DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Parts 20 and 101

[Docket No. 85N-0061]

Food Labeling; General Requirements for Health Claims for Food

Agency: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health related condition on the labels and in labeling of foods in conventional food form (conventional foods), and (2) the content of petitions regarding the use of such health, claims pertaining to specific substances in such food. This action is being taken in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims for conventional foods. However, in the Dietary Supplement Act of 1992 (the DS Act), Congress imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements with only very limited exceptions. Therefore, these final rules do not apply to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Elsewhere in this issue of the **Federal Register**, FDA is issuing final rules that respond, at least, with respect to conventional foods and, to the extent that they would permit claims, with respect, to dietary supplements, to the 1990 amendments' directive that the agency consider 10 topics associating substances with diseases or health-related conditions. Those final rules have been developed in accordance with the general principles of the requirements in this document.

EFFECTIVE DATE: May 8, 1993, except § 101 9(k)(1) which will become effective February 14, 1994, and §§ 101.14(d)(2)(vii)(B) and 101.14(d)(3) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on May 8, 1994.

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SUPPLEMENTARY INFORMATION

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60537), FDA published a proposed rule to establish, general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of both conventional foods and dietary supplements, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in food. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims. With respect to health claims, the 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) by adding a provision (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims. The House Report of June 13, 1990, states, "Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet" (Ref. 1). Senator Orrin Hatch, one of the primary authors of the 1990 amendments, noted that diet has been implicated as a factor in the three leading causes of death (heart disease, cancer, and stroke) (Ref. 2). In addition, the statement of the House Floor Managers noted that "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims" (Ref. 3). The House Report characterized the need for regulation as "compelling" (Ref.1).

FDA's first step in support of the congressional goals of the 1990 amendments appeared in the form of the proposed health claims regulation. The proposed regulation contained: (1) Definitions to clarify the meaning of specific terms used in the regulation, (2) preliminary requirements that a component of food must meet to be eligible to be the subject of a health claim; (3) a scientific standard for assessing the validity of claims both for dietary supplements and for conventional food, general labeling requirements for hearth claims that are permitted by regulation, and prohibitions on certain types of health claims; and (4) the required content of petitions for health claims.

In response to the proposed rule, FDA received over 6,000 letters, each containing one or more comments, from consumers, health care professionals, universities, State and local governments, foreign governments, trade organizations, consumer advocacy organizations, research institutes, industry, and professional organizations. In addition to receiving these written comments, the agency held a public hearing on January 30 and 31, 1992 (57 FR 239, January 3, 1992), on a number of food labeling issues, including the requirements for health claims. Some of the comments agreed with one or more provisions of the proposed rule without providing further grounds for support other than those presented by FDA in the preamble to the proposal. Other comments disagreed with one or more provisions of the proposed rule without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of the regulations and will not be addressed in this document. Most of the comments provided specific grounds in support of their positions concerning provisions of the proposed regulations. The agency has summarized and addressed the issues raised in the sections of this document that follow.

In October, 1992, the DS Act was enacted. This statute states that with certain limited exceptions, the Secretary (and FDA, by delegation) may not implement the 1990 amendments with respect to dietary supplements earlier than December 15, 1993. As a result, this final rule applies only to conventional food (Ref. 34). The DS Act establishes a timetable for the adoption of final rules implementing the 1990 amendments with respect to dietary supplements by December 31, 1993. One exception to the moratorium on the implementation of the 1990 amendments is a provision (section 202(b)) that stoles that FDA may, earlier than December 15, 1993, approve claims with respect to dietary supplements that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the 1990 amendments. FDA is responding to this provision in the documents on the 10 specific substance-disease topics that accompany the final rule.

II. Definitions

FDA proposed definitions for "health claim," "substance," "nutritive value," and "'dietary supplement" to serve as tools for clearly establishing the scope of the types of claims that would be

subject to the regulations promulgated under section 403(r)(1)(B) of the act. In addition, the agency proposed a definition for "disqualifying nutrient levels" to establish limits on the amounts of certain nutrients that are known to increase the risk of disease that can be in a food if that food is to bear a health claim in its labeling.

A. Definition of a Health Claim

As proposed, §101.14(a)(1) stated:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include only those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition.

(56 FR 60537 at 60563)

As was explained in the preamble of the proposal (56 FR 60542), FDA derived this definition almost directly from the provisions of section 403(r)(1)(B) of the act. The proposed definition establishes that a claim must have at least two basic elements for it to be regulated as a "health claim." First, the claim must be about a "substance" as that term is defined in proposed § 101.14(a)(2). Secondly, the claim must characterize the relationship of the substance to a "disease or health-related condition." If a claim has one of these elements without the other, it would not be a "health claim," although it may still be subject to regulation under other provisions of the act (e.g., the requirement of section 493(a)(1) of the act that a label statement be truthful and not misleading).

Although FDA attempted in the proposed definition of a "health claim" to draw clear lines between health claims and other types of claims about diet and health, comments raised significant questions about the applicability of one or both of the elements highlighted in the definition. Many of these questions resulted because, at the time that it issued the proposal, FDA had not itself decided on the precise coverage of the definition, For example, in the proposal (56 FR 60537 at 60542). FDA stated:

While the act focuses on the substance-disease relationship, it is clear that the Congress was concerned about any disease claims that are made on food (Ref. 1). In reviewing the evidence on the 10 topic areas, however, FDA has become aware that there may be certain relationships between foods and diseases that are supported by the available evidence but that cannot be attributed to a particular nutrient. For example, the scientific evidence shows that diets high in whole grains, fruits, and vegetables, which are low in fat and rich sources of fiber and certain other nutrients, are associated with a reduced risk of some types of cancer. The available evidence does not, however, demonstrate that it is total fiber, or a specific fiber component, that is related to the reduction of risk of cancer. The question is thus whether, to fulfill Congress's intent in the 1990 amendments, FDA should regulate claims about apparent food-disease relationships and, if so, how it should do so.

In response to comments questioning the meaning of the proposed definition of a "health claim," the agency has sought to clarify this definition as well as the meaning of the terms "substance" and "disease or health-related condition."

B. Substance- The First Basic Element

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.

1. Some comments maintained that because section 403(r)(1)(B) of the act specifically addresses only a claim that characterizes the relationship of any nutrient required to be on the label of a food to a disease or health-related condition, claims about other types of nutrients or about foods are not subject to the provisions of section 403(r). Many of these comments contended that claims about foods and other types of claims must be controlled under the general regulatory regime that requires that a label be truthful and not misleading, and they maintained that FDA could not therefore require preapproval of such claims.

However, other comments stated that Congress intended to control claims about foods as well as nutrients. One comment pointed out that people do not eat nutrients as such; they eat foods that contain (or do not contain) those nutrients. Another comment advised that consumers would more readily understand claims about foods than about nutrients, and that where food claims were appropriate, consumers might be more likely to improve their diets. One comment stressed that FDA has historically defined "substance" expansively, asserted that this policy should not be changed, and suggested that the definition of "substance" should be consistent with the wording of § 170.3(g) (21 CFR 170.3(g)), which defines "substance" as including "a food or food component consisting of one or more ingredients." A few comments pointed out that an understanding of Congress' intent can be obtained by considering the legislative history of the 1990 amendments. One comment advised that before the enactment of these amendments, Congress considered a great deal of testimony about how health claims should be related to an overall diet of various foods. For example, a representative from one professional organization told the House of Representatives in a hearing on the bill that ultimately became the 1990 amendments (Ref. 24) that health claims should be compatible with the dietary recommendations of the National Research Council's (NRC's) report "Diet and Health: Implications for Reducing Chronic Disease Risk" (the Diet and Health report) (Ref. 6), That NRC report recommends that people eat five or more servings per day of vegetables or fruits and increase their intake of starches and complex carbohydrates. This recommendation is tied to the conclusion that "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."

In addition, the comment stated that this theme was echoed by the American College of Physicians, which told the House in a prepared statement that the NRC, the Surgeon General, and other organizations "recommend a reduction in fat and an increase in complex carbohydrates and fruits and vegetables in order to reduce the risk of these cancers." Further, the comment advised that the Senate hearing held on November 13, 1989, before the Committee on Labor and Human Resources (Ref. 25), also included significant testimony about the overall health benefits of foods. For example, an official with the American Dietetic Association told the Senate that that organization supported the dietary recommendations of NRC and the Surgeon General, and that health claims should reflect those recommendations and "should assist the public to integrate specific food products into a well-balanced diet." Thus, the comment maintained that both the House and the Senate had before them a record in which various private and public health organizations endorsed the linking of health claims to foods consumed as part of an overall diet, an endorsement validated by repeated references to the dietary recommendations of the NRC and the Surgeon General, sources that FDA has considered authoritative.

Another comment stated that the congressional debates reveal an equal, if not a greater, concern for the health benefits of foods, as opposed to nutrients, and that this concern makes sense when one considers that many public and private health organizations recommend obtaining an adequate nutrient intake through the consumption of a variety of foods. The comment pointed out that it is clear that during the debates over the 1990 amendments. Congress drew no distinction between foods and nutrients. The comment cited a variety of statements from the Congressional Record to substantiate its contention. For example, the comment pointed out that Senator John Chafee of Rhode Island, cosponsor of S.1425 (the Senate's version of the bill that became the 1990 amendments), said that the proposed legislation would provide definite guidelines governing "the claims and statements that can be made about food" (Ref. 26). Similarly, Senator Orrin Hatch of Utah, cosponsor of the Senate amendments to the House's version of the 1990 amendments, viewed the bill as covering health and diet-related claims about food products (Ref.2).

FDA does not agree that section 403(r)(1)(B) of the act addresses health claims for only those nutrients required to be on the label of a food and does not include claims about other types of nutrients. The language of section 403(r)(1)(B) of the act is clear in that it pertains to a claim that "* * * characterizes the relationship of any nutrient which is *of the type* required by paragraph (q)(1) or (q)(2) to be in the label or labeling of a food * * *" (emphasis added). Section 403(q)(1) of the act lists specific nutrients that are required for food labeling as part of nutrition labeling. Section 403 (q) (2) of the act permits the Secretary of Health and Human Services (the Secretary) to include by regulation any other nutrient. not required to be listed by section 403(q)(l) if information about tire nutrient, will assist consumers in maintaining healthy dietary practices. Moreover, section 403(r)(5)(D) of the act relates to vitamins, minerals, herbs, or other similar substances. Thus, claims relating to a broad range of substances are potentially subject to regulation under section 403(r)(1)(B) of the act, and claims about a nutrient-disease relationship are not outside the coverage of section 403(r) simply because the nutrient in question is not required to be listed in the nutrition label. For these reasons, FDA is retaining the broader term "substance" in the regulations and will use it in this preamble.

In fact, FDA agrees with the comments that contended that the proposed rule interpreted the 1990 amendments too narrowly with respect to the regulation of claims about foods. The agency has reviewed the legislative history of the 1990 amendments and concluded that this history does indeed contain evidence to support the conclusion that Congress intended that foods could be the subject of claims that are regulated under section 403(r)of the act. However, this legislative history also makes clear that, to be subject to section 403(r) of the act, a claim about a food must be. at least by implication, a claim about a substance in the food. The House Report (Ref. 1) states:

> The requirement applies to any disease claim that is made with respect to required nutrients and other nutrients in food. However, a statement about the importance of good nutrition which does not make a direct or implied connection between any nutrient in the food and a particular disease is not necessarily a disease claim that will be covered by this section.

Thus 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.

However, a claim about the benefits of a broad class of foods that does not make an express or implied connection to any of the substances that are found in foods that comprise that class would not constitute an implied claim. Such claims about classes of foods (e.g., fruits and vegetables) are not health claims because they are not about a substance.

Accordingly, FDA has revised the definition of "substance" in new § 101.14(a)(2) to include a specific food as well as a component of food. Although, the agency's tentative view is that the term "substance" has the same meaning regardless of whether the food is a conventional food or a dietary supplement that includes vitamins, minerals, herbs, or other nutritional substances, in response to the DS Act, FDA is not reflecting this view in the final regulation. FDA will decide whether to do so in the rulemaking it will undertake in response to the DS Act. For consistency with the revised definition of "substance," new § 101.14(d)(2)(vii) has also been revised, as explained in section V.E. of this preamble, to provide guidance for identifying the appropriate dietary intake of a specific food necessary to achieve the claimed effect.

FDA has not modified new § 101.14(a)(2) to be identical to § 170.3(g). However, new § 101.14(a)(2) and § 170.3(g) are fully consistent, and any differences in their wording reflect the different contexts to which they apply. The definition of "substance" in § 170.3(g) is specific to the definition of the term "food additive," and in that context it is appropriate because of the statutory definition of "food additive" as "any substance the intended use of which results or may reasonably be expected to result * * * in its becoming a component or otherwise affecting the characteristics of any food " (See section 201(s) of the act (21 U.S.C. 321(s))). Proposed § 101.14(a)(2) was drafted to reflect the broad coverage of section 403(r)(1)(B) of the act. Importantly, a substance under § 170.3(g) would also be a substance under new § 101.14(a)(2) and vice versa.

Under the revised definition of a substance that FDA has included in new § 101.14(a)(2), phrases on labeling such as "eat apples to ——," "eat low sodium foods to ———-," "eat fruits high in fiber to ———," or "cook with garlic to———" would constitute references to a substance and would thereby satisfy one of the two essential elements of a health claim. However, phrases on labeling such as "eat a variety of foods to ——," "eat a variety of fresh fruits and vegetables to ———-," or "follow the food pyramid to ———," without any reference, either express or implied, to a substance that might be in the foods, would not satisfy this element. The latter types of claims would not be subject to regulation as health claims. Of course, such claims would still be subject to the requirement in section 403(a) of the act that they be truthful and not misleading.

C. Disease or Health Related Condition—Second Basic Element

As mentioned previously in this preamble, the proposed definition of "health claim" contains two basic elements, "substance" and "disease or health-related condition," that must be present for a claim to be a "health claim." FDA did not define the phrase "disease or health-related condition" in the proposal. This omission raised many questions and concerns in the comments.

2. Many comments objected that FDA's interpretation of the phrase "health-related" could be too broad. One comment was concerned that FDA might interpret the phrase to apply to statements pertaining to general good health. The comment noted that food itself sustains life, so the mere

identification of a product as a food is to that extent a "health-related" claim.

Another comment argued that such phrases as "invigorating," "relaxing," "stimulating," "feel better," "enjoy a good night's sleep," and "perform at your best" should be exempt from regulation because they do not refer to a disease. A few comments contended that claims about relationships between nutrients and the structure or function of the body (e.g., "this calcium fortified product helps build strong bones") should not be considered health claims.

Some of the comments suggested that the definition of a "health claim" should refer only to "disease" or "disease-related" claims because such a characterization more accurately reflects the nature of claims regulated by section 403(r)(1)(B) of the act. One comment asserted that the statutory phrase "a disease or health-related condition" does not sot up two categories and maintained that the phrase "health-related" as used in the law appears to be nothing more than an expansion of the word "disease." The comment submitted a definition of the word "disease" from "Stedman's Medical Dictionary," (25th ed., p, 444,1990), which states that a disease is "a morbid entity characterized by at least two of the following criteria: (1) Recognized etiologic agent(s), (2) identifiable group of symptoms, or (3) consistent anatomical alterations."

Although the legislative history of the 1990 amendments gives clear direction that Congress intended, that health claims do include disease-specific claims, this history is not as explicit concerning what kind of claims are claim s about a "health-related condition." As FDA pointed out in its response to the previous comment, Congress did, however, give clear direction that a statement about the importance of good nutrition that does not make a direct or implied connection between any substance in the food, and a particular disease is not necessarily a disease claim that will be regulated as a health claims (Ref. 1). Thus, it is clear that Congress did not intend that all claims pertaining to general good health be considered health claims.

However, the inclusion of the phrase "health-related condition" in section 403(r)(1)(B) of the act in addition to the term "disease" leaves no question that Congress intended that claims about conditions other than diseases be regulated under this provision. Further, the legislative history of the 1990 amendments confirms this fact. In hearings before the Senate and the House of Representatives preceding the passage of the 1990 amendments, many references were made to two texts, the Diet and Health report by the NRC (Ref. 6) and "The Surgeon General's Report on Nutrition and Health" (the Surgeon General's report) (Ref. 5). In the former text (Ref. 6), a section entitled "Hypertension and Hypertension-Related Diseases" states the following:

> Deaths related to hypertension have been variously classified over recent years. They have either been considered as a separate entity or combined with such classes of atherosclerotic cardiovascular diseases as CHD and stroke. Thus, it is not useful to consider vital statistics alone in discussing the epidemiology of hypertension. Hypertension is treated here primarily as a risk characteristic of atherosclerotic cardiovascular diseases rather than a disease entity in itself.

Elsewhere in the Diet and Health report (Ref. 6), hypertension is defined as sustained, elevated arterial blood pressure measured by an inflatable cuff and pressure manometer. The text goes on to say:

> It [hypertension] has been clearly shown to increase the risk of developing stroke, coronary heart disease, congestive heart failure, peripheral vascular disease, and nephrosclerosis.

Further, the Surgeon General's report identifies high blood pressure as a common, chronic medical problem in the United States responsible for a major portion of cardiovascular disease. It then states that public health efforts have increased public awareness and knowledge of the risks and treatment of this condition (Ref. 5).

The repeated references in the legislative history to texts that place significant importance on the control of risk factors as a means of reducing the risk of disease persuader FDA that the agency should include such factors in any definition of a "health-related condition." In view of the explicitly stated intention of Congress to help Americans maintain a healthful diet (Ref. 1), Congress intended that the 1990 amendments facilitate communication to consumers of information about risk factors such as hypertension, which is a risk characteristic or factor for several diseases, including coronary heart disease and stroke. Accordingly, the agency concludes that the inclusion of "a health-related condition" in the coverage of section 403(r)(1){B) of the act means that claims about risk factors related to disease, as well as claims about a disease, can be health claims.

Having reached this conclusion, FDA finds that one limitation on the coverage of the phrase "disease or health-related condition" is appropriate. The limitation is for claims about nutrient deficiency diseases. In the legislative history, Congress focused only on those health claims that related to chronic diseases affected by diet, such as cancer, heart disease, and osteoporosis. There is no indication that it intended to cover classical deficiency diseases (diseases resulting directly from a deficiency of a vitamin, essential mineral, or other essential nutrient. The relationships between nutrients and classical deficiency diseases are well established. Moreover, such diseases are of little public health significance in this country. Under such circumstances, FDA believes that it would not be appropriate to subject such relationships to the health claims regime. Claims about such classical nutrient deficiency diseases are adequately regulated under the provisions of section 403(a) of the act and thus must be truthful and not misleading. However, as discussed in more detail further in this document, a claim about the benefits of vitamin D in preventing vitamin D deficiency, for example, would be misleading where the claim does not explain that few individuals in the United States are at risk of such a deficiency. Of course, some claims about such diseases may result in a product being regulated as a drug. Thus, claims about the administration of a nutrient either intravenously or nasally will be regulated as drug claims. This position is consistent with the position that the agency took in the February 13,1990, proposal (55 FR 5176) with respect to nutrient deficiency diseases.

Therefore, to assist affected parties in clearly understanding what the second element of a health claim encompasses, FDA is adopting the following definition of "disease or health-related condition" in new § 101.14(a)(6):

> *Disease or health related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to §§ 101.14 or 101.70).

This definition does not differentiate between a "disease" and a "health-related condition." The two states are often so closely related that no bright-line distinction is practicable. Further, both states are regulated under section 403(r) of the act. Thus, there is no reason to separate one state from the other as long as both are covered.

FDA structured this definition primarily after the common sense definition of "disease" that appears in

the second edition of "Random House Dictionary of the English Language" (Random House, Inc., New York, NY. copyright 1987) without referring to examples of the causes of the dysfunctioning that were cited in that definition. For purposes of this rule, the agency did not pattern the definition after the one suggested in the comment because the clinical nature of the suggested definition would not be readily understandable. Thus, it is not suitable for use in a regulation.

The definition of "disease or health-related condition" would not generally encompass terms or phrases such as "invigorating," "relaxing," "stimulating," "feel better," and "perform at your best." Such terms would be covered under the regulatory regime of a label needing to be truthful and not misleading. Moreover, they may also subject the product to regulation under the structure or function of the body aspect of the "drug" definition (section 201(g)(1)(C) of the act). However, the definition would clearly encompass terms such as "osteoporosis," "heart disease," "cancer," and "high blood pressure."

For further clarification, the definition of "disease or health-related condition" is not considered by FDA to include a change in a biological parameter, such as a decrease in platelet (a type of blood cell that promotes blood coagulation) aggregation time or an increase in serum cholesterol, unless the parameter is associated with a disease or health-related condition, and there is evidence that altering the parameter can improve the condition. Of the two examples cited, high serum cholesterol is generally accepted as a predictor of risk for coronary heart disease, and there is evidence that decreasing high serum cholesterol can decrease that risk. For the health claim in new § 101.73, published elsewhere in this issue of the **Federal Register**, which associates dietary lipid intake with an increased risk of coronary heart disease, it may be appropriate, then, to permit as optional information a discussion of how dietary saturated fat, cholesterol, or both, affect blood cholesterol levels and, thereby, the disease that is the subject of the claim. Nevertheless, the agency considers it is inherently misleading for the claim to be articulated as an association between dietary lipids and serum cholesterol because of the potential to confuse consumers about the relevant disease for which the claim is authorized. It is not the biological indicator that is the disease or health-related condition for which the claim is authorized. Where there is no well-documented association or specificity between a biological parameter and a disease or health-related condition and some evidence that improving the parameter improves the condition, the agency will be disinclined to consider a petition for a health claim for that parameter because it fails to meet the definition of a disease or health-related condition.

3. Some comments asked if FDA intended to regard any statements that describe the "special dietary uses" of foods (e.g., hypoallergenic, lactose-free, wheat gluten-free, and dietetic foods) as health claims. The comments were concerned that health claim disqualifying levels would bar many such foods from disclosing dietary information. One of the comments requested that FDA revise the definition of a "health claim" to include advice that a statement in the labeling of a food subject to part 105 (21 CFR part 105) shall not be deemed to be a health claim solely because it represents the food to be for special dietary use.

FDA advises that any statement that appears on the label or in the labeling of a food intended for "special dietary use" that is consistent with provisions of the regulations promulgated under section 403(j) of the act will not be regulated as a health claim by the agency. Thus, such foods will not be subject to health claim disqualifying levels. However, FDA cautions firms that information not specifically provided for by specific regulations for foods for special dietary use may create an express or implied health claim and thereby subject such a food to the provisions of new § 101.14, including the disqualifying levels.

FDA has not revised the final rule to address foods subject to part 105 in the definition of "health claim." The requested revision is unnecessary in view of the agency advice in the previous paragraph. Further, the agency believes the requested revision might mislead some firms to assume that such foods would be exempt from the health claim provisions regardless of the nature of claims appearing in labeling where the claims are not specifically authorized in part 105. In addition, if FDA were to revise the final rule with respect to part 105, the rule should also be revised with respect to other provisions in the act and the regulations promulgated thereunder (e.g., infant formula subject to section 412 of the act (21 U.S.C. 350a)), and the agency does not believe that it would be appropriate to have the rule reference every other similar situation in the regulations in Title 21, Code of Federal Regulations.

D. Implied Health Claims

The agency proposed to define "implied health claim" as:

> * * * those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a disease or health-related condition.

The agency then provided some examples of such claims—"third party" endorsements, written statements such as a brand name including a term such as "heart," and symbols such as a heart symbol.

1. General

4. Comments varied widely on whether FDA should regulate implied health claims. Some comments, noting the difficulty in specifically defining an implied health claim, suggested that implied health claims should not be regulated under the proposed regulations. One of these comments asserted that FDA could regulate implied health claims only under the general requirement that a label must be truthful and not misleading. However, other comments urged FDA to strictly regulate implied health claims because they have the potential to undermine the sound regulatory approach for explicit health claims.

FDA advises that there is no basis under the act for it not to regulate implied health claims. Regulation of such claims Is specifically mandated. Under section 403(r)(1)(B) of the act, a food is misbranded if "* * * a claim is made in the label or labeling of the food which expressly *or by implication* * * * " (emphasis added) characterizes the relationship of any substance to a disease or health-related condition unless the claim is made in accordance with the health claims provisions of the act. Thus, FDA must reject the comments that suggested that it not regulate implied health claims.

5. While a number of comments encouraged FDA to take a broad view of what constitutes an implied claim, other comments argued that any "bright-line" definition of an implied health claim would be too inflexible to enforce fairly because labeling displays can have different meanings in different contexts. Some comments urged that both manufacturers' intent and consumer perception be considered in determining whether an implied claim has been made. One comment proposed that if vendor intent is not considered, then the test should be whether consumers acting reasonably under the circumstances would interpret language on labels or labeling in a particular

fashion and noted that such a test has been applied by the Federal Trade Commission (FTC) in the context of misleading advertising claims. The comment contended that the fact that a few credulous people may perceive a claim in a particular manner should not suffice if the vast majority perceive it otherwise.

FDA agrees that no. "bright-line" definition can be established for implied health claims. Labeling claims need to be considered in their entirety and in context to determine if the elements of a health claim are present. FDA has therefore revised the definition of an implied health claim in new § 101.14(a)(1) to clarify that the claim will be evaluated within the context of the total labeling to determine if an implied health claim has been made.

FDA has also revised the list of the types of claims that may be implied claims. The agency has substituted the term "'third party' references" in place of the term "'third party' endorsements" because it has become clear that a third party endorsement is only one type of reference to a third party that may constitute a health claim in the context of the entire labeling. Further, FDA has corrected the phrase "health or disease-related condition" in the definition of an implied health claim in the last sentence in new § 101.14(a)(1) to "disease, or health-related condition," FDA had intended to consistently use this latter phrase throughout proposed § 101.14(a)(1) but the terms "disease" and "health" inadvertently were interchanged in the proposal.

In the case of imp tied claims, FDA will evaluate ail of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Where both elements are present in a product's labeling, the product bears a health claim, regardless of whether one or both of the basic elements are explicit or implied.

In making en evaluation of a claim within the context of the labeling, FDA agrees that it should consider both manufacturer's intent, and consumer perception. However, the agency notes that intent means more than the manufacturer's subjective intent. Therefore, the agency concludes that the focus of its determination as to whether a claim is an implied claim should be on what the claim is saying. To be consistent with the definition of "implied nutrient content claim" in new § 101.13(b)(2) in the nutrient content claims document published elsewhere in this issue of the **Federal Register**, the agency is striking the phrase "* * * a manufacturer intends, or would be likely to be understood, to assert * * *" and is replacing it with the word "suggest" in the defintion of a health claim in new § 101.14(a)(1). Section 101.14(a)(1) now reads:

> *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

The agency believes that this will clarify what the agency's inquiry will be when it determines whether a claim is an implied claim.

FDA has not used the comment's proposed "reasonable person" test for deciding when a claim is implied. The regulation reflects the fact that courts have construed the act as protecting not just the reasonable person but also the "ignorant, the unthinking and the credulous." (See *United States v. an article * * * consisting of 216 cartoned bottles * * * "Sudden Change*" 409 F.2d 734, 741 (2d Cir. 1969).) Given relevant case law construing the act, it is unnecessary to look to the standard applied by FTC for guidance.

2. Brand names

6. A number of comments asserted that all brand names containing words such as "heart" are inherently misleading and therefore should be banned. Other comments urged FDA to permit the use of words such as "heart" in the brand names of foods only when the food qualifies for an approved heart-related health claim. Other comments maintained that some brands that incorporate the word "heart" (e.g., Sweetheart) have been used for decades in a nonmisleading manner to convey an old-time, homey feeling and therefore should not be banned or construed to be an implied health claim.

FDA does not agree that all brand names containing words such as "heart" are inherently misleading. Certainly where this term is placed on a product that qualifies for an express health claim on cardiovascular disease that is provided for in part 101, subpart E, and where such a claim is appropriately included elsewhere in the labeling, consumers would not be misled by the term "heart." In addition, there may be situations in which, when considered within the context of the full labeling, the terns cannot be reasonably understood to be a health claim (e.g., "sweetheart" or "from the heartland of America," where no claims about the Fat, cholesterol, or sodium content of the food are made).

However, comments from several consumer, health professionals, and regulatory organizations demonstrate that the use of the word "heart" in the brand name of a food may lead consumers, to believe that the specific food bearing that brand name has properties deriving from a substance that it contains that are beneficial for reducing the risk of developing a disease or health-related condition, specifically cardiovascular disease. Both basic elements of a health claim may be implied in a brand name containing the terra "heart." Therefore, any product bearing such a brand name is subject, depending of course on the full content of the labeling, to be viewed by FDA as bearing an implied health claim. Thus, FDA has retained the term "heart" as an example of what may be an implied claim in the definition of "health claim" in new § 101.14(s)(1) to alert firms to the agency's position on this matter. However, FDA will review the context in which this term is presented and consider how the term would be understood in deciding whether a particular use of the term "heart" or a use of a heart symbol on: a particular label is a health claim.

3. Other written statements

7. A number of comments suggested that any statement on a labels including nutrient content claims such as the word "healthy" or other terms that may lead consumers to believe that a food has health benefits, should be regarded as implied health claims. Comments suggested that FDA use broad latitude In considering such words as health claims.

As FDA advised earlier in this preamble, the agency will evaluate all of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Thus, FDA will take a flexible case-by-case approach to assessing whether labeling contains a health claim.

In the case of the word "healthy," the agency does not believe that the use of this word would normally be a health claim. "Healthy" has a wide variety of meanings in addition to ones that would satisfy the second basic element of a health claim. For example, "healthy" can certainly imply general nutritional well-being. Thus, while a claim such as "Eat a diet low in fat for a healthy heart" may be a health claim, "Eating

five fruits or vegetables a day is a good way to a healthy lifestyle" is not. Moreover, as explained in the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**, FDA may also regulate the term "healthy" in certain circumstances as an implied nutrient content claim. A proposal on how to define the term in such circumstances appears elsewhere in this issue of the **Federal Register**. The varied uses of the term "healthy" demonstrate the need for FDA to take a flexible case-by-case approach in deciding whether a claim is an implied health claim.

4. Third party references

8. Some comments requested that FDA explain its interpretation of the term "third party endorsement" and clarify when such an endorsement constitutes a health claim. One comment observed that the courts have been careful not to define the concept of "endorsement" too broadly and noted that disclaimers can be used where the perception of endorsement may be construed. Other comments asserted that the mere presence of endorsements should not automatically constitute health claims. One suggested that regulatory limits concerning such endorsements should be set.

FDA agrees that third party endorsements do not automatically constitute health claims. "Funk & Wagnall's Standard Dictionary," Harper Paperbacks, New York, 1980, defines the term "endorse" as "to state one's personal support of (a product) to promote its sale." FDA views third party endorsements as references, made through a name or logo, to a person or organization such as a professional society or association that is independent of the product's manufacturer or distributor, on product labeling or advertising, to promote that organization's approval of a product.

In response to the comments addressing the term "third party endorsements," as explained in the agency's response to comment 5 of this document, the codified language of new § 101.14(a)(1) has been revised to refer to "'third party' references." This term, which includes third party endorsements, better describes the type of information from an organization or individual not directly associated with the manufacturer that may be included in a label and that could constitute an implied or express health claim.

Third party references on food labels include a wide variety of information about diet and general health that is disseminated by reputable public or private organizations. Such information will be regulated as a health claim if, within the context of the total labeling, the third party reference can be reasonably understood to characterize the relationship between a substance and a disease or health-related condition. Thus, an endorsement by the American College of Nutrition or the National Nutritional Foods Association would not, of itself, cause a product to be considered to bear a health claim, even if these organizations were promoting the consumption of a specific food or nutrient, if the resultant claim did not include reference to a disease or health-related condition.

However, a third party endorsement would constitute an implied health claim if the endorsement references a particular food or substance, and the name of the endorsing organization references a particular disease (e.g., American Heart Association). In such an endorsement, both basic elements would be present. As a result, a link would be created between the food/substance and the specific disease that could be reasonably understood by consumers as asserting that the product is useful in reducing the risk of developing that disease.

The following illustration using the National Cancer Institute's (NCI's) Five-a-Day Program (Ref. 27) exemplifies how the context of the label will determine whether a statement is a health claim or dietary guidance. A cereal label that says "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables" is not a health claim because the information cannot be reasonably understood to be about a substance. There is neither a nutrient nor a product-specific element in the claim, and there is therefore no characterization between a substance and the disease included in the name or the organization. However, if the statement said "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables to increase your intake of fiber," it would be a health claim because of the reference to a specific nutrient, fiber, and to a disease, cancer.

9. Several comments questioned the status of the American Diabetes Association's "Exchange Lists for Meal Planning." One comment questioned the status of the American Diabetes Association's "Self-Test" public awareness program printed on the back of certain cereal boxes, which is designed to enable consumers to recognize diabetes based on warning signs and symptoms of the disease. The comments expressed the belief that these situations should not be interpreted as either an endorsement or a health claim because no claim is made about a specific nutrient in the foods, and no link is created between the products and diabetes. Comments also requested clarification of FDA's position on fund raising activities conducted with the cooperation of manufacturers using organizational logos and messages such as: "A proud sponsor of the American Diabetes Association" or "A contribution from the sale of this product has been made to the American Diabetes Association." The consensus of these comments was that these situations should not be interpreted as endorsements because no claim is made about the nutrient content of the foods, and there is no association between the products and the disease, diabetes mellitus.

FDA recognizes the value that providing exchange lists on food labeling has for certain consumers and advises that the mere inclusion of that information on a food will not, of itself, subject the labeling to the Health claim regime. Reference to the exchange lists lacks the substance element of the "health claim" definition because it relates to many foods rather than to a specific food or a nutrient. Such information is instead subject to section 403(j) of the act and, more specifically, to § 105.67 relating to foods for use in the diets of diabetics. Of course, the labeling would be subject to regulation under section 403(r) of the act if the labeling bears any implication that a substance in the food is helpful in reducing the risk of diabetes or any other disease.

In the absence of an explicit or implied reference to a substance in food labeling, the "Self-Test" program and sponsorship/fundraising information also are outside the coverage of section 403(r)(1)(B) of the act. However, labeling for both of these programs would be subject to section 403 (a) of the act, which requires that a label be truthful and not misleading, and section 201(n) of the act which describes the circumstances in which labeling is misleading.

10. Some comments requested that paid third party endorsements be prohibited. These comments stated that such references often give the public the impression that endorsed products are superior in terms of health, safety, or nutrition to other foods not bearing the same endorsement, when, in fact, they are not.

FDA has no authority under the act to prohibit either paid or unpaid third party endorsements or references provided that, when such statements are included on food labeling, the

statements are made in a manner that is in compliance with ail applicable provisions of the act. However, the agency recognizes that endorsements made for compensation by private organizations or individuals may be misleading to consumers. The agency is advising that when such endorsements are made, a statement should be included in close proximity to the claim, informing consumers that the organization or individual was compensated for the endorsement. Failure to divulge this information on a label that bears a paid endorsement would cause the product to be misbranded under sections 403(a) and 201(n) of the act for failure to reveal a fact that is material.

11. A number of comments suggested that all unpaid endorsements be regarded as explicit health claims.

FDA disagrees, because the issue of whether an endorsement is made in exchange for monetary compensation is not germane to the issue of whether the endorsement or other third party reference constitutes a health claim. As discussed in the response to comment 8 of this document, for a third party reference to be a health claim, two criteria must be met. There must be an implied or explicit reference to both a substance and to a disease or health-related condition. In the absence of these elements, a third party reference is not a health claim, regardless of any financial arrangement that may have been entered into before making the endorsement.

12. Other comments urged FDA to allow the use of third party endorsements of specific products. Many of these comments asserted that references from credible health organizations reduce or eliminate consumer confusion about specific products, provide useful and relevant information about products, and assist consumers in making healthy food choices. The comments also argued that the use of third party endorsements and references should also encourage the development of new products that attract such endorsements.

FDA has no basis in principle for objecting to the use of third party endorsements and other third party references for specific products, provided that such references are made in compliance with all applicable provisions of the act, including the nutrient content claims and health claims requirements of the 1990 amendments and sections 403(a) and 201(n) of the act. The agency is aware of the potential impact of the 1990 amendments on the development of more healthful products that will appeal to consumers and encourage people to improve their eating habits. In the Congressional Record of October 24, 1990, Senator Hatch (Ref. 2) stated

> * * * manufacturers should have the economic incentives they need to be creative and innovative so that more and more low-fat, reduced sodium, and high-fiber foods come into the market. We should not deter such benefits for the consumer.

FDA is very much in favor of product innovation as a means of bringing more healthful products to the American public and recognizes that appropriate and lawful third party endorsements may have some potential to stimulate innovation and play a useful role in educating consumers about the importance of developing diets that will improve their health.

13. A number of comments recommended that FDA selectively designate which governmental and nongovernmental organizations are allowed to make third party endorsements. One comment suggested that FDA require organizations that grant endorsements to have the expertise in the area in question as well as a formal product approval process. The organization should actively disseminate additional explanatory information concerning the meaning of the endorsement and manner of its use. Other comments recommended that third-party endorsements be considered to be misleading unless the reason for the presence of the endorsement is clearly explained (including but not limited to disclosure of financial arrangements).

With the exception of disclosing the fact that an endorsement has been paid for, as discussed in comment 10 of this document, FDA believes that it lacks the factual and legal basis at this time for imposing such requirements on third party endorsements. FDA recognizes, however, that third party references have significant potential to be abused or to be misleading if, for example, they come from organizations or programs that exist primarily for commercial or marketing purposes, they are not based on sound nutritional criteria, or they appear on products that are not appropriate in light of the actual or implied nutritional purpose underlying the endorsement. Therefore, the agency will closely monitor the use of endorsements on food labels. Interested persons should submit their views on the need for additional regulatory controls to the Center for Food Safety and Applied Nutrition. FDA intends to consider in a future rulemaking proceeding whether additional criteria or controls are necessary.

In the meantime, any labeling generated with a third party endorsement or reference would be subject to regulation under sections 201(n) and 403(a) of the act and must, therefore, be truthful and not misleading. Further, if the reference meets the definition of a nutrient content claim or a health claim, such a claim must be consistent with FDA's regulations.

14. A number of comments suggested that all written health claims be banned in favor of third party endorsements. One of the comments favored allowing third parties, such as the American Heart Association and the American Dental Association, to independently review products and to place their logos on the labeling if they determine that use of the product would be helpful in reducing the risk of their specialty disease.

FDA has an obligation under the act to ensure that health claims comply with section 403(r) of the act, and that they are truthful and not misleading under section 403(a). Delegation of this responsibility to private organizations associated with specific diseases would not be consistent with the act. Such organizations are free to submit well-supported petitions pertaining to the health benefits of any substance to FDA, as provided for in new § 101.70. However, FDA will always have the obligation of ensuring compliance with the act.

5. Symbols

In the preamble to the proposed rule (56 FR 60537 at 60542), FDA recognized that there is often ambiguity in the message conveyed by a symbol or logo and solicited comments on the appropriate meaning to be attributed to a heart symbol and other currently used logos and symbols. The agency also invited comments on the issue of how logos should be regarded: as nutrient content claims, health claims, or both? The comments, which are summarized below, ranged from those that wanted strict regulation of symbols to those that felt symbols should not be regulated as health claims. Many comments took an intermediate position, arguing that symbols should be evaluated within the context of total labeling.

15. Many comments supported FDA's proposal to regulate symbols as health claims. These comments stated that the uncontrolled use of medical symbols (e.g., a heart, or an electrocardiogram (EKG)) should not be permitted. Some comments suggested that symbols be allowed only when the food qualifies for the health claim implied by the symbol, and then only if they are not misleading

and increase consumer's comprehension of the claim.

Many industry comments argued that symbols cannot practicably be included in the definition, of a health claim. One comment pointed out that candy packages bearing a heart symbol near Valentine's Day should not be regulated as an implied health claim. Another comment cited examples where the heart symbol may do nothing more than operate as a design motif with no implicit health claim (e.g., the combination of a heart symbol plus the statement "Hey Fudge Lovers! More Fudge Filling!"). The comments maintained that any analysis of how the symbol is construed must focus on the entire label, not on an isolated aspect of it.

FDA agrees that a determination as to whether a symbol constitutes a health claim must be made based on the entire food label. As explained in the response to comment 5 of this document, FDA has provided for such flexibility by revising new § 101.14(a)(1) to state:

> Implied health claims include those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or that would be reasonably understood in the context in which they are presented, to assert a relationship between the presence or level of a substance in the food and a disease or health-related condition.

"Funk & Wagnall's Standard Dictionary" defines the term "symbol" as "something chosen to represent something else; esp., an object used to typify a quality, abstract idea, etc." Determining whether a symbol on a label represents an implied health claim requires an evaluation of all of the labeling to ascertain whether, within the context of that labeling, the presence of that symbol results in both basic elements of a health claim being present in the labeling.

Because of the abstract nature of symbols, they have considerable potential for conveying a wide variety of meanings on labeling. As the comments pointed out, the same symbol on a food label may have a multitude of meanings for the same food as the context of the labeling is changed from one label to another. Certainly, the combination of a heart symbol and the statement "Hey fudge Lovers!" on a food containing fudge adequately explains the meaning of the heart symbol and prevents consumers from being misled about its meaning. Under such circumstances, the heart symbol would not convey either of the basic elements of a health claim. The statement "Hey Fudge Lovers!" clarifies that the symbol does not refer to a substance in the specific food bearing the symbol or to any health benefits from consuming that food.

However, if the statement "Hey Fudge Lovers!" does not appear on the product, and no other explanation of the heart symbol appears on the labeling, the context of the labeling no longer explains the meaning of the symbol. Under such circumstances, the symbol may well be perceived by consumers in a wide variety of ways, many of which would not be true. FDA believes that most of the perceptions about heart symbols fall under the regulatory regime of a health clam. For example, consumers may logically assume that the symbol is equivalent to the term "heart." Under such circumstances, these consumers may conclude that the symbol means that the food has properties that are beneficial for reducing the risk of developing a disease or, health-related condition, specifically cardiovascular disease. Thus, the second basic element (i.e., disease or health-related condition) would be conveyed by the symbol. Further, the first basic element (i.e., substance) would also be present. In the absence of an explanation for the symbol, consumers would likely infer that the symbol pertains to the specific food bearing the symbol and to the substances that it contains. Thus, both basic elements of a health claim can be implied through the unexplained presence of a heart symbol on a label.

Even if the heart symbol is not perceived by some as a health claim, the symbol would still be misleading within the meaning of section. 403(a)(1) of the act because the context of the labeling would not explain what the symbol means and thus would fail to disclose a material fact. Accordingly, FDA advises that the use of health-related symbols in food labeling without some clarification of their meaning in context is likely to cause the food to be misbranded.

Similarly, an EKG h record of the electrical current produced by the action of the heart muscle) also constitutes a health claim where the context of the labeling does not explain the meaning of the EKG. Although it is unlikely that most consumers would be able to interpret an EKG leading as representing a healthy or unhealthy heart, most consumers would probably make a connection between an EKG graph and heart function. Under such circumstances, the symbol alone could lead consumers to believe that a substance in the product is related to the risk of cardiovascular disease and thereby constitute a health claim.

Of course, symbols with specific reference to nutrients may also constitute health claims. For example, a heart on a label that also makes a claim that the product is low in fat would be an implied health claim. The explicit nutrient content claim would satisfy the substance basic element, and the disease or health-related basic element would be provided by the symbol because it implies that the low level of fat has a beneficial effect relative to a disease of the heart. (This decision assumes the label does not contain sufficiently clarifying information to change the meaning of the heart symbol, so that the symbol would not constitute a basic element.)

However, in some circumstances, the context of the labeling may make it obvious that there is no connection between the symbol and a substance in the food or between the symbol and a disease or health-related condition. In such a situation, the symbol would not constitute an implied claim. For example, a heart shaped box of candy or a heart shaped candy, whose label does not include an explicit or implied reference to a disease or health-related condition, would not be an implied claim.

In addition, some symbols, such as the U.S. Department of Agriculture/ Department of Health and Human Services (USDA/DHHS) Health Pyramid, a symbol for the American Heart Association, or a symbol for the American Cancer Society, may not constitute health claims when the labeling contains no other references to a substance or a disease or health-related condition. In all of these situations, organizations provide general dietary guidance for good health. Thus, consumers should not assume from the name of the organization that the symbol implies an association with the disease or health-related condition basic element.

When symbols constitute a health claim, they should only be used on foods that qualify for the express claim they represent. Since it is unlikely that a symbol alone can convey all the information necessary as part of a health claim, health claims implied by symbols must be accompanied by a written message that includes the essential elements of the claim authorized by FDA's regulations in part 101, subpart E. To prevent misinterpretation of the claim by consumers, this message should be located in close proximity to the symbol could be located in other labeling provided that a reference statement appears next to the symbol. The appropriate content of health claims reference statements is discussed subsequently in section V.C. of this preamble, FDA has revised the

provision of the final rule addressing reference statements in new § 101.14(d)(2)(iv) to provide that such statements shall appear in immediate proximity to the graphic material (e.g., symbol). Anyone wishing to use a symbol alone to deliver a health claim may submit a petition with supporting data that demonstrate that the essential elements of the health claim are conveyed to consumers by the proposed symbol.

FDA recognizes that symbols are an important means of conveying information to consumers, and that they are useful when used in a truthful and nonmisleading manner. The agency will continue to protect the interests of the public by monitoring the use of symbols and will take appropriate action, under either section 403 (a) or (r) of the act when symbols ere used to mislead consumers.

16. Some comments proposed that, if symbols such as a heart are to be regulated as implied health claims, products that bore such symbols before the implementation of the regulation should be exempted iron's the health claims regime.

Although the statute provides very explicit guidance regarding grandfathering of nutrient content claims in sections 403(r)(2)(C) and (r)(2)(D) of the act, it is silent with respect to any such provision regarding health claims. In light of this omission, it is clear that Congress did, not intend to provide such relief for labeling making either implied or explicit health claims (see *Andrus v. Glover*, 446 U.S. 608 (1980)). Further, grandfathering of labels that do not qualify to bear an implied health, claim would result in confusion on the part of consumers and reduce the credibility of symbols on food labels that are eligible to bear such claims. Therefore, FDA is rejecting this proposal.

17. Several comments suggested that the final rules should make some provision for the use of FDA standardized symbols and logos on products that would qualify for health claims. The comments stated that such logos and symbols would help individuals with poor reading skills plan a more healthful diet, although they did not make clear whether the use of symbols and logos should be optional or mandatory.

As stated above, FDA recognizes the value that symbols and emblems have in promoting good health and dietary guidelines to consumers. However, at this time the agency feels that it is inappropriate to permit an emblem alone to deliver the substance of a health claim, and it would be difficult for FDA to design standardized symbols or logos in a manner that would be in compliance with the statute. Section 403(r)(3)(B)(iii) of the act requires that a health claim be accurate and comprehensible within the context of the daily diet. New § 101.14(d)(2)(iii) requires the inclusion of factors other than consumption of the substance when such factors affect the substance disease relationship (e.g., exerciser

Further, under section 201 (n) of the act, labeling can be misleading based on what is omitted as well as on what appears on the label. Designing an emblem that would deliver the message required by the act while also meeting the criterion of being truthful and not misleading, as mandated by section 403(a)(1) of the act, would be extremely difficult.

However, the agency will consider petitions for use of a symbol or emblem for approved claims or as part of a new health claim petition, provided that appropriate data are submitted that provide the agency with some assurance that consumers accurately interpret the claim. Such data should include the results of tests using the suggested symbol.

6. Dietary guidance

As FDA explained earlier in this preamble, when the proposal was issued, FDA had not yet decided how certain types of claims should be regulated when they pertain to truthful information about health and diet and are not in the form of an explicit health claim. FDA referred to "dietary guidance" as a class of claims that might not be regulated under section 403(r) of the act. The agency cited, the NCI "Five-A-Day" program as an example of dietary guidance that is not a health claim. Unfortunately, use of that program as an example created confusion because, even though most of the messages in the program only encouraged consumers to eat fruits and vegetables, a small number of the messages refer to nutrients (e.g., fiber) and disease (cancer).

Further, use of the term "dietary guidance" to describe claims that do not constitute "health claims" is also confusing because "health claims" themselves provide a form of dietary guidance. In addition to "health claims" and "dietary guidance," there is a broader class of claims that encompasses all other truthful information about diet and health as well as drug claims. In view of the overlapping nature of these categories of claims, it is understandable that there was considerable confusion among the comments about "dietary guidance."

For the sake of clarity in this preamble, FDA will use the term "dietary guidance" to refer to claims that do not contain both basic elements of a health claim and are therefore not "health claims." However, use of this term in the comments may, or may not, have encompassed a "health claim." FDA will attempt to clarify the use of the term by the comments in the summaries to the comments.

18. Some comments asserted that dietary recommendations that relate to a specific disease but provide guidance concerning general food choices without unduly emphasizing a particular substance, or recommendations that emphasize a particular substance but are related to a variety of diseases or to a healthy lifestyle in general, should not constitute implied health claims.

As discussed in the response to comment 1 of this document, claims that do not satisfy either the substance element or the disease or health-related condition element of the "health claim" definition are not health claims. Accordingly, claims that provide guidance about a general food choice or about how to achieve a healthy lifestyle would not be health claims. Claims that are related to a variety of diseases are likely to be health claims, although a specific determination will be made based on the context, in which a claim is made and on its specific content.

19. A number of comments contended that the agency unjustly regulated accessibility to recommendations from authorities, such as the National Institutes of Health and USDA. Most comments felt that such dietary guidance should not be regulated as health claims on food labeling because such regulation would discourage education of the public on sound nutrition practices. One comment suggested that the furtherance of consumer information was mandated under the 1990 amendments and asserted that industry and FDA need to focus more attention on the education authority provided therein. This comment and others stated that public health organizations, such as NCI, can more effectively reach consumers with valuable advice if products that fit into their recommendations are free to display this information on their labels, and that consumers are more likely to notice and appreciate recommendations from a respected source. Other comments felt that nongovernmental sources (e.g., the American Dietetic Association and the American Heart Association) also provide credible dietary guidance.

FDA has reconsidered the tentative position that it took in the proposal (56

FR 60537 at 60555) that references to programs sponsored by such organization as the American College of Nutrition, the American Heart Association, the American Medical Association ("Campaign Against Cholesterol"), and the American Medical Women's Association would always be regulated as implied health claims. The comments have convinced the agency that it would not be appropriate to establish by regulation the specific types of statements that may be used on food labeling concerning either Federal programs or private sector programs because the guidance offered by such organizations may not include a reference to a substance or to a disease or health-related condition. The agency has therefore concluded that publicly available dietary information provided to consumers by Federal or private programs and used in food labeling by manufacturers may be either dietary guidance or a health claim depending upon the content of the information and the context in which it is presented in the labeling.

In taking this position, FDA hopes to encourage the dissemination of information to consumers regarding nutrition and health that has been provided by such sources as the U.S. Surgeon General, the National Academy of Sciences, USDA/DHHS Dietary Guidelines, NRC, and the National Cholesterol Education Program. However, information from such programs presented in labeling in a context that includes explicit or implicit references to both elements of a health claim is subject to the health claims provisions of the act.

20. Many consumers asserted that dietary supplements, including supplements containing herbs, should be permitted to include all types of nutritional and dietary guidance in their labeling, including information based on folklore and historical use, provided that the claims are made truthfully. These comments maintained that such information is essential to making informed choices of such alternatives to conventional drug therapies.

Manufacturers of dietary supplements are free to provide dietary guidance within the regulatory framework discussed above. However, if a product's labeling characterizes the relationship between a disease or health-related condition and a substance, the product will be subject to the provisions of section 403(r) of the act, although in the case of dietary supplements they will not be subject to section 403(r) of the act. until the expiration of the moratorium established by the DS Act. If the claim reveals that the product is intended to be used In the diagnosis, cure, mitigation, treatment, or prevention of a disease, the product, like any other product that does so, is a drug under section 201(g)(1)(B) of the act. When the moratorium expires, and subject to the regulations in place at that time, supplement and herb manufacturers, like all other food manufacturers, will be welcome to submit health claim petitions that establish the validity of claims that characterize the relationship of a substance to a disease or a health-related condition.

E. Definition of Nutritive Value

21. A number of comments asserted that FDA's definition of "nutritive value" in proposed § 101.14(a)(3) is unduly restrictive and does not fully recognize the important role that nutrients play in helping to reduce the risk of chronic disease. Other comments requested that FDA state in the definition that the list of processes cited is not all-inclusive. Another comment asked that the proposed rule be modified to specifically recognize the nutritive value of fat substitutes (triglycerides and other substances that contain fatty acids but are modified in ways that limit the bioavailabiiity of those acids).

FDA recognizes that certain substances can play a major role in reducing the risk of certain chronic diseases and may confer their benefits through a number of processes. Accordingly, the agency has worded the definition of "nutritive value" in new § 101.14(a)(3) to provide significant flexibility in determining whether a substance possesses such value. FDA used the phrase "such * * * as" in the definition to insure that the three referenced processes will be understood to be general examples of the ways in which a substance may legitimately confer nutritive value, rather than as an all-inclusive list.

The agency believes that it is inappropriate to codify findings of nutritive value for specific substances. Such findings would only serve to undermine the intended flexibility of the definition because an extended listing of those substances that possess nutritive value could be interpreted as an exclusive list.

FDA considers it more appropriate for the agency to evaluate the nutritive value of substances that are the subjects of health claim petitions on a case-by-case basis. This approach will best ensure that the definition retains its intended flexibility and does not become an unintentional barrier to the approval of legitimate health claims.

F. Definition of Dietary Supplement

22. A number of comments suggested that the proposed definition of "dietary supplement" in proposed § 101.14(a)(4) should be revised to include foods as well as components in foods (e .g., herbs as well as components in herbs).

FDA advises that the proposed definition of "dietary supplement" already covers foods. Reference to a "component" with nutritive value encompasses the specific portion of the food, that is, of the dietary supplement, responsible for this value. Under section 201(f)(3) of the act, a component of a food is itself a food. However, because of the provisions of the DS Act, FDA is not adopting § 101.14(a)(4) at this time. FDA will reach a final decision on the appropriate definition of this term following in accordance with the provisions of the DS Act.

G. Definition of Disqualifying Nutrient levels

As proposed, "disqualifying nutrient levels" was defined in proposed §101.14(a)(5)as:

> Disqualifying nutrient levels means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium, per reference amount commonly consumed, per label serving size, and per 100 g. Any one of the levels, on a per reference amount commonly consumed, a per label serving size or a per 100 g basis, will disqualify a food from making a health claim.

For consistency with the final rule on serving sizes published elsewhere in this issue of the **Federal Register**, the word "commonly" in the term "reference amount commonly consumed" in the definition above is corrected to read "customarily."

1. Consistency with statute

23. Most industry comments contended that the proposed definition of "disqualifying nutrient levels" in proposed § 101.14(a)(5) is either overly restrictive or inconsistent with the statutory provision of section 403(r)(3)(A)(n) of the act. The comments based their arguments on the language of the provision that provides that a health claim cannot be made by a food that contains "any nutrient in an amount which increases * * * the risk of a disease or a health related condition." Several comments stated that the agency correctly acknowledged that there are no generally recognized levels at which nutrients in an individual food pose an increased risk of disease, although there are

recommended levels associated with decreased risk of disease for dietary intake of total fat, saturated fat, cholesterol, and sodium. A number of these comments argued that the acknowledgment by FDA of a lack of recognized risk levels in an individual food should prevent the agency from establishing any disqualifying nutrient levels because the 1990 amendments require FDA to consider whether the individual food for which the claim is made contains a nutrient at a level, that increases to persons in the general population the risk of a diet-related disease, taking into account the significance of the food in the total daily diet.

The Comments argued that single foods, even when their significance in the total dally diet is considered, do not increase disease risk because only total diets consisting of many foods consumed over time have that potential. Thus, these comments argued that FDA cannot reasonably take the position that the analysis upon which the proposed disqualifying levels are based constitutes a credible scientific determination that the specific levels are the levels that, if exceeded in an individual food, increase the risk of disease in the general population. Other comments stated that if the agency believes that it has in fact determined levels that will increase the risk of diet related disease when present in individual foods, then either the marketing of such foods should be disallowed under the act by virtue of their being injurious to health under section 402(a)(1) of the act (21 U.S.C. 342(a)(1), or warning labeling should be required on all foods containing such levels regardless of whether they contain health claims.

Some comments asserted that Congress intended for FDA to disallow a health claim on the basis of disqualifying nutrient content only if there exists an actual risk as determined by the analysis of actual consumption data for the specific food, and not as determined from models based on theoretical diets and extrapolation. Therefore, these comments argued that Disallowing health claims on the basis of theoretically-derived nutrient disqualifying levels is contrary to the legislative intent of section 403(r)(3)(A) of the act, which reads, "If the Secretary determines * * *" and not "The Secretary shall determine * * *." These comments maintained that FDA had failed to show that a person exposed to foods with levels of fat, saturated fat, cholesterol, and sodium above the disqualifying levels were actually at an increased risk for various diseases and maintained that such an actual risk must be shown for FDA to legally establish disqualifying levels for these nutrients.

One comment noted that FDA's proposed model health claims emphasize the role of the total diet in reducing the risk of various diseases and do not allow manufacturers to claim that an individual food will reduce the risk. The comment stated that it was ironic and inappropriate, then, that FDA would single out individual foods as increasing the risk of those same diseases, and set disqualifier levels for those foods. Other comments agreed, saying that an individual food could no more cause a disease than prevent one.

FDA disagrees that the 1990 amendments require that FDA consider whether the individual food for which the claim is made contains a nutrient at a level that increases to persons in the general population the risk of a diet-related disease. There is nothing in the legislative history of the 1990 amendments that would support such a contention. To the contrary, the legislative history and the language of the statutory provision that ultimately resulted suggest that Congress intended that. the risk of diet-related disease be considered in a far broader context than that of an individual food, Section 403(r)(3)(A)(ii) of the act states that the risk of a disease or health-related condition be considered "* * * taking into account the significance of the food in the total daily diet * * *." Thus, FDA must consider the role that a particular food plays in the total diet, and the effect that its nutrient levels will have on a person's ability to structure a healthy diet in making a determination under section 403(r)(3)(A)(ii) of the act. That provision contains no language implying that risk should be considered in terms of the immediate impact of consuming the particular food at issue.

Further, if Congress had been concerned about the impact of consuming a nutrient in a particular food, it would not have provided an exemption to disqualification in section 403(r)(3)(A)(ii) of the act when FDA finds that a claim will assist consumers in maintaining healthy dietary practices. Under the comment's view of this provision, no such circumstances could exist. Similarly, Congress would not have elected to provide for nutrient content claims with only disclosure requirements for such nutrients in section 403(r)(2)(B) of the act if the risk from a particular food was the concern that it was addressing. Further, if risk from a particular food was its concern, Congress would not have exempted nutrient content claims on restaurant foods from these disclosure requirements (see section 403(r)(5)(B) of the act).

Congress intended that health claims would not merely provide information on particular substance-disease relationships, but that they would help individuals to maintain healthy dietary practices. The House Report (Ref. 1) states:

> * * * Health claims supported by significant scientific agreement can reinforce the Surgeon General recommendations and help Americans to maintain a balanced and healthful diet * * *.

Health claims on foods with levels of fat, saturated fat, cholesterol, or sodium that exceed the disqualifying levels will make it much more difficult for consumers to follow the Surgeon General's recommendations and to construct a healthy diet. An increase in risk in a diet-related disease follows as a result. All references in the legislative history concerning the meaning of section 403(r)(3)(A)(ii) of the act show that Congress was concerned with general levels of nutrients in broad food classes that could increase risk rather than levels of nutrients that could increase risk from individual foods. For example, the House Report (Ref. 1), in addressing the meaning of this provision, states:

> By requiring the Secretary to decide this issue in the total daily diet, the bill permits the Secretary to differentiate between different foods which have the same level of a nutrient. For example, a particular level of fat in a frozen dinner might not trigger the provision [disqualification], whereas the same amount of fat in a snack food product might trigger it.

Further, in testimony presented before the House of Representatives on a predecessor bill to the 1990 amendments (Ref. 24), a consumer organization identified ways by which health claims on produces in the U.S. marketplace can deceive consumers. One such way was for a product to highlight a characteristic that may help reduce the risk of a disease but remain silent about another characteristic that may affect the risk of the same, or another, disease. An example cited in the testimony was a breakfast cereal bearing a health claim approved by NCI and cancer while containing 4 g of fat per serving—an amount characterized as quite high for a breakfast cereal. In testimony presented before the Senate on a predecessor Senate bill to the 1990 amendments (Ref. 25), another consumer organization stated that a health claim on a product must provide consumers with the assurance that the

product does not also contain properties that are potentially harmful to health. The testimony continued:

> But a health claim on whole milk, promoting its calcium content [relative to osteoporosis], could encourage consumption of a product high In saturated fat. Low-fat milk has all the benefits of whole milk, without the accompanying risks, and would be a more appropriate vehicle for health claim labeling.

Congress obviously recognized the fact that, as pointed out in some of the comments, single foods, when their significance in the total daily diet is considered, do not generally increase disease risk. It is the total diet, consisting of a number of foods consumed over time, that has the potential to increase disease risk. Thus, FDA believes that the purpose of section 403(r)(3)(A)(ii) of the act is to ensure that FDA establishes appropriate disqualifying levels for those nutrients that have the potential, at high levels of consumption, to increase disease risk so that consumers who rely on health claims will be consuming foods that will assist them in meeting dietary guidelines in constructing their total dally diet, and not foods that make it more difficult to do so.

FDA also does not agree that Congress intended that section 403(r)(3)(A)(n) of the act only prohibit health claims where the level of risk from a nutrient is sufficient to invoke the adulteration provisions of the act. Disqualifying levels in no way should be construed as nutrient levels that FDA believes are harmful in an individual food. The House Report (Ref. 1) explains that this provision pertains to nutrients required to appear on the label and specifically points out that certain levels of fat in foods may trigger this provision. Foods that are 100 percent fat are still safe and lawful under the act. FDA believes that fat was cited to make it obvious that the provision is intended to provide a measure of control for diet-related diseases that are influenced by excessive consumption of safe and lawful nutrients.

In appropriate amounts, such nutrients have a necessary or useful place in the total daily diet. In fact, where the only safety issue is an increased risk of a chronic disease from excessive consumption, the safety provisions of the act would not provide regulatory sanctions against such components of foods, at least if they have not been added to foods. For such components, FDA must show that the component is a poisonous or deleterious substance that would ordinarily render the food injurious to health. If Congress had intended that section 403(r)(3)(A)(ii) of the act to prohibit health claims only where the level of risk from a nutrient is sufficient to invoke regulatory sanctions, the provision would have been unnecessary. Clearly, Congress had something else in mind.

The agency also disagrees with the comments that argue that FDA developed disqualifying nutrient levels based on a misconstruction of the statutory language and intent of section 403(r)(3)(A)(ii) of the act. That section does not read, as one comment stated, that disqualifying nutrient levels may be established * * * "if the Secretary determines * * * ." Instead, it states that a health claim may only be made "* * * if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition which is diet related * * *." FDA believes that the most straightforward reading of this provision is as an instruction to the agency to establish a list of levels of nutrients in food that, taking into account the makeup of the total daily diet, increase to persons in the general population the risk of diet-related diseases or health-related conditions.

In addition, the agency disagrees with the contention that the definition of "disqualifying nutrient levels" is either overly restrictive or based on an inappropriate scientific basis. The agency stated in the November 1991 proposal that although there are well-established recommendations for dietary intake for fat, saturated fat, cholesterol, and sodium that are consistent with maintaining good health, there are no levels for these nutrients in an individual food generally recognized by the health community to pose an increased risk of disease. However, this statement was intended to point out that scientists have not developed a scheme for transposing quantitative information on the nutrient content of a diet to comparable quantitative information for the broad array of individual foods as they may fit within the context of a healthful diet. Because of this fact, the agency stated in the November 1991 proposal that it did not know of an established or accepted approach for identifying levels for fat, saturated fat, cholesterol, and sodium in an individual food that would increase the risk of a diet-related disease and that would, therefore, disqualify that food from bearing a health claim. In the absence of an established approach, FDA arrived at an approach in which the amounts of fat, saturated fat, cholesterol, and sodium that the agency proposed as disqualifying nutrient levels were the amounts that, in a single food, would make it difficult to construct a diet that meets dietary guidelines, particularly if consumption of the food is encouraged and emphasized by a health claim. Because the guidelines identify dietary levels for specific nutrients (e.g., saturated fat) for which higher levels of intake are linked to an increased risk for a diet-related disease (e.g., heart disease), failure to meet them can reasonably be expected to increase the risk of a disease. Indepth discussions of the agency's conclusions about risk inherently associated with each of the disqualifying nutrients appear elsewhere in this issue of the **Federal Register** in the preambles of the final rules for health claims for dietary lipids and cardiovascular disease, dietary lipids and cancer, and sodium and hypertension.

Accordingly, the definition for disqualifying nutrient levels is fully consistent with the information contained in the legislative history of the 1990 amendments.

2. Disclose rather than disqualify

24. Several comments suggested that Congress sought through the exception process permitted by section 403(r)(3)(A)(ii) of the act to limit the disqualifying effect of nutrient levels to only those nutrients that have a direct effect on the disease that is the subject of the health claim. Some comments suggested that the agency should have utilized the flexibility accorded by Congress to opt for disclosure of nutrients that are not directly related to the disease mentioned in a claim, rather than disqualification of the product from bearing any health claim. In support of their position, the comments cited the discussion on section 403(r)(3)(A)(n) of the act contained in the House Report on the 1990 amendments (Ref. 1). Comments argued that even though sodium is linked to hypertension, which is a risk factor for heart disease, a product with high sodium content should not be disqualified from bearing a claim about dietary lipids and heart disease because of the lack of major linkage between sodium as a causative factor for heart disease. Another comment, which asserted that prohibiting an osteoporosis claim for whole milk would be misleading because none of the disqualifying levels have any relevance to osteoporosis, also maintained that FDA had made no room for the disclosure permitted by section 403(r)(3)(A)(u) of the act for a food

containing a nutrient exceeding the disqualifying level.

The agency disagrees with these comments. Section 403(r)(3)(A)(ii) of the act states that a health claim "may only be made if the food for which the claim is made does not contain * * * *any* nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related * * *" (emphasis added). That language is clear in that it does not permit a claim for a product containing a nutrient that increases the risk of any diet-related disease or condition and is not limited to a substance that is associated only with the subject disease. The provision then goes on to state that exceptions to this requirement may be made by regulation in the interest of providing consumers with information in maintaining healthy dietary practices. Contrary to the assertion, by one comment, FDA provided for the disclosure permitted by section 403(r)(3)(A)(ii) of the act for a food containing a nutrient exceeding the disqualifying level in proposed §101.14(e)(3).

Because of the time constraints for issuing regulations on health claims, the agency did not exercise the option to develop exceptions to disqualifying nutrient levels. Nevertheless, the changes made in the disqualifying levels that are explained in response to comments 29 and 32 of this document will reduce, but may not eliminate, any need to develop exceptions to disqualifying levels. With those changes, the number of foods that would be disqualified from making a claim will decrease significantly.

Even though § 101.14(e)(3) provides for exceptions from disqualifying levels and the use of an appropriate referral statement, FDA believes that the use of disqualifying levels will be clearer if § 101.14(a)(5) also reflect the fact that exceptions are possible. Thus, FDA has revised this section to state that exceptions to the disqualifying levels may be provided in the specific health claim regulations in part 101, subpart E. The agency will be receptive to petitions that present the reasons that, and the circumstances in which, an exception to disqualification would assist consumers in maintaining a healthy diet.

3. Additional disqualifiers

25. Several comments recommended that health claims be prohibited in labeling for candies, soft drinks, and other sugars-containing foods on the basis of added sugars content. Some comments stated that a Daily Reference Value (DRV) of 50 g for added sugars should be established, and they recommended a disqualifying nutrient level of 8 g of added sugars. This disqualifying level would represent 15 percent of the DRV recommended by the comments. The comments noted that sugars have been associated with the development of plaque, dental caries, and periodontal disease and further noted that the Dietary Guidelines for Americans (Ref. 7) urges the public to consume sugars only in moderation. Another comment asserted that health claims should not be allowed on the label or labeling of a food when more than 15 percent of the food's total calories is contributed by added sugars.

The agency finds that it would not be appropriate to limit health claims on foods on the basis of added sugars either in terms of an absolute amount per serving or as a function of percent of calories per serving. In determining the disqualifying nutrient levels for fat, saturated fat, cholesterol, and sodium, the agency used an approach based on the DRV's for these nutrients. As explained in the proposal to establish DRV's (55 FR 29476), the values for fat, saturated fat, cholesterol, and sodium were based on recommendations that American consumers limit or reduce dietary intake of these nutrients in order to lower their risk of a number of diet-related diseases whose incidence in the general population is considered by the vast majority of public health experts to be unacceptably high. Such recommendations were derived from two publications: The Surgeon General's report (Ref. 5) and the Diet and Health report (Ref. 6) and are reflected in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7). One of these recommendations, for example, is for Americans to reduce dietary fat intake from about 37 percent of total energy intake to 30 percent or less Accordingly, the DRV for total fat is derived from the recommendation that daily total fat intake not to exceed 30 percent of calories. This and other recommendations are believed to have the potential for a substantial reduction in the risk of diet-related chronic disease in the general population.

Of the comments recommending a DRV of 50 g of added sugars as the basis for a disqualifying level of 8 g, only one provided a rationale for the suggestion. The comment arrived at its recommendation by first, estimating in a nonrigorous fashion that the current consumption level is about 100 g per day. The comment then offered that, because FDA concluded in a 1986 report (Ref. 28) that the average American consumes 53 g of added sugars per day, one-half of their 100 g estimate is close to 53 g which should be rounded to 50 g to become the DRV. It offered that, if the agency sets the DRV for added sugars at what the agency considers to be a current consumption level, it would be difficult to argue that the agency has restricted sugars intake too severely.

FDA does not believe that a disqualifying level for sugars can presently be established because of the lack of suitable criteria in the aforementioned comment on which to base a DRV. Even if the comment's estimate of current consumption is scientifically sound, it is significant that no other DRV has been established with average daily consumption as the criterion. Moreover, the public health community has not identified a dietary level above which consumption of sugars has been demonstrated to increase the risk of a disease. Thus, the agency finds that there is no sound basis on which to establish the requested DRV for sugars. Accordingly, the agency is declining to set a disqualifying level for added sugars at this time. Nevertheless, the agency points out that the criteria established in response to comment 87 of this document for limiting health claims based on the nutritional value of a food will provide at least some of the relief requested in that a food fabricated with sugars and few other nutrients will not qualify for a claim.

26. A few comments recommended that FDA prohibit health claims on foods containing any "unnecessary substances," food or color additives or flavor enhancers. One of these comments justified the recommendation by stating that saccharin is associated with a major disease.

FDA does not believe it is appropriate for it to judge whether use of an ingredient is necessary, or to make the mere presence of a food additive disqualify foods from bearing health claims unless the use of the food additive has not been listed by FDA for use in food under section 409 of the act (21 U.S.C. 348). When it passed the Food Additives Amendment in 1958, Congress concluded that use of food additives is in the public interest, provided that their use is safe and not deceptive. For those comments concerned about the safety of food and color additives, the agency advises that the act requires that the use of these additives be shown to be safe before they are listed for use in food. Other ingredients that may be added to food are limited to those that are generally recognized as safe (GRAS) by the scientific community by virtue of their history of use or other scientific knowledge (i.e., GRAS), or whose use

was sanctioned by FDA or USDA before the enactment of the Food Additives Amendment (i.e., prior sanctioned ingredients).

With respect to the comments that specifically mentioned saccharin, FDA did propose on April 15,1977 (42 FR 19996), to ban its use, based on its interpretation of evidence available from animal studies at that time. However, Congress decided that the additive should be permitted in food and blocked the proposed ban through enactment of the Saccharin Study and Labeling Act. Therefore, unless there is a change in its legal status, the use of saccharin in compliance with § 101.11 (21 CFR 101.11) and § 180.37 (21 CFR 180.37) must be treated the same as any other legally authorized use of an ingredient.

4. Fifteen Percent of the DRV

a. Criticism of approach.

27. A number of comments stated that, despite FDA's assertions to the contrary, a total ban on health claims for foods exceeding a disqualifying level would create a good food/bad food image in the minds of consumers. The comments claimed that consumers may turn away from foods that provide significant amounts of essential nutrients simply because the foods do not carry a health claim. One comment noted that whole milk would be prohibited from making a claim about calcium and osteoporosis in spite of the fact that it is recommended as a source of calcium for children 1 to 2 years of age. The comment cautioned that parents may inappropriately substitute skim and low fat milk because of an assumption that whole milk is inferior.

Other comments proposed that if FDA decides to establish disclosure/disqualifying levels for nutrients, the agency should employ extreme care in informing consumers that individual foods do not increase the risk of disease, because it is the total daily diet that must be taken into account.

FDA disagrees with the contention that if foods that exceed a disqualifying level are ineligible to bear a health claim, consumers will perceive those foods as bad. A food without a claim, even if it does not exceed a disqualifying level, may not have the appropriate level of a nutrient to qualify for a claim. For various reasons, a food manufacturer may decide not to label a product with a claim even if the product qualifies. On the other hand, a product bearing a claim is required to provide the consumer with sufficient information to understand how the product may be useful to achieve the claimed effect within the context of the total daily diet. The agency believes that there are sufficient safeguards within section 403(r) of the act that are fully implemented in the final rules on health claims to prevent consumers from being misled about the value of any food based on whether it does or does not bear a health claim.

The agency acknowledges, however, that the full array of all of the new labeling regulations effected by the 1990 amendments may not be immediately understood by consumers. To deal with this, FDA will conduct an education program to effectively communicate how this new food labeling can assist consumers to maintain a healthy diet through informed food selection.

In response to the last group of comments, the agency reiterates that the disqualifying levels represent the amount of these nutrients in a single food that would make difficult the construction of a diet that meets dietary guidelines. They in no way represent a finding by the agency that these levels will cause diet-related disease or that foods that contain nutrients at these levels are unsafe, dangerous, or bad.

28. Other comments contended that an across-the-board disqualifying level based on a set percentage of the DRV for a nutrient could not be justified. One comment stated that it could not support the food composition analysis the agency used in developing the proposed disclosure/disqualifying levels because that approach does not fully meet the requirements of section 403(r)(3)(A)(ii) of the act. Specifically, the comment asserted that FDA's approach to disclosure/disqualifying levels ignores the legal requirement of accounting for the "significance of the food in the total daily diet." The comment claimed that this requirement implies a food consumption analysis that considers how a food is customarily used in the context of a daily diet. Further, the comment said that only a careful examination of food consumption data, in which foods are inherently related to their use in daily diets, can properly address the requirements of the law. The comment offered that the agency's proposed disclosure/disqualifying levels have some basis in daily consumption because of the use of DRV's. However, it said that the evaluation of individual foods in the agency's model is based on food composition values compared to food consumption values derived from DRV's. The comment argued that the composition of a food has no meaning in the context of the daily diet until its customary use is considered. The comment concluded that FDA did not do this, and that this error invalidates the agency's analysis.

The food composition methodology used by the agency in arriving at the proposed disclosure/disqualifier nutrient levels is fully consistent with section 403(r)(3)(A)(ii) of the act. As FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish these levels by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. The focus of this provision was clearly not on consumption of the individual food. Thus, references to "the significance of the food in the total diet" in that section does not imply that a food consumption analysis of how individual foods are used in a daily diet should be made. Instead, that section requires that FDA consider consumption in a far broader context. As explained in the subsequent paragraphs of this response, FDA's approach considers daily food consumption through use of the DRV's.

The DRV's were developed from recommendations in, for example, the Surgeon General's report (Ref. 5) and Dietary Guidelines for Americans (Ref. 7). They reflect current and established scientific evidence related to overall nutrient intake and risk of diet-related diseases. They also reflect total dietary intake from foods in general, but not intake from individual foods. Thus the disclosure/disqualifying nutrient levels are also based on food consumption in general, not just food composition.

Further, in arriving at the numerical value for the disclosure/disqualifying levels, the agency looked at the daily diet as being composed of approximately 20 servings of food and the likely distribution of the subject nutrients in the diet. The agency concluded that such nutrients were likely to be found at significant levels in as many as 10 of those 20 foods. Thus, while the agency did not consider the role of specific individual foods in the diet in arriving at the disclosure/disqualifying levels, the significance of particular types of food, such as those that contain a significant amount of fat, were considered. In sum, FDA's approach considers consumption in a broad manner that enhances the chances of consumers constructing total daily diets that meet dietary guidelines. Accordingly, contrary to the point made in the comment, the agency concludes that it did effectively consider food consumption data in which foods were related to their use in the diet in establishing the disclosure/disqualifying nutrient levels.

b. Fifteen percent should increase to 20 percent.

29. A number of comments, mostly from, consumer organizations, agreed with the agency's rationale for selecting 15 percent of the DRV as the disclosure disqualifying level for a specific nutrient; however, many comments from industry objected. In lieu of the 15 percent level chosen by FDA, the latter comments recommended 20 percent of the DRV because that is the amount the agency proposed as a "high" or "major source" nutrient content claim. Other comments strongly urged FDA to raise the disqualifying level to 20 percent of the DRV for cholesterol and sodium.

In addition, comments from industry and a Federal agency expressed concern that the disqualifying levels for fat, saturated fat, cholesterol, and sodium would prevent manufacturers from making potentially beneficial health claims on food that could assist consumers in making dietary changes. Some of the comments claimed that 99 percent of the food items in the categories of poultry, meat, and fish are disqualified from mentioning the health reasons for changes in consumption, despite recommendations from dietary authorities to substitute lean chicken and fish for meat. Similarly, the comments argued that the disqualifying levels would prevent nearly 90 percent of the items in mixed foods (grain), ready-to-eat cereal, and cheese categories and over 80 percent of the items in bread and crackers/salty snacks categories from making health claims. One comment concluded that the disqualifying levels would preclude many foods that could contribute to a better diet from mentioning truthful health reasons for making desirable substitutions, even where there is general scientific agreement on the desirability of these changes.

The agency agrees that the disqualifying levels for fat, saturated fat, cholesterol, and sodium should not serve as impediments to providing consumers with important information on diet and health by precluding health claims for major food groups, such as fish and whole grain cereals, that can be significant foods in a balanced and healthy diet. As FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish disqualifying levels by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus it would not be appropriate for FDA to establish disqualifying nutrient levels mat would be o stringent that major food groups that have an appropriate place in a healthful diet would not qualify for health claims.

In concert with the Surgeon General's recommendations, USDA and DHHS provided the American consumer with food guide information on food selection to achieve a healthy diet in the current edition of "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 7). Most recently, USDA published "USDA's Food Guide Pyramid" (Ref. 29), which is intended to assist consumers in putting these dietary guidelines into action. The pyramid booklet provides information on dietary moderation, proportionality, and variety to ensure that consumers get the nutrients they need without too many calories or too much fat, saturated fat, cholesterol, sodium, sugar, or alcohol. The pyramid booklet suggests a range of daily servings from five major food groups, one of which includes meat, poultry, fish, dry beans, eggs, and nuts. As the comments indicate, a very large proportion of the items in this food group would exceed one or more of the disqualifying nutrient levels. Consequently, products in this group would not be permitted to bear health claims despite recommendations from dietary authorities to choose, for example, fish, lean meat, and poultry without skin as a way to reduce dietary fat intake. Accordingly, the agency has decided to revise the disqualifying nutrient levels to make it possible for a greater variety of foods in all food groups that are consistent with dietary guidelines to bear health claims.

FDA developed the disclosure/disqualifying levels for fat, saturated fat, cholesterol, and sodium to ensure that health claims are not made for foods that contain a nutrient in an amount that makes it difficult for consumers to comply with dietary guidelines. In developing these levels, FDA found no ready guidance on how to calculate them. The legislative history of section 403(r)(3)(A)(ii) of the act does not suggest what amount of a nutrient in a food should be considered as the limit to ensure compliance with dietary guidelines. Furthermore, current dietary guidance is presented in terms of daily nutrient intake rather than intake from individual foods.

Thus, in the absence of an accepted means for deriving the levels of nutrients in food that could be considered to increase the risk of disease, FDA, after considering the language of the act and its legislative history and based on the agency's scientific expertise, arrived at a tentative approach that was based on the proposed DRVs and available information on food composition and dietary intake patterns. The agency considered that a consumption pattern of individual foods that allowed for the intake of 100 percent of the DRV's would not increase the risk of diet-related disease, but that intakes resulting in the consumption of 200 percent of the DRV would do so. Therefore, an amount of a nutrient that would not increase the risk of disease would fall somewhere between 100 percent and 200 percent of the DRV. Based on the assumptions that diets generally include approximately 20 food/beverage items per day (Refs. 8 through 10), and that, given the uneven distribution of nutrients among the food categories, only about half of the foods consumed during a day will contain the nutrients of concern, the agency tentatively concluded that an increase in risk from an individual food was likely to result if it contained between 10 and 20 percent of the DRV per serving of fat, saturated fat, cholesterol, or sodium.

Based on food composition data available to the agency, FDA evaluated the kinds and types of foods that would be disqualified from bearing a health claim on the 10,15, and 20 percent levels. Erased on this evaluation, FDA tentatively concluded that 15 percent of the DRV represented the amount of the nutrients in question that increases to persons in the general population the risk of a diet-related disease or health-related condition.

After reviewing additional information on food composition (Ref. 30) and the comments recommending that the disclosure/disqualifying levels be raised from 15 to 20 percent of the DRV's, FDA is persuaded that its approach to calculating this level should be modified. FDA acknowledges that its primary concern in its initial development of these criteria was that foods that contain levels of nutrients that are not consistent with dietary recommendations be precluded from making a health claim. However, comments on this approach strongly urged that FDA also ensure that types of foods that are consistent with dietary recommendations—or, more specifically, types of foods whose increased consumption has been promoted in dietary recommendations—be able to bear claims if they meet the specified definition for the claim. In other words, comments argued that the disclosure/disqualifying levels should be sufficiently liberal so as to maximize the number of foods that bear claims and to allow claims on foods that are generally regarded as desirable components of an overall healthy diet.

assuming that the food meets the basic definition for the claim.

Based on consideration of foods highlighted by the comments as well as on a review of the food composition data available to the agency, FDA agrees that the use of a 20 percent DRV criterion will permit foods that are appropriately included in an overall healthy diet, for example a greater variety of bran and oat breakfast cereals or legume and vegetable products, to bear a health claim, even though they would not have been permitted to do so under the 15 percent DRV criterion. Furthermore, FDA finds compelling the argument made in comments that the criterion for "high" levels of a nutrient in a food can be applied not only as proposed, (i.e., to emphasize the presence of a nutrient when it is considered desirable) but also can provide a consistent and appropriate basis for defining the levels at which the presence of a nutrient may be undesirable.

FDA acknowledges the debate on the issue that an exact level is not readily identifiable for a nutrient In a food that increases the risk of a disease or health-related condition to persons in the general population. With levels set at 20 percent of the DRV's for fat, saturated fat, cholesterol, and sodium, the question arises as to whether there are foods included among those containing 20 percent or less of a DRV that may lead to a diet inconsistent with dietary guidelines for maintaining good health. On reconsideration, the agency believes that the answer is no. Since the primary consideration from dietary guidance for avoidance of disease risk focuses on nutrient composition of the diet, and since there is no generally accepted way to extend that risk to the multiplicity of foods that may be selected in a daily diet while remaining consistent with dietary guidance, the agency finds that, taking into account the significance of the foods in question (that is, foods with 20 percent or less of the DRV for fat, saturated fat, cholesterol, or sodium) in the total daily diet, it is appropriate to adjust the disqualifying levels to the higher value of 20 percent of a DRV. In doing so, the agency is balancing the availability of valid information against the probability that food with that information will result in diets that increase the risk of a disease or health-related condition. FDA believes that, in the 15 to 20 percent range for establishing disqualifying levels, the importance of providing health claim information is greater than the possibility that risk of disease will be increased. Above 20 percent, however, the agency believes that that risk will increase and thus section 403(r)(A)(ii) of the act should be brought to bear. Therefore, FDA finds that, if a food contains more than 20 percent of the DRV for fat, saturated fat, cholesterol, or Sodium (i.e., more than 13 g of fat, 4 g of saturated fat, 60 mg of cholesterol, or 480 mg of sodium) per reference amount customarily consumed or per label serving size it may not bear a health claim because these levels in an individual food can lead to a diet inconsistent with dietary guidelines for maintaining good health. Moreover, as explained in the response to comment 32 of this document, if a food that has a reference amount of 30 g or less or of 2 tablespoons or less contains more than 20 percent of the DRV for any of these nutrients per 50 g of food, it may not bear a health claim because claims on such nutrient-dense foods would be inconsistent with dietary guidelines.

c. Increase for meals and meal replacements.

30. Some comments suggested that FDA establish separate disqualifying levels for meal-type products at 25 percent of the DRV. They contended that products ordinarily consumed as meals contribute much more to the total diet than do individual foods. The comments argued that the single-food disqualifying levels for these meal-type items is too strict. A disqualifying level of 25 percent DRV for saturated fat, total fat, sodium, and cholesterol would ensure that persons eating three meals a day plus a snack would not exceed 100 percent DRV of any nutrients of concern.

The agency agrees that single food disqualifying levels are too strict when applied to meal-type products, which contain multiple servings of food. Because disqualifying levels for health claims are the same as disclosure levels for nutrient content, claims, and because both are derived from the same statuary standard regarding nutrient levels in amounts that increase the risk of a diet-related disease in the general population, the definition for disqualifying levels in new § 101.14(a)(5) has been revised to be consistent with comparable requirements in new § 101.13 on disclosure levels for nutrient content claims for meal-type products published elsewhere In this issue of the Federal Register.

FDA is now providing for the definition of "meal product" in new § 101.13(l) and "main dish product" in new § 101.13(m) within the context of providing for nutrient content claims. As described in the nutrient content claims final rule, the agency is adopting different criteria for nutrient content claims for these products as compared with individual foods. The definition for a "meal product," which is described in more detail in the nutrient content claims final rule, is that: (1) It is represented as, or commonly understood to be, a dinner, lunch, breakfast, or other meal; and (2) it makes a major contribution to the diet by weighing at least 10 ounces (per labeled serving), containing at least 3 different foods from at least 2 of 4 food groups, and containing not less than 40 g of each of the 3 different foods. The definition for a "main dish product" is that: (1) It is represented as or is in a form commonly understood to be a main dish, and (2) it weighs at least 6 ounces per labeled serving, contains at least 2 different foods from 2 of 4 food groups, and contains not less than 40 g of a food from each of 2 food groups.

FDA has considered the appropriate disclosure/disqualifying level for main dish and meal products. As mentioned above, comments have suggested that the criterion be based on the amount per 100 g of product. Using this approach, the amounts used for individual foods (i.e., 13 g of total fat, 4 g of saturated fat, 60 mg cholesterol, and 480 mg sodium) would be the amount per 100 g of a meal or a main dish. FDA however notes that, on this basis, a meal weighing 10 ounces (280 g) would be subject to disclosure/disqualification if it contained approximately 36 g of fat or 55 percent of the DRV. A single meal product weighing 1.2 ounces (336 g)---not an uncommon weight for a meal—would be subject to disclosure/disqualification if it contained approximately 44 g of fat or about 67 percent of the DRV for total fat., If it is assumed that a "meal" constitutes one-fourth of a total day's nutrient/calorie intake, which, if anything understates the contribution of a meal, this criterion is seen to be too high because a meal could contribute more than half of the total amount of one of the nutrients in question (i.e., fat, saturated fat, cholesterol, or sodium) generally recommended as a total daily intake and yet still bear a health claim.

The comments received offered no approaches other then use of the "per 100 g" basis relative to disclosure/disqualifying levels for main dishes and meals. FDA, therefore, has developed an approach that extends the rationale used for individual foods to main dishes and meals. Specifically, given that main dishes and meals constitute a larger portion of the diet than individual foods, the criterion for disclosure/disqualification for main dishes and meals should be a greater percentage of the DRV than for individual foods.

FDA has determined that criteria of 30 percent of the DRV as a disclosure/ disqualifying level for main dishes and of 40 percent of the DRV as that level for meals are appropriate. Assuming a typical consumption of three meals and a snack, each of which contain 40 percent of the DRV for a particular disclosure/disqualifying nutrient, and foods that sometimes accompany meals such as beverages, bread, and desserts that contribute an additional 40 percent of the DRV for the nutrient, 200 percent of the DRV would be consumed during the day. As discussed in the response to comment 2-3 of this document, FDA has concluded that on balance, given the benefits and the probabilities that risk of disease will be increased, a disqualifying level based on a total dietary intake of 200 percent of the DRV is appropriate.

Disclosure/disqualifying levels, for main dishes are appropriately placed at 30 percent because it is likely that consumption levels of these products is between the level for individual foods and the level for meals. Therefore, FDA has set the criterion at 30 percent which is between the 20 percent criterion for individual foods and the 40 percent criterion for meals. Finally, FDA's review of available data suggests that these criteria have practical application in that the criteria of 30 and of 40 percent of the DRV would not be overly restrictive (Ref. 35). Accordingly, the definition of disqualifying nutrient levels in new § 101.14(a)(5) has been revised to incorporate these changes for meals and main dish products.

31. One comment from a manufacturer of foods for special dietary uses suggested that the proposed disqualifying provisions of proposed § 101.14(e)(5) should not apply to a .formulated product presented as a meal replacement where a serving provides one-fourth to one-third of the daily nutrient: intake based on calories. Rather, the comment suggested that the disqualifying levels should be based on the amount of total fat, saturated fat, cholesterol, or sodium when the amount of any of these substances exceeds the equivalent portion of the DRV on a caloric basis. For example, according to the comment, a meal replacement that provides 25 percent of the daily caloric intake in a single serving should have the disqualifying levels set at or above 25 percent of the DRV's. The comment said that such a provision would provide a standard for these products consistent with the regulation. Each "serving" of the formulated product would represent an entire meal and would replace several servings of conventional food. Establishing disqualifying levels on this basis, the comment said, would allow consumers access to important health information. The comment suggested that the proposed regulation be modified to read as follows:

> Formulated meal replacement products that provide 25 to 33-1/3% of the daily caloric intake shall be disqualified when the level of fat, saturated fat, cholesterol, or sodium exceeds, on a caloric basis, the equivalent portion of the Daily Reference Value [1 CFR 101.9(c)(12)(i)].

The agency acknowledges the point made by this comment that a meal replacement product, particularly one that is a food for special dietary use, may be sufficiently different from a serving or amount of a conventional food to warrant a different criterion for disqualifying nutrient levels. Nevertheless, the agency does not believe that it is appropriate to modify the codified language as recommended because of a lack of essential information needed to implement the change. Specifically, where the proposed codified language applies to "formulated meal replacement products," there is no definition or other characterizing information that identifies this class of products.

The agency published proposed regulations on June 14, 1974, to establish a nutritional quality guideline and a common or usual name for formulated meal replacements (39 FR 20905). Subsequently, however, those proposals were withdrawn. Although they may serve as a basis to reconsider what had been proposed, a significant number of changes have occurred in the intervening 18 years with regard to the regulations and policy on the nutrient content of foods.

For example, the proposed nutrition quality guideline regulation defined a formulated meal replacement, in part, as a product that supplies a minimum of 700 kilocalories per serving (the term "calorie" has the same meaning as "kilocalorie" in the text that follows), unless the product is represented for use in a reduced calorie diet (39 FR 20905, June 14, 1974). On the presumption that a meal should provide at least 25 percent of daily caloric intake, the value of 700 calories per serving was derived from a proposed intake standard of 2,800 calories per day. Subsequently, as reflected in the current fortification policy (21 CFR 104.20), the energy intake standard has been lowered to 2,000 calories per day. This value is the same as the reference caloric intake that FDA used in determining the DRV's, published elsewhere in this issue of the **Federal Register**. Accordingly, the agency advises that with the necessary steps to establish a definition and nutrient composition and. nutrition quality requirements for the class of "meal replacement products," particularly those that are foods for special dietary use, consideration may be given to providing an. exception to disqualifying levels for that class of products.

The agency has examined several products currently in the marketplace promoted for use, among other things, as either a "meal replacement" or as a "balanced meal" that included a formulated ready-to-consume fluid product and dry mixes for addition to fluid milk to produce an "instant breakfast drink." The former, but not the latter, type product bore other labeling for use of the product to either lose or gain weight, thus classifying the product as a food for special dietary use. A single serving of the ready-to-consume product provides 360 calories, whereas the dry mixes provide 220 calories when combined with 8 fluid ounces of skim milk. From nutrition labeling information, neither type of product exceeds the disqualifying levels for fat and sodium defined in new § 101.14(a)(5) for an individual food. From the list of ingredients and nutrient content information from standard data bases, it is also unlikely that either product would exceed the disqualifying levels for saturated fat or cholesterol. Further, it appears that if a serving of the ready-to-consume meal replacement were adjusted to increase the caloric yield from 360 to 470 calories, per serving, the disqualifying levels for fat, saturated fat, cholesterol, and sodium would still most likely not be exceeded. Although this assessment, admittedly, is extremely limited in scope, the agency concludes that the disqualifying levels in new § 101.1.4(a)(5) for an individual food will apply to a product promoted as a meal replacement until a more appropriate requirement is established by regulation.

d. Per 100 grams.

32. A number of comments from industry and from other Government agencies objected to the part of the proposed definition for "disqualifying nutrient levels" in proposed §101.14(a)(5) that tied such levels to the amount of fat, saturated fat, cholesterol, or sodium "per 100 g." One comment asserted that 100 g means nothing to the public and suggested that standardized serving sizes should be the basis of labeling. Others agreed that the "per 100 g" criterion is unnecessary with the adoption of standardized serving sizes, which, the comments asserted, effectively eliminate the agency's concern that manufacturers may

manipulate serving sizes to make their products appear more attractive. One comment cautioned that using both the 100 g and serving size requirements risks substantial confusion.

FDA does not agree that a weight-based criterion is unnecessary. The agency notes that section 403(r)(3)(B)(iii) of the act states that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet. Because certain foods are consumed in small amounts and thus have small serving sizes, it is possible that a food dense in a nutrient such as fat or sodium could qualify for a health claim because the serving size of the food is so small that there is not a sufficient amount of the nutrient present to disqualify the food. Accordingly, the nutrient density, or weight-based, criterion was developed to deal with foods with small serving sizes that maybe consumed more frequently than once a day.

However, the food itself could be inconsistent with dietary guidelines in that it has been identified as a food to be limited in the diet. "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7) states that certain types of foods high in fat, for instance, should be limited in the diet without regard to the amounts typically consumed in a single serving. Furthermore, the recommendations provided in "USDA's Food Guide Pyramid" (Ref. 29) are consistent with the guidance to limit the intake of certain types of foods regardless of serving size. Claims on such foods would promote their consumption and, thus, fail to set the food in its proper dietary context.

Therefore, FDA has concluded that criteria for health claims based solely on serving size would be inconsistent with dietary guidance and would fail to respond to section 403(r)(3)(B)(iii) of the act, which requires that the claim set the food properly in the context of the diet. This conclusion is supported by the comments to the docket discussed in the response to comment 87 of this document, which stated that health claims should be prohibited on foods that are inconsistent with a sound dietary pattern. Moreover, claims intended to promote the consumption of a food that appear on a food that is inconsistent with dietary guidelines could be misleading to consumers under section 403 (a) of the act and, thus, such claims are inappropriate.

However, the agency has concluded that the weight-based criterion is only needed for foods with small serving sizes that include those foods with reference amounts of 30 g or less or 2 tablespoons or less. For foods with reference amounts above 30 g or 2 tablespoons, the per label serving size or per reference amount customarily consumed criteria are sufficient to prevent nutrient-dense foods from bearing health claims.

Accordingly, FDA has provided for a weight-based criterion in addition to the criterion that specifies the amount of nutrient present per reference amount customarily consumed and per label serving. The weight-based criterion precludes claims on nutrient-dense foods and would qualify for a health claim solely because they have very small serving sizes.

A weight-based criterion for foods with small serving sizes is also used with nutrient content claims, which are discussed in a final rule published elsewhere in this issue of the **Federal Register**. As discussed in that document, comments to the nutrient content claims proposal stated that basing the criterion on per 100 g may be overly restrictive. These comments pointed out that the per 100-g criterion precludes claims on foods that are consistent with dietary guidelines, such as whole grains and cereals. Alternative and less restrictive criteria were suggested including a criterion based on 50 g rather than 100 g. As discussed in the nutrient content claims final rule, FDA has been persuaded that it is appropriate to use 50 g rather than 100 g as the weight-based criterion.

To ensure that its treatment of disqualifier and disclosure levels is consistent, FDA has reexamined the 100-g criterion for use with health claims. Data analyses (Ref. 31) demonstrate that changing from 100 g to 50 g and applying the criterion only to foods with small serving sizes allows a number of foods that would otherwise have been precluded from bearing a claim and that are consistent with dietary recommendations, such as certain cereals and whole grains as well as fish and milk products, to qualify for health claims. Moreover, such a change would allow only a few foods that are inconsistent with dietary guidelines to bear claims. Therefore, to provide for claims that are consistent with dietary guidance, FDA is providing for a weight-based criterion for foods with small serving sizes based on per 50 g rather than per 100 g. In addition, for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" (that is, hydrated) form.

The agency also disagrees that using three criteria, nutrient density, reference amount customarily consumed, and label serving size, to determine disqualifying levels runs the risk of confusing consumers. The determination as to whether a food contains a disqualifying level of a nutrient is not discussed on the label or in labeling. Thus, there is no basis on which a consumer could be confused

e. Relevant nutrients.

i. Fat and saturated fat.

33. One comment recommended that in conjunction with the health claim on skim milk and 1 percent lowfat milk, the agency requires that the products display a statement that "whole milk is more appropriate for the growth and development of children under two years who are drinking milk." The comment noted that children in this age group require an adequate amount of tat in their diet for proper growth and development.

FDA does not believe that skim and lowfat milk should be required to bear the suggested statement. The health claim about calcium and osteoporosis is directed primarily to those individuals with known family histories of osteoporosis and to adolescent and young adult Caucasian and Asian American women. Such claims are not directed to children. In fact, health claims are prohibited, except in very limited circumstances, wherever a food is represented or purports to be for infants and toddlers less than 2 years of age. Therefore, FDA rejects the request in this comment.

34. Some comments asserted that the disqualifying levels for fat and saturated fat were too high and should be lowered.

The agency disagrees with tills contention. Absent a showing to the contrary, and the comments did not contain such a showing, the agency has no basis to find that levels in a food of fat and saturated fat of less than 15 percent of the respective DRV's increase the risk of a diet-related disease. Further, as explained above, FDA has reassessed the issue and concluded that the disqualifying levels for fat and saturated fat should be raised to 20 percent of their DRV's. The agency finds that this decision is consistent with dietary recommendations to limit energy Intake from fat and saturated fat to 30 and 10 percent of calories, respectively. Accordingly, the agency rejects the comment's recommendation.

35. One comment stated that the disqualifying regulations for fats and saturated fats should be adjusted to reflect the use of reduced calorie novel fats and fat replacers. The comment

explained that products employing novel fats should be eligible to display a lipid and cardiovascular health claim consistent with other requirements for this claim. The comment asserted that the identity of fat should he limited to those materials that do in fact provide measurable bioavailable fatly acids and calories. The comment asserted that fatty acid containing fat substitutes that are essentially nondigestible do not qualify as fats and should be treated separately. The comment stated that the quantity of fat should be determined by the amount of bioavailable fatty acids that such a fat substitute contains. This approach, the comment said, would provide a common basis for quantifying the fat equivalence of novel fats as well as mono- and diglycerides, phospholipids, and "natural" fats of limited digestibility. Under it, total fat could be quantified, and fatty acid type could be expressed as the triglyceride equivalent of the bioavailable fatty acid fraction. For the novel fats, the average characterizing bioavailability could be established by the manufacturer and submitted to FDA as part of a petition for regulatory food-use approval. Application of a "bioavailability" index for fats would be similar to the use of the Protein Digestibility Corrected Amino Acid Score or Protein Efficiency Ratio used to characterize proteins and of the bioequivalence values assigned to vitamin products.

The agency does not disagree with the comment's main point that the quantity of fat in a product, which determines whether a claim can be made, should be determined by the amount of bioavailable fatty acids that the product contains. Total fat content is a part of nutrition information mandated by section 403(q)(1)(D) of the act. Thus, any claim (i.e., a health claim or nutrient content claim) based on fat content must be based on the amount of fat declared in the nutrition label. How total fat content is determined is addressed in the regulation on mandatory nutrition labeling, new § 101.9, published elsewhere in this issue of the **Federal Register**. Thus, the agency sees no need to provide for a separate method in the health claims regulation for purposes of declaring whether a food contains a disqualifying, or a qualifying level of fat.

The agency advises that any proposal to modify the methods for determining the total fat and fatty acid content of a food may be submitted as a petition to amend new § 101.9. Moreover, as explained in the final rule on mandatory nutrition labeling, when seeking approval from the agency for use of a fat replacer or novel fat in food, the petitioner should include information on the caloric value and macronutrient content of the ingredient. Nutrient content requirements for health claims will be subject to the appropriate requirements for nutrition labeling and any other related regulation

ii. Cholesterol

36. Many comments expressed support for the proposed cholesterol disqualifying levels. One Federal agency objected to the proposed cholesterol disqualifying level which, it contended, appears to be based on behavioral assumptions about consumption patterns that are not borne out by USDA data. Another comment, urged that FDA raise the disqualifying level fur cholesterol to one-third of the DRV.

As discussed in detail above, FDA has reassessed the disqualifying levels for cholesterol, fat, saturated fat, and sodium. The agency has concluded that the levels for all 4 can be set at 20 percent of the DRV's. Accordingly, having concluded, for the reasons set out previously, that a nutrient level in excess of 20 percent of the DRV for each of the 4 disqualifying nutrients is associated with an increased risk of a diet-related disease or health-related condition, the agency rejects the recommendation that the disqualifying level for cholesterol be raised to one-third of the DRV.

iii. Sodium.

37. Some comments challenged FDA's decision to set a disqualifying level for sodium. One of these comments noted that it was FDA and not Congress that identified sodium as a nutrient of concern because sodium, like fat, saturated fat, and cholesterol, has been "associated with increased risk of disease." Several comments asserted that there is a lack of significant scientific agreement on a link between dietary sodium and hypertension.

One comment cited reports by the Surgeon General and others as proof of the divided and inconclusive opinions of experts in the field. Furthermore, the comment charged that FDA had failed to independently analyze the results of the INTERSALT study, which, the comment alleged, refutes the traditional sodium-hypertension hypothesis.

Another comment submitted published studies that it claimed supported the comments position that there is no rational basis for concluding that any single food contains sodium "in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related," and that "FDA has absolutely no statutory or scientific basis by which to establish any disqualifying level for sodium." One comment warned that a final decision by FDA to set such a level without proper regard to conflicting scientific data would not meet the statutory requirements of sections 403(r)(3)(A)(ii) or 403(r)(2)(B)(ii) of the act governing the establishment of disqualifying and disclosure nutrient levels and would clearly constitute arbitrary and capricious rulemaking.

The agency disagrees with the contention that sodium has not been associated with increased risk of disease. As explained in detail in the specific health claim document on the subject that is published elsewhere in this issue of the **Federal Register**, the available data, including the INTERSALT study, establish that dietary sodium intake is associated with hypertension. This discussion is referenced. For example, "Dietary Guidelines for Americans" (Ref. 7) states:

> Many American diets hove too many calories and too much fat (especially saturated fat), cholesterol, and sodium. * * * Such diets are one cause of America's high rates of obesity and certain diseases—heart disease, high blood pressure, stroke, diabetes, and some forms of cancer.

FDA is convinced not only of the scientific soundness of the sodium/hypertension health claim but also of the appropriateness of a disqualifying level for sodium.

38. One comment suggested that it would be appropriate to include on the label of a food, in immediate proximity to any health claim, information on the sodium content (such as that required by new § 101.13(h) published elsewhere in this issue of the **Federal Register**), thus benefitting the small segment of the population for which sodium may be of concern, while providing a health message that could potentially benefit a much larger population.

FDA recognizes that there may be a number of different ways to display selected information, like sodium content, to meet various consumer needs or preferences, Although a display of sodium content information like that recommended by the comment may benefit a certain segment of the population, the 1990 amendments do not provide the agency with authority to require for health claims the type of nutrient disclosure required for nutrient content claims by new § 101.13(h). That regulation derives from section 403(r)(2}(B)(ii) of the act which states that if a food that bears a nutrient content claim that increases to persons in the general population the risk of a disease or health-related condition, the claim shall also identify such nutrient. Under those same circumstances,

however, the 1990 amendments do not permit a health claim to be made. The regime by which nutrient content claims are made is different than that for health claims.

The agency points out, nevertheless, that any food with a health claim will also bear nutrition information listing sodium and other nutrient content. Although the information on sodium content may not be displayed as conveniently or prominently as that recommended by the comment, it will, nevertheless, be readily accessible on a product's label.

39. Other comments called for a higher disqualifying level for sodium. One comment argued that the decision to set the sodium disqualifying level at 15 percent of the DRV is not as solidly based as the disqualifying levels for fat, saturated fat, and cholesterol. The comment further concluded that because much of the sodium in the American diet is concentrated in a few products, a product containing 20 percent of the DRV for sodium (480 mg) could easily be incorporated into a diet without increasing the risk of hypertension. Another comment agreed that the proposed sodium disqualification levels are too strict and noted that many breads would be restricted from making any health claims, if the proposed level is adopted.

Another comment urged that FDA raise the disqualifying level for sodium to one-third of the DRV. The comment warned that setting such a low disqualifying level as 15 percent of the DRV for sodium would discourage manufacturers from producing lowfat products, because salt is required to improve the taste, and thus the marketability, of many such lowfat products.

As discussed previously in this section, FDA has reassessed its analysis for defining disqualifying levels and determined that the levels can be set for sodium and the 3 dietary lipids at 20 percent of the DRV's. Having concluded that nutrient levels greater than 20 percent of the DRV's, including that for sodium, increase the risk of diseases of health-related conditions that are diet related, FDA rejects the recommendation that the disqualifying level for sodium be set at one-third of that nutrient's DRV.

f. Exception from disqualification.

40. Some comments stated that exceptions to the disqualifying levels should not be granted. Other comments urged FDA to consider requests for exemptions from the disqualifying levels only on a case-by-case basis, and only when virtually all foods containing significant levels of the nutrient would otherwise be disqualified. One of these comments asserted that none of the currently proposed health claims would warrant an exception. Furthermore, many of the comments suggested that if FDA did grant an exception, a statement disclosing the level of the disqualifying nutrient should appear prominently next to the health claim.

The agency disagrees with those comments recommending that exceptions to the disqualifying levels should not be granted. Similarly, it is not convinced that the only basis to permit exceptions is when virtually all foods containing significant levels of the health claim nutrient would be disqualified. Section 403(r)(3)(A)(ii) of the act provides the Secretary (and FDA, by delegation) discretionary authority to permit a claim for a food that would otherwise be disqualified if the Secretary determines that the claim would assist consumers in maintaining healthy dietary practices. The agency is prepared to consider whatever arguments may be brought to bear with respect to a particular claim or with respect to a particular nutrient as to why an exception to a disqualifying level should be granted. Thus, the agency is not prepared to limit its discretion in the manner suggested by several of the comments.

If an exception to the disqualifying levels is authorized, section 403(r)(3)(A)(ii) of the act specifies that the label of the product contain a disclosure of the type required by section 403(r)(2)(B)(ii) of the act. Thus, the disclosure will have to be made prominently and in immediate proximity to the claim. It will have to identify the nutrient, and it will have to refer the consumer to the labeling panel where nutrition information may be found.

41. Other comments urged the use of discretion in permitting health claims for foods in cases where such claims would assist consumers in maintaining healthy dietary practices. Oils and margarine were cited as examples of foods for which exceptions should be made, to provide consumers with in formation on the health, reasons for choosing oils that are lower in saturated fat, because all oils exceed the disqualifying level of 11.5 g of fat. One comment emphasized the importance of focusing on the type of fat in the fats that are consumed, and concluded its comment by suggesting that FDA could address its concern about total fat by requiring a clear message on such products that consumers should consume less fat.

The agency intends to use discretion in permitting health claims that encourage certain dietary practices generally recognized by the public health community as being consistent with guidelines for maintaining and promoting good health. FDA acknowledges that "Dietary Guidelines for Americans" (Ref. 7), while recommending that diets low in fat be chosen, also provides advice on how certain fats and oils used sparingly can assist the consumer in maintaining a relatively low saturated fat intake. Although fats and oils obviously exceed the disqualifying level for fat, section 403(r)(3)(A)(ii) of the act does permit exceptions, as discussed previously. Accordingly, FDA is willing to consider a petition that provides a basis for excepting certain fats and oils based on compositional or other characteristics from being disqualified from bearing a particular health, claim.

42. A number of comments asked that FDA exempt milk and other dairy products from the disqualifying levels for fat and saturated fat. One comment noted that dairy products contribute 76. 8 percent of the dietary calcium in the food supply, yet contribute only 20 percent of the saturated fats and 12 percent of the total fat. The comment contended that allowing only fat-reduced dairy products to make a calcium/osteoporosis claim would be misleading to those individuals who prefer whole milk to reduced-fat milk.

While milk and other dairy products do in fact contribute a large percentage of the daily supply of calcium, the agency noted in the preamble to the proposed regulations that lowfat and skim milk will be able to bear a health claim under proposed § 101.14(a)(5), as will many products made from these reduced-fat milks. FDA, therefore, cannot conclude that an exception for whole milk and other dairy products that. exceed the fat disqualifying level would assist consumers in maintaining healthy dietary practices.

III. Preliminary Requirements for a Claim

FDA proposed several criteria in proposed § 101.14(b) that would have to be met before e substance would qualify to be the subject of a health claim. These criteria reflect not only the requirements of section 403(r) of the act but also the fact that FDA is charged with ensuring that the food supply is safe, and that the food label is not misleading. Given that agency evaluations of the validity of a health claim will be resource intensive, FDA proposed not to make such an evaluation unless a petition for a health claim demonstrates that the preliminary requirements are met.

A. Effect on General Population

As proposed. § 101.14(b)(1) stated:

> The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains, the prevalence of the disease or health related-condition in the U.S. population and the relevance of the claim in the context of the total dally diet and satisfies the other requirements of this section.

43. Several comments endorsed, or advised that there was no objection to, the agency's preliminary requirement in proposed § 101.14(b)(1), Some of these comments stressed that the agency should always interpret this provision with flexibility. One comment asked for clarification as to whether a proven substance-disease claim would be allowed if the effected population was few in number or not readily identifiable as a subpopulation e.g., vitamin D insufficiency in an undefined population group).

FDA intends to apply a flexible approach in interpreting this provision. The proposed alternative aspect of the provision, which would permit petitioners to explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet, evidences a determination by FDA to disqualify as few proposed claims as possible under this provision. However, if a proposed claim is ultimately authorized by FDA that involves an affected population that is few in number, that fact will have to be declared in the labeling in conjunction with the claim. Where the affected population is not readily identifiable, information about the prevalence of the disease or health-related condition in the U.S. population will be a material fact and thus will have to be provided in conjunction with the claim if the claim is not to misbrand the product.

As explained previously in this preamble (see comment 2 of this document), FDA does not believe that the 1990 amendments pertain to claims classical deficiencies of vitamins and essential minerals. Thus, for example, a claim about the benefits of vitamin D in representing the product as a drug, needs no preclearance under the provisions of new § 101.14. However, such claims must be truthful and not misleading. In view of the fact that very few people are at risk of vitamin D deficiency disorders, a claim about the benefits of vitamin D in preventing vitamin D insufficiency would be misleading where the claim does not explain that few individuals in the United States are at risk of such insufficiency. Further, the claim would need to be more specific about the affected population be adequately informative. For example, the claim might advise that although the vast majority of the U.S. population is not at risk for vitamin D deficiency disorders, the vitamin may be effective in reducing the risk of vitamin D deficiency problems in some segments of the elderly who are house-bound for prolonged periods and are not exposed to sunlight.

B. Components of Food within the Context of a Daily Diet

New § 101.14(b)(2) and (b)(3)(i) contain provisions requiring that the substance be a component of food. If the substance is present at decreased dietary levels, under new § 101.14(b)(2), it must be a nutrient that is required to be included in nutrition labeling (e.g., cholesterol, total fat). If the substance is present at other than decreased dietary levels, under new § 101.14(b)(3)(i), it must contribute taste, aroma, or nutritive value, or any technical effect listed in § 170.3(o) to the food, and must retain that attribute when consumed at levels that are necessary to justify a claim.

1. General.

44. One comment suggested that FDA predetermine for each nutrient appearing in an approved health claim a level below which the nutrient is considered to be present in the context of the total daily diet and above which the nutrient is considered to be present at therapeutic levels.

FDA does not believe that it is practicable or appropriate for the agency to attempt to ideality any single nutrient level as a boundary between those levels that are within the context of the daily diet and those which are therapeutic. The agency simply does not have sufficient resources to devote to the suggested determinations without unduely sacrificing resources from other high priority regulatory matters. Instead, FDA believes that it is more appropriate that the burden be upon the petitioner to demonstrate that the claimed effect actually can be achieved through consumption of dietary levels of the substance. At such levels, the presence of therapeutic effects should not be at issue.

2. Section 101.14(b)(3)(i)

45. Some comments stated that the eligibility restrictions on the term "substance "in proposed § 101.14(b)(3)(i) are too restrictive and asked that they be removed. One comment asserted that the agency is creating needless procedural confusion by having a broad definition of the term "substance" in proposed § 101.14(a)(2), which it then immediately narrows in proposed § 101.14(b)(3)(i). A few comments contended that, if FDA retains the food eligibility restrictions in the final rule, the agency should permit a broader interpretation of what constitutes food. Another comment stated that although the phrase "taste, aroma, or nutritive value" is borrowed from the Seventh Circuit's opinion in *Nutrilab Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983), the court noted in that decision that these food characteristics were only the primary reasons why people consume food. The court, according to the comment, did not intend to give an all-inclusive list. One comment stated that not all of the other possible food characteristics are encompassed in the listing provided in § 170.3(o). Some comments asserted that food should include everything that can be consumed.

FDA does not believe that it is overly restrictive to require, as it does in proposed § 101.14(b)(3)(i), that a substance be a food or a component of food for it to be the subject of a health claim. Section 403(r) of the act describes the circumstances in which a food will, and will not be, misbranded if it bears a health claim. Thus, it is appropriate for the agency to make it incumbent upon the proponent of a health claim to demonstrate that the substance that is the subject of the claim is a food or component of food.

FDA believes that the framework that it has created in its regulations is appropriate and fully consistent with the act. Under it, manufacturers will be able to make claims that characterize the relationship between any substance and a disease or health-related condition so long as the substance achieves its effect through its use as a food, that is, through its nutritional value.

FDA disagrees with the comments' interpretation of the *Nutrilab* decision and believes that the agency's reliance on the case is justified. The *Nutrilab* court adopted a "common sense" definition under section 201(f)(1) of the act: "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." *Nutrilab*, 713 F.2d at 338. Other courts have followed suit. (See *United States vs. Undetermined Quantities of Cal-Ban*

3000, 776 F. Supp. 249, 254-55 (E.D.N.C. 1991); *American Health Products Co. v. Hayes*, 574 F. Supp. 1498, 1508-09 (S.D.N.Y. 1983), aff'd, 744 F.2d 912 (2d Cir. 1984).) By describing taste, aroma, and nutritive value as the "primary" reasons for consuming food, the *Nutrilab* court acknowledged that a food consumed for one of these reasons might sometimes also be consumed for an additional purpose. 713 F.2d at 338 (giving prune juice and coffee as examples/of foods that "may be consumed on occasion for reasons other than taste, aroma, or nutritive value"). Under *Nutrilab*, a substance whose uses do not include taste, aroma, or nutritive value is not a food.

FDA does not believe that the word "food" should be defined any more broadly than it is in the proposed regulation, and the agency specifically rejects the proposal to define "food" as "any substance that is consumed by people for any purpose other than the treatment of disease." Under such an expanded definition, the parenthetical exception for food to the definition of drug in section 201(g)(1)(C) of the act would swallow the rule. Section 201(g)(1)(C) of the act states that "articles (other than food) intended to affect the structure or any function of the body of man or other animals" are drugs. Under the definition of food suggested in the comment, the only products consumed by people that would be considered drugs under section 201(g)(1)(C) of the act would be those intended both to affect the structure or function of the body and to treat a disease. Substances taken to treat a disease are already drugs under section 201(g)(1)(B) of the act, regardless of whether they are foods. The suggested definition of "food" would thus render section 201(g)(1)(C) of the act meaningless. It is a basic principle of statutory construction that a statute should not be construed in such a way as to render certain provisions superfluous or insignificant. *United States v. Leonard*, 868 F.2d 1393, 1395-96 (5th Cir, 1989), cert. denied, 496 U.S. 904 (1990).

46. Numerous comments from producers and consumers of dietary supplements expressed concern that the proposed provision represents an attack by the agency against dietary supplements. Some comments maintained that FDA lacks the legal authority to restrict approved health claims on nutritional supplements that are beyond daily diet limits. Other comments asserted that FDA intends to use regulations based on the proposal to ban health claims on dietary supplements wherever the supplements contain a substance above the context of an ordinary daily diet. Other comments stated that the agency would ban the supplements themselves by making them available only by prescription or by limiting the potency of the supplements. A few comments believed that FDA would also ban supplements where they lack a therapeutic effect at levels within the context of an ordinary daily diet. While most of the comments did not specify any particular proposed provisions that could lead to these actions, they strongly protested that any restriction on dietary supplements would infringe on consumers' freedom of choice and would be in conflict with the Proxmire Amendment (21 U.S.C 350) and the 1990 amendments.

As stated above, the DS Act imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Thus, nothing in these final rules will affect dietary supplements in any way. However, FDA disagrees with the comments' characterization of its proposal and disagrees with the statement that the proposed regulations were in conflict with section 411 of the act (21 U.S.C. 350) (the Proxmire Amendment). Nothing in the proposed regulations would have affected the availability of dietary supplements. Rather, these regulations were intended to regulate claims that may be made for all foods, including dietary supplements.

Nothing in the regulations would necessarily prevent a supplement from bearing a health claim when that supplement contains a level of a substance that exceeds the level achievable in the context of the daily diet. To the contrary, the final rule concerning calcium (where health benefits are provided within the context of the daily diet), for example, which is published elsewhere in this issue of the **Federal Register,** permits a calcium health claim for dietary supplements and requires only that the supplement labeling advise consumers that there is no known benefit from consuming more than 200 percent of the U.S. Recommended Dietary Allowance (U.S. RDA) for calcium.

Section 411 of the act does not authorize health claims for dietary supplements or in any way affect FDA's authority under section 403(r)(5)(D) of the act to regulate such claims. Under section 411(a)(1)(B) of the act, FDA may not classify a dietary supplement's a drug solely because it contains vitamins or minerals exceeding the level of potency that the agency determines is nutritionally rational or useful. Nothing in the proposed regulations would have done so. Absent a claim, FDA will not consider a dietary supplement to be a drug simply because it contains vitamins or minerals at levels above those normally found in food. However, a claim on a product may indicate the product's intended use. If a claim reveals that the product is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body (other than food), the product is a drug. (See 21 U.S.C. 321(g)(1)(B) and (g)(1)(C)).

47. Another comment asked for assurance that approved health claims appearing on dietary supplements will not automatically be considered drug claims. The comment noted that section 201(g)(1)(B) of the act exempts approved health claims on foods from consideration as drug claims and stated that dietary supplements should be afforded the same exemption under FDA regulations.

Section 202(b) of the DS Act does permit FDA to approve health claims with respect to dietary supplements. FDA advises that, as provided in section 201(g)(1)(B) of the act, any food, including dietary supplements, for which an authorized health claim is made in accordance with the requirements of section 403(r) of the act, and of the regulations that FDA has adopted to implement that section of the act, is not a drug under section 201(g)(1)(B) solely because its label or labeling contains such a claim. FDA considers this provision to provide the same type of assurance as that in sections 406, 408, and 409 of the act that foods containing substances used in accordance with regulations issued under those sections of the act are not subject to regulatory action under section 402(a)(1) of the act. This provision does not create an exception to the "drug" definition. Thus, a product whose intended use is as a drug will continue to be regulated as a drug.

3. Drugs

48. One comment contended that FDA should permit the use of health claims on over-the-counter (OTC) antacid products containing only calcium carbonate. The comment noted that the preamble to the proposed regulations cited the potential for confusion if health claims were allowed for bulk-fiber laxatives that have not been shown to be useful in lowering cholesterol and for which appropriate labeling for that claim does not exist. The comment asserted that while health claims may be inappropriate for laxatives, such claims would be appropriate for antacids. The comment stated that calcium has been

identified as an essential nutrient which, unlike psyllium, has a defined intake requirement as well as a claim that FDA has proposed to authorize relating to the role of calcium in helping to reduce the risk of developing osteoporosis. The comment asserted that FDA's objection to OTC drugs bearing health claims is not appropriate in the case of calcium-based antacids because antacids have been labeled for years with both food and drug labeling. The comment explained that many antacids bear calcium nutrient content claims with directions for using the products as calcium dietary supplements as well as antacids.

Further, the comment pointed out that, in addition to calcium carbonate, there are several multiple use products currently in the marketplace (e.g., sodium bicarbonate). The comment stated that sodium bicarbonate, marketed under the name "baking soda," is labeled as a baking ingredient, a deodorizer, and an antacid. The comment suggested that FDA approve health claims on drugs under the following conditions: (1) The drug is properly labeled; (2) a health claim has been approved by FDA for an ingredient in the drug; (3) the OTC product meets or exceeds the requirement for a minimum recommended intake of "the natural supplement" as established by regulation; and (4) all labeling is in compliance with the authorizing regulation.

Multiple use products that are both foods and drugs present a difficult set of competing concerns for the agency. Such products are likely to be, like the product that is the subject of the comment, both an OTC drug and a dietary supplement.

Most OTC drug products are developed to address some type of acute physical problem that is expected to be of short duration. If the problem persists, it is important that the person with the problem know that it may be more severe than he or she otherwise thought, and that he or she seek medical attention. Labeling on such products, therefore, includes instructions to use the product for a limited period of time and, if the problem persists, to seek medical intervention. Thus, the time limits on use of the product are important to the health of the users.

Dietary supplements, on the other hand, are developed for inclusion in a daily diet at levels that are consistent with dietary use and may often be consumed throughout most of a person's lifetime. Labeling on dietary supplements contains no instructions for seeking medical intervention or for limiting the duration of consumption of the supplement. Rather, under the 1990 amendments (subject to the DS Act), they will be able to bear nutrient content and health claims, which focus the consumer's attention on the advantages that consuming the product will have in helping the consumer to maintain a healthy diet. Moreover, where the supplement bears a health claim, the claim will contain information about how long-term ingestion of the supplement may promote health.

The comment's reference to baking soda (sodium bicarbonate) as an example of a dual labeled drug/food is not apposite. As a food, baking soda is consumed only as an ingredient in other foods, and it is unlikely that labeling would result in increased consumption of this product. Baking soda is not labeled with either a nutrient content claim or a health claim. Thus, there is little opportunity for consumer confusion presented by this product.

Where dietary levels and therapeutic levels differ (as is generally the case and is in fact the case with antacids and calcium supplements), an apparent conflict is created when both food and drug labeling appear on the same product. In the case of the drug labeling, consumers are given directions for use that involve high consumption during a limited time period. In the case of the food labeling, consumers are given directions for lower consumption with no time constraints. Even though label instructions may identify those directions for food and drug use in separate locations, FDA is concerned that consumers will incorrectly assume that the therapeutic dosage is appropriate for dietary use, and that the directions for food use will undercut the warning in the drug labeling to seek medical care if use persists. Where the labeling is not properly followed, significant adverse consequences may result.

The agency knows of no broad approach that it can use to harmonize a nutrient content claim or a health claim with drug labeling. A drug that is labeled with instructions for use that both limit and do not limit consumption would be misbranded under section 502(a) of the act (21 U.S.C. 352(a)) if it foiled to contain a material fact—-that is, how to reconcile these conflicting instructions. Therefore, FDA advises that it will tend to view dual claims as misbranding the product.

However, FDA does not believe that it would be appropriate to preclude such claims under all circumstances. Such claims may be permissible if a firm can demonstrate that dual claims can be made in a manner that will neither misbrand the product nor create a safety problem. The agency suggests that anyone desiring to make a health claim or a nutrient content claim that complies with section 403(r) of the act on a product that is both a food and a drug contact the Center for Drug Evaluation and Research, OTC Compliance Branch (HFD-312), FDA, 7500 Standish Pl., Rockville, MD 20855, to discuss whether it would be possible to put such a claim on the product and still comply with the drug provisions of the act.

49, Some comments asserted that FDA should permit the use of health claims on herbs whose only known use is for medicinal effects. A few of these comments objected that the herbs that FDA cited in the preamble of the proposal also have food uses.

As FDA explained fully in the preamble of the proposal (56 FR 60554), Congress clearly intended that the health claim provisions of the 1990 amendments apply only to foods. A product that is intended, for medicinal effects, that is, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, is a drug and not a food. Thus, there is no basis under the act for FDA to permit health claims for herbs whose only known use is for medicinal effects. Health benefits of such herbs may appear in the labeling only in accordance with the drug provisions of the act. Where herbs have a history of use both as foods and drugs, the context of all of the available information on the intended use of the product will determine whether FDA will regulate the herbs as foods, as drugs, or as both foods and drugs.

In this regard, the agency points out that the relationship of a food or a food component to a disease is quite different from that of a drug. The Surgeon General's report (Ref. 5) points out that, apart from classic disorders resulting from dietary deficiencies of essential nutrients (e.g., pellagra and niacin), it has proved difficult to demonstrate causal associations between specific dietary factors and chronic or other diseases (e.g., dietary fiber and cancer). The report states:

> Development of the major chronic disease conditions—coronary heart disease, stroke, diabetes, or-cancer—is affected by multiple genetic, environmental, and behavioral factors among which diet Is only one—albeit an important—component. These other factors interact with diet in ways that are not completely understood. In addition, foods themselves are complex; they may contain some factors that promote disease as well as others that are protective. The relationship of dietary fat intake to causation of atherosclerotic heart disease is a prominent example. An excess intake of total fat, if

characterized by high saturated fat, is associated with high blood cholesterol levels and therefore an increased risk for coronary heart disease in many populations. A higher proportion, of mono- and polyunsaturated fats in relation to saturated fats is associated with lower blood cholesterol levels and, therefore, with a reduced risk for coronary heart disease.

Because of these complexities, definitive scientific proof that specific dietary factors are responsible for specific chronic disease conditions is difficult— and may not be possible—to obtain, given available technology.

(Ref. 5). Thus a claim that a substance can be used in the prevention, diagnosis, cure, mitigation, or treatment of a disease or symptom is inappropriate on a food. (See § 101.9(k)(1).)

C. Safety

Proposed § 101.14(h)(3)(ii) would require that to justify a claim for a substance that is to be consumed at other than decreased levels, the use of the substance must be shown by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act.

The preamble of the proposed rule stated further:

* * * This showing can be based on : (1) A demonstration that the substance is generally recognized as safe (GRAS) within the meaning of 21 CFR 170.30; (2) a listing of the substance as GRAS in 21 CFR part 182 or as affirmed as GRAS in 21 CFR part 184; (3) a food additive regulation; or (4) a sanction or approval granted by FDA or the United States Department of Agriculture prior to September 6, 1958. If the safety and lawfulness of the substance is not expressly recognized in an FDA regulation, the burden will rest on the claim's proponent, as a prerequisite to FDA's evaluation of the health claim, to submit all the scientific data and other relevant information required to demonstrate safety and lawfulness in accordance with applicable petition requirements. FDA will withhold review of the health claim until it is satisfied on these points.

(56 FR 60537 at 60346 through 60547)

50. Many industry comments objected to the safety provisions as proposed. Some of these comments asserted that the 1990 amendments do not require a separate showing of safety for nutrients that are the subject of disease-related claim petitions, and that FDA should not add such a requirement to its regulation. Many comments particularly disagreed with the application of FDA's preliminary safety requirement to dietary supplements and herbs. The comments pointed out that many herbs and supplements have been used for thousands of years with no known, ill effects. Requiring further evidence of safely for these products, the comments contended, would be superfluous and expensive. However, other comments agreed with. FDA that it would be inappropriate to allow a health claim on a product that contains a substance that is not GRAS, is not the subject of a food additive regulation, or has not received a prior sanction of approval.

FDA believes that the preliminary requirement that substances must be components of food that are safe and lawful must be included in the health claims final rules. Sections of the act, enacted by the 1990 amendments cannot be implemented independently of the remaining portions of the act. The act must be considered as a whole, and FDA's responsibility for ensuring the safety of foods is explicitly provided for in other sections of the act (see sections 201(s), 402(a)(1) and (a)(2), and 409 of the act).

This fact is particularly significant because the agency will be specifically providing for the health claims that will be made. In view of this affirmative action, FDA authorization of a health claim places the agency's imprimatur on the claim. It would be a violation of the agency's responsibility under the act to authorize a health claim about a substance without being satisfied that the use of the substance is safe. Furthermore, safety considerations are also of unique importance in the case of health claims because such claims will inevitably change consumption patterns of many Americans.

Even though there is no explicit provision, in the 1990 amendments requiring a separate showing of safety, it must be kept in mind that the act " * * * is designed to ensure the safety of the food we eat * * ." Les v. Reilly —— F.2d ———— (9th Cir. 1992). This requirement is implicit in the 1990 amendments. Section 403(r)(3)(A)(ii) of the act states that a health claim may be made only for a food that does not contain any nutrient in an amount that increases the risk of a disease or health-related condition that is diet related to persons in the general population, taking into account the significance of the food in the total daily diet. FDA believes that, in addition to requiring establishment of disqualifying levels, this provision evidences a concern by Congress that a substance that is the subject of a health claim be used in a manner that is safe. This concern was reflected in the statements of the sponsors in both the House and the Senate (Refs. 2 and 3).

Further, section 9 of the 1990 amendments states that the amendments "shall not be construed to alter the authority of the Secretary of Health, and Human Services * * * under the Federal Food, Drug, and Cosmetic Act * * *." Thus, FDA's responsibility for ensuring the safety of foods has in no way been diminished by the passage of the 1990 amendments.

As a result of the DS Act, herbs and other substances in dietary supplements are generally not subject to the provisions of this final rule. However, to the extent that these substances bear an approved health claim under section 202(b) of the DS Act, they will also bear the agency's imprimatur. To that extent, they will be treated in the same manner as other substances that bear such claims. Other issues with respect to the safety of substances in dietary supplements will be addressed in the rulemaking provided for in the DS Act.

51. Some comments argued that the agency should give full weight to manufacturers' private GRAS determinations in instances where food manufacturers seek to use substances that are not listed by FDA as safe. Some of these comments asserted that if FDA does not recognize private GRAS determinations for fulfilling the preliminary safety requirement, the agency will frustrate Congress' intent to permit health claims, because the GRAS petition procedure is usually quite lengthy, and many GRAS affirmation petitions ere pending that are more than 10 years old. Some of the comments requested that if the agency does not recognize private GRAS determinations, FDA should shorten the timeframe for making its GRAS determination or establish an alternate procedure. One suggested that FDA relinquish responsibility for making GRAS determinations to USDA.. Another comment suggested that FDA recognize the findings of an independent panel of experts, pending the results of the formal review process.

FDA acknowledges that the GRAS affirmation and food additive listing process can be lengthy. Thus, FDA designed new § 101.14(b)(3)(ii) to provide flexibility with respect to the type of showing of safety that is necessary to make a substance eligible to be the subject of a health claim. GRAS affirmation and food additive listing are but two of the procedures by which a substance may meet this preliminary requirement.

FDA intends to consider the basis of .manufacturers' independent GRAS determinations where such determinations are submitted with petitions for health claims and may use its discretion to accept, without formal affirmation, the independent determination of GRAS where FDA believes that such action would be

appropriate. As FDA pointed out in the previous comment, however, the agency would not be fulfilling its responsibilities under the act if it were to permit a substance to be the subject of a health claim without satisfying itself that the use of that substance is safe.

Although FDA will consider all Manufacturers' independent GRAS determinations where the bases for such determinations are submitted with petitions for health claims, the agency advises that it will generally not be possible for FDA to judge whether GRAS determinations based on complex scientific evidence are valid within the short timeframes mandated under the 1990 amendments for health claims petitions. Instead, agency agreement with an independent determination that a substance is GRAS will be most likely where the substance is an ingredient, or a component of a food ingredient, that was in common use in food prior to January 1,1958, in a similar context. However, where such agreement occurs, the agreement does not constitute GRAS affirmation. Instead, the history of common use in food, coupled with the fact that FDA knows of no reason to question the safety of the food ingredient, means that the substance will be treated as if it is an unlisted GRAS substance (as provided for in §§ 170.30(d) and 182.1(a) (21 CFR 170.30(d) and 182.1(a))) in the manner provided for in the food ingredient list in21 CFR part 182.

In response to comments requesting that FDA relinquish responsibility for making GRAS determinations to USDA, or that FDA recognize the findings of an independent panel of experts pending the results of the formal review process, the agency advises that neither course of action would be appropriate. FDA is charged under the act with the responsibility of protecting interstate commerce from adulterated foods. There is no basis under the act for delegation of this responsibility to other Federal agencies or to individuals outside of FDA.

IV.Validity Requirements for a Claim

A. The Scientific Standard

As proposed, the scientific standard in § 101.14(c) stated:

> * * * FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there Is significant agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.
>
> (1) It must be supported by the totality of publicly available scientific evidence (including evidence from welldesigned studies conducted in a manner which is consistent with generally recognized scientific procedures and principles); and
>
> (2) There must be significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims-that this support exists.

(56 FR 60537 at 60563)

In the preamble of the proposal (56 FR 60547), FDA advised that this standard embodies the language in the statutory requirements for conventional food in section 403(r)(3)(B)(i) of the act that there be significant scientific agreement about the support for the claim and the mandate provided in the legislative history of the 1990 amendments that FDA have "a high level of comfort that the claim is valid" (Ref. 1). Thus, the agency will authorize a claim when the evidentiary and review components of the scientific standard are met. However, FDA also stated in the proposal:

> It has been suggested that FDA should allow claims that reflect more preliminary * * * scientific findings so long as such claims are qualified in a way that appropriately reflects the state of the scientific evidence. For example, under this suggestion, FDA would allow a claim such as "Preliminary data show that diets rich in fiber reduce the risk of heart disease," so long as there is significant scientific agreement that this is in fact what the evidence shows, FDA has significant reservations about these types of claims, however, because of their potential to be misunderstood by consumers and therefore to be misleading. The agency is also concerned that such claims will undercut the credibility of the food label. This concern exists despite the fact that because such claims arguably do not assert a [causal] relation between diet and diseases they can never by disproved. FDA requests comments on whether it should authorize these types of claims in Implementing the health claim provisions of the act.

(56 FR 60537 at 60552)

52. A number of comments objected that the wording of proposed § 101.14(c)(1) and (c)(2) changes the meaning of the scientific standard presented in section 403(r)(3)(B)(i) of the act. One comment asserted that the proposed provisions treat the totality of publicly available scientific evidence as a separate evidentiary element in showing that the claim is sound, thus distorting Congress' clearly-expressed intent. Similarly, the comment asserted that the language "supported by" in proposed § 101.14(c)(1) "eviscerates" the provisions of the statute because the level of support called for by this requirement is not consistent with the "significant scientific agreement" that the act prescribes. Some comments appeared to interpret the basis of the standard proposed in section 403(r)(3)(B)(i) of the act as being primarily or exclusively the review component, which incorporates the criterion of "significant scientific agreement."

FDA did not intend to change the meaning of the scientific standard presented in section 403(r)(3)(B)(i) of the act through the inclusion of paragraphs (c)(1) and (c)(2) in proposed § 101.14 (c). The agency merely intended to clarify that, in accordance with the language of the 1990 amendments, the scientific standard does, in fact, include both a body of evidence component and a review component. However, the agency now recognizes that this attempt to provide greater clarity within the regulatory language itself was unnecessary and, to the extent that it has been interpreted as an attempt to change the meaning of the scientific standard, undesirable. The agency is therefore deleting proposed § 101.14(c)(1) and (c)(2). Without these paragraphs, the wording in new § 101.14(c) is virtually identical to that in section 403(r)(3)(B)(i) of the act.

The wording in section 403(r)(3)(B)(i) of the act and in new § 101.14(c), as amended, clearly establishes two components within the scientific standard. The evidentiary component arises from the inclusion of the phrase "evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles" in the statutory qualification of "the totality of publicly available scientific evidence." This aspect of the standard clearly mandates that the claim be based on a body of sound scientific evidence. The requirement that there be "significant agreement among experts qualified by scientific training and experience to evaluate such evidence * * * that the claim is supported by such evidence" constitutes the separate and distinct review component of the standard.

53. Some comments objected to the standard and suggested modifications. Several comments stated that Congress intended the scientific standard to be one of substantial evidence (i.e., "more than a scintilla and less than a preponderance"). The comments asserted that the 1990 amendments require that FDA adopt such a standard. The comments contended that a standard of substantial scientific evidence, even in the absence of significant scientific agreement, would be in accordance with sound scientific

principles and prevention of consumer fraud. They argued that such a standard would better serve public health through the prompt communication of the health and disease information. Further other comments objected that the requirement of significant scientific agreement in the proposed standard expands FDA authority beyond legislative intent.

A number of comments maintained that, instead of "significant scientific agreement," FDA should use a scientific standard encompassing different degrees of certainty for different types of health claims. Most industry comments urged FDA to allow health claims based on preliminary evidence if the preliminary status of the claim is truthfully disclosed on the label (e.g., "preliminary data suggest"). Many of these comments contended that such claims would not be misleading and asserted that there was no evidence that the public might misunderstand such claims. Some of the comments asserted that such claims would be consistent with the statutory scientific standard because that standard requires only that there be agreement that the claim is supported by some of the available scientific evidence. Other comments argued that any preliminary study that is sufficiently well-designed and well-conducted should be sufficient to engender "significant scientific agreement" that it supports the health claim being made. Another comment stated that there was no evidence to warrant FDA concern that the public might misunderstand such claims, and that past regulatory policies and court cases involving both FDA and FTC clearly allowed such claims.

Some comments maintained that preliminary claims should be permitted because the benefit to a consumer if a preliminary claim is later proven to be true is significantly greater than the loss if it proves to be false. The comments cited various cases in which preliminary evidence has proven to be correct only after a period of several years. For example, one comment asserted that many lives would have been saved had FDA allowed preliminary health claims regarding cholesterol and heart disease. Other comments expressed concern that one effect of limiting health claims on food labels will be that manufacturers, not being able to assert the dietary characteristics of new foods which fail to meet the new standards, will lose a significant incentive to conduct nutrition research of new food formulations.

A few comments maintained that FDA should permit all preliminary claims, including claims about those nutrient-disease relationships that the agency proposed not to authorize, because those claims that FDA proposed to permit are actually preliminary claims. The comments explained that the claims that FDA proposed use qualifying words such, as "may," as in the phrase "may help to reduce disease risk," rather than absolute claims.

However, other comments, primarily from the health care and regulatory sectors, favored the scientific standard as proposed and strongly opposed permitting preliminary health claims, stating that preliminary evidence does not meet the scientific standard of the 1990 amendments. The comments pointed out that one of the main purposes of this new standard is to prevent the type of questionable health claims that have grown all too common in recent years. They noted that if a health claim is still the subject of conflicting reports, it is entirely inappropriate for the food label. Many comments suggested that, even with a disclosure statement as to the preliminary nature of the claim, many consumers would be misled, as the word "preliminary" does little to lessen the impact of a claim, and many consumers would not understand that the findings could be disproved later. Other comments stated that allowing preliminary claims could open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of the valid health claims on food labels.

FDA does not have authority to modify the scientific standard for health claims. Section 403(r)(3)(B)(i) of the act directs FDA to promulgate regulations authorizing health claims only if it determines:

> * * * based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

FDA has incorporated this standard into its regulations. Thus, the requirement objected to by several of the comments, that there be significant scientific agreement that the claim is supported by the publicly available evidence, derives directly from the act.

FDA does not agree that a "substantial evidence" standard, as described by one comment, was intended by Congress, or that the agency is under any obligation to adopt such a standard. Congress adopted the scientific standard for health claims in section 403(r)(3)(B)(i) of the act from FDA's February 13, 1990, reproposal (55 FR 5176). Congress had the opportunity to adopt a different standard, to modify FDA's proposed standard, or to equate the standard with the substantial evidence standard, but it did not. The standard adopted permits FDA to make case-by-case determinations on the scientific validity of a claim, giving greater weight to studies that it finds more persuasive (Ref. 1). Congress intended the scientific standard to be "strong" and for the agency to have a high level of confidence that a claim is valid. Id. Of course, in applying this standard, FDA will act in a manner that is fair and neither arbitrary nor capricious.

In determining whether preliminary evidence would provide the basis for a health claim under this standard, FDA looked carefully at the language of the act and its legislative history. The legislative history establishes that Congress' intent was to ensure the scientific validity of authorized health claims. (See statement of Rep. Waxman; Ref. 4. H5844: "What we have sought to do is to permit health claims but only health claims based on *scientifically* valid information * * *" (emphasis added).) If Congress' aim had been solely to prohibit false or misleading claims, it could have left FDA with its authority under sections 403(a) and 201 (n) of the act. Instead it added section 403 (r) of the act to ensure not only that claims are not false or misleading, but also that they ere scientifically valid.

The fact that Congress adopted in section 403(r)(3)(B)(i) of the act the standard that FDA set out in its reproposed rule on health messages is significant in other respects. In the reproposal, the agency slated that it would not accept preliminary support for a label statement (55 FR at 5180). FDA proposed to permit only claims "supported by a sound body of scientific evidence" (55 FR at 5180). Congress adopted FDA's proposed standard without staling that it was expanding the standard to include preliminary claims; instead it stated that it was adopting the same standard (Ref. 1).

Allowing claims based only on preliminary data would thus not be consistent with the terms of the statute and indeed wound undercut the statutory scheme. The standard for permitting a health claim requires that the claim be supported by the totality of publicly available scientific evidence and that there be significant scientific agreement among qualified experts that this support exists. A claim based on

preliminary data would not reach the threshold of scientific validity required by this standard. It is not sufficient that there simply be agreement among scientists that a statement accurately characterizes the preliminary nature of the data, or that preliminary data could be interpreted in the way stated. Authorizing a claim in such circumstances would produce claims that are little more than hypotheses. While such claims might not be false or misleading, they would not be scientifically valid. Under the statutory scheme, a health claim is to describe the scientifically established relationship between a nutrient and a disease or health-related condition, not the state of the evidence that might support such a claim. FDA is to focus on the state of the evidence in determining whether the claim is valid. Thus, preliminary claims are not permissible under the act.

FDA does not agree that its past regulatory practices dictate that it permit preliminary or controversial health claims. The 41 year-old consent decree in *United States v. Mytinger & Casselberry*, referenced by one comment, is not relevant to the current situation and has been superseded by subsequent developments. With the 1990 amendments, Congress added the specific requirement to the act that any health claim on a food must not only not be misleading but also must be scientifically valid. The agency does not have the authority to permit preliminary or controversial health claims that are qualified by an explanation that a difference of scientific opinion exists. Moreover, the agency does not consider itself in any way obligated to follow the FTC consent decree referenced by a comment.

While FDA concludes that preliminary claims are not consistent with the act, that does not mean that the agency concludes that any qualification in a health claim would bar its use. Elsewhere in this issue of the **Federal Register**, FDA is authorizing health claims on food labels that are qualified claims. FDA is authorizing these claims because it. finds that they meet the standard of scientific validity. For each of the claims that FDA is authorizing, there is significant scientific agreement that there is a high probability that a reduction in risk of disease will occur.

Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term "may" with respect to the potential to reduce the risk of disease. However, use of this term would not be appropriate for health claims on food labeling where significant scientific agreement does not exist that there is a high probability that a reduction in disease risk will occur.

Furthermore, Congress clearly concluded that there is a great deal of consumer confusion over health claims on food labeling (Ref. 1). FDA believes that much of the confusion results from claims based on preliminary data, and the agency believes that comments opposed to permitting preliminary claims are correct in their assessment that many consumers do not understand that preliminary claims are based on science considerably weaker than claims based on science about which there is a significant amount of scientific agreement. Also, FDA agrees with those comments maintaining that allowing preliminary claims would open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of valid health claims on food labels and of the food label itself. FDA believes that health claims must be credible if they are to be useful to consumers.

If FDA were to focus only on the impact of a single preliminary claim, arguments that benefits to consumers from permitting that claim where it might be true would outweigh losses where the claim later proved to be false might have merit. However, FDA must focus on the ultimate impact that permitting a multitude of preliminary claims would have on public health and on public confidence in the food label. That ultimate impact could easily involve a perception among many consumers that health claims and food labels are not reliable. To the extent that consumers do not change their dietary patterns to reduce their risk of disease, they will be less healthy, and there will be needless deaths from disease as well as costs to the national economy. Thus, FDA disagrees with comments asserting that preliminary claims would be in the best interests of consumers.

Further, FDA doubts the accuracy of comments asserting that manufacturers will lose significant incentive to conduct research on new food formulations. The agency believes that the high credibility of FDA sanctioned claims and their impact on consumer purchasing decisions will prove to be sufficient incentive to continue such research. Further, if the agency were to permit almost all health claims of a preliminary nature, the value of such claims as marketing tools would surely be considerably weakened as consumers lose faith in all claims.

Of even more importance, however, is the fact that, even though FDA's approach to permitting health claims may not permit as many claims as some firms desire, FDA's approach will provide for scientifically valid health claims. Over time, FDA's approach is likely to prove to be of far greater value in promoting good public health than permitting almost all preliminary claims. Further, FDA's approach does not require absolute proof of the validity of a claim. Instead, this approach requires that there be sound science to support the claim.

54. A number of comments called for a consensus among scientists prior to the approval of a claim.

The legislative history of the 1990 amendments makes clear that Congress did not intend, in calling for significant scientific agreement about the support for a claim, to require that such agreement represent a full consensus among scientists. The House Report (Ref. 1) states: "* * * the standard does not require that there be a unanimous agreement among experts. Instead there roust be a significant agreement among experts, but it does not require that every expert in the field approve or agree with the claim."

The agency believes that a consensus, if defined as unanimous agreement among scientists about the validity of a particular claim, would be difficult to achieve, and that a standard requiring consensus would therefore prove impracticable. The agency is concerned that the stringent requirement of consensus would cause many valid health claims not to be approved and by restricting such claims, would counter Congress' intent that health claims supported by a significant scientific agreement be made available to consumers. In view of these concerns, and in conformity with the expressed intent of Congress and with the statutory language of the 1990 amendments, the agency will not require that claims be supported by a consensus among scientists.

55. Several comments objected that the scientific standard, particularly the phrase "significant scientific agreement," is vague and subjective. One comment asked for clarification as

to the degree to which this phrase is qualitative or quantitative in nature and noted that a standard of evidence must be specific and consistent. Several comments suggested that the manner in which FDA applied the scientific standard is overbroad.

The agency is sensitive to the comments' perception that the scientific standard, particularly the phrase "significant scientific agreement," is subjective. The agency believes, however, that any standard involving the evaluation of scientific evidence and the opinions derived from that evidence must be somewhat subjective. FDA, in choosing not to define "significant agreement" among experts in the November 27, 1991, proposal (56 FR 60548), noted that each situation may differ with the nature of the claimed substance/disease relationship. The agency believes that in deciding whether significant scientific agreement about the validity of a claim exists, it is necessary to consider both the extent of agreement and the nature of the disagreement on a case-by-case basis. The agency is concerned that if scientific agreement were to be assessed under any quantitative or rigidly defined criterion, the associated inflexibility of such a criterion might cause some valid claims to be disallowed where the disagreement, while present, is not persuasive.

The House Report (Ref. 1) affirms the intended flexibility of the "significant scientific agreement" standard by pointing out that, in reviewing scientific studies, FDA may give greater weight to the studies that it finds more persuasive. The House Report also clarifies that the overriding consideration in assessing whether to authorize a claim should be the Secretary's level of comfort about the validity of the claim. Id. The agency believes that this clarification provides clear guidance for the application of the standard.

56. Several comments suggested that FDA should look to the new drug provisions in section 505 of the act (21 U.S.C. 355), for direction in assessing significant agreement with the proposed validity requirement and suggested that the degree of scientific agreement needed for health claims approval should be significant but less than that necessary for approval of a new drug application.

FDA agrees that the scientific standard for health claims is less stringent than the requirements for approval of a new drug. In the case of a new drug, section 505(d)(5) of the act provides that the Secretary shall refuse to approve an application for approval of such a drug where there is a lack of substantial evidence that the drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. The term "substantial evidence" is not, in and of itself, a particularly stringent standard. Section 505 (d) of the act provides, however, that the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations (human studies conducted in a controlled clinical setting), by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. (In identifying the source of substantial evidence, the law limits the kinds of studies that can be used. Even this high standard, however, has a degree of flexibility.) Based on this statutory direction, the agency has identified a number of characteristics that are present in "adequate and well-controlled." studies in 21 CFR 314.126.

However, section 403(r) of the act does not mandate requirements as stringent as those for drugs in section 505(d)(5) of the act Section 403(r) of the act does not reference substantial evidence, adequate and well-controlled investigations, or clinical investigations. To the contrary, section 403(r) of the act contains more flexibility than the drug provisions of the act by providing FDA with authority to authorize claims based on "scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence" (section 403(r)(3)(B)(i)).

The legislative history of this section of the act evidences a concern by Congress that health claims should not necessarily be restricted to the stringent evidence necessary to support a drug claim. H. Rept. 101-538 states: "Under this standard, the Secretary must review all the scientific evidence available that is pertinent to a claim." (Ref. 1).

In debate preceding passage of the 1990 amendments, the sponsors of the bill raised concerns as to whether food claims should not be subject to a more flexible standard than drug claims. For example, in the July 30,1990, Congressional Record (H5844) (Ref. 3), Congressman Waxman stated:

> And then there is the issue of health claims. Prior to the mid-1980's, health claims were simply not permitted. A health claim on a food product turned that food product, in a legal sense, from a food to drug because if the health claim were made, then the product had to go through the approval process at FDA to show the efficacy of that claim was Valid, the same as would be required by a pharmaceutical.
>
> That was an awfully stringent requirement.

Further, on October 26,1990 (Ref. 3), Congressman Madigan, the other House sponsor of the 1990 amendments, stated:

> Neither Federal regulation nor industry efforts have kept pace with scientific knowledge about diet and nutrition. This bill is an effort to remedy this situation while allowing FDA sufficient flexibility to modify the rules when valid, new scientific information is presented. Given increased awareness and advances in our scientific knowledge on the relationship between diet and health, this legislation is very timely.

Consistent with this flexibility, FDA is not now prescribing a specific set, type, or number of studies as being necessary to support a health claim. The agency will consider all relevant data on a topic, including clinical studies, epidemiological data, and animal studies. Of course, the type, quality, and relevance of a study from which data are derived have an important bearing on how much weight is placed upon the data. For example, FDA will give the greatest weight in its evaluation to well-designed studies conducted with human subjects. Data from laboratory studies using animals, in vitro tests, and chemical analyses of the food substance may be useful, however, in providing an understanding of the nature of the relationship between the substance and the disease or health-related condition.

In the preamble to the proposal (56 FR 60537 at 60548 through 60549), FDA drew heavily on chapter two of the Diet and Health report (Ref. 6) for a discussion of how it will evaluate the studies that are submitted on the impact of intake of a substance on health. Interested persons are referred to that preamble discussion for further information about how the agency intends to apply the validity standard in new §101.14(c).

In summary, FDA sees the standard for health claims as different from the standard for establishing the effectiveness of a new drug. The agency is not now establishing any minimum data requirements under this standard, although the agency might find it appropriate to do so in the future as it

gains more experience under the health claims regime. Rather, the agency will review all available scientific evidence that is pertinent to a claim and decide whether, on the basis of that evidence, the characterization of the relationship of a substance to a disease or health-related condition that is presented in the claim is scientifically valid.

B. Assessment of Conformity to Scientific Standard

1.General

57. A few comments expressed concern about specific types of studies that FDA advised that It would consider in evaluating health claims. One comment objected that human studies in general would not be very useful. Another comment objected that human studies based on non-U.S. populations that exhibit consistent results may not be useful. Another comment noted that case-control and cohort studies based on the U.S. population are often not powerful enough to detect diet-disease relationships because the range of nutrient intakes within the population is too narrow. However, most comments agreed with the agency's intention not to prescribe a specific set, type, or number of studies as being sufficient to support a disease-related claim, and with its statement that it will "seek to avoid the pitfalls of inflexible adherence to rigidly defined criteria" (56 FR 60548).

The statutory language of section 403(r)(3)(B)(i) of the act is specific in directing the Secretary to consider the totality of publicly available scientific evidence. FDA cannot therefore, and would not be inclined to, exclude any scientific evidence from consideration in assessing the validity of a claim. The agency recognizes, however, that the evidence relating to a particular claim may vary in its usefulness, and that some types of studies may be more probative than others in establishing the validity of particular nutrient-disease relationships. The agency will consider, therefore, as it stated in the November 1991 proposal (56 FR 60537 at 60548). the type, quality, appropriateness of design and relevance of each of the studies and of the other information that together constitute the totality of scientific evidence when assessing the validity of a claim. The agency will evaluate the strengths and weaknesses of each individual study an d weight it accordingly in reaching a decision about the validity of a particular claim.

58. Other comments urged FDA to consider with fairness any proposed health claim that relies on data derived from non-Western cultures.

The agency advises that it will consider the evidence submitted in support of a claim on its scientific merits and in the context of the totality of available evidence. It will not underrate any study on the basis of its cultural or geographic origin. Evidence in support of a proposed health claim, however, will attain value in direct proportion to the significance in the U.S. population of the effects of the disease or health-related condition addressed by the claim.

2. Dietary supplements

59. Many comments asserted that FDA should establish a more lenient standard for substances in dietary supplements. Some of these comments argued that such a standard is mandated by Congress and cited the statement of Senator Hatch, one of the primary authors of the 1990 amendments, that "a more lenient standard for dietary supplement[s] is envisioned." (Ref. 2). Other comments argued that the standard should be sufficiently lenient to permit marketing of supplements without any labeling restrictions. Some of these comments argued that dietary supplements needed no stringent requirements because supplements could be adequately regulated under the regulatory regime of a label needing to be truthful and not misleading under section 403(a)(1) of the act. A number of comments asserted that the standard effectively renders section 403(r)(5)(D) of the act superfluous. Some comments asserted that, by not adopting a more lenient standard, FDA would restrict the amount of health information available to consumers and stated that such information is important to consumers in deciding which products to buy. A number of comments asserted that the standard for supplements is counter to the intent of the 1990 amendments because Congress intended to make more, rather than less, information about the health benefits of foods available to consumers.

However, other comments agreed with FDA's proposal to use the same scientific standard for dietary supplements that the act provides for conventional foods. One comment noted that it is especially important to place dietary supplements under the same standard because they are marketed mainly on the basis of their purported health benefits. Another pointed out that the proposed standard will facilitate purchasing decisions for consumers by reducing fraudulent labeling claims.

A few comments contended that FDA should establish a more stringent .standard for substances in dietary supplements. One comment asserted that FDA has adequate authority to do so and asserted that the legislative history of the 1990 amendments supports a more stringent standard. The comment stated that FDA recognized, when it proposed not to authorize a health claim for omega-3 fatty acids in Docket No. 91N-0103 (56 FR 60663, November 27, 1991), that it does make a difference whether one receives nutriment from food or from pills. In that document, the comment maintained, FDA asserted that benefits have been shown for fish but not for omega-3 fatty acids.

Under the DS Act, there is a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Therefore, FDA is not adopting a standard to implement section 403(r)(5)(D) of the act. The agency will adopt a standard in accordance with the procedures established in the DS Act. However, FDA has carefully considered these comments and, in response, would make the following observations.

Although Congress did convey flexibility in resolving this issue to FDA and one sponsor did state that this flexibility should be used to establish a more lenient standard, as the agency explained in the preamble of the proposal (56 FR 60537 at 60539 through 60540), the legislative history concerning section 403(r)(5)(D) of the act makes clear that Congress did not intend to require that the agency adopt a different standard for these products (Refs. 2 and 3). Instead, the exemption on its face gives the agency the discretion to adopt a scientific standard respecting the validation of claims for supplements, regardless of whether the standard is more lenient or more stringent (Ref. 3). The exemption gives the agency the same discretion with respect to establishing a procedure under which claims may be made.

The statement of House Floor Managers (Ref. 3), addresses section 403(r)5)(D) of the act by stating, in part:

> The Senate version of the bill, which we are voting on today, retains this standard for all foods except vitamins, minerals, herbs, and other similar nutritional substances (referred to below as "vitamins"). The bill requires that vitamins that include claims defined under section 403(r)(1)(B) shall be subject to a "procedure and standard" defined by the Secretary in regulations that require an evaluation of the validity of the claim. The FDA is given the discretion to define both the procedure and thy standard because the principals in the Senate could not agree on the appropriate procedure or the appropriate standard.

It is obvious from the language that the agency could adopt the same procedure and standard that Congress has adopted for disease claims on food other than vitamins,; it is also obvious that It could adopt a stronger standard for vitamins, minerals, herbs, and other similar nutritional substances.

In addition, the Metzenbaum-Hatch Manager's statement m the Senate (Ref. 2) addresses section 403(r)(1)(B) of the act by stating, in part: "The purpose for the different handling of conventional food products and dietary supplements is to provide the Secretary flexibility in the development of the procedure and standard for health claims for dietary supplements."

Thus, both the Senate and the House of Representatives agreed that FDA has the flexibility to adopt the standard and procedure for dietary supplements that appears appropriate to the agency. As pointed out by the comments, Senator Hatch left no question about his position that FDA should use this flexibility to adopt a more lenient standard. However, other members of Congress were equally clear about their position that FDA should not adopt a more lenient standard. In the October 24,1990, Congressional Record, (Ref. 2), Senator Metzenbaum, the other primary author of the Senate amendments, stated:

* * * It is my view that there is no reason to do anything other than utilize the same procedure and standard for dietary supplements.

Whatever approach the Secretary takes, he must establish a system that evaluates the validity of health claims for dietary supplements. The system must be based on the same considerations that guide other agency, decisions: public health, sound scientific principles and consumer fraud.

Further, the House of Representatives clearly did not support a more lenient standard for dietary supplements. The statement of House Floor Managers that appears in the October, 26,1990, Congressional. Record (Ref. 3) states:

* * * Whatever approach the agency takes, it must adopt a system that evaluates the validity of any disease claims made with respect to these substances. Its system must be based on considerations of public health and consumer fraud. As in every similar decision made by the agency today, we fully expect that the agency's evaluation of disease claims made with respect to vitamins will be based on sound scientific principles.

There is a great potential for defrauding consumers if food is sold that contains inaccurate or insupportable health claims. The potential is just as great for vitamins as it is for other products. In our view, vitamins and other substances covered by this provision should be subject to at least as strong a standard as is applicable to other foods that contain claims that the food will treat a disease or health condition.

Thus, some members of Congress opposed a more lenient standard for dietary supplements. However, it also seems that assertions that Congress supported a more stringent standard in the legislative history of the 1990 amendments are not well-founded. The above-mentioned statements on a more stringent standard were included in the legislative history to demonstrate that one could be established, if appropriate.

The agency will consider this legislative history together with the legislative history of the DS Act in proposing rules to implement the 1990 amendments, with respect to the DS Act. The agency notes that if it were to adopt a more lenient standard and procedure for supplements, there might be a significant potential for consumer confusion when confronted with a situation in which there would be health claims for substances when they are present in supplements but not when they are present in conventional foods. If there is reason to conclude that this would not in fact be the case, FDA urges interested persons to come forward with evidence to support such a conclusion during the rulemaking mandated by the DS Act.

The Managers Report on the DS Act (Ref. 34) states that among the policy goals of the DS Act is to assure the public that health or disease-related claims for dietary supplements are properly supported. In the rulemaking under the DS Act, FDA will try and determine what proper support should include. In particular, the agency is interested in why the standard for the scientific validity of health claims in section 403(r)(3)(B)(i) which applies by law to claims for all substances for which claims are made except for those in dietary supplements, is not also appropriate for substances in dietary supplements.

The agency also points out that it did not tentatively conclude in the omega-3 fatty acids proposal that it makes a difference whether one receives nutriment from food or from pills, as the comment suggested. While FDA did state in the summary of that docket that there is inadequate evidence to support a beneficial relationship between reduced risk of coronary heart disease and increased consumption of omega-3 fatty acids, and that there is some evidence that benefit may be gained through the consumption of fish, the agency noted that benefits attributed to fish could not necessarily be ascribed to the presence of omega-3 fatty acids. The example, therefore, does not show that a substance is any more beneficial when it is in a conventional food than when it is not in a conventional food.

60. A number of comments suggested that the agency should adopt a separate mechanism for evaluating the validity of claims for herbs. Under the suggested mechanism, an oversight committee would appoint an expert panel that would consist of a director and at least four scientists with training and experience related to herbal and botanical products. (FDA would participate as a nonvoting member.) The panel could hire outside consultants. The committee, which would be charged with the responsibility of reviewing ail health claims petitions pertaining to herb or botanical components, would relieve FDA of all responsibility for initial review of these petitions. Such petitions would not be permitted to be submitted directly to FDA. The expert panel that was selected by the committee would conduct an evaluation of scientific data pertaining to the requested claim, subject the evaluation to peer review, and prepare a final recommendation about the claim. The recommendation and all supporting documents would then be forwarded to FDA, and the agency would be permitted 120 days to approve, disapprove, or modify the report. Under draft regulations submitted by one of the comments, there would be a codified presumption in favor of the committee recommendation.

The comment asserted that this mechanism for evaluating petitions would not involve a transfer of the agency's authority and obligation to enforce the act because the final authority for decisions rests with FDA. Further, the comment asserted that there is precedent for the requested mechanism in FDA's past use of reviews of food and cosmetic ingredients that have been prepared by the Federation of American Societies for Experimental Biology (FASEB) and the Cosmetic Ingredient Review (CIR).

Although the DS Act establishes a moratorium on the implementation of the 1990 amendments with respect to dietary supplements of herbs, the agency considers it appropriate to respond to this comment. FDA believes that the mechanism suggested by the comment would involve a significant transfer of agency authority for the control of health claims on herbs, and there is no basis under the act for such a transfer. Although the comment asserts that such a transfer would not take place by maintaining that the final authority for decisions rests with FDA, the assertion is not correct. Because of the codified provision providing that there would be a presumption in favor of the committee recommendation, the agency would be obligated to prove that

the committee was wrong or else it would be required to follow the committee's recommendation. Under such circumstances, FDA could be forced to propose to authorize a health claim that the agency believed, but was unable to prove, was not valid. Thus, there would, in fact, be a significant transfer of authority under the requested mechanism.

Further, there is no precedent for the requested mechanism in FDA's use of FASEB and CIR reviews of food and cosmetic ingredients. Neither type of review created a presumption in favor of the review recommendation. Also, FDA has never required that petitions pertaining to food and cosmetic ingredients be submitted for such reviews. With respect to FASEB reviews, FDA contracted for these reviews as part of its GRAS review in the early 1970's and then once to update in formation on sulfiting agents. FASEB only submitted a recommendation as to whether, and what, uses of a substance were GRAS. FDA conducted its own review of the evidence and was free to elect to use the FASEB review as it saw fit.

With respect to CIR reviews, such reviews are used primarily by industry to make self-determinations of cosmetic ingredient safety. The agency may, or may not, comment on any CIR review. Even where FDA comments on a CIR review, there would be little likelihood that agency rulemaking would result. In situations where such a review does serve as a stimulus for a rulemaking proceeding, the review would not be the sole reason for the proceeding. The agency fully retains its en force merit authority in both situations.

Moreover, the committee suggested by the comment would be subject to the Federal Advisory Committee Act (5 U.S.C. App. 2). The burdens imposed on an agency by this statute are heavy. FDA has limited resources for advisory committees. While the agency may, on occasion, use advisory committees as part of the health claims process, it believes that it would be an inappropriate expenditure of those limited resources to commit them to the committee suggested by the comment.

Of course, both the conventional food and dietary supplement industries may, if desired, work through committees in preparing well-supported petitions for submission to FDA, and FDA will cooperate with such committees at a scientific level by explaining the agency's requirements to them and sharing publicly available information. However, the agency would not require firms to use such committees, and FDA would still have the ultimate obligation of determining whether the petitioned-for claim is scientifically valid. To clarify that the agency will consider all recommendations by such committees, FDA has revised provisions of new §101.70(b) to provide that information that is submitted with petitions may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area at issue. While the agency will consider any findings of a panel included in a petition, the agency will not use that panel to make its decision.

61. Some comments asserted that in addition to the proposed regulatory framework for evaluating health claims, which involves permitting supplement claims on the same terms as for conventional foods, FDA should also subject dietary supplements to an alternative involving a different level of validity substantiation and a different procedure. Under the alternative procedure, claims for which there is substantial scientific evidence but not yet significant scientific agreement would have to undergo a certification and notification procedure rather than rulemaking proceedings. Under the alternative, claims could be made for supplements so long as: (1) The claim expressly discloses the absence of scientific agreement as to the relationship, (2) the manufacturer provides FDA with a rally documented certification by a panel of at least three qualified, experts that there is substantial scientific evidence supporting the claim, and (3) FDA does not disapprove the claim within 90 days of receipt of the certification. (When additional information is needed, the 90 day period could be extended an additional 45 days.) Under the alternative, FDA would have an opportunity to participate in the selection of the expert panel.

Given the moratorium on the implementation of the 1990 amendments established by the DS Act, the agency is reserving making a detailed response to these comments at this time. The Managers Report on the DS Act (Ref. 34) states that FDA may wish to propose new rules or to repropose rules under section 403(r)(5)(D) of the act, FDA will consider these comments in deciding what action to take with respect to section 403(r)(5)(D) of the act in responding to the DS Act.

V. General Labeling Requirements

Proposed § 101.14(d)(1) provides that when FDA determines that a health claim is valid, the agency will propose a regulation in part 101, subpart E to authorize the use of the claim. Further, the provision states that if the claim pertains to a substance not provided for in § 101.9 or § 101.36, FDA will propose amending those regulations to include declaration of the substance. FDA points out that § 101.9(a) requires that where a claim about a nutrient is made, the nutrition labeling information shall include appropriate information about that nutrient. Proposed § 101.36(a) also would require nutrition information on dietary supplements. However, given the moratorium established by the DS Act, FDA is not adopting § 101.36 at this time. FDA has deleted the reference to that section from § 101.14(d)(1).

62. Several comments argued that FDA should not permit firms to place any health claims on the labels of conventional foods or of dietary supplements.

Through enactment of section 403 (r) of the act, Congress has mandated that firms be permitted to place health claims on food labels when FDA finds that the claims are valid and establishes regulations authorizing their use. Although the comments cited a wide variety of reasons to support their objections, FDA is not addressing these reasons because the 1990 amendments settled this issue. The agency has, therefore, not made any changes in response to these comments.

A. Consistency with Summary of Scientific Information and Model Health Claim

Proposed § 101.14(d)(2)(i) stated that all label or labeling statements about the health benefit that is the subject of the health claim shall be based on, and consistent with, the conclusions set forth in the summary of scientific information and model health claims provided in regulations in part 101, subpart E.

63. Some comments urged FDA not to allow manufacturers to paraphrase an established model health claim. These comments stated that claims should be repeated in the same way on each qualifying food product to ensure that only one clear message is being given to consumers. One of these comments cautioned that consumers faced with health claims stated in a wide variety of ways will be confused about the possibility of differences among the claims. Another suggested that in light of the practical inability of FDA to police varying wordings for accuracy, the only way to ensure that claims are an accurate representation of the facts is to require that agency-drafted claims be used. The comment noted that although the 1990 amendments did not specifically contemplate mandatory FDA-created wording for the health

claims, section 403(r)(3)(B)(iii) of the act could be interpreted to allow such an approach on the basis that the agency wording is the only one that "enables the public to comprehend the information provided in the claim."

However, other comments maintained that manufacturers should not be held to the specific language in the model health claims and asked that the regulations be amended to specifically state that label claims need not be identical to the model claim language. The comments explained that the model claims are too complex to be meaningful to consumers and expressed concern that the proposed requirement for consistency might be interpreted in such a rigid manner that effectively only the model claim would be permitted.

FDA does not believe that the 1990 amendments allow the agency to prohibit manufacturers who wish to place a health claim on a product from paraphrasing language in the model claim. Section 3(b)(1)(A)(vii) of the 1990 amendments prohibits FDA from requiring persons to secure agency approval before placing a health claim on a product, provided that the claim is in compliance with the applicable regulation. The House Report (Ref. 1), states that this section "makes it clear that the regulations will not require premarket review of each claim; they will only require that the claim be consistent with the terms and requirements of the regulations." The agency believes that it is possible to paraphrase a model health claim while remaining consistent with the terms and requirements of the regulations permitting that claim. This position is similar to agency policy that permits the use of terminology other than that established in a final OTC drug monograph in labeling of an OTC drug product to describe indications for use (51 FR 16258, May 1, 1986), Consistent with that policy for OTC drug labeling, the agency believes that the goal of ensuring scientifically valid, truthful, and nonmisleading labeling without inhibiting effective consumer communication does not require exclusive use of language in a mode! health claim. The model language along with other requirements for that claim will, nevertheless, provide the standard for measuring the accuracy of alternative language developed by food manufacturers for their products because FDA has included all mandatory labeling elements of a health claim in the model claim. Of course, manufacturers should recognize that a paraphrased health claim that fails to convey all the mandatory elements of the claim will subject a product to regulatory action.

Section 403(r)(3)(B)(iii) of the act does not require the verbatim use of the agency's model health claims. The provision states that the agency must require in a regulation authorizing a health claim that the claim be stated in such a way as to allow the public to comprehend the presented information and to understand the relationship of the substance to the disease or health-related condition, the significance of the substance in affecting the disease or health-related condition, and the significance of the information in the context of the total daily diet. The agency's model wording of a health claim is likely not to be the only way in which one can convey all the required information.

Although FDA agrees that manufacturers should not be held to the specific language in the model health claims, the agency does not believe that it is necessary to state this fact in the regulations. Just as some could misinterpret the proposed codified requirement that claims be "consistent with" model claims, others could misinterpret a provision stating that claims "need not be identical to the model claim language." Thus, FDA has revised new § 101.14(d)(2)(i) to require that labeling statements conform to the conclusions set forth in the regulations in part 101, subpart E without any specific reference to provisions contained therein.

64. Some comments contended that FDA's proposed regulations would require too much information in health claims, and that the appearance of so much information in a health claim would confuse consumers. Some of these comments suggested that this confusion could thwart FDA's goal of educating the public. Others asserted that, rather than trying to clear up their confusion, many consumers would simply assume that the product is unhealthy for them and choose products that did not bear the lengthy claims. One of these comments stated that the calcium/osteoporosis claim was, according to computer analysis, so complex that a "fourteenth-grade" reading level was required to properly understand it.

Another comment objected that the proposed policy of codifying "all" effects of a nutrient on a condition or disease would lead to the inclusion of effects that were of tangential importance or that were not the subject of significant scientific agreement. Instead, the comment stated, FDA should limit its description to significant effects on which there was such scientific agreement.

However, other comments agreed with FDA's proposal that health claims should include information on factors that affect the nutrient-disease relationship (e.g., exercise). One consumer advocacy organization strongly asserted that it is important that nutrient intake not appear to be the sole factor in matters affecting the risk of disease when other factors are considered to be of similar importance. The comment stated that use of such language as "one of several factors" and "can help" in health claims will help the public to understand that the nutritional characteristics of the foods bearing claims are not "cure-alls" for the disease/health condition mentioned.

FDA agrees that consumers should be presented with health claim information in a clear, nonconfusing manner, and the agency realizes that there is a limit to the amount and complexity of information that can be presented in a health claim. However, the agency believes that it must require enough information in a health claim to ensure that consumers understand that factors other than dietary intake of the nutrient may bear on the substance-disease relationship. Given these imperatives, the agency is faced with the difficult task of determining what information is necessary in a claim, and what information is not.

FDA has reviewed the requirements for the health claims that it is authorizing elsewhere in this issue of the **Federal Register** to determine whether they call for the inclusion of information in the claim that is not absolutely necessary to allow the consumer to understand the claims in the context of a total daily diet. FDA has deleted information that is not necessary from the list of mandatory information and instead has listed this information as information that a manufacturer may opt to include in a health claim. FDA will take a similar approach in the future. FDA believes that its regulations in part 101, subpart E now represent an acceptable balance between the consumer's right to understand the full context of the claim and the manufacturer's concern over claim length. By delineating the information that is mandatory and optional in a claim, FDA is relieving manufacturers from having to include information that is of tangential importance but allowing those who wish to use the information to do so without violating the authorizing regulation.

As for the comments that asserted that the sentence structure and phrasing of

the model claims are too complex, the agency has sought to minimize complexity but has found that some unavoidably results from trying to provide the information necessary to ensure that consumers understand the claim in its proper context. FDA believes that the versions of the claims that it is adopting mandate less information, and are significantly less complex, than those proposed. However, manufacturers who are not satisfied with the model claims are free to develop their own versions of the claim, provided that those versions include all of the information required by the authorizing regulation.

65. One comment asserted that product-specific health claims, which emphasize the role of a specific product or brand of product in a diet-disease relationship already the subject of an agency regulation, should be allowed and even encouraged.

FDA disagrees with this comment. Section 403(r)(3)(B)(iii) of the act directs the agency to require that health claims enable the public to understand the information in the context of the total daily diet. FDA believes that a claim that refers specifically to the health benefits conferred by the consumption of a certain brand name of product would unduly emphasize the importance of that brand in the context of the daily diet. Also, such claims could imply that other brands of the same food, as well as other foods containing the substance, might not have the same effect on the disease or health-related condition and thus be misleading under section 403 (a) of the act. Accordingly, the agency rejects this comment's recommendation.

66. A number of comments suggested that FDA should develop health claims about general food choices, rather than substances, and a disease or health-related condition. Other comments, however, cautioned that such an approach might create more consumer confusion than benefit.

As FDA pointed out in its response to comment 1 of this document, claims about the benefits of general classes of food such as fruits and vegetables that do not make an express or implied connection to any specific substances do not constitute health claims because the multiplicity of substances found in those foods renders the claim too general to satisfy the first basic element of a health claim (i.e., substance). However, where a claim about a general food choice is an implied claim for a substance or specific substances contained in the food and a disease or health-related condition, it would be subject to the health claims regime.

Development of information about general food choices and diseases or health-related conditions, to the extent it is not subject to section 403(r) of the act, is an activity authorized by the National Nutrition Monitoring and Related Research Act of 1990 (Ref. 32) which was enacted at about the same time as the 1990 amendments. In brief, the Nutrition Monitoring and Related Research Act authorizes the Secretary of the Department of Health and Human Services and the Secretary of the Department of Agriculture to establish dietary guidance by jointly publishing at least every 5 years a report entitled "Dietary Guidelines for Americans." Each such report is to contain nutritional and dietary information and guidelines for the general public which are based on the preponderance of the scientific and medical knowledge that is current at the time the report is prepared. The Secretaries are also authorized to review and approve any dietary guidance for the general population or identified population subgroup proposed to be issued by any Federal agency to assure that the guidance either is consistent with the "Dietary Guidelines for Americans," or that the guidance is based on medical or new scientific knowledge that is determined to be valid by the Secretaries.

The goals to be achieved by both the 1990 amendments and the Nutrition Monitoring and Related Research Act (7 U.S.C. 5341) are complementary in every respect. Where the 1990 amendments ensure the validity of health claims, the Nutrition Monitoring and Related Research Act ensures the validity of dietary guidance. In considering whether to authorize health claims, the agency will exercise great care to see that the claims that it authorizes are fully compatible with national dietary guidance.

B. Complete, Truthful, and Not Misleading

Proposed § 101.14(d)(2)(iii) stated that a health claim shall be complete, truthful, and not misleading. In keeping with these requirements, FDA asserted that where factors other than consumption of the substance bear on the claimed effect on a disease or health-related condition, such factors must be addressed in the claim.

67. One comment proposed that the word "complete" as used in proposed § 101.14(d)(2)(iii) is vague and would lead to confusion. It noted that each company in the food industry will be free to paraphrase FDA's model health claims and, since such paraphrasing necessarily implies different words and sentences, to the extent that a company 's claim does not track the model exactly, such claims will not be "complete." The comment suggested that the word "complete" be deleted from the final regulation.

FDA disagrees that the word "complete" should be deleted from the regulation. The agency believes that it is imperative that consumers be informed of factors other than the consumption or nonconsumption of the substance that significantly bear on the claimed effect on a disease or a health-related condition. To this end, FDA will codify all such information in part 101, subpart E. FDA believes that the word "complete" is necessary in § 101.14(d)(2)(iii) to ensure that manufacturers understand that their health claims must include all such mandated information. This policy is consistent with section 201(n) of the act, which provides that an article's labeling may be misleading if it omits material facts.

68. One comment stated that dietary supplements should be required to balance their health claims by including warnings against any negative health effects that might result from their use. The comment also suggested that the labels of such products should declare the maximum amount of the dietary supplement that can be consumed without incurring risk of toxicity.

FDA disagrees. To be eligible for a health claim, a substance, if it is to be consumed at other than decreased dietary levels, is required to be a food or a food ingredient whose use at the levels necessary to justify the claim is safe and lawful under the applicable food safety provisions of the act. Thus, there is no reason to treat dietary supplements any differently than other food by requiring that they bear special warnings.

To avoid any misunderstanding as to the appropriate level of consumption in relation to the daily diet, the agency may require, in its authorizing regulation for a claim, that the claim state the level of consumption beyond which no additional benefit is likely to be gained. The agency notes as an example that the calcium/osteoporosis health claim includes the statement that "adequate calcium intake is important, but daily intakes above about 2,400 mg are not likely to provide any additional benefit."

If at some point in the future, the agency approves a health claim that has some safety concern to any subpopulation of consumers, the agency will, of course require that the claim include sufficient information to alert that subpopulation. For example, if FDA

ever approves a health claim for vitamin D, the claim would be required to inform consumers of the potential for an adverse effect from excess consumption.

C. Layout

Proposed § 101.14(d)(2)(iv) stated that all claims must appear in one place, in the same type sizes without intervening material. FDA included in this provision an exception to allow a short reference statement to appear on the label, "See ———— for information about the relationship between ————and ———," with the blanks filled in with references to the location of the labeling (other than the label) on which the full claim appears, the name of the substance, and the disease or health-related condition.

69, A number of comments suggested that proposed § 101.14(d)(2)(iv) be amended to allow the use of a front panel reference to a full health claim appearing on the aide or back panels. Many of these comments contended that a referral statement on the principal display panel would help make consumers aware of the full claim, which itself might be too long to appear on the principal panel. Some comments suggested that abbreviated forms of a health claim be allowed to serve as reference statements. One of these comments suggested that this approach would avoid overcrowding of the principal display panel, would place the health claws where they would be of greatest use to consumers, and would still provide conveniently located, detailed information to consumers.

FDA takes note of those comments on reference statements and abbreviated health claims. Some of the issues raised by these comments have been resolved with revisions made in all of the model health claims. For example, among the sample claims for sodium and hypertension in new § 101.74 (e) is one that reads: "Diets low in sodium may reduce the risk of high blood pressure, a disease that is dependent upon many factors." Similarly short claims have been developed for other health claims. Since these abbreviated claims are not much different in length than a reference statement that would have been used on the principal display panel or elsewhere in labeling of a product, it is now possible to present the health claim in place of a reference statement. However, since the agency cannot provide assurance that future health claims will be crafted to be as short as the example given above, FDA has retained proposed § 101.14(d)(iv). The agency's responses to comments on reference statements and abbreviated claims follow.

FDA does not believe that it is appropriate to use abbreviated health claims as referral statements. Shortened health claims used as referral statements, even those as simple as "See side panel for information on how calcium may reduce the risk of osteoporosis," still constitute a health claim because they clearly characterize the relationship between a substance and a disease or health-related condition. Further, such a health claim is misleading because it does not include facts that are material in light of the representation that is made, and that are necessary to understand the claim in the context of the daily diet. For example, in the case of calcium and osteoporosis, the shortened claim does not reveal that regular exercise and a balanced diet are important to the maintenance of good bone health, and that a daily intake of calcium in excess of 2,400 mg is not likely to provide additional benefit for reducing the risk of osteoporosis.

Such situations are possible whenever the full health claim information appears in a location different from that of the reference statement and are especially likely to occur when a multiplicity of labeling is associated with a product. For example, a cereal manufacturer could place an abbreviated claim as a reference statement on the principal display panel of the cereal box and then bury the full claim on one of several paper inserts. In such a case, a consumer is unlikely to search through the inserts to find the full claim. A similar situation might arise were a grocer to display an abbreviated calcium-osteoporosis claim as a referral statement on a dairy case and then place the full claim on a billboard in a far corner of the store. A consumer is not likely to search through the store for the detailed health information.

In each of these examples, the consumer would be misled because he/she has received an incomplete health claim that does not disclose information on nondietary factors that may affect the nutrient-disease relationship and that does not allow the consumer to understand the claim in the context of the total daily diet. Case law clearly supports the agency's position that the mere presence of the full health claim elsewhere in the product labeling does not counteract the misleading nature of the abbreviated reference statements in such instances. See, e.g., *U.S. v. An Article of Food* * * * "Manischewitz * * Diet Thins,"* 377 F. Supp, 746, 749 (E.D.N.Y. 1974).

The referral statement provided in § 101.14(d)(2)(iv) does not constitute a health claim, as it does not characterize the relationship between a substance and a disease or health-related condition. The statement simply refers the consumer to a location where the complete health claim appears. A consumer who reads the referral statement without reading the full health claim may realize that there is some relationship between the nutrient and the disease. The nature of that relationship, however, is only presented in a context that is complete, truthful, and not misleading and that thus allows the consumer to fully understand and evaluate the claim. Thus, the consumer will not be misled by reading the provided referral statement. Accordingly, the referral statement provided in proposed § 101.14(d)(2)(iv) is the only one that should be used. As explained previously in this preamble (section I.D.5. of this document), the statement must appear in immediate proximity to any graphic material such as a symbol that, constitutes an explicit or implied health claim.

70. A number of comments suggested that the complete health claim should be allowed only on the principal display panel unless the panel is too small to accommodate it.

FDA does not agree that health claims should be required to appear only on the principal display panel. The adoption of such a policy, for those labels that are physically large enough to contain the full health claim, could easily lead to overcrowding of some principal display panels and would eliminate their use on those that are not. Such a requirement would significantly undercut the congressional intent in providing for health claims in section 403(r) of the act. Therefore, FDA rejects this comment.

71. A number of comments asserted that the type size requirement proposed for health claims is not mandated by law. It was also argued that the requirement may make it impossible for manufacturers to include other truthful and nonmisleading information on the principal display panel.

FDA recognizes that the proposed type sizes are not mandated by law. The agency proposed this requirement because it was concerned that many consumers, when faced with a health claim printed in differing type sizes, might read only those portions of the claim that appear in larger type and thus would overlook the information printed in smaller type. However, FDA has reconsidered this issue and now believes that, as proposed, the provision is unnecessarily restrictive. Certainly consumers would not likely ignore portions of a health claim that are

printed in a reasonably related type size to the largest printed matter in the claim. FDA believes that any abusive use of type size could adequately be prevented under § 101.14(d)(2)(iii), which requires, in part, that a claim not be misleading. Accordingly, FDA has removed the requirement that a claim appear in the same type size. While the agency encourages manufacturers to observe the minimum type size required by §101.2 for mandatory labeling information to ensure that the claims are easily legible, manufacturers who went to include a complete health claim on the principal display panel of a product may utilize whatever type size they feel is necessary to achieve this end.

72. One comment recommended that, in order to avoid the label space problems that would result from the appearance of lengthy bilingual claims, health claims on imported products should be allowed to appear in English without translations into the foreign languages that appear on the label. The comment asserted that competitive pressure will force U.S. importers to make label claims comparable to domestically produced products and cited the model health claim for calcium and osteoporosis in exemplifying the difficulty that would result from providing lengthy bilingual claims. Another comment from a foreign industry organization objected to permitting any health claims on food labels because multi-language labeling will be so burdensome that it will serve as a nontariff trade barrier.

FDA advises that the provisions of § 101.15(c)(2) require only that all mandatory labeling information be translated into any foreign languages that appear on any part of a product's labeling. Because the presence of a health claim on a food label is voluntary, manufacturers who place an English-language health claim on a multi-language label may choose whether to translate that claim into one, all, or none of the foreign languages appearing on the label.

D. Enables Public to Understand Significance of Claim in Context of Total Daily Diet

Proposed § 101.14(d)(2)(v) stated that a health claim must enable the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet.

73. Some comments asserted that the multiplicity of labeling requirements exceeds the statutory language of the 1990 amendments and stated there is no evidence in the legislative history to suggest that Congress intended label claims about nutrient/disease relationships to include the kinds of detailed information mentioned in the preamble. One of these comments stated that FDA is authorized under the amendments to require only that information that is necessary to prevent the health claim from being misleading.

Another comment, disagreed with FDA's conclusion that section 403(r)(3)(B)(iii) of the act allowed "only those effects found to be substantiated" to be included in the health claim. The comment instead asserted that the requirements of the provision would be fulfilled if a health claim merely characterized the level of a nutrient vis-a-vis a disease, provided that there was significant scientific agreement that the intake of the nutrient at the level present in the food was beneficial in reducing the risk of the disease.

FDA disagrees with these comments. Section 403(r)(3)(B)(iii) of the act requires that a regulation that authorizes a claim require that the claim be stated in a manner that enables the public to comprehend the information in the claim and to understand the relationship of the substance to the disease, the significance of the substance in affecting the disease, and the significance of the information in the context of the total daily diet. Thus, a wide variety of factors may need to be addressed in the claim in order to fulfill these requirements, and the agency is not limited to requiring only that information that is necessary to prevent a claim from being misleading.

For example, the regulation authorizing a claim on the relationship between calcium and osteoporosis requires that the claim explain that adequate calcium intake during adolescence and early adulthood appears to have a positive effect on bone health, and that optimizing peak bone mass during that period may reduce the risk of osteoporotic fracture in old age (see new§ 101.72(d)(3)). Additionally, the regulation requires that claims point out that adequate calcium intake be accompanied with exercise and the maintenance of a balanced diet. The claim must also identify factors such as the age range within which women can expect to achieve the greatest effect for decreasing the risk of developing osteoporosis in later life (see new § 101.72(d)(2)). These are considered to be facts essential for consumers to understand the conditions and circumstances under which the claimed effect of calcium on the risk of osteoporosis is more likely to be obtained.

Accordingly, if FDA were to permit a health claim that simply characterized the level of a nutrient vis-a-vis a disease or health-related condition, the agency would not meet the statutory requirements of section 403(r)(3)(B)(iii) of the act. Therefore, FDA rejects the comments.

74. Some comments stated that the model health claims were themselves misleading in that the identification of certain high-risk groups in a claim might easily lead consumers in other groups to believe that the information presented in the claim does not apply to them, when in fact it may (for example, osteoporosis affects some men as well as women).

The model claims that are targeted to specific subpopulations have been carefully worded to encompass all of the affected subpopulations. The agency, therefore, sees no potential for a consumer who is in a group that is at increased risk of a disease that is discussed in a health claim to be misled by the claim into believing that he/she is not at an increased risk of the disease. The agency addresses concerns about specific model health claims in the preambles to the specific regulations authorizing those claims.

75. Other comments asserted that model health claims should emphasize the importance of good nutrition habits to all consumers. One also recommended that FDA require a statement about the need to seek medical advice for treating the related disease as part of the health claim.

FDA does not agree that it is appropriate to require that all health claims emphasize the importance of good nutrition to all consumers. In many cases, a health claim may be targeted toward a specific subpopulation. The inclusion of a statement directed at the general U.S. population could lead some consumers who are not targets of the claim to mistakenly believe that the entire health claim has relevance to them. For example, a calcium-osteoporosis claim targeted toward teenage women that bears a statement concerning the importance of good nutrition to the general population could mislead some middle-age men with no family history of osteoporosis to believe that the claim was also targeted toward them.

Also, FDA does not believe that it is appropriate for health claims to bear statements concerning the need to seek medical advice for treating the disease or health-related condition mentioned in a claim. The agency is concerned that the appearance of a statement concerning the treatment of a disease on the label of a food could mislead some consumers to believe that the food possesses therapeutic value for an

existing disease or health-related condition. Further, such an interpretation could encourage some consumers who suffer from the disease or condition to attempt "home remedies" by consuming more of the product and, ironically, temporarily or even permanently foregoing the medical attention that they need.

E. Presence of "Low" Level of Nutrient to be Consumed at Decreased Dietary Levels: Presence of "High" Level of Nutrient to be Consumed at Other Than Decreased Dietary Levels

Proposed § 101.14(d)(2)(vi) stated that to bear a claim about the benefits of consuming a substance at reduced dietary levels, a food must be sufficiently low in that substance to meet the definition of the term "low" if the term has been defined for that substance, or if the term has not been defined, to meet the level set in the regulation authorizing the claim. Proposed § 101.14(d5(2)(vii) stated that to bear a claim about consuming a substance at other than decreased dietary levels, a food must be sufficiently high in that substance to meet the definition of "high" if the term has been defined for that substance, or if the term has not been defined, to meet the level set in the regulation authorizing the claim.

With the decision in section II.B of this document to revise the definition of "substance" in proposed § 101.14(a)(2) to include a specific food as well as a component of food, the requirements of proposed § 101.14(d)(2)(vii) (i.e., the requirements for "high") must be revised as they apply to a health claim for a specific food. Where a health claim for a specific food (e.g., garlic, rice bran) is established by the agency, it is presumed that the claim will deal with either inclusion of the food in the diet or increased dietary intake to effect the benefit that is the object of the claim. The agency does not envision authorizing a health claim for a specific food based on decreased intake of that food because, where moderation in or a decrease in daily intake is at issue, that action is directed toward food components rather than whole foods (e.g., "choose a diet low in fat, saturated fat, and cholesterol;" "use sodium only in moderation").

Accordingly, FDA has revised proposed § 101.14(d)(2)(vii) to state that, where no definition for "high" has been established, that is where the claim pertains to a whole food or to the food's use as an ingredient in other foods, the claim must specify the daily dietary intake necessary to achieve the claimed effect as established in the regulation authorizing the claim.

76. Most comments concurred with the proposal to allow a health claim only when a food contains the claimed substance in en amount that meets the criterion for either a "high" or "low" level of that substance. However, some comments qualified their concurrence by saying that they did not agree with the definitions for "high" and "low." One comment stated that, absent a definitive showing that health claims would be misleading on foods that do not meet the "high" or "low" definitions, FDA's approach cannot be considered narrowly tailored to directly advance the government's interest in providing important diet and health information to consumers. Unless deception could be proved, the comment urged FDA to eliminate the requirements linking health claims to "high" and "low" definitions for nutrient content of foods.

The agency has considered these comments and concludes that it is appropriate to retain the requirements in proposed §§ 101.14(d)(2)(vi) and (d)(2)(vii) linking health claims to "high" and "low" definitions for nutrient content of foods. The definitions for "low" and "high" levels of a substance (nutrient) have been developed specifically to assist consumers in maintaining healthy dietary practices (see section 403(r)(2) of the act). The same basis underlies the purpose for health claims. This is evident from the House of Representatives report on the 1990 amendments (Ref. 1):

> The Surgeon General has advised Americans that diets low in fats, low in salt and high in fiber can reduce the risk of chronic diseases such as cancer and heart disease. Health claims supported by a significant scientific agreement can reinforce the Surgeon General'[s] recommendations and help Americans to maintain a balanced and healthful diet. Similarly, statements regarding the level of these nutrients in foods will assist Americans in following the Surgeon General's guidelines.

Accordingly, a requirement with respect to the level in a food of a substance that is the subject of a health claim is consistent with the intent of the 1999 amendments. The definitions of "high" and "low" are addressed by FDA in the rule on nutrient content claims published elsewhere in this issue of the **Federal Register**.

77. One comment urged FDA to modify the proposed requirement that would permit a health claim on a product for which a nutrient (specifically sodium) is assessed only on the basis of the reference amount customarily consumed (as defined in the final rule on serving size published elsewhere in this issue of the **Federal Register**). The comment suggested that the product should additionally comply on the basis of the total amount of the nutrient in the actual package if the package contains less than 200 percent of the reference amount customarily consumed.

This comment misinterpreted FDA's proposal, In the proposal on serving sizes (56 FR 60394), FDA proposed that both the reference amount customarily consumed (hereinafter referred to as the reference amount) and the label serving size be used to determine whether a product met the criteria for both nutrient content and health claims. The agency solicited comment on another approach that is based solely on the reference amount and that would require a disclaimer where, for example, a reference amount of a product would qualify for a sodium claim, but a single-serving container with 150 percent of the reference amount would not.

As discussed in detail in the preamble to the final rule on serving sizes published elsewhere in this issue of the **Federal Register**, the agency has considered the comments on this issue, along with the advantages and disadvantages of both options, and acknowledges that nutrient content claims should reflect, and health claims should be based on, the reference amount customarily consumed. The agency has concluded that problems created when the amount of the substance in the labeled serving size would not qualify for a claim are resolved by requiring a disclaimer that makes clear the basis for the claim. This disclosure is necessary to ensure that the consumer is not misled. On this basis, the agency is rejecting the recommendation made by this comment.

The agency has reflected this determination with respect to claims in new § 101.12(g) of the final rule on serving sizes, published elsewhere in this issue of the **Federal Register**, which has been revised in response to comments to that proposal to state, in part:

> The reference amount [i.e., the reference amount customarily consumed] set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall Include the reference amount as it appears in § 101.12(b)

followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl. oz)")

That declaration is necessary because in containers of this type, consumers customarily consume more than the reference amount. The declaration is necessary to ensure that the claim is not misleading. The criteria for health claims referenced in proposed § 101.12(g) are the qualifying criteria contained in proposed §§ 101.14(d)(2)(vi) and (d)(2)(vii). Therefore, to reflect the modification that has been made in § 101.12(g) that a health claim can be made on a product when the product meets the criteria of proposed §§ 101.14.(d)(2)(vi) or (d)(2)(vii) only on the basis of the reference amount customarily consumed, new § 101.14(d)(2)(vii)(A) has been added to state:

Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in salt and sodium may help lower blood pressure in many people. A serving of —— ounces of this product conforms to such. diets.").

F. Requirements for Restaurants

1.Health claims on restaurant foods

FDA received many comments regarding the proposed health claims criteria as they would apply to restaurant foods and to foods sold in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act. Issues with respect to menus are discussed separately below.

78. Many comments objected that the proposed health claim provisions should not apply to restaurant foods and foods sold in other establishments in which food that is ready for human consumption is sold. These comments asserted that Congress did not mandate the application of the proposed health claim regulations to restaurant foods. A number of continents observed that section 403(q)(5)(A)(i) of the act exempts restaurant foods from mandatory nutrition labeling requirements, and that sections 403M(2)(A)(iii) and (r)(2)(A)(iv) exempt them from the restrictions placed on claims related to cholesterol, fat, and fiber content. The comments further noted that the 1990 amendments are silent with respect to the regulation of health claims made in connection with restaurant foods, and that, at a minimum, FDA is not required to regulate restaurant foods. Other comments maintained that even if the agency does believe that restaurants must he subject to health claims regulations, FDA is not obligated to regulate these foods in mi identical manner to that proposed for packaged foods.

However, many other comments disagreed. Some of these comments maintained that because the 1990 amendments contain no specific exemptions for health claims in restaurants. Congress intended for restaurants to be fully subject to the health claim regulations. Other comments argued that restaurant food plays too great a role in the American diet not to have been covered by the 1990 amendments. One comment pointed out that a large percentage of the money spent for food by Americans is spent away from home in restaurants. Several comments stated that requiring restaurants to comply with all of the health claims regulations where they choose to make health claims would best support the philosophy of an "even playing field" between restaurateurs and other food vendors. Others expressed concern that the preemption clause of the 1990 amendments could prohibit state and local authorities from enacting regulations concerning health claims made on restaurant foods if FDA fails to do so. One consumer comment proposed that FDA ban restaurants from making any health claims for any of their products, rather than exempting them from the health claim regulations.

FDA believes that the provisions of the 1990 amendments pertaining to health claims clearly encompass restaurant food wherever a health claim is made (except, for the reasons discussed below, when the claim is made on a menu). FDA disagrees with comments that asserted that the absence of specific exemptions for restaurant food from the health claims provisions in these amendments conveys flexibility to the agency to exempt such food from § 101.14, The House Report (Ref. 1) states that "under sections 493(r)(1)(B) and 403(r)(3) of the act, restaurants and similar food service establishments would have to comply with the bill in order to make a disease claim concerning a food sold in such establishment." In view of this explicit statement of congressional intent on the matter and the presence of specific exemptions for restaurant food pertaining to other provisions of the 1990 amendments where Congress wanted different regulatory treatment for restaurant food, the absence of a restaurant food exemption pertaining to health claims can only mean that Congress intended for restaurants to be subject to health claim regulations. Because of the congressional intent that restaurants be subject to the health claim regulations, FDA disagrees with assertions that the agency should not permit health claims on restaurant food.

However, FDA agrees that it is not legally required to regulate claims on restaurant foods in a manner identical to that for packaged foods. Nevertheless, it is only logical that if claims on food are to be useful for consumers, the criteria for those claims must be consistent. Therefore, the agency has determined that additional flexibility is needed to facilitate the helpful provision of health claims on restaurant foods, but that there must be assurance that the claims being made are indeed valid. The agency's responses to the following comments discuss how FDA intends to achieve this degree of flexibility with appropriate assurance of validity.

79. Many comments argued that all health claims provisions affecting packaged food should also apply to restaurant food. Several comments stated that the regulation of restaurant foods would be practical because many of the menu items are centrally manufactured and are required to conform to system-wide composition and quality standards. One comment asserted that many restaurant chains, especially the larger ones, already have access to nutrition information about their products. Another comment stated that private services that determine the level of various nutrients in foods are readily accessible to restaurants. A comment from an organization representing the nation's state, local, and Federal food regulatory officials asserted that the proposed regulations would not place an additional burden on restaurants seeking compliance with the health claim requirements, as most state laws already require that foods be labeled in compliance with all applicable laws and regulations and do not differentiate between, labeling at the wholesale or manufacturing level and the retail level. The comment cited the model regulations developed jointly

between FDA and the Association of Food and Drug Officials (Rules of Food Service Sanitation and the Retail Food Store Sanitation Code) as an example. Other comments argued that health claims are misleading without nutrition labeling information. Some comments suggested that restaurants be required to at least provide an abbreviated nutrition statement, consisting of a disclosure of the amount of calories, fat, and sodium as well as of all nutrients relevant to the health claim.

However, many comments confirmed that restaurant food differs in a number of significant respects from other types of food that is mass-produced and packaged and maintained that the differences make it impracticable for restaurants to conform to some of the health claims provisions that were proposed. The comments advised that the provisions at issue are those pertaining to qualifying levels (e.g., the "low" or "high" levels of the substance, as appropriate) and the "disqualifying nutrient levels," as well as nutrition labeling. The comments asserted that the cost of providing nutrient content information would be unreasonable for each of these provisions. Some of these comments explained that restaurants experience significant variations in the foods they serve because of variations in the manner of preparation, varying ingredients, consumer preferences, varying serving sizes, and the lack of central control over food preparation in many restaurants. Because of this wide variation, frequent nutrient analyses would have to be performed to determine nutrient content, so that restaurants may conform to these provisions. The comments advised that these analyses could become very burdensome, and that the cumulative costs of these analyses could prevent establishments from making health claims, prevent them from making frequent changes in the dishes they offer, or force them to limit the options that consumers have in ordering a food. Further, the comments advised that small businesses would be especially burdened by such cumulative costs.

Even In "standard" items in multi-unit operations, the comments asserted, there is inherent variation. The comments advised that such variation is present in items such as daily specials, test products, local optional items, promotional items, and all items in restaurants offered for limited periods of time. A number of comments objected to the application of the proposed health claim regulations to traditional ethnic restaurants and similar small businesses on the grounds that it is extremely difficult to modify many of their foods to the degree necessary to meet the various provisions of the health claim proposals.

In addition, some comments pointed out that the proposal requires that qualifying and disqualifying levels be met per reference amount, per serving, and per 100 g. This aspect of the proposed definition, the comments maintained, wreaks havoc when applied to restaurant foods. Comments advised that restaurant foods that conform to the proposed qualifying and disqualifying levels in terms of reference amounts and 100 g are nonetheless ineligible to use health claims because their larger serving size results in the food failing to conform to the disqualifying nutrient levels. A number of comments suggested that restaurant food claims be judged on a per 100 g basis consistent with FDA's meal proposal, since most consumers view restaurant foods as a "meal."

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30 percent of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet can not be ignored. Further, FDA believes that dietary information, including health claims, provided to consumers at point of purchase in restaurants may be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such information. However, FDA firmly believes that consumers expect health claims made at point of purchase to be truthful and not misleading.

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Because of the importance of context, a restaurant may be able to use symbols next to the listing of an item where the symbols are clearly explained in terms that would not subject the claim to the 1990 amendments. Thus, restaurant labeling may use symbols or make reference to the criteria of a health professional organization and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the dietary guidelines of the American Heart Association will be considered dietary guidance, and not a health claim subject to section 403(r) of the act. If the restaurateur went on to link the claim with levels of substances in the food, however, it would subject the food and the claims to the health claims regime (see discussion above about implied health claims).

When a restaurant makes explicit or implied reference to a substance and directly or indirectly links levels of that substance in the food to an effect on the risk of a disease or health-related condition (i.e., when both basic elements of a health claim are present) on a sign or placard, it must comply with the health claims regime.

How the restaurant demonstrates compliance with that regime is a difficult matter. FDA recognizes that, as detailed hi the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels that result from seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making health claims or to prevent the agency from being able to assure consumers that the health claims that are made for restaurant foods are valid. Because of the nature of the difficulties, however, FDA is providing in § 101.14(d)(2)(vii)(B) that a restaurant food may bear a health claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the regulations for the claim that FDA has established under section 403(r) of the act, and that basis is provided upon request. The difficulties and costs outlined in the comments would make it unfair to require that restaurateur determine whether their food qualifies for a claim in the same manner that a manufacturer of a packaged food makes this determination. By requiring that the restaurateur have a reasonable basis to believe that the food qualifies, the restaurateur, is provided with a readily achievable way to make claims for his or her food, and the consumer is provided with a reasonable assurance that the claim is valid. Thus, if a

restaurateur labels a vegetarian main dish or meal as "heart healthy," he must have a reasonable basis for believing that the product contains less than the disqualifying level for sodium and meets the "low" definitions for fat, saturated fat, and cholesterol.

The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guidelines on nutrition labeling of fruits and vegetables show that meal or main dish is "low fat," "low saturated fat," "low cholesterol," and does not contain a disqualifying level of sodium, and that the method of cooking the meal or main dish would not add fat or any disqualifying nutrient. In addition, the restaurateur could show that he or she used a reliable cookbook that gave values for fat, saturated fat, sodium, and cholesterol in the finished food that met FDA's requirements for making the health claim. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients, inappropriate substitutions of ingredients), FDA will consider this use to be a reasonable basis for believing that the food meets the qualifying and disqualifying levels. Upon demand, the restaurateur will be expected to present to appropriate regulatory officials Information on the pertinent nutrient levels in the foods and the basis on which these levels were determined. A determination will then be made as to whether the basis of calculation reasonably supports the restaurateur's use of a permitted health claim. FDA believes that the reasonable basis approach will make it practicable for all restaurants, including those that are very small businesses, to provide consumers with better information on more healthful dietary choices for the foods that they offer for sale.

Further, this reasonable basis approach for making a health claim will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that claims made for restaurant-type foods are truthful and not misleading and in accordance with FDA regulations. While health claims used in restaurants are under FDA's jurisdiction, the agency does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that State and local authorities may enforce section 403(r) of the act in Federal court.

While restaurants, and particularly small restaurants, have nominally been subject to FDA's existing nutrition labeling regulation (see § 101.10), they have, as a practical matter, not been required to comply with these regulations or with State or local regulations that focused on the nutrient content of the food. Thus, the efforts that will be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with the health claims requirements will be significant. These efforts will place particularly great demands on the resources of the small business segment of the industry, that is, restaurant firms that have ten or less individual restaurant establishments (Ref. 37). FDA will refer to this segment of the industry as "small restaurants."

Small restaurants generally do not have the established nutrition support component that larger restaurant chains have. Thus, it will be more difficult for small restaurants to determine how to adapt health claims information to their food preparation methods. In addition, it is likely that they will not be as aware of available information sources, like nutrient content data bases, as large chains. Moreover, because of resource limitations, a small restaurant is not as likely as a large restaurant chain to be familiar with Federal requirements. Thus, small restaurants will have to become familiar with not only FDA's requirements, but with available FDA information, like the nutrient content information that FDA published in conjunction with its regulation on the voluntary labeling of raw fruits and vegetables (56 FR 60880, November 27, 1991).

Because of the great initial demands that small restaurants will find if they wish to make claims, FDA has decided that they should be given additional time to come into compliance with these regulations. Without additional time for the reasons discussed above, small restaurants will be place at a disadvantage with respect to their ability to make claims. As a result, they may decide not to even attempt to provide useful nutrition information to consumers about the foods they serve. To provide for equitable implementation of these requirements for small restaurants, FDA has decided to not make part 101 effective with respect to such establishments until May, 1994.

While the statute will be in effect during that period, FDA will not enforce the statute's health claim requirements in small restaurants until the regulations are effective. Although state action is not preempted under section 403A(a)(5) of the act until Federal regulations are effective, the agency expects that states will refrain from enforcing any health claim requirements in small restaurants until the Federal regulations are effective for those restaurants.

FDA believes that this action is fully consistent with the 1990 amendments and with the act. The 1990 amendments impose no date by which the agency's regulations must be effective, only when they must be promulgated (see sections 3 and 10 of the 1990 amendments). Moreover, FDA believes that this action will facilitate effective enforcement of the act. FDA believes that the agency's and State resources can best be used during this initial period, in educating small restaurants about the requirements of the law and by developing a better understanding of the unique practical circumstances of small restaurants in complying with health claims labeling requirements. Moreover, during this period, there will be an opportunity for interested persons to develop new data bases that will help facilitate the provision of nutrition information on foods sold in restaurants and particularly in small restaurants.

As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating health claims in restaurants. As the comment's have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to health claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention. The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. State's remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for health claims on restaurant foods, FDA does not consider the problem of restaurant

food to be solved. It is possible that there are other health claim criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, restaurant foods as compared to packaged foods. If so, different criteria for use of health claims in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how health claims are used on restaurant foods, and whether such claims are appropriate. For example, with FDA's cooperation, the National Restaurant Association, has undertaken a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for health claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of currently existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found lo be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods, FDA regulations state that, for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared and for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims verification based on nutrient levels from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

80. Some comments cautioned that any adopted health claims provisions applied to restaurants must be flexible in format and content. These comments asserted that the distinct differences between the delivery systems of restaurant foods and packaged retail products must be factored into the regulations if they are to apply to restaurant foods, as most consumers select and purchase their food before ever seeing it or its container. Other comments asserted that the impracticality of compliance with the current inflexible health claims regulations would tempt restaurant operators to simply choose not to promote healthful menu alternatives.

FDA does not agree that firms should be given special flexibility concerning the content of health claims that appear on restaurant food. FDA believes that section 403(r)(1)(B) and (r)(3)(b)(iii) of the act require that a health claim be complete and consistent with the authorizing regulation. Specific health claims regulations in part 101, subpart E set forth certain mandatory aspects of permitted health claims. Where any mandatory aspect of a health claim is absent, the claim will be misleading, and the agency cannot sanction such a situation.

With respect to format, FDA believes that there is already ample flexibility in the rules that it is adopting. For example, new § 101.14(d)(2)(iv) permits full health claims to appear on any part of a food's labeling, including a sign or a placard. Accordingly, labeling listing 20 items, 3 of which qualify for the fat-cardiovascular disease claim, could carry the full health claim next to each of the 3 qualifying items. Alternately, it could list the names of the three items in a distinct area, such as a box or section, and print the full health claim once within that area.

New § 101.14(d)(2)(iv) also provides for the use of a short referral statement that directs the consumers' attention to another part of the food's label or labeling where the full health claim appears. Therefore, in the example above, the message "See ———— for details concerning the relationship between fat and cancer" could appear next to each of the items or in the box, with the full health claim printed only once in the label or in the labeling location identified in the blank. For example, the labeling could be in the form of placards placed in full view of the consumer, flyers made available to the public, and other such items. The agency cautions, however, that the referral statement must clearly be associated only with the item or items that qualify for the health claim, and that the location of the full health claim must not be such that it is likely to be associated with a product that does not qualify for the claim.

2. Nutrition labeling on restaurant foods making health claims

81. Many comments asserted that the cost of providing nutrient content information for restaurant foods making health claims would be unreasonable. Some comments that opposed any form of mandatory labeling requirements offered ways in which FDA could minimize the financial burden on restaurants, if any such regulations were in fact adopted. Many of these comments proposed that only fixed items should be required to bear nutrition labeling, thus exempting items such as daily specials, test products, local optional items, promotional items, and all items in restaurants for limited periods of time. Some comments asserted that FDA should permit the use of various data bases, including computer reference bases, for the determination of a food's nutrient content. Other comments suggested that only chains should be required to furnish nutrition labeling for their foods. Other comments suggested that any restaurant with profits of below $50,000 be exempted from any nutrition labeling requirements. However, comments from larger restaurant chains argued that any nutrition labeling requirements should be applied equitably to the restaurant industry as a whole, because a selective application of the regulations could place major chains at an economic disadvantage.

FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general requirements proposal (56 FR 60553). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make health claims to adhere to the requirements for such claims including nutrition labeling. Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal for nutrient content claims (56 FR 60427),

the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, fit this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable health-related characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a health claim is made for restaurant foods. The agency is adopting a somewhat different approach to the provision of nutrient information to the consumer, as explained below.

FDA believes that consumers should have information about the nutrient content of restaurant foods on which health claims are based. The agency has therefore established alternative nutrition labeling provisions for restaurant food in new § 101.14.(d)(3) providing for such information in lieu of full nutrition labeling. For example, if a meal is characterized as being "heart healthy," the restaurateur should be able to provide consumers with information about the level of the nutrients that provide the basis for the claim. Therefore, the agency will require that if a restaurateur makes a health claim for a meal, he or she must be prepared to advise the consumer about the information that provides the reasonable basis for believing that the food complies with FDA's requirements for the claim (e.g., nutrient levels from data bases, cookbooks, or analyses). For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.

82. Many comments asserted that if restaurants are required to provide nutrition labeling, they should be afforded significant flexibility in determining where to present the required nutrient information. Some comments pointed out that restaurant food frequently is not packaged, and that, when it is packaged, the packaging is frequently too small to physically accommodate nutrition information. Other comments stated that much of the labeling used in restaurants is too small to physically accommodate nutrition information for all of the products which could potentially bear health claims. Some suggested that flyers, leaflets, and other printed handouts are acceptable places for such information to appear. Others suggested that all such information should be allowed to appear in a fixed location, such as in a wall display. Others suggested that tray liners be allowed to provide the nutrition information in fast food restaurants.

FDA agrees that restaurants do need significant flexibility in determining where to present the required nutrient information. Accordingly, the agency has revised the nutrition labeling provision in new § 101.14 (d)(3) to provide that restaurants may provide nutrition labeling information through conformance with the provisions of § 101.9 or § 101.10, as appropriate. (In response to the DS Act, FDA has removed the reference to § 101.36 in this regulation.) As explained in the next comment, § 101.10 has been revised to convey considerable flexibility for nutrition labeling for restaurants.

83. Many comments contended that in view of the above mentioned problems outlined in the foregoing comments, any regulations regarding health claims on restaurant foods should be promulgated under a separate rulemaking more tailored to the unique nature of the restaurant industry's needs. A number of comments asserted that existing nutrition labeling provisions pertaining to restaurants in § 101.10 are outdated by the application of the proposed health claim regulations to restaurant foods and suggested that those provisions be revoked or modified accordingly.

FDA has determined that § 101.10 should not be deleted. Rather this section is being revised to reflect the agency 's determinations with respect to the need for a reasonable basis for believing that the food complies with the qualifying and disqualifying levels and with respect to the provision of information to the consumer. The revision of new § 101.10 has been addressed in the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**.

3. Other restaurant issues

84. One comment suggested that FDA develop educational materials that explain the obligations of restaurateurs relevant to health claims, and that FDA offer alternative, nonmisleading ways in which restaurants might communicate health-related information. The comment noted that the 1990 amendments called for FDA to educate the public about the regulations adopted under them.

Section 2(c) of the 1990 amendments directs the Secretary to carry out activities to educate consumers about the availability of nutrition information in the label or labeling of food and the importance of that information in maintaining healthy dietary practices. While the language of the act does not specifically direct FDA to develop educational materials for industry segments, the agency intends to work with industry, particularly trade associations and small restaurants, so that all parties; (e.g., consumers, industry, and State/local regulators) understand the regulations and their obligations and rights under them. Further, FDA believes that the preamble to this document clearly defines those obligations and rights and thus should give the restaurant industry much of the guidance it needs. Where an issue is not resolved in the preamble to the full understanding of a restaurateur, the agency invites correspondence on the specific matters that are unclear.

VI. Prohibited Health Claims

A. Claims not Authorized by FDA

The provisions of new § 101.14(e)(1) and (e)(2) prohibit on a food label or in labeling any claim that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition unless: (1) The claim is health claim specifically provided for in part 101, subpart E; and (2) the claim conforms to all general provisions of new § 101.14 as well as to all specific provisions in the appropriate section of part 101, subpart E. These provisions embody the statutory restriction in section 403(r)(1)(B) of the act that directs that a food shall be deemed misbranded if a health claim is made in its label or labeling unless the claim is made in accordance with section 403(r)(3), which make such claims subject to the requirements adopted by the Secretary (and FDA, by delegation) by regulation. (Section 403(r)(1)(B) of the act also references section 403(r)(5)(D). However, action on that section is deferred based on the moratorium established by the DS Act).

85. Numerous comments voiced support for or opposition to the proposal to prohibit unauthorized health claims.

FDA has adopted new § 101.14(e)(1) and (e)(2) as proposed under section 403(r)(1)(B) and (r)(3) of the act. Because these regulations respond directly to the language of the act, FDA is constrained to adopt them.

B. Disqualifying Levels Exceeded

New § 101.14(e)(3) requires that none of the disqualifying levels identified in new § 101.14(a)(5) be exceeded in a food that bears a health claim, unless specific alternative levels have been established for the substance in part 101, subpart E, or unless FDA has by regulation

permitted such a claim based on a finding that such a claim will assist consumers in maintaining healthy dietary practices. If FDA makes such an exception, the label of the food will have to bear a statement in immediate proximity to the claim that refers the consumer to the nutrition label for information about the nutrient that exceeds the disqualifying level. This statement must be made in a manner that complies with proposed §101.13(h).

FDA received numerous comments on its proposed disqualifying levels. Some comments voiced unsubstantiated support or disapproval for the proposals, while others offered substantive arguments for their positions. These comments are discussed in section II.G. of this document (see comments 23 through 42 of this document).

C. Inappropriate Levels of Other Substances

New § 101.14(e)(4) will prohibit claims for any food where a substance, other than one for which a disqualifying nutrient level is established, is present at an inappropriate level as determined in the specific provision authorizing the claim in part 101, subpart E. In the preamble to the proposed regulations, the agency .explained that this provision will prevent health claims from appearing on foods that contain substances other than the substance that is the subject of the claim if any of those other substances, although not harmful in their own right, could interfere with the claimed effect on the risk of disease. For example, foods containing phosphorus in equal or greater proportion to calcium would not be eligible to bear the calcium-osteoporosis health claim, because diets high in phosphorus and relatively low in calcium result in osteoporosis in experimental animals.

FDA did not receive any comments on this proposed regulation. However, the agency did receive several comments that suggested that disqualifying levels be set for minimum nutrient content, sugars, saccharin, food colors, and various other food additives. These comments are discussed in section II.G.3. of this document (see comments 25 and 26 of this document) and further in this section in response to comment 87 of this document.

D. Infant foods

Proposed § 101.14(e)(5) provided that no food may bear a health claim if it is represented or purports to be for infants and toddlers less than 2 years of age.

86. One comment questioned the prohibition of health claims on foods promoted for use by infants and toddlers. The comment asserted that claims for all infant formulas, including those formulas that are not subject to the requirements of section 412(h) of the act (i.e., "nonexempt" infant formulas). were meant by Congress to be regulated solely under section 412. More specifically, the comment contended that the agency has already successfully used the premarket notification process of section 412(d) of the act to obtain substantiation of claims from manufacturers of both exempt and nonexempt infant formulas. Further, the comment asserted that the notification process provides the agency adequate oversight of claims for all infant formulas, in keeping with the intent of the requirements for health claims in the 1990 amendments, without impeding product innovation or denying access to product information. Accordingly, the comment recommended deleting proposed § 101.14(e)(5) and revising proposed § 101.14(f)(1) to exclude nonexempt infant formulas, in addition to exempt formulas from the requirements in that section for health claims.

Another comment viewed a total ban of infant food health claims as an abridgement of commercial free speech protected by the First Amendment. The comment suggested that a more acceptable approach would be to require explanatory information to accompany such claims in order to eliminate any consumer misconceptions.

Although section 403(r)(5)(A) of the act excludes exempt infant formulas from the requirements in section 403(r) for health claims, the 1990 amendments are silent on the applicability of section 403(r) to health claims for nonexempt infant formulas. Thus, health claims on such products are subject to the requirements of section 403(r) of the act. However, in the proposal on general requirements for health claims, FDA pointed out that it had received a letter from the American Academy of Pediatrics that expressed concern that a health claim directed to adults may be inappropriate or harmful to infants and young children (56 FR 60537 at 60556). The letter pointed out that where health claims primarily embody dietary recommendations for the adult U.S. population to reduce the risk of chronic, degenerative diseases, such recommendations are not meant to apply to infants and young children. "Nutrition and Your Health—Dietary Guidelines for Americans" (Ref. 7) states, for example, that the guidelines are "advice for healthy Americans ages 2 years and over—not for younger children and infants, whose dietary needs differ." Accordingly, the agency proposed in § 101.14(e)(5) to prohibit a health claim in labeling of a food represented or purported to be for infants or children less than 2 years of age. The proposed prohibition would have applied to nonexempt infant formulas.

In view of the concerns expressed by the comments, FDA has reconsidered the propriety of health claims on infant food. The agency now believes that the proposed prohibition on infant and toddler foods may have been overbroad. Although health claims based on current dietary recommendations for Americans do not include infants and toddlers, FDA believes that Congress did not intend to limit health claims to only the adult population or to diseases affecting only that population. Thus, the agency cannot discount the possibility that, in the future, information may be developed to support a claim appropriate for infants and young children on the relationship between a substance and a disease or health-related condition. A claim that characterizes this substance-disease relationship would meet the definition for a health claim and thus be subject to the requirements of section 403 (r) of the act. The agency has therefore revised new § 101.14(e)(5) to provide for exceptions from the prohibition of infant and toddler health claims when a regulation has been established in part 101, subpart E.

However, the agency has the option, and believes that it may be more prudent, to regulate claims for infant and toddler foods under sections 403(j) and 411(c) of the act, which deal with foods for special dietary use. Thus, should the agency receive a petition that appears to justify a health claim directed to infants and toddlers under section 403(r) of the act, it will decide how best to proceed to authorize the inclusion of the information in the food label.

The agency disagrees with the contention that health claims for nonexempt, as well as exempt, infant formulas should be exempt from section 403 (r) of the act and be subject only to the requirements of section 412 of the act. Congress specifically chose to exclude only exempt infant formulas from section 403(r) of the act. Section 412 of the act, although specific to infant formulas, does not exclude such formulas from requirements that are based on other parts of the act. Hence, a labeling claim for an exempt or nonexempt infant formula may be found to misbrand the product under section

403(a) or (j) of the act. In addition, a claim for a nonexempt formula, but not an exempt formula, may also be subject to section 403(r) of the act.

Although the agency has reviewed Manufacturers' claims to ensure their validity for both exempt and nonexempt infant formulas in premarket notifications submitted in compliance with section 412 of the act, the agency's conclusions were based on compliance with all applicable sections of the act, not just section 412. The agency is obliged to administer the act as a whole. Because section. 412 of the act is not the only section governing labeling for infant formulas (see section 412(e)(1)(B)), the agency must reject the comment's recommendation that health claims requirements in proposed § 101.14 not apply to nonexempt infant formulas.

In light of the agency's conclusion that it will consider health claims for infant and toddler foods, where appropriate, and will establish specific regulations providing for their use, the constitutional issue of a ban on health claims for such foods is now moot. New § 101.14(e)(5) has been revised to prohibit only those claims on infant and toddler foods that are not specifically provided for in part 101, subpart E. Comments that have raised constitutional questions will be dealt with at length later in this document.

E. Additional Limits on Health Claims

87. Some comments urged the agency to allow health claims only on foods that are consistent with dietary guidelines. A number of these comments suggested that this could be done by prohibiting health claims on foods with insignificant amounts of all nutrients required on the label (e.g., coffee), as well as on candies, soft drinks, and other snack foods characterized as not being recognized as part of a sound dietary pattern. However, comments from the snack food industry protested such limitations on health claims and maintained that any food that provides a "high" (or "low") level of a nutrient without exceeding the disqualifying levels for fat, saturated fat, cholesterol, and sodium can be consumed within the framework of a healthy diet and should be allowed to bear health claims.

FDA is not persuaded that a prohibition from bearing a health claim based on a food's categorization or characteristic use—such as a snack food—is in keeping with the intent of the statute. The House Report (Ref. 1) contains an example intended to illustrate the Secretary option to decide whether to grant an exception from a disqualifying nutrient level in the context of the total daily diet. The example compares a frozen dinner with a snack food, both with a particular level of fat, and suggests that the frozen dinner may be considered sufficiently more significant in the total daily diet than the snack food. Implicit in this example, however, is a recognition by Congress that snack foods would be able to bear health claims if they did not contain a level of a nutrient that exceeds the disqualifying level. Thus, the agency concludes that Congress did not intend that snack foods or other foods that could be in general use in the diet should be subject to a per se prohibition on bearing a health claim.

However, as FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish provisions of health claims regulations by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus, FDA finds merit in the suggestion that foods bearing health claims should be those consistent with dietary guidelines, find that the value of health claims should not be trivialized or compromised by their use on foods of little or no nutritional value. The agency, therefore, agrees that the final rule should be modified in some way to more fully assure consistency with dietary guidelines.

Dietary guidelines do stress the importance of selecting foods so that dietary sources of calories are coupled with sources of nutrients. FDA specifically notes that "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7) states that foods that supply calories but are limited in nutrients should be used in moderation. Furthermore, the recommendations provided in "USDA's Food Guide Pyramid" (Ref. 29) expand on this approach to food selection. Given the requirement in section 403(r)(3)(B)(iii) of the act that states that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet, FDA concludes that it is appropriate to provide a basis for health claims that takes into account the nutritional contribution of the food beyond its role as a source of calories. Without such a criterion, foods that are not compatible with dietary guidelines could bear health claims. The claim would promote the consumption of the food but would fail to set the food in its proper dietary context. In addition to being inconsistent, with section 403(r) of the act, claims intended to promote the consumption of a food that is incompatible with dietary guidelines would be misleading to consumers and, thereby, be in violation of section 403(a). Such claims would be misleading because consumers would be purchasing the food, in part, to achieve a more healthful diet. However, foods inconsistent with dietary guidelines should not be associated with the more healthful diets recommended by Federal agencies that are mentioned above.

Therefore, in addition to the requirements m new § 101.14(d)(vi) and (d)(vii) for content in a food of a substance that is the subject of a health claim, the agency has developed an approach that would limit health claims to foods that contribute certain nutrients to the diet and, thus, are sources of more than calories. This approach incorporates established levels of significance for nutrients in food and is based on the amounts in foods of certain nutrients required to be listed on the label as part of mandatory nutrition labeling. As such, this approach applies to all foods in conventional food form.

Dietary supplements not in conventional food form are not subject to this requirement. Such supplements are not intended to provide more than nutritive value to the daily diet and make no pretense that they should serve as substitutes for conventional food. As a result it would not be logical to hold such products to criteria designed to assure consistency with dietary guidelines for conventional food. A dietary supplement that meets the qualifying criterion in proposed § 101.14(d)(2)(vii) and does not contain a nutrient at a disqualifying level specified in proposed § 101.14 (a)(5) possesses nutritive value for a health claim irrespective of whether or not it may also provide calories. (FDA is including the exception for dietary supplements in § 101.14(e) because under section 202(b) of the DS Act, the agency can approve claims for such products).

The final rule for mandatory nutrition labeling published elsewhere in this issue of the **Federal Register** requires the listing of 12 nutrients apart from calories as follows: Total fat, saturated fat, cholesterol, total carbohydrates, sugars, fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. As described in that document, FDA concluded that these nutrients are of sufficient public health importance to warrant their inclusion in the nutrition label. Therefore, these same nutrients provide an appropriate basis for a criterion intended to preclude health

claims on foods that do not make a nutritional contribution to the diet and thus ere inconsistent with dietary guidelines. This conclusion is supported by comments that suggested that FDA should establish such a criterion based on the nutrients required in the mandatory listing on the food label.

Of the 12 mandatory nutrients, vitamin A, vitamin C, iron, calcium, protein, and fiber constitute nutrients. for which the levels in foods can serve as a basis for determining a food's nutritional contribution to the overall diet. Total fat, saturated fat, sodium, and sugars are nutrients for which the current recommendations are to limit intake. Therefore, the presence of the latter nutrients in a food would not provide an appropriate basis for measuring the positive contribution of a food to the diet. While total carbohydrates reflects the contribution to the diet of complex carbohydrates, a nutrient for which current recommendations are to increase intake, it also reflects the contribution of sugars for which current recommendations are to limit intake. Therefore, total carbohydrates is not an appropriate component of a nutritional contribution criterion.

The final rule on nutrient content claims published elsewhere in this issue of the **Federal Register** states that a food is a good source of a nutrient when the nutrient is present in the food at a level of 10 percent or more of the label reference value. The agency concludes, therefore, that this defined level is an appropriate basis for a criterion to measure the nutritional contribution of a food. Therefore, assuming that a food meets the definitions prescribed in this final rule for bearing a health claim, the food must also contain one or more of the six nutrients listed above (vitamin A, vitamin C, iron, calcium, protein, or fiber) in an amount at or above 10 percent of the Reference Daily Intake (RDI) or DRV per reference amount customarily consumed for that nutrient, Based on a review of the regulatory food composition data base (Ref. 33), the agency notes that most foods consistent with dietary guidelines meet this criterion.

Furthermore, in order to preclude the fortification of foods solely for the purpose of making a claim, the nutrient or nutrients must not be derived from fortification or other additions to the food. Fortification of a food of little or no nutritional value for the sole purpose of qualifying that food for a health claim is misleading for several reasons. There is great potential to confuse consumers if foods like sugars, soft drinks, and sweet desserts are fortified to qualify for a health claim when, at the same time, dietary guidance as contained in USDA's Food Guide Pyramid (Ref. 29), for example, states that "[T]hese foods provide calories and little else nutritionally. Most people should use them sparingly." Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines. Further, fortifying such foods is not consistent with FDA's fortification policy in § 104.20 that has been in effect for many years. The fundamental objective of FDA's policy on appropriate fortification of foods is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. In the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**, FDA is including a provision requiring that added nutrients must be in compliance with § 104.20 for a food to be eligible to bear the term "more" on its label.

FDA stresses that the exclusion of fortification pertains only to fortification to specifically meet the requirements of this provision and not to fortification of the food itself. Thus, a fortified food including a dietary supplement in conventional food form, may still qualify for a health claim/provided the qualification is not on the basis of that fortification. Accordingly, FDA has added a new § 101.14(e)(6) to require that, except for dietary supplements not in conventional food form, the food shall contain 10 percent or more of the RDI or DRV for vitamin A, vitamin C, iron, calcium, protein, or fiber prior to any nutrient addition.

VII. Exemption of Medical Foods and Exempt Infant Formulas

FDA proposed in § 101.14(f) that medical foods, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), and infant formulas subject to section 412(h) of the act are specifically exempted from requirements for health claims and nutrient content claims. This exemption reflects the exemption in section 403(r)(5)(A) of the act.

FDA received no comments on this aspect of the proposal. Therefore, the agency is adopting this section as proposed.

VIII. Applicability of Health Claims

FDA proposed in §101.14(g) that the requirements for health claims in proposed § 101.14 only apply to foods intended for human consumption that are offered for sale.

FDA received no comments on this aspect of the proposal. Therefore, this section is being adopted by the agency as proposed.

IX. Petitions

A. Agency Review Period

88. One comment asserted that FDA should not establish any health claim petition provisions because citizen petition regulations in § 10.30 (21 CFR 10.303 are adequate to provide for petitions to FDA that request that the agency authorize a health claim.

FDA disagrees with this comment. Section 403(r)(4)(A)(i) of the act establishes unique statutory procedures for the handling of health claim petitions that ere not applicable to the existing citizen petition regulation. The statute has specific timeframes for FDA to evaluate health claim petitions and, unlike the provisions of § 10.30, provides for not releasing the content of a petition if it is denied prior to acceptance for filing. If FDA were to accept health claims petitions in accordance with § 10.30, petitions that the agency denies after its initial 100-day review might be released. Further, FDA believes that a procedural regulation for health claims petitions is necessary so that petitioners will clearly understand what is required, that the agency's review will be conducted on a consistent and equitable basis, and that the grounds for agency action on the petition will be clearly understood.

89. Some comments objected that the timeframes in the petition provisions for FDA assessing the validity of the proposed claim and for issuing a proposed regulation are too rigid. One of these comments suggested that in cases where there is minimal or nonexistent controversy, FDA should streamline the petition approval process. The comment noted that while the statutory filing period gives the agency time to determine whether a proposed claim is valid, that filing period also serves to deprive the public of truthful claims until final approval is granted. The comment suggested that FDA adopt a mechanism to quickly determine whether there is a large consensus among scientists on the validity of a proposed claim and, if so, to shorten the timeframes. However, other comments suggested that longer timeframes are needed so that the agency can review the data and request additional information if needed, after which FDA should allow, modify, or reject the health claim application and notify the applicant.

FDA advises that the agency may not consider longer timeframes for the evaluation of petitions about health claims because the timeframes are specifically established in section 403(r)(4) of the act. These short timeframes do not provide an opportunity for continuing correspondence between the petitioner and FDA. With respect to for shorter timeframes, FDA advises that the agency's ability to meet timeframes is influenced by many factors such as work priorities end availability of personnel. FDA considers the statutory timeframes for assessing the validity of health claims and for issuing a proposed regulation to be extremely short, given the need to evaluate the totality of available scientific evidence on a substance and a disease. Given the agency's limited resources, it would not be practicable to shorten these timeframes further. However, FDA points out that although action on petitions for most claims will require virtually all of the time provided by the statutory timeframes, nothing would prohibit the agency from acting in less time than the timeframes provide if it is possible to do so. Thus, it is likely that a petition for a claim on a well-accepted substance/disease relationship would be reviewed more expeditiously than one for which scientific agreement is not as clear.

90. Some comments recommended that FDA allow new health claims to be used as soon as the proposal issuer instead of waiting until the final regulation becomes effective. One comment asserted that this approach would greatly benefit the public by quickly disseminating truthful health claim information, and that there would be little risk to consumers from consuming additional amounts of a food if the health claim is eventually denied.

The agency advises that there is no basis under the act to provide for the use of proposed health claims. Section 403(r)(1)(B) of the act deems a food misbranded when its label or labeling bears a health claim unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D). Section 403(r)(3) end (r)(5)(D) of the act requires that the health claim be made in accordance with regulations. Proposed rules are not "regulations."

Further, even if FDA had a basis under the act to permit the use of proposed health, claims the agency does not believe that it would be prudent to provide for such use. The comment period following the publication of proposed rules is a critical step in determining whether a proposed regulation is appropriate for adoption. In the instance of health claim regulations, significant information concerning validity of the substance-disease relationship underlying the proposed health claim may be submitted by interested parties during the comment period. In addition, the comment period may bring to light a previously unforeseen potential for the health claim to be misleading to consumers if adopted without modification.

B. Public Disclosure

91. Some comments expressed concern regarding public release of private or propriety data submitted as part of the health claim petition. Other comments agreed with the proposal as written in 101.70(j)(2) on the grounds that allowing the public to scrutinize information submitted in a petition will help ensure that the evidence is scientifically sound and unbiased.

Section 403(r)(3)(B)(i) of the act mandates that the Secretary (and FDA, by delegation) determination as to whether to authorize a health claim be based on the totality of "publicly available evidence." Moreover, section 403(r)(4)(A)(i) of the act provides for not making a petition available to the public only when FDA decides to deny it without filing it. Consequently, FDA does not have authority to withhold this information from public scrutiny and will make all information submitted in support of a health claim publicly available when the petition is filed.

C. Preparation of Model Health Claim

92. One comment objected to the petitioner having to propose model health claims, asserting that the format and wording of model health claims should be the responsibility of FDA. The comment stated that the 1990 amendments did not require the petitioner to prepare model health claims. Another comment, however, endorsed the proposal that a petitioner include a model health claim, because it will promote the public's health.

FDA agrees with the latter comment. Because the petitioner should be one of the parties most knowledgeable about the relevant substance-disease relationship, the agency does not believe that requiring the inclusion of a model health claim will constitute a significant burden on the petitioner. Such a requirement will, however, provide significant benefit by ensuring that the agency can easily and correctly identify what the petitioner believes to be the full substance-disease relationship within the short review timeframes.

D. Summary of Scientific Data

93. Some comments argued that unpublished research findings including proprietary data, should be considered in support of proponed health claims. However, a number of comments disagreed asserting that only data suitable for publication and data already accepted for presentation in a scientific community would be suitable for the substantiation of health claims.

FDA will consider all unpublished findings that are submitted in support of proposed health claims. Although the agency will consider such finding, FDA points out that, as suggested in the legislative history (Ref. 1), the agency may give greater weight to a research report published in a peer-reviewed journal because such reports have been subjected to scientific evaluation before publication. The agency is likely to give greatest weight, however, to research reports of well-conducted, relevant studies regardless of publication status.

E. Denial of Petitions

94. A number of comments stated that if the agency is to deny a petition without filing it, FDA should do so based on a review of the petition as a whole. One comment said that even if the "Preliminary Requirements" section of the petition is inadequate FDA should still examine the "Summary of Scientific Data." The comment stated that if the agency did so, and discussed that review in the denial notice, it would provide the petitioner with some indication as to whether a redrafted petition would be justified. The comment contended that such a procedure would be more efficient in the longrun and presumably would save FDA from having to review repeatedly submitted petitions.

FDA does not believe that it would be prudent to adopt a general policy of conducting exhaustive reviews of petitions that are to be denied because they fail to meet preliminary requirements. The denial of a petition on the grounds that the preliminary requirements are not met would reflect a fundamental problem with the petition. Such problems may take a fair amount of time to remedy. Therefore, to ensure that it uses its resources most effectively and efficiently, FDA will not undertake an evaluation of the scientific validity of a claim unless the preliminary requirements are satisfied.

95. Several comments dealt with the language of the regulation disapproving the health claim. They particularly disapproved of the language. "FDA has

concluded that there is no basis for claims about the following * **." The comments suggested alternate wordings for proposed § 101.71 that would recognize that "although there is considerable interest in these areas, and although new evidence is continually emerging, the data are not yet strong enough to permit approval of health claims for the reasons summarized below." The comments stated that this language should be followed by an enumeration of the disapproved claims together with a short paragraph describing both the strength and the perceived shortcomings of the evidence in each case. This approach would, according to comments, establish an appropriate record of FDA's determination, without unnecessarily damaging any of these active areas of scientific research.

FDA agrees with the comments that there should be some codified record of its consideration of the health claims on which it proposed action, either in response to the 1990 amendments or a petition, but ultimately decided not to authorize. That record is provided by the citation to the final rule denying the health claim that is included in the listing in new § 101.71. The discussion in the preamble to the final rule summarizes the agency's consideration of the claim. Thus, the agency does not believe that paragraphs describing the strengths and shortcomings of the evidence regarding specific health claims are needed in the codified language to "establish an appropriate record of FDA's determinations."

The agency disagrees that a negative decision regarding a particular health claim will be damaging to active areas of scientific research. It is obvious that the extensive literature regarding the complex relationships between substances and diseases and health-related conditions developed without consideration of whether specific health claims on particular foods might be allowed at some time in the future. FDA's denial is just as likely to highlight the matters on which further research is needed as it is to damage the prospects for further research. However, for greater clarity, the agency has revised the statement in new § 101.71 that there is "no basis for claims" to state that there is "not a sufficient basis for claims * * *."

F. Other Petition Issues

96. Another comment urged that FDA Not redelegate to the Director and Deputy Director of CFSAN all the functions of the Commissioner concerning petitions for label claims under section 403(r) of the act that do not involve controversial issues. The comment stated that all petitions that will be submitted to the agency concerning health claims will involve controversial issues that will require a response from the Commissioner.

FDA does not agree. Based on the agency's experience with petitions that have been submitted to FDA for consideration, it is not uncommon for a petition to contain major deficiencies that necessitate denial of the petition. The agency believes that redelegating such functions to the Director and Deputy Director of CFSAN will permit the agency to take the required actions (e.g., denial of a petition) in the most resource efficient manner.

Further, the agency does not agree that it should assume that all petitions submitted under section 403(r) of the act will involve controversial issues. The agency should have the prerogative to take action on a petition in the most resource efficient manner. For example, in the future, it is certainly possible that some substance-disease relationships will become established, and that there will be no controversy about the scientific basis for a claim. If such a situation occurs, the agency should have the flexibility to authorize information about such relationships in food labeling in an efficient manner. Therefore, the agency is retaining the redelegation provision in the final rule.

X. Constitutional Issues

A. The First Amendment

97. Several comments from industry and nonprofit organizations asserted that truth nil information about health and diet consists of speech protected under the First Amendment, and at the very least is protected commercial speech. According to the comments. such truthful information encompassed a wide variety of labeling information ranging from information that FDA classifies as a "health claim" to general information about what food categories should be included in a diet to affect disease that FDA classifies as "dietary guidance." (As explained previously in this preamble, for the sake of clarity in this preamble, references by FDA to "dietary guidance" will refer to claims that do not contain both basic elements of a health claim and are therefore not "health claims.") Comments stated that the commercial speech doctrine recognizes that such speech not only serves the economic interests of the speaker but assists consumers and furthers society's interest in "the fullest possible dissemination of information." Therefore, while such speech is entitled to less protection than other forms of expression, that protection is nonetheless substantial. Several comments cited case law that stated that if the commercial expression at issue is neither false nor misleading, then any regulation restricting it must directly advance the governmental interest asserted and must be no more extensive than necessary to serve that interest. Comments contended that any suggestion that consumers should be screened from truthful information "in their own best interest" is the type of paternalism rejected by the Supreme Court in *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council Inc.*, 425 U.S. 748 (1976), and the concept that the public cannot be trusted to make valid judgments based on truthful information contravenes the basic principles of the First Amendment. Comments asserted that the public interest and, indeed, the public right is in obtaining useful information, and the government's interest is best served by placing no barriers to its free circulation. Another comment specifically requested that FDA clarify how the health claims regulations comply with Supreme Court standards for constitutionally protected civil or commercial speech.

However, other comments stated that the health claim regulations do not violate manufacturers' First Amendment rights, because food labels that are not in compliance with the act are inherently misleading and therefore not entitled to constitutional protection. The comments argued further that, even if a court found that a nonconforming health claim was not misleading, it would uphold these regulations because they are tailored specifically to meet the substantial Government interest of protecting the public.

FDA advises that neither these regulations, nor the act as amended by the 1990 amendments, violate the First Amendment. The act has withstood numerous First Amendment challenges. (See, for example, *United States v. Genera Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977); *United States v. Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419 (D. Idaho 1975); *United States v. 8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626 (W.D.N.Y. 1951).) The 1990 amendments amended the act to permit certain information about the relationship of nutrients in food and disease to appear on a food label without misbranding the food under section 403 of the act or transforming it into a drug under section

201(g)(1)(B) of the act. The regulations implementing these amendments thus permit more information on food labels than has previously been allowed under the act.

Nonetheless, parts of the act and these regulations may have an incidental effect on speech in a narrowly defined area, food labeling. (See *NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 912 (1982).) The Supreme Court, however, "has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech and association." Id. The Government may regulate in areas of economic activity such as securities, antitrust, and labor in ways that affect speech. *SEC v. Wall Street Publishing Institute*, 851 F.2d 365, 372-73 (D.C. Cir. 1988), cert. denied, 489 U.S. 1066 (1989); see also *SEC v. Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (the First Amendment does not remove a business engaged in the communication of information from general laws regulating business practices). The Government "does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity." *Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 456 (1978); see also *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 46 (D.C. Cir. 1977), cert, denied, 434 U.S. 829 (1977) ("[R]ules restricting speech do not necessarily abridge freedom of speech.")

As with securities, labor, and antitrust regulation, the Government exerts extensive regulatory authority over the economic activity surrounding food and its labeling. Yet the regulation of food and food labeling clearly encompasses more than mere economic activity: It protects consumer health and safety in an area where harm to the public can be direct and immediate. (See Ohralik, 436 U.S. at 456.) FDA's crucial role in ensuring that food labels are informative, are not misleading, and do not otherwise misbrand products under the act has long been recognized. (See 79 Congressional Record 4734 (1935), reprinted in "Dunn, Federal Food, Drug, and Cosmetic Act," 280 (1938) (statement of Sen. Copeland) ("No one disputes that the [FDA] should determine the quality of the product; no one disputes that it should determine what is on the label.")] In such an area of extensive Federal regulation, the Government may place restrictions on speech that bears directly on the Government's objectives. *SEC v. Wall Street Publishing Institute*, 851 F.2d at 373. Indeed, regulation of food labeling would be impossible if the Government could not restrict speech. Id.

Thus, when FDA seeks to ensure that food is not misbranded, it may place restrictions on label contents. "Freedom of Speech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act." *United States v. Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975). "[C]ertain speech in a certain limited context" becomes part of the labeling of a product and may serve as evidence of a violation of the act. *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986). Thus, the seizure and condemnation of a book that misbrands a product is not a violation of the First Amendment, even though in another context the book might be protected. (See *United States v. 8 Cartons, Containing Plantation The Original etc, Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States v. Article of Drug*, 32 F.R.D. 32 (S.D. Ill. 1963).) "It is the product and the manner in which the product is marketed which is said to be illegal," rather than the speech itself. *General Nutrition*, 638 F. Supp. at 562. A prohibition on selling a misbranded product restrains the violative act of selling, not speech itself. *KeIlogg Co. v Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex. 1991) (construing Texas food and drug law). "The substantial government interest in the goals of the Act justif[ies] this extremely narrow encroachment" on speech. *General Nutrition*, 638 F. Supp. at 562. Indeed, where certain claims misbrand a product, "[a] requirement that the claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product." Kellogg, 763 F. Supp. at 1381.

With the provisions of the 1990 amendments that govern health claims, Congress sought to "permit health claims but only health claims based on scientifically valid information." (statement of Rep. Waxman; Ref. 4). In order to assist consumers improving their eating habits, Congress devised a scheme to permit certain claims not previously allowed under the act. Under this scheme, only those claims that FDA finds to be "supported by science" are permitted, (statement of Rep. Waxman; Ref. 3), and a food that bears an unapproved health claim is misbranded. Because FDA case law makes clear that a label statement that misbrands a food product is not subject to First Amendment protection, an unapproved health claim on a food label would not be protected speech. (See *United States v. General Nutrition, Inc.*, 638 F. Supp. 556 (W.D.N.Y 1986); *United States v. Articles of Food * * * Clover Club Potato Chips*. 67 F.R.D 419 (D. Idaho 1975); *United States v. 8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626 (W.D.N.Y. 1951); *United States v. Article of Drug*, 32 F.R.D. 32 (S.D. Ill.1963).)

Congress considered the use of "unfounded" health claims on the food label to be harmful to the public (statement of Rep. Waxman; Ref. 3); cf. *Ohralik*, 436 U.S. at 456 ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity.") Congress dealt with this problem by Drafting a system to permit certain useful information to appear on the food label, while ensuring that the information is scientifically valid and not misleading (statement of Rep. Waxman; Ref. 4). Congress considered these restrictions on speech necessary to further the Government's interest in ensuring the scientific validity of health claims on the food label. The Government's action in regulating the food label does not offend the First Amendment simply because speech is involved. *Ohralik*, 436 U.S, at 456. The case law establishes that FDA's power to regulate the food label derives from its broad regulatory powers over food, and these regulations are valid under the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity. (See *SEC v. Wall Street Publishing Institute*, 851 F.2d at 372-73; see also *Dun & Bradstreet, Inc. v. Greenmoss Builders*, 472 U.S. 749, 785 n.5 (1985); *Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 456 (1978).)

Many comments argued that labeling is commercial speech, and that restrictions placed on it must pass the tests enunciated by the Supreme Court in cases involving commercial speech. Unlike "advertising pure and simple," labeling does not fall clearly within the bounds of commercial speech. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985). The agency does not consider it necessary for its First Amendment analysis to determine whether or not food labeling fits the definition of commercial speech. (See *SEC v. Wall Street Publishing Institute*, 851 F.2d at 3723. Rather, the agency considers labeling on foods to form "a distinct category of communications in which the governments power to regulate is at least as broad as with respect to the general rubric of commercial speech." *SEC v. Wall Street Publishing Institute*, 851 F.2d at 373.

Recognizing, however, that at least one court has categorized labeling as commercial speech. *General Nutrition*, 638 F. Supp. at 582. FDA agrees that labeling should certainly be considered closer to commercial speech than to "pure" speech.

Even if labeling is analyzed as commercial speech, however, these regulations do not violate the First Amendment. First, speech that is Inherently misleading is not protected and may be prohibited. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 553-64 (1980). Secondly, speech that is only potentially misleading may be restricted, so long as the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest Id. at 566. These regulations govern speech that is inherently misleading, health claims on the food label. However, even if such claims are considered to be only potentially misleading, the regulations pass the test enunciated in *Central Hudson*.

Commercial speech receives only limited protection under the First Amendment, (See, for example, *Bolger v. Youngs Drug Products Corp*., 463 U.S. 60, 64-65 (1983).) For commercial speech to be protected, it must concern lawful activity and not be misleading. *Central Hudson*, 447 U.S. at 563 through 564. The Supreme Court has recognized that restrictions on commercial speech may be appropriate to prevent deception. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. at 771 n.24. These regulations will have the effect of ensuring that the health claims that appear in food labeling are scientifically valid and not misleading. (See *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C.Cir. 1977)) (FDA regulation constituted the agency's conclusion "that labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act," and as such it did not violate the First Amendment).

The Supreme Court has labeled as misleading—and thus not protected—both speech that is inherently likely to deceive and that "experience has proved * * * is subject to abuse." In re R.M.J., 455 U.S. 191, 203 (1982). For example, in Friedman v. Rogers, 440 U.S. 1,14-15 (1979), the Court held that Texas could prohibit the use of trade names by optometrists where there was a history of deception and abuse of the public. See also *Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 468 (1978) (upholding state bar's rules against ill-person solicitation where there was an inherent potential for abuse and prophylactic regulation was needed).

By enacting the 1990 amendments, Congress sought to ensure that health claims would be scientifically valid and not misleading. (See, for example, statement of Rep. Madigan, and statement of Rep. Waxman, Ref. 4). Experience had shown that many "unfounded" health claims were being used on foods (statement of Rep. Waxman; Ref. 3). Congress recognized the "great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims." Id. (statement of House floor managers).

In response to the high potential for health claims to be misleading, Congress legislated that any claim that is not consistent with FDA regulations will misbrand a food. Section 403(r)(1)(B) of the act states that a food is misbranded if its label or labeling contains a claim that "expressly or by implication * * * characterizes the relationship of any nutrient * * * of the food to a disease or a health-related condition *unless* the claim compiles with regulations promulgated by FDA. § 403(r)(1)(B)" (emphasis added). By taking this approach, Congress chose to permit only those health claims on food that FDA determines to be scientifically valid, effectively recognizing that health claims are so potentially misleading as to be inherently misleading.

Indeed, particular attributes of health claims on the food label make them inherently misleading. Because health claims are of great importance to the public, they have a great potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce consumer purchases may take on increased importance in the mind of the public and thus be more likely to mislead. *FTC v. Pharmtech Research, Inc.*, 576 F. Supp. 294, 301 (D.D.C. 1983) (advertisements for food supplement were misleading where they '"played on the average consumer 's well-founded fear of cancer"). A health claim on a food label is the type of information that a consumer would have difficulty verifying independently. *American Home Products v. FTC*, 695 F.2d 681, 698 (3d Cir. 1982); cf. *Peel v. Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 110 S. Ct 2281, 2288 (1990) (a lawyers certification is a "verifiable fact"). Consumers place great reliance on the portions of the food label that they believe to be regulated by the Government (Ref. 36). Unapproved health claims that consumers assume to be consistent with government regulations are therefore more likely to be misleading. "Pervasive government regulation * * * and consumer expectations about such regulation, create a climate in which questionable claims * * * have all the more power to mislead." *American Home Products v. FTC*, 695 F.2d at 697.

Even if health claims are considered only potentially misleading, rather than actually or inherently misleading, these regulations are constitutional. The government may place restrictions on commercial speech that is merely potentially misleading. Such restrictions roust directly advance a substantial governmental interest and be no more extensive than necessary to serve that interest. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). These regulations pass that test.

First, the government's interest is clearly substantial. The 1990 amendments and these regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, understandable, and not misleading. This information will enable consumers to make more healthful food choices. The Supreme Court has recognized "the health, safety, and welfare of * * * citizens" as a substantial government interest. *Posadas de Puerto Rico Associates v. Tourism Co*., 478 U.S. 328, 341 (1986). Moreover, consumers have a First Amendment interest in obtaining information on which to base a decision whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." *National Commission on Egg Nutrition v. FTC* 570 F.2d 157, 162 (7th Cir. 1977). cert. Denied, 439 U.S. 821 (1978) "The fact that health is involved enhances the interests of both consumers and the public in being assured that the stream of commercial information flow clearly as well as freely." Id. (*citing Virginia State Board of Pharmacy*, 425 U.S. at 772): *American Home Products*, 695 F.2d 681, 714. Moreover, FDA is implementing legislation whose purpose is "essential if the consumer is to obtain reasonable information regarding * * * the foods he buys." *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd 555 F.2d 1059 (D.C. Cir. 1977).

Secondly, the regulations directly advance the government interest. Under the 1990 amendments and these regulations, FDA will assess the relevant scientific evidence on a proposed health claim before permitting that claim to

appear on the food label. In this way, the regulations ensure that health claims are scientifically valid, reliable, understandable, and do not mislead consumers. At the same time, the regulatory scheme encourages the provision of information to consumers that will enable them to improve their diets. There is an "immediate connection" between health claims on food labels, and consumers' food choices. *Central Hudson*, 447 U.S. at 569.

Finally, these regulations are no more extensive than necessary to serve the government interest. Under *Board of Trustees v. Fox*, regulations that are narrowly tailored, to serve the government interest will meet this prong of the *Central Hudson* test. 109 S. Ct. 3028, 3032-35 (1989). Narrow tailoring requires a reasonable fit between regulatory ends and means: "not necessarily the single best disposition but one whose scope is 'in proportion to the interest served.'" Id. at 3035. These regulations reasonably and effectively ensure that health claims on food labels will be scientifically valid, informative, and not misleading. (See *Word v. Rock Against Racism*, 109 S. Ct. 2746. 2757-58 (1989).) Thus they meet the third prong of the *Central Hudson* test, and they do not violate the First Amendment.

98. Some comments maintained that dietary guidance may, in appropriate circumstances, be classified as pure speech entitled to constitutional protection, and that merely because speech is presented in a commercial context does not necessarily categorize it as "commercial speech." Thus, for example, "speech is not rendered commercial by the mere fact that it relates to an advertisement." *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376,384 (1973). Speech is also "not commercial merely because it proposes a transaction or because there is an economic motivation." *Asian American Business Group v. City of Pomona*, 716 F. Supp. 1328, 1330 (C.D.Cal. 1989) (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983)). The consensus of the comments was to conclude that where a manufacturer, either on a label or in package inserts or accompanying brochures, accurately summarizes dietary guidance promulgated by some public health body or medical institution, that message should be treated as noncommercial speech deserving full protection under the First Amendment, and that the such messages are not solely the product of economic motivation.

FDA believes that its approach to dietary guidance, as discussed above, does not raise First Amendment. concerns. Dietary guidance on labeling will be considered to fall outside the coverage of section 403(r)(1)(B) of the act, although it would remain subject to other provisions of the act (e.g., sections 403(a) and 201(n) of the act).

FDA disagrees with the comments that argue that certain dietary guidance—e.g., label summaries of information promulgated by a public health body—should be considered pure, noncommercial speech. To the extent that it may be necessary to categorize these statements, FDA believes they should be considered commercial speech. Labeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would "propose" such a transaction, (See *Bolger, Youngs Drug Products*, 463 U.S. 60, 66, 103 S. Ct. 2875, 2880 (1983); *Central Hudson Gas v. Public Service Commission*, 447 U.S. 557, 562 n.5,100 S. Ct 2343, 2349 n.5 (1980).) A label is not entitled to the protection due noncommercial speech simply because it contains a discussion of an issue of broad public interest. *Board of Trustees v. Fox*, 109 S. Ct. 3028, 3032 (1989); *Bolger*, 463 U.S. at 68, 103 S. Ct at 2881; *Central Hudson*, 447 U.S. at 562 n.5, 100 S. Ct. at 2349 n.5. Nor is dietary guidance that discusses a product generically, rather than by specific name, exempt from categorization as commercial speech. *Bolger*, 463 U.S. at 66 n.l3, 103 S. Ct at 2880 n.13. And in determining whether the statements on a label are pure speech, it is irrelevant that they might be considered protected in other contexts. (*See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 637 n.7, 105 S. Ct 2265, 2274 n.7 (1985).) Just as informational pamphlets were considered commercial speech in *Bolger*, so too dietary guidance on food labels should be considered commercial speech. (See *Bolger*, 463 U.S. at 66-68, 103 S. Ct. at 2880-81.)

99. Some comments suggested that the proposed regulations were in conflict with the First Amendment because it protects manufacturers from burdensome and unnecessary labeling requirements.

FDA disagrees with the comments' assertion that the agency is imposing unduly burdensome and unnecessary labeling requirements. Nothing in the regulations goes beyond the statutory requirements imposed by the 1990 amendments. In formulating those regulations, the agency has attempted to reach a reasonable balance between the interest in making information available about the relationship between diet and disease and the Interest in ensuring that this information is scientifically valid. The regulations are narrowly tailored to serve a significant governmental interest and do not violate the First Amendment.

100. A number of comments recommended that foods exceeding a disqualifying nutrient level be allowed to bear an approved health claim if they also bear a statement disclosing the level of the disqualifying nutrient. Comments contended that the legislative history of the 1990 amendments clearly establishes Congress' intent to require increased information and disclosure on food labels, and that section 403(r)(3)(A)(ii) of the act is consistent with this approach. Some comments argued that this procedure is consistent with the public's "right to know" and the manufacturers' First Amendment rights to present consumers with information that is truthful and not misleading. Most maintained that the First Amendment principles discussed under the Preliminary Health Claims and Dietary Guidance sections also prohibit FDA from using disqualifying levels to ban health claims on products.

FDA agrees that section 403(r)(3)(A)(ii) of the act gives it the ability, to permit approved health claims on foods exceeding a disqualifying nutrient level if they bear a statement disclosing the level of the disqualifying nutrient. The agency "may by regulation permit. * * * a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices" (section 403(r)(3)(A)(ii)of the act).

FDA disagrees, however, with the Implication expressed by the comments that it should permit approved health claims for all foods exceeding a disqualifying nutrient level if their labels disclose the level, of the disqualifying nutrient. The agency will permit such claims on a case-by-case basis, when it finds that a claim would assist consumers in maintaining healthy dietary practices. Reading the statute to mandate disclosure rather than disqualification would ignore the terms of the statute and would be inconsistent with Congresses intent. When the bill that became the 1990 amendments was reported, out of committee in the House, the prohibition in section 403(r)(3)(A)(ii) of the act on health claims was on food, containing "any nutrient, in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food

in the total daily diet." H. Rept. 538, 101st Cong., 2d sess. 5 (1990). Subsequently, while the bill was awaiting passage in the House, language was added to section 403(r)(3)(A)(ii) of the act permitting the agency to exempt certain foods from the prohibition (statement of Rep. Waxman; Ref. 4). Had Congress chosen to require disclosure rather than disqualification in all cases, it could have done so explicitly rather than providing for exceptions to the general rule.

In its proposal, the agency noted that "a health claim on a food label is a promise to consumers that including the food in a diet, along with other dietary modifications, will be helpful in attaining the claimed benefit and will not introduce a risk of another disease or health-related condition" (56 FR 60537 at 60544). Including a health claim on the label of a food that contains unhealthful levels of nutrients would be misleading, and the First Amendment permits the government to ban misleading speech. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). FDA recognizes that the Supreme Court has expressed a preference for disclaimers or explanations over prohibitions in the context of commercial speech that is merely potentially misleading. In re R.M.J., 455 U.S. 191, 203 (1982). Nothing in these regulations is inconsistent with that approach. Section 403(r)(3)(A)(ii) of the act specifically permits the agency to allow disclosure instead of disqualification where a claim "would assist consumers in maintaining healthy dietary practices." In situations where the government's substantial interest in improving dietary practices would be promoted by permitting disclosure rather than disqualification, and where disclosure would ensure that the health claim was not misleading, FDA will permit disclosure instead of disqualification.

101. Several comments asserted that the First Amendment allows manufacturers to place preliminary health-related statements on labeling as long as those statements are properly qualified. In support of this position, comments cited a series of opinions in *FTC v. National Comm'n on Egg Nutrition*, 517 F.2d 485 (7th dr. 1975), appeal after remand, 570 F.2d 157 (7th-Cir. 1977), cert. denied, 483 U.S. 921 (1978). The comments noted that in affirming the grant of a preliminary injunction, the Seventh Circuit held that the Commission could not "prohibit NCEN from stating that there is scientific evidence supporting the theory that dietary cholesterol intake is not unhealthy, provided that it also states that there is substantial contrary evidence." 517 F.2d at 489-490. The comments also noted that the Seventh Circuit struck down an anti-egg warning statement that FTC had asked be mandated in all future advertising, saying that "the First Amendment does not permit a remedy broader than that which is necessary to prevent deception * * * or correct the effects of past deception * * *." The desired preventative effect can be achieved by requiring the disclosure that there is a controversy among the experts and NCEN is presenting its side of that controversy. The additional statement in the form now ordered by FTC should be required only when NCEN chooses to make a representation as to the stats of the available evidence or information concerning the controversy." (570 F.2d at 164)

The comments also cited Court of Appeal decisions that followed the Seventh Circuit in requiring a manufacturer to qualify controversial or preliminary claims with statements that a substantial question exists regarding their scientific validity. Bristol-Myers Co., 102 F.T.C. 21, 294-295 (1983), Enforced, 783 F.2d 554 (2d. Cir. 1894), cert. denied, 459 U.S. 1189 (1985); American Home Prods. Corp., 98 F.T.C. 136, 333 (1981), enforced as modified, 695 F.2d 681 (3d. Cir. 1982). The comments asserted that FDA policy must therefore allow the inclusion of properly disclosed health claims that are based on preliminary or controversial findings, as long as the studies that led to those findings are sufficiently well-designed and well-conducted to garner "significant scientific agreement" about how the findings should be interpreted.

FDA does not agree that there is a First Amendment right to make preliminary claims on the food label, regardless of the statutory constraints imposed by the 1990 amendments. As discussed in greater detail above, FDA does not have the authority to permit preliminary health claims under section 403(r)(1)(B) of the act. The statutory scheme and these regulations that produce this result do not violate the First Amendment.

As explained above, misleading commercial speech is not protected under the First Amendment. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). Health claims have such a high potential to be misleading as to be inherently misleading, as Congress recognized when it chose to permit only those health claims on food that FDA determines to be scientifically valid (section 403(r)(1)(B) of the act). In the context of inherently misleading claims, there is no requirement that explanatory information be permitted to eliminate consumers' misconceptions. (See In re *R.M.J.*, 455 U.S. 191, 203 (1982).)

FDA does not agree that it is bound to follow cases involving FTC's regulation of advertising and to permit labeling that presents one side of a scientific controversy, so long as there is a statement that a controversy exists. Although cases involving FTC may sometimes be relevant, it is important to note that fundamental differences exist between the regulatory schemes administered by the two agencies. (See *Bristol-Myers Co. v. FTC*. 738 F.2d 554, 559 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985).) Congress has long recognized the division of roles between the two agencies. (See 79 Congressional Record 4734 (1935). reprinted in "Dunn, Federal Food, Drug, and Cosmetic Act," 280-281 (1938) (statements of Senators Copeland and Austin) (FTC concentrates on the interests of commerce and economic needs, whereas the objective of FDA is "the health of the people.")) FTC regulates unfair competition and trade practices, including food advertising. (See, for example, 15 U.S.C. sections 45 and 52.) In contrast, FDA is a scientific agency empowered to regulate the food label, among other things. Under section 403(r)(3)(B)(i) of the act, FDA may permit health claims on foods only if it has determined that those claims meet the statutory test for scientific validity. The laws under which FTC operates do not include a comparable statutory standard. Thus, it would not be appropriate for FDA to follow the law involving FTC.

B. Other Amendments

102. Some comments alleged that outlawing brand names that include an unapproved health claim could violate the Fifth Amendment, as brand names reasonably constitute cognizable private party interests, and banning their use could amount to "taking" those interests without just compensation. Comments warned that the courts have frowned upon banning the use of trade names when less drastic measures would eliminate the possibility of deception. (See In re *R.M.J* , supra.)(Also, see *Jacob Seigel Co. v. FTC*, 327 U.S. 608, 612 (1946) (the policy of the law to protect [brand names] indicates that their destruction should not be ordered if less drastic means will accomplish the same result'")) The comments further suggested that, in keeping with Executive Order 12630 (March 15, 1988). "Governmental Actions and

Interference with Constitutionally Protested Property Rights," FDA should complete a Takings Impact Analysis (TIA) in order to asses whether compensation to the brand name owners would be appropriate, and whether there were viable alternatives to banning the use of the brand names.

In the November 1991 Regulatory Impact Analysis (RIA) (55 FR 6085 at 60865), FDA considered the takings issue and concluded that a TIA was not necessary because the proposed regulations "serve to reemphasize existing regulations as to-how products may be named." In view of the comments and concerns raised involving the takings issue, the agency has concluded that it was necessary to conduct the more formalized TIA as set forth in Executive Order 12630. The agency has completed the TIA and concludes that the regulations as set forth below do not present a potential takings. Under the provisions of the Executive Order, the TIA is en internal government decision making document to assist the responsible agency in reducing the likelihood that a "takings" will occur and to provide the decision maker for the agency with information as to any likely cost due to compensable takings. As such, the TIA is not released for public review.

In its November 1991 RIA statement (56 FR 60856 at 60865), FDA stated that the required alteration of trade names did not constitute a taking, and that, as a result, no takings analysis was necessary. FDA still believes that there is no regulatory taking under the Fifth Amendment if a manufacturer is required to alter its brand name whim that brand name asserts by implication a relationship between the presence or level of a substance in the food and a disease or health-related condition, and that relationship is not the subject of an approved health claim. These final regulations on health claims constitute a reasonable exercise of the agency's authority to promote policies in the interest of public health. (See *Keystone Bituminous Coal Association v. DeBenedictis*, 480 U.S. 470, 488 (1987).) The 1990 amendments made explicit FDA's authority to permit certain health claims if it determines, based on the totality of publicly available scientific evidence, that the claims are scientifically valid. H. Rept. 533, 101st Cong., 2d sess. 9 (1990). The food industry "has long been the focus of great public concern and significant government regulation," and "the possibility was substantial" that the government would, "upon focusing on the issue," decide that the actions now being undertaken are in the public interest. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 968, 1009 (1984); see also Connolly v. Pension Benefit GuamnteQ Corp., 475 US. 211, 227 (1986) ("Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end.")

Companies that use brand names that contain implied health claims lack a reasonable investment-backed expectation that they will be able to continue to use those names. *Monsanto*, 467 U.S, at 1005. Under the act before the 1990 amendments, and under prior FDA policy, products whose labeling included implied health claims were subject to regulation as drugs without regard to the content of the claim. In 1987, FDA proposed to permit certain health claims on food, but this proposal was never made final and thus cannot be considered to provide the basis for reasonable expectations that specific claims would be allowed. The 1990 amendments for the first time provided companies with the basis for an expectation that certain implied claims, if approved, could be made. Only with the publication of these final rules does the possibility arise that a company might have a reasonable investment-backed expectation in continuing to use an approved claim.

103. One comment noted the possibility that the scientific standard for health claims has the potential to be unconstitutional, either facially or as applied, under the First (manner of application is overbroad and limits constitutionally protected free speech), the Fifth (the vagueness of the standard is such that due process will be violated when organizations are not given fair notice of what conduct is prohibited), the Ninth (without a clearer definition of the standard, oversight of agency actions that exceed its authority would be hindered), and the Fourteenth Amendments.

FDA disagrees with the comment's assertion that these regulations are unconstitutional. As discussed in greater detail at the beginning of this section of tills preamble, these regulations do not violate the First Amendment.

FDA further disagrees that the scientific standard is unconstitutionally vague or overbroad, and it questions the applicability of the vagueness and overbreadth doctrines in the current context. The vagueness doctrine is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. (See, for example, *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982); *Grayned v. City of Bockford*, 408 U.S. 104, 108 (1972).) This is not the case here. Only approved health claims will be permitted on the food label, and all other health claims will misbrand a food. It will thus be clear which type of speech is prohibited and which permitted. Further these regulations are narrowly tailored to meet a substantial government interest and are not overbroad. They do not "sweep[ ] within [their] prohibition what may not be punished under the First * * * Amendment[ ]." *Grayned*, 408 U.S. at 115. In any event, it is doubtful that the overbreadth doctrine would apply to these regulations, particularly if they were considered to regulate commercial speech, because the overbreadth doctrine does not apply to commercial speech. *Village of Hoffman Estates*, 455 U.S. at 497.

The comment does not explain its reasons for arguing that the regulations violate the Ninth and Fourteenth Amendments, and the agency does not agree that they do so. These regulations do not deny any fundamental rights not enumerated in the Constitution and so do not violate the Ninth Amendment. Because these regulations involve Federal and not State action, the Fourteenth Amendment does not apply.

The agency also disagrees that the regulations violate the due process clause of the Fifth Amendment because organizations will not be on notice of what constitutes prohibited conduct. Under the statutory scheme, as implemented by these regulations, certain health claims will be permitted to appear on food labels without misbranding the food or making the food a drug. No other health claims will be permitted. Organizations will be on notice that the use of an unapproved health claim is prohibited conduct.

The agency also disagrees that Congress has unconstitutionally delegated legislative power to FDA. "Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors. As long as Congress 'lay[s] down by legislative set an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power.'" *Touby v. United Slates*, 111 S. Ct 1752, 1756 (1991) (citing *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

XI. Consumer Summaries

FDA's 1990 proposal (55 FR 5176), Issued prior to the enactment of the

1990 amendments, would have required that a health claim reference a consumer summary that provided full information about the relationship between the food and the disease about which the claim pertained. The summary was intended to facilitate the consumer's assessment of whether the health claim applied to him or her, and, in certain instances, to what extent it applied. The summary was also intended to help evaluate the potential problem of information overload on the label.

In the 1991 proposal for health claims (56 FR 60537), issued in response to the 1990 amendments, FDA suggested that consumer summaries may no longer be necessary. Section 403(r)(3)(B)(iii) of the act provides that the regulation authorizing a claim shall require that the claim be stated in a manner that: (1) Accurately reflects the relationship between a substance and a disease or health-related condition, and the significance of the substance in affecting the disease or health-related condition; and (2) enables the public to comprehend the information provided in the claim and understand the relative significance of such information in the context of a total daily diet. This statutory provision requires that the claim, present the most significant aspects of the information that the agency was intending to require in the consumer summaries.

104. Some comments contended that FDA should require or strongly encourage the use of consumer summaries. Several of these comments asserted that their use is necessary to put health claims into the perspective of the total daily diet and alluded to their use as being similar to the package inserts employed for certain drug products. Others stated that their use would be an excellent vehicle for consumer education, and they should be provided and widely disseminated.

However, other comments argued that consumer summaries will have limited benefit in the light of the provisions of the 1990 amendments. Some of these comments stated that any of the proposed health claims will succinctly express the same message originally intended by FDA to be contained in the corresponding summary.

FDA is not persuaded that the use of consumer summaries is necessary in light of the provisions of this final rule. The comments did not contain a basis for the agency to require the summaries. New § 101.14(d)(2) requires, in part, that a health claim that appears in labeling be based on, and consistent with, the authorizing regulation in part 101, subpart E, and that the claim allow the public to understand the information provided in the claim and to understand the significance of that information in the context of a total daily diet. The agency agrees that these requirements fulfill the objectives of the consumer summaries, and that requiring the use of consumer summaries would therefore not be of additional benefit to the consumer. Furthermore, FDA knows of no basis under the act nor any other reason to require more information in the health claim than that that is already required under these rules.

105. Other comments suggested that FDA prepare and distribute a consumer guide containing information on how to use the new nutrition labels and health claim messages to improve eating habits.

Section 2(c) of the 1990 amendments directs the Secretary to carry out activities to educate consumers about the availability of nutrition information in the label or labeling of food and about the importance of that information in maintaining healthy dietary practices. Although FDA has not yet determined ail of the measures that it will undertake to fulfill this directive, the agency believes that the guide suggested by these comments would be extremely useful in assisting consumers to achieve healthier dietary habits. Thus, the agency advises that it will prepare such a guide in partial fulfillment of this provision of the law. These comments, as well as those received in response to the 1990 proposal (55 FR 5176), will be considered in developing this guide.

XII. Other Issues

106. One comment objected to allowing a health claim for a nutrient that has been added to a food, arguing not only that the food containing the added nutrient would be subject to undue emphasis in the diet, but that the added nutrient would have a "dilution effect" on the food's naturally-occurring nutrients. The comment made specific reference to added fiber.

FDA disagrees. FDA believes that it is almost always the nutrient content of the diet that is significant, not the source. The comment provided no data to justify a change in the agency's belief. However, wherever the agency becomes aware of a situation in which the relationship of a particular nutrient to a disease or health-related condition is dependent upon the source of the nutrient, FDA will make appropriate provisions in the specific regulation in part 101, subpart E to ensure that the health claim is valid with respect to the source of the nutrient.

107. One comment objected that foods should not be permitted to bear multiple health claims because they might be viewed as "wonder foods." The comment submitted no to support this position.

The agency has no basis to conclude that multiple valid health claims, will be misleading to consumers. To the contrary, FDA believes that if it were to limit the number of different health claims that could appear on the label of a single product, it would place the manufacturer in the position of having to choose which of several valid health claims should appear on the label. Such choices would inevitably lead to a situation where the same food would bear different health claims depending on the particular manufacturer's marketing preferences. Under such circum stances consumers may question which clam was valid, or whether there were differences in the beneficial nutrients in the same food packaged by different manufacturers. Further, if the agency were to restrict the number of health claims on food, such a restriction would be contrary to the Congressional intent, of the 1990 amendments that consumers be helped by health claims to maintain a healthful diet (Ref. 1).

108. A comment stated that a manufacturer may occasionally run an offer inviting consumers to submit requests for brochures containing dietary guidance or specific recommendations of a private organization, such as NCI. The comment requested that FDA clarify whether such brochures should conform to the health claims regulations.

For many years, the agency has taken the position that brochures containing nutrition information about a food constitute labeling. For example, § 101.9(f) provides that a statement may be included on the label or in labeling offering additional nutrition information upon written request to a specified address. The provision states further that any additional labeling, furnished to consumers or professionals shall comply with all applicable requirements of chapter 1. (The preamble discussion about this provision appears in the response to comment 37 in the **Federal Register** of March 14, 1973 (38 FR 6950 at 6957).) Accordingly, FDA advises that where a food label contains an offer inviting consumers to submit requests for a brochure, and the brochure explicitly or implicitly characterizes the relationship of a substance to a disease or a health-related condition, the brochure is labeling that contains a health claim and thus must conform to the health claims regulations.

109. Some comments contended that in-store educational programs should not be subject to the health claim regulations. One comment noted that

such programs provide beneficial health and dietary information to consumers and can assist the agency in educating the public about the new labeling initiative. Another comment advised that the guidance in these programs may, or may not, conform to health claims regulations.

FDA recognizes that a wide variety of in-store nutrition education programs incorporating written, printed, or graphic materials, videotapes, or other media, may serve a useful role in assisting consumers maintain a balanced and healthful diet and thereby make a positive contribution toward one of the major goals of the 1990 amendments. Accordingly, the agency wishes to encourage, rather than discourage, their use, provided that such programs conform to health claims regulations if they characterize the relationship of a substance to a disease or health-related condition.

However, the agency points out that such programs, by virtue of their association with the articles of food in the retail store, generally constitute food labeling under section 201(m)(2) of the act and, as such, would be subject to regulation under section 403(r) of the act if a health claim is made. FDA does not agree that such programs should be exempt from these regulations. Consumers could be confused by differing claims on food labels and in those programs. For example, if under an in-store program, informational placards with a calcium/osteoporosis health claim were placed on a dairy case containing a wide variety of dairy products, some of the products contained in the case would likely be misbranded, as a number of dairy products exceed the disqualifying nutrient levels for fat and saturated fat or fail to meet other provisions of new § 101.14. Even those products that would otherwise qualify for a health claim would likely be misbranded if the placard claim itself did not conform to the provisions of new § 101.14 and part 101, subpart E.

The agency's regulations are designed to enable consumers to understand the significance of the consumption of the substance on the risk of disease within the context of the daily diet. Relevant in-store programs should be carefully crafted to convey such an understanding.

110. A number of comments took a position that one or more of the proposed provisions should not be established because they are subjects for regulatory review under the January 28, 1992, Presidential memo, "Reducing the Burden of Government Regulation." The comments asserted that these requirements are exercises in discretion by the agency rather than requirements mandated by Congress.

FDA advises that after considering these comments, it has concluded that none of the preliminary requirements reaches beyond the act to impose an unnecessary burden on manufacturers. As explained in the preamble of the proposal (56 FR 60537 at 60545 through 60547), each of these requirements is directly derived from existing provisions of the act. Even though these provisions are derived from the act, FDA has carefully reviewed each provision in accordance with the direction provided, by the January 28, 1992, Presidential memo. FDA has carefully considered the benefits to society of these rules and concluded that the benefits clearly outweigh the expected costs (see the final RIA, published elsewhere in this issue of the **Federal Register**). Each provision of the rules has been fashioned to maximize net benefits to society. Further, the provisions have been crafted to clearly convey to the regulated community what is required of firms choosing to make health claims.

XIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60855), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments Is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23,12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XIV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (November 27, 1991 (56 FR 60537 at 60562)). At that time, FDA determined under 21 CFR 25.24(a)(8) and (a)(11) that this action was of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rules on health claims suggested that there would be significant adverse environmental effects from these rulemakings because it would cause large stocks of labels and labeled packaging materials to be discarded and require a great number of trees to be harvested to provide new labeling material. One comment estimated the number of label units from the dairy industry that would need to be discarded following publication of FDA's final rules on several food labeling actions, including tins action. However, this comment did not: (1) Show how these estimates were derived, (2) identify what portion of the estimated amounts are attributable solely to this action, or (3) describe what impact the discarded labeling and packaging would have on the disposal of solid waste. Another comment questioned the appropriateness of requiring lengthy explanations on the labels of foods to which health claims are made because those requirements might result in extra packaging so that sufficient label space would be available for the required elements of the health claims. The comment said that this extra packaging might increase the burden on the environment but did not estimate the amount of extra packaging that might be needed or describe what impact this extra packaging would have on the environment.

According to section 10(a)(25 of the 1990 amendments, section 403(r) of the act does not apply to food labeled before May 8, 1993. Thus, all labels that are

applied to food prior to that date will not have to be destroyed. The comments contained no data with respect to labels that might remain that would fail to comply with the requirements of section 403(r)(1)(B) of the act. In the absence of such data, FDA has no basis on which to assess the validity of assertions that considerable label stocks will be destroyed and thereby determine the extent of any potential adverse environmental impact. Given the fact that section 10(a)(2) of the 1990 amendments provides an exemption for labeled products, and that FDA is authorizing various health claims elsewhere in this issue of the **Federal Register**, FDA believes that very little, if any, labeling will have to be discarded because of this final rule. Also, in its final rules, FDA has limited the required elements of many of the health claims compared to the elements that were proposed. Thus, FDA believes that the information required on a label when a health claim is made can be incorporated into the label without significantly increasing the amount of packaging required. Consequently, FDA concludes that the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XV. Paperwork Reduction Act

In the **Federal Register** of February 14,1992 (57 FR 5396), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60537) that provided, in proposed § 100.70, for petitions regarding the use of health claims in conjunction with food labeling. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

FDA considered over 6,000 written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling in developing this final rule, FDA has not been persuaded by the comments or any other relevant information to modify, in this final rule, the health claim petition requirements that it proposed last year. Thus, the agency's estimated annual reporting and recordkeeping burden from the health claim petition requirements contained in this final rule remains unchanged from that announced in February.

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

XVI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. House of Representatives, House Report, 101-538, "Nutrition Labeling and Education Act of 1990," June 13,1990.
2. 136 Congressional Record—Senate, S16607-16612, October 24,1990.
3. 136 Congressional Record—House, H12951-12955, October 26, 1990.
4. 136 Congressional Record—House, H5836-5845, July 30,1990.
5. DHHS, Public Health Service, "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 88-50210 (GPO Stock No. 017-001--00465-1), U.S. Government Printing Office, Washington, DC, 1988.
6. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, NRC, "Diet and Health: Implications for Reducing Chrome Disease Risk," National Academy Press, Washington, DC. 1989.
7. USDA and DHHS, "Nutrition and Your Health: Dietary Guidelines for Americans," 3d ed., Home and Garden Bulletin No. 232, U.S. Government Printing Office, Washington, DC, 1990,
8. Dresser, C. M., National Center for Health, Statistics, Interagency memorandum to Marilyn Stephenson, FDA, December 3, 1981.
9. USDA, Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food intakes by Individuals, Report No, 86—3, Hyattsville, MD, p. 168, September 1988.
10. Buzzard, I. M., Letter to Virginia Wilkening, FDA, February 12, 1991.
11. Clinical Nutrition Branch, memo to file: Data Analysis HM1, Percent Daily Reference Value Per Serving, October 16,1991.
12. Clinical Nutrition Branch, memo to file: Data Analysis HM2, Presence of Nutrients in Food Categories, October 16, 1991.
13. Clinical Nutrition Branch, memo to file: Data Analysis HM3, Assessment of Disqualifying levels of 10, 15, and 20 Percent of the DRV Per Serving, October 16,1991.
14. Clinical Nutrition Branch, memo to file: Data Analysis HM4, Assessment of Need for Disqualifying Levels Based on 100 Grams, October 16,1991.
15. Senate Report No. 493, 73d Cong., 2d sess., March 15, 1934. Cited in: Food and Drug Administration, "A Legislative History of the Federal Food, Drug, and Cosmetic Act," vol. 2, pp. 721-3, FDA, Rockville, MD, 1979.
16. Fosmire, G.J., "Zinc Toxicity," *The American Journal of Clinical Nutrition*, 51:225-227,1990.
17. Fischer. P. W. F., A. Giroux, and M. R. L'Abbe, "Effect of Zinc Supplementation on Copper Status in Adult Man," The *American Journal of Clinical Nutrition*, 40:743-746, 1984.
18. FDA, "Compliance Program Guidance Manual," Chapter 21, Program No. 7321.002 (1988-1991), FDA, 1990.
19. Schoeller, D. E., "How Accurate is Self Reported Dietary Energy Intake?", *Nutrition Reviews*, 48:373-379,1990.
20. Food and Nutrition Board, NRC, "Recommended Dietary Allowances," 10th ed., Chapter 1, National Academy Press, Washington, DC, 1989.
21. Yetley, E. A. and Y.K. Park, "Obtaining Data on Intake of Supplements," in *Nutritional Status of the Individual*, G. E. Livingston. Ed., pp. 113-123, Food and Nutrition Press, Inc., Trumbull, CT, 1989.
22. Burke Marketing Research, "Analysis: Restaurant Users Focus Group Session," Study BMR No. 39-545 conducted for the American Heart Association, Dallas, TX, March 1989.
23. Burke Marketing Research, "Logo/Name Study for American Heart Association," Study BMR No. 39-651 conducted for the American Heart Association, Dallas, TX, June 1989.
24. U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, Hearing on the Nutrition Labeling and Education Act of 1989, H.R. 3028, August 3, 1989. Serial. No. 101-65, U.S. Government Printing Office, Washington, DC, 1989.
25. U.S. Senate, Committee on Labor and Human Resources, Hearing on the Nutrition Labeling and Education Act of 1989, S. 1425, November 13,1989, U.S. Government Printing Office, Washington, DC, 1990.
26. Congressional Record—-Senate, S8894-8895 July 27, 1989.
27. NCI "Eat More Fruits and Vegetables—Five-a-Day For Better Health." NIH Publication No, 92-3248, October, 1991.
28. Glinsmann, W. H., H. Irausquin, and Y. K. Park, "Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners," *The Journal of Nutrition*, 116:S1-S216,1986.
29. USDA, Human Nutrition Information Services. "USDA's Food Guide Pyramid," Home and Garden Bulletin No. 249, April, 1992.
30. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC1, Disqualifying Levels at 20 Percent versus 15 Percent of the Daily Reference Value, October 15,1992.
31. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC2, Disqualifying Levels per 50 Grams versus per 100 Grams, October 15,1992.
32. The National Nutrition Monitoring and Related Research Act of 1990, Pub. L. 101-445, October 22,1990.
33. FDA. Clinical Nutrition Branch, memo to file: Data Analysis HC3, Health Claim Requirement for Minimum Levels of Nutrients, October 15,1992.
34. Managers Statement on the DS Act of 1992.
35. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC4, Disclosure/Disqualifying Levels for Meals and Main Dishes, October 15, 1992.
36. FDA's 1990 Health and Dietary Survey, Division of Consumer Studies, Center for Food Safety and Applied Nutrition, FDA.

37. Food Retailing Review—1992 Edition, The Food Institute Information and Research Center, Fairlawn, NJ, p. 245, February 1992.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20 and 101 are amended as follows:

PART 20---PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); sees. 301, 302, 303, 307, 310 311, 351, 352, 354-360F, 361, 362, 1701-1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a,242l, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-1); 5 U.S.C. 552; 18 U.S.C. 1905.

2. Section 20.100 is amended by revising the section heading and by adding new paragraph (c)(34) to read as follows:

§20.100 Applicablility; cross-reference to other regulations.

* * * * *

(c)* * *

(34) Health claims petitions, in §101.70 of this chapter.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority; Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.9 is amended by adding new paragraph (k)(1) to read as follows:

§101.9 Nutrition labeling of food.

* * * * *

(k) * * *

(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Information about the relationship of a dietary properly to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and part 101, subpart E.

* * * * *

5. New § 101.14 is added to read as follows:

§101.14 Health claims: general requirements.

(a) *Definitions*. For purposes of this section, the following definitions apply:

(1) Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) Substance means a specific food or component of food.

(3) Nutritive value means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) [Reserved]

(5) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(1) The levels for a meal product as defined in § 101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of, cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in § 101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(6) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in tills definition (claims pertaining to such diseases are thereby not subject to § 101.14 or § 101.70).

(b) *Eligibility*. For a substance to be eligible for e health claim:

(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q)(1)(C) or (q)(1)(D), or one that the Food and Drug Administration (FDA) has required to be included in the label or labeling under 21 U.S.C. 343(q)(2)(A); or

(3) If the substance is to be consumed at other than decreased dietary levels:

(1) The substance must contribute taste, aroma, or nutritive value, or any technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food or a food ingredient or a component of a food ingredient whose use et the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act.

(c) *Validity requirement*. FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(d) *General health claim labeling requirements*. (1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of this

section, FDA will propose a regulation in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in § 101.9, FDA will propose amending that regulation to include declaration of the substance.

(2) When FDA has adopted a regulations in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statements about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the regulation in subpart E of this part.

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the label or labeling may bear the reference statement, "See ————- for information about the relationship between ————-and ————," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other labeling, Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied, health, claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term "low" has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term "high" for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established (e.g., where the claim pertains to a food either as a whole food or as an ingredient in another food), the claim must specify the daily dietary intake necessary to achieve the claimed effect, as established in the regulation authorizing the claim; *Provided* that:

(A) Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed» and the labeled serving size differs from that amount, the claim shall be followed by a statement, explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in salt and sodium may help lower blood pressure in many people. A serving of———ounces of this product conforms to such a diet.").

(B) Where the food that bears the claim is sold in a restaurant (except if the claim is made on a menu) or in other establishments in which food that is ready for human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) and (d)(2)(vii) of this section and providing that basis upon request.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9 or, for restaurant foods, in accordance with §101.10.

(e) *Prohibited health claims.* No expressed or implied health claim may be made on the label or in labeling for a food unless:

(1) The claim is specifically prowled for in subpart E of this part; mid

(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(5) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a disqualifying level of a nutrient is present in the food based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E of this part that makes such a finding, the label bears a referral statement that complies with § 101.13(h), highlighting the nutrient that exceeds the disqualifying level;

(4) Except as provided in paragraph (e)(3) of this section, no substance is present at an inappropriate level as determined in the specific provision authorizing the claim in subpart E of this part;

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age except if the claim is specifically provided for in subpart E of tills part: and

(6) Except for dietary supplements not in conventional food form, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient . addition.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act

(g) *Applicability*. The requirements of this section apply to foods intended for human consumption that are offered for sale.

6. Subpart E, consisting of §§ 101.70 and 101.71, is added to read as follows:

Subpart E—Specific Requirements for Health Claims

Sec.

Subpart E—Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug

Administration (FDA) to issue a regulation regarding a health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format.. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of tills chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petitiion shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with § 56.104 or § 56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigational reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

(Date)
Name of petitioner ———
Post office address ———
Subject of the petition ———
Food and Drug Administration,
Regulatory Affairs Staff (HFF-204).
Office of Nutrition and Food Sciences,
200 C St SW.,
Washington, DC 20204,

The undersigned,
——— submits this petition pursuant to section 403(r)(4) or (r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of § 101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of § 101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS), listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in §101.14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC), where available. If no AOAC method is

available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Yours very truly,

Petitioner ————

By————————

(Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(1) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) Agency action on the petition. (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in B. *Summary of Scientific Data* if the information in A. *Preliminary Requirements* is inadequate in explaining how the substance conforms to the requirements of § 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. A petition that has been denied without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by letter of notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the **Federal Register**. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for the requested use of the health claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

§101.71 Health claims: claims not authorized.

In response to the Nutrition Labeling and Education Act of 1990, FDA has reviewed the evidence on the following topics that Congress specifically asked FDA to evaluate and has concluded that there is not a sufficient basis for claims about the following:

Dated: December 17,1992.

David A Kessler,

Commissioner of Food and Drugs.

Luis W. Sullivan,

Secretary of Health and Human Service

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