranding” [see 21 U.S.C. 321(n)] as well as specific legal authority to require highlighting of important nutrient information on the food label to assist consumers in maintaining healthy dietary practices [see 21 U.S.C. 343(q)(1)]. The AMA encourages the FDA to use this authority to make food labels more informative and useful for consumers by requiring companies to include precautionary information when appropriate.

We believe that a strong argument can be made that the misbranding provisions in 21 U.S.C. 321(n) allow the FDA to require companies to include precautionary statements on food labels. For example, for foods high (e.g., $\geq 20\%$ DV per serving) in saturated fat, the FDA could require the statement, “This product is high in saturated fat, which can increase the risk of developing heart disease in healthy people. Individuals with heart disease should use this product with caution and may want to talk with their doctors.” Similarly, for foods high (e.g., $\geq 20\%$ DV per serving) in sodium, the FDA could require the statement, “This product is high in sodium, which can increase the risk of developing high blood pressure in healthy people. Individuals with high blood pressure should use this product with caution and may want to talk with their doctors.” These types of statements should clearly inform consumers about unhealthy food products and warn those individuals with a relevant disease that such products could exacerbate their disease.

We also believe that the nutrition labeling provisions at 21 U.S.C. 343(q)(1) allow the FDA to require highlighting of problematic nutrients on the “nutrition facts panel.” The AMA recommends the FDA consider the development of a red-yellow-green highlighting system to identify nutrients that make a food product unhealthy (or healthy). For example, food products containing saturated fat, cholesterol, or sodium $\geq 20\%$ DV per serving would have the relevant nutrient(s) highlighted in red. Also, any product with *trans* fat would have that nutrient highlighted in red. Other products containing saturated fat, cholesterol or sodium would have the respective nutrient(s) highlighted in yellow. On the other hand, products that have no saturated fat, cholesterol or *trans* fat, and with no added sodium or sugar, could

have those nutrients highlighted in green. This information should be prominently displayed on the food product label (e.g., on the front panel of the label) so that consumers can readily identify it. Combined with an extensive consumer education campaign, such a system should make it much easier for consumers to differentiate healthy from unhealthy food products and to make appropriate choices.

Finally, in the *Federal Register* Notice the FDA discusses GRAS (“generally recognized as safe”) and how to obtain GRAS for substances that are added to conventional foods. However, the Agency says nothing about the revocation of GRAS status for a substance that is ultimately shown not to be safe. In that regard, the AMA recommends that the FDA revoke the GRAS status for sodium chloride (salt). There is strong evidence that across populations, the level of blood pressure, the incremental rise in blood pressure with age, and the prevalence of hypertension are related to salt intake. Thus, sodium chloride is not safe in levels commonly consumed in the diet and its GRAS status should be revoked.

Conclusion

In conclusion, the FDA can protect consumers and promote the health of the public by ensuring that the foods we eat are safe, and that food labeling is accurate, balanced, and based on sound science so that consumers are not confused or misled. While labeling can be used to promote healthy food products, the FDA also should require labeling to identify unhealthy food products. The AMA urges the FDA to consider our specific recommendations, as discussed above, to achieve these goals. If you have any questions or need additional information, please do not hesitate to contact Joseph W. Cranston, PhD, Director, Science, Research and Technology, at 312-464-4554 or by email to joseph.cranston@ama-assn.org.

Sincerely,

A handwritten signature in cursive script, reading "Mike Maves", is written in black ink. The signature is positioned to the left of a vertical red line.

Michael D. Maves, MD, MBA

Enclosure