

the marker substances was to distinguish certain fruits and vegetables that were characterized by compositions known to help reduce cancer risk from other fruits and vegetables that might not provide the same benefit.

B. Issues Relating to Dietary Guidance

FDA recognizes the importance of dietary guidance in assisting and encouraging the U.S. population to make better food choices and establish healthier eating patterns. Although these types of statements are not health claims, consistent and scientifically sound dietary guidance statements can be useful to consumers when they are truthful and nonmisleading. As previously mentioned, FDA has no regulatory authority to review or authorize dietary guidance statements before use. When used in labeling for foods, however, such statements must be truthful and not misleading under sections 201(n) and 403(a)(1) of the act. The agency generally has viewed most dietary guidance for the general U.S. population as originating from Federal agencies with public health missions related to diet and disease. For example, major Federal documents such as the Dietary Guidelines for Americans issued by USDA and U.S. Department of Health and Human Services exemplify government consensus about dietary recommendations. Given the important role that information on food labels can play in affecting consumers' health and dietary decisions, FDA sees a need to foster enhanced federal cooperative efforts to identify and agree upon dietary guidance that is appropriate for food labels and how such guidance may be used.

1. Definitions

Dietary guidance—FDA requests comments on an appropriate definition of “dietary guidance” for labeling purposes, as well as the current approach, outlined previously, to distinguish between health claims and dietary guidance statements.

Substance—Since the distinction between dietary guidance statements and health claims often focuses on whether the “substance” element is present in the claim (whether express or implied), FDA requests comments on ways in which the definition of “substance” in § 101.14(a)(2) can or should be clarified. Additionally, in regard to the appropriate definition of “substance” for purposes of a health claim, FDA is interested in comments on whether a specific authorized health claim about whole grain foods (described later) properly refers to a substance as compared to a broad

category of food. This health claim is authorized based on a statement from an authoritative body under section 403(r)(3)(C) of the act.¹⁵

On March 10, 1999, General Mills, Inc., submitted to the agency a notification containing a prospective claim about the relationship of whole grain foods and heart disease and certain cancers. The notification cited the following statement from the Executive Summary of the National Academy of Sciences report, “Diet and Health: Implications for Reducing Chronic Disease Risk” (page 8), as an authoritative statement: “Diets high in plant foods—i.e., fruits, vegetables, legumes, and whole-grain cereals—are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach.” For purposes of eligibility to bear the prospective claim, the notification defined “whole grain foods” as foods that contain 51 percent or more whole grain ingredient(s) by weight per RACC. It suggested that compliance with this definition could be assessed by measuring the dietary fiber level of whole wheat, the predominant grain in the U.S. diet. The level of fiber was intended for compliance purposes only and was not defined as the substance that was the subject of the health claim or as a marker for that substance.

FDA's decision not to prohibit or modify the claim means that, as of July 8, 1999, manufacturers may use the following claim on the label and in labeling of any product that meets the eligibility criteria described in the notification: “Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.” FDA seeks comments on whether this claim properly refers to a substance as compared to a broad category of food. The notification and additional materials regarding the claim are publicly available from the Division of Dockets Management (Docket No. 99P-2209) (see **ADDRESSES**).

¹⁵ Under the provisions of the FDAMA, a manufacturer may submit to FDA a notification of a health claim based on an authoritative statement published by an appropriate authoritative body (i.e., a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions) (21 U.S.C. 343(r)(3)(C)). If FDA does not act to prohibit or modify such a claim within 120 days of receipt of the notification, the claim may be used.

2. The Substance as the Subject of a Health Claim

FDA's experience demonstrates that most substances that are the subject of an authorized health claim are substances that can be found in a number of foods (e.g., calcium) or spread throughout the food supply (e.g., saturated fat). FDA has provided for health claims that include reference to the common substance to assist consumers in their understanding of the nature of the diet/health relationship, and more importantly so that consumers recognize that they can construct healthy diets by using a variety of foods and nutrient sources rather than just one. For instance, in the example of the calcium/osteoporosis claim, FDA requires that the substance that is the basis of the claim (i.e., calcium) be included in the wording of the claim (21 CFR 101.72). FDA requests comments on the usefulness of statements that expressly include the substance that is the basis for the claim (e.g., “Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis”) versus “food-specific” claims such as: “Yogurt may reduce the risk of osteoporosis.”

3. The Use of Food Category “Substitutions” or “Replacements” as a Form of Dietary Guidance

FDA views food substitution/replacement recommendations as potentially helpful to consumers, but also potentially problematic because they might be misleading or confusing to consumers. For example, the message to substitute mono- and polyunsaturated fats for saturated fats to promote heart health is intended to help consumers reduce their intake of saturated fat and cholesterol within the dietary context of moderate fat intakes. A message to choose fish, shellfish, lean poultry and other lean meats, beans, or nuts daily while limiting intakes of high-fat processed meats has a similar intention. However, the likelihood that these messages will positively affect the ability of consumers to choose healthful diets depends on an understanding of the total dietary context of the message, which may prove confusing or difficult to effectively communicate to consumers. FDA is requesting comments on whether dietary guidance statements should include recommendations for making food or substance “substitutions” or “replacements.” If these types of dietary guidance statements are encouraged, how can FDA ensure that they are made in clear and nonmisleading ways that will enhance and benefit public health?