

purpose of such dietary guidance statements is to assist and encourage individuals in making better food choices and establishing healthier eating patterns. If FDA's mission is properly understood to include a role in assisting the public in making wise dietary choices that benefit long-term health, a number of possible strategies become evident. Those strategies include, for example, challenging industry to channel competitive energies into disseminating health information in food labeling and promoting food products on the basis of nutritional value, as well as taste, price, amount, and convenience. Importantly, as mentioned previously, there is also the possibility to pursue a range of consumer information options in collaboration with other Federal agencies, health researchers, and stakeholders as more information about diet/health relationships becomes available.

A. Regulatory Distinctions Between Dietary Guidance and Health Claims

As previously stated, section 403(r) of the act contains statutory provisions for the regulation of health claims, among other types of label statements. Under §§ 101.14 and 101.70, a "health claim" has a specific definition and is regulated differently from other types of statements on labels of conventional foods and dietary supplements. Health claims are specifically about the relationship between a substance and a disease; they are required to be reviewed and authorized by FDA prior to use. Health claims are limited to claims about disease risk reduction, and cannot be claims about the cure, mitigation, or treatment of disease. The latter claims are currently regarded as constituting drug claims under section 201(g) of the act (21 U.S.C. 321(g)) (see *Whitaker v. Thompson*, 239 F.Supp. 2d 43, 52–53 (D.D.C. 2003)). The following is an example of a health claim about the relationship between calcium (a substance) and osteoporosis (a disease): "Calcium may reduce the risk of osteoporosis." In comparison, the following is an example of a drug claim: "Consumption of 320 mg daily of Saw Palmetto extract may cure cancer."

Unlike health claims, which target a specific substance and a specific disease or health-related condition, dietary guidance statements focus instead on general dietary patterns, practices, and recommendations that promote health. In addition, such statements can be made on conventional food and dietary supplement labels without FDA review or authorization before use. Like all statements in food labeling, dietary

guidance statements must be truthful and nonmisleading as required under sections 201(n) and 403(a)(1) of the act. An example of a dietary guidance statement is: "Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases." As part of a cooperative effort with the National Cancer Institute (NCI), FDA recently encouraged the produce industry and food manufacturers to use this statement in the labeling of fruits, vegetables, and foods that meet the criteria for NCI's 5 A Day for Better Health Program (Ref. 5).

FDA addressed the issue of dietary guidance during the development of health claim regulations (58 FR 2478, January 6, 1993 (for conventional foods); 59 FR 395; (for dietary supplements)). In the preambles to the final rules, the agency stated that a health claim contains two basic elements: A substance and a disease or health-related condition. To clarify the difference between dietary guidance statements and health claims, FDA stated that it would use the term "dietary guidance" to refer to statements that do not contain both basic elements of a health claim¹³ (58 FR 2478 at 2487 and 59 FR 395 at 418). Thus, dietary guidance statements may make reference to a disease or substance, but not both. For example, dietary guidance statements might focus on general dietary patterns or practices and broad categories of foods, rather than a specific substance. Alternatively, they may link a specific substance to a nondisease endpoint such as building bones, a healthy lifestyle, or promoting health. In this case, the substance element is present in the statement but not the disease element.

A health claim expressly or by implication characterizes the relationship of certain substances to a disease or health-related condition (21 U.S.C. 343(r)(1)(B)). Hence, the elements (i.e., the substance element, and the disease or health-related condition element) of a health claim may be either express or implied.

The term "substance" means a specific food or component of food, regardless of whether the food is in conventional food or dietary supplement form (§ 101.14(a)(2)). In discussing the definition of "substance" in the preamble to the final rule on general requirements for health claims for conventional foods (58 FR 2478 at 2479–2480), FDA noted that it agreed

¹³ In this ANPRM, FDA is using the term "statement(s)" in place of the term "claim(s)" to emphasize the distinction between a health claim and dietary guidance when the discussion relates specifically to dietary guidance.

with comments that its proposed definition for substance interpreted the NLEA too narrowly with respect to the regulation of health claims about foods, and that Congress intended that foods (in addition to food components) could be the subject of health claims regulated under section 403(r) of the act. (As proposed, § 101.14(a)(2) stated: "Substance means a component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances" (56 FR 60537 at 60563, November 27, 1991)). However, based upon the legislative history of the NLEA,¹⁴ the agency noted that to be a health claim, a claim about a food must be, at least by implication, a claim about a substance in the food (58 FR 2478 at 2480). FDA further explained that when a consumer could reasonably interpret a claim about the relationship of a food to a disease or health-related condition to be an implied claim about a substance in that food, that claim would satisfy the first element of a health claim (i.e., the substance element). *Id.*

In addition, FDA concluded that a claim about the benefits of a broad class of foods (e.g., fruits or vegetables) that does not make an express or implied connection to a substance found in that class of foods would not constitute an implied claim, and that such a claim is not a health claim. Rather, such a statement would be dietary guidance because it is not expressly or impliedly about a substance. If a substance in a broad class of foods cannot be expressly identified, it may be possible to find that it is implied. For example, in the preamble to the final rule concerning a specific health claim about an association between antioxidant vitamins and cancer (58 FR 2622, January 6, 1993), FDA introduced the concept of a marker for the substance element of an implied health claim. In that final rule, FDA decided not to authorize a health claim about a relationship between antioxidant vitamins and cancer, and instead authorized a health claim relating substances in diets low in fat and high in fruits and vegetables to a reduced risk of cancer. In short, the agency authorized a health claim in which the subject was fruits and vegetables that were low in fat and were good sources of certain substances (e.g., fiber, vitamin A, or vitamin C). It was not clear whether the marker substances were actually the active substances or merely served as markers for other unidentified substances. The purpose of identifying

¹⁴ See H.R. Rep. No. 101–538, at 20 (1990), reprinted in 1990 U.S.C.A.N. 3336, 3350.