the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX number 202-472 1542.

(g) FDA will notify the state of the date on which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Regulatory Guidance (HFF-310) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, will respond to the State's notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(i) Information contained in State notification letters required by this section shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§ 20.61, 20.64, and 20.88 of this chapter.

(j) *Definitions.* (1) "Informal enforcement actions" include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question.

(2) "Formal enforcement actions" include seizures, injunctions, prosecutions, or other judicial enforcement actions that pertain to the food in question.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27152 Filed 11-26-91; 8:45 am]

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21 CFR Parts 20 and 101

[Docket No. 85N-0061]

RIN 0905-AB67

Labeling; General Requirements for Health Claims for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general requirements pertaining to: (1) The use of health claims that characterize the relationship of a food component 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. This proposal is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims. It supersedes in all respects FDA's reproposed rule concerning health messages (February 13, 1990, 55 FR 5176). Elsewhere in this issue of the **Federal Register**, FDA is issuing proposals that respond to the 1990 amendments directive that the agency consider 10 topics associating nutrients with diseases or health-related conditions. Those proposals have been developed in accordance with the general principles of the proposed requirements in this document.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following publication of a final regulation pertaining to health claims in food labeling in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT: Victor P. Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drig Administration, 200 C St., SW., Washington, DC 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). This new law amends the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments is that they confirm FDA's authority to regulate nutrient content claims and health claims on food labels and in labeling. With respect to health claims, the new provisions provide 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 the procedures and standards contained in regulations established under section 403(r)(1)(B) of the act (21 U.S.C. 343 (r)(1)(B))

The enactment of the 1990 amendments reflects a determination by Congress that an orderly and accountable process is needed to control the dissemination of information concerning the relationship between diet and disease or other health-related conditions on the food label and in labeling. Congress characterized this need as "compelling" (Ref. 1). FDA is proposing general requirements to ensure that this information in food labeling will be valid, truthful, nonmisleading, and useful for consumers.

The agency fully recognizes the importance of conveying to American consumers information on the value of improved nutrition to help achieve or maintain good health. FDA is committed to facilitating the provision of such information wherever adequate scientific evidence confirms the validity of the information.

II. Regulatory History

For many years, FDA has permitted firms to label foods with truthful, nonmisleading information about the nutrient content of food. In the past, however, the agency did not permit firms to provide consumers with information on the label or in labeling concerning how the food may be used to affect a disease or health-related condition. FDA generally took a position that including disease-related information on food labeling resulted in the food being a drug within the meaning of the act. The act (section 201(g)(1)(B)) defines a drug, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease in man * * *" (21 U.S.C. 321(g)(1)(B)). Thus, the agency has viewed mention of a disease on a food label as evidence that the product was intended to be used as a drug.

In addition, in the **Federal Register** of March 14, 1973 (38 FR 6950 at 6951), FDA promulgated regulations that provided, in part, that a food shall be deemed to be misbranded if its labeling represents, suggests, or implies 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 (currently, 21 CFR 101.9(i)(1)). This provision reinforced the agency's policy concerning disease-related information on food labels. In the **Federal Register** of August 4, 1987 (52 FR 28843) (the 1987 proposal), however, FDA proposed to change its policy to permit the use on food labeling of health messages (in this proposal, the term "health claim" is used in place of "health message" for consistency with terminology used in the 1990 amendments). The agency was responding to the developing scientific data on the relationship between the nutrient content of the diet and disease.

The 1987 proposal proposed to amend nutrition labeling regulations in § 101.9 to permit health claims when:

(1) They are truthful and not misleading;

(2) They are supported by valid, reliable, and publicly available scientific evidence derived from well-designed and well-conducted studies consistent with generally accepted scientific procedures and principles performed and evaluated by persons qualified by expertise and training in the appropriate disciplines;

(3) They are consistent with generally recognized medical and nutritional principles for a sound total dietary pattern; and

(4) The food bears nutrition information in accordance with the requirements of § 101.9.

The agency advised in the 1987 proposal (52 FR 28843) that firms could make health claims consistent with the proposed provisions without prior FDA approval. Thus, FDA created a "safe harbor" from agency enforcement action for such claims.

After publication of the 1987 proposal, health claims began appearing on foods with increasing frequency. In a number of situations, these claims conformed only partially with the proposed provisions. Some manufacturers took advantage of the broad manner in which the proposal was written by making drug claims on products and then, when challenged by FDA, asserting that these claims were consistent with how food could be labeled under the proposal.

Because of the wide divergence of opinion expressed in comments that responded to this proposal, the agency concluded that the issues raised by this proposal could not be resolved without additional and more specific comments from interested persons. In recognition of this need, FDA solicited additional comments on health claims in an advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** of August 8, 1989 (54 FR 32610), that requested public comment on a wide range of food labeling issues. On December 7, 1989, FDA held a public hearing in Seattle at which the topic of health claims was a prime focus.

Based on the comments on the August 1987 proposal, on the August 1989 ANPRM, and at the public hearing, FDA withdrew the August 1987 proposal and published a reproposal in the **Federal Register** of February 13, 1990 (55 FR 5176) (the 1990 reproposal), stating that the former proposal was superseded in all respects. The agency stated that the 1987 proposal was too broadly written and allowed some manufacturers to take advantage of it by making drug claims on health fraud products. The 1990 reproposal proposed to more narrowly define appropriate health claims and offered criteria to be met to allow a claim. Further, the agency revoked the advisory opinion in the 1987 proposal that permitted firms to make health claims on food labeling where the claims were consistent with the proposal. The agency advised that, pending adoption of a final rule, there would be no "safe harbor" for any health claim in food labeling, and that any health claim may subject a food product to regulatory action.

However, the agency also set forth in the 1990 reproposal an interim enforcement policy that provided general guidance as to how the agency would likely exercise its enforcement discretion regarding health claims until a final rule was promulgated (55 FR 5176 at 5184). The agency stated that manufacturers could continue to include health claims on their products, but that FDA would scrutinize them on a case-by-case basis and exercise its enforcement discretion in deciding when it would bring a regulatory action.

FDA set out four basic principles that it said would guide its exercise of enforcement discretion. It also pointed to six topic areas about which significant evidence appeared to exist. The agency stated that claims regarding these topic areas were least likely to run the risk of regulatory action. In addition, FDA stated that a claim that used the phrases "may reduce the risk" or "may forestall the premature onset" would be less likely to be subject to regulatory action than one that more firmly asserted that a relationship exists between a food component and a disease.

After publication of the 1990 reproposal, FDA sent regulatory letters to a number of firms whose products bore labeling that contained false or misleading health claims. Most firms contacted made appropriate changes in their labels and labeling.

FDA received more than 200 comments on the 1990 reproposal from consumers, health professionals, industry, academia, government agencies, and organizations representing consumers, industry, and health professionals. Relevant comments are addressed throughout this document in locations appropriate for their content.

III. The 1990 Amendments

The 1990 amendments address health claims by amending the act to add section 403(r). This section specifies, in part, that a food is misbranded if it bears a claim that expressly or by implication characterizes the relationship of certain nutrients to a disease or health-related condition unless the claim meets the requirements of a regulation authorizing its use (section 403(r)(1)(B) of the act). Section 403(r) also directs FDA to issue regulations authorizing health claims for nutrients in conventional foods and in dietary supplements in appropriate circumstances. In addition, the 1990 amendments (section 3(b)(1)(A)(vi) and (b)(1)(A)(x)) require that FDA determine whether health claims respecting 10 specific nutrient disease topics are appropriate under the requirements of the act.

A. FDA Authority

Several comments on the February 13, 1990 reproposal questioned the agency's authority to regulate health claims. Congress specifically recognized these questions in the legislative history of the 1990 amendments (Ref. 1). Enactment of the 1990 amendments renders these comments moot. The agency now has clear authority to regulate all health claims on food.

B. Conversion to New Statutory Requirements

The passage of the 1990 amendments marks the beginning of a period in which FDA is endeavoring to convert the general requirements of the new law into specific, usable, and enforceable regulations. The issuance of this proposal, which supersedes the 1990 proposal in all respects, is an important step in this transition. During this period of transition, FDA is responsible for protecting the integrity of the food label.

The agency advises that it intends to evaluate any health claims that appear in labeling on a case-by-case basis. FDA is prepared to take action against products that bear false or misleading health claims or claims that evidence an intent that the product is to be used as a

drug but has not been approved for that use.

C. Statutory Provisions on Health Claims

Section 403(r)(1)(B) of the act identifies the substances that may be the subject of a health claim, that is, those nutrients of the type required by section 403 (q)(1) or (q)(2) of the act (new provisions concerning nutrition labeling added by the 1990 amendments) to appear on the label or labeling of a food and those present in dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances (section 403(r)(5)(D) of the act).

Section 403(q)(1) of the act provides that nutrition labeling shall include information on the total number of calories derived from any source; the number of calories derived from total fat; the amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein; and any vitamin, mineral, or other nutrient required to be placed on the label before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices. In the agency's supplementary proposal on the mandatory status of nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is proposing to require the listing of vitamin A, vitamin C, calcium, and iron under this provision. Section 403(q)(2) of the act provides that the agency may require information concerning additional nutrients in nutrition labeling when the Secretary concludes that the information will assist consumers in maintaining healthy dietary practices. Consequently, other vitamins and minerals may be required to be listed on the label in the future.

To assure the validity of health claims, Congress enacted a scientific standard in section 403(r)(3)(B)(i) of the act for conventional food that provides that the Secretary (and by delegation, FDA) shall promulgate regulations authorizing nutrient health claims only if 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) supports the claim, and there is significant scientific agreement among qualified experts that the claim is supported by such evidence. For health claims for dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, Congress provided that the standard for the validity of such claims must be established by the Secretary (and by delegation, FDA) (section 403(r)(5)(D) of the act).

Where claims can be justified for conventional food, section 403(r)(3)(B)(ii) of the act requires that a regulation describe the relationship between the nutrient and the disease or health-related condition and describe the significance of the nutrient in affecting the disease or health-related condition. Section 403(r)(3)(B)(iii) of the act requires that the claim be "stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet."

Under section 403(r)(3)(A)(ii) of the act, health claims may only be made on foods that do not contain nutrients in an amount that 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 * * *." However, this provision goes on to say that the Secretary may by regulation permit such a claim if he or she finds that such a claim would assist consumers in maintaining healthy dietary practices, and he or she provides for disclosure of the presence of the nutrient in conjunction with the claim.

In addition, the 1990 amendments revise the definition of "drug" in section 201(g)(1) (21 U.S.C. 321(g)(1)) of the act to provide that food for which a health claim is made in accordance with the requirements of section 403(r) of the act is not a drug solely because the label or labeling contains such a claim.

D. Same Scientific Standard for Dietary Supplements

FDA is proposing the same scientific standard for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances as for all other foods. The agency recognizes that proposing the same standard for conventional food and dietary supplements is contrary to the view expressed by some members of Congress, and by some individuals in comments to the agency in response to a notice in the **Federal Register** of March 14, 1991 (56 FR 10906), on petition procedures, that a separate, more lenient standard should be established for supplements. However, FDA has reviewed the legislative history concerning section 403(r)(5)(D) and has tentatively concluded that Congress did not intend that the agency be forced to adopt a different standard for these products (Refs. 2 and 3). Instead, the exemption on its face gives the agency the discretion to adopt any appropriate scientific standard for supplements. 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 the 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. (Congressional Record, July 30, 1990).

In addition, the Metzenbaum-Hatch managers' statement in 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.
> (Congressional Record, October 24, 1990).

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.

Regarding the ability of the Secretary of Health and Human Services (and by delegation, FDA) to determine the appropriate procedure and standard for dietary supplements, the Metzenbaum-Hatch managers' statement further says that the following two factors should be taken into account:

> The rapid pace of scientific advance linking nutritional substances to the maintenance of long-term human health and prevention of long-term disease; and
>
> The ways in which dietary supplements are marketed and used by individuals differently from conventional food products.
> (Congressional Record, October 24, 1990).

Some consumers seek to ensure that the nutrient content of their diet is

adequate through conventional foods, others through dietary supplements. Ultimately, however, it is the nutrient content of the diet that is significant, not its source. For this reason, neither the pace of scientific advances with respect to nutritional substances nor the way individuals use supplements justifies different treatment for dietary supplements than for conventional foods.

From the Senate, there were mixed opinions as to what the agency should do with this flexibility. In the October 24, 1990 Congressional Record, on page S16611 (Ref. 2), Senator Hatch, one of the primary authors of the amendments made by the Senate, stated:

> By their very nature, the dietary supplements must be marketed so that the consumer is informed of the health or disease-prevention benefits that may be conferred. Greater flexibility is thus required to permit communication of these benefits. This increased regulatory flexibility is also mandated by the very rapid pace of scientific advances here and abroad linking the prevention of long-term disease to improved nutritional supplementation. For these reasons, a more lenient standard for dietary supplement[s] is envisioned. (Congressional Record, October 24, 1990).

However, in this same Congressional Record, (Ref. 2), Senator Metzenbaum, the other primary author of these 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.

The statement of House Floor Managers also addresses this issue (Ref. 3):

> * * * 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 unsupportable 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.

In the absence of clear Congressional direction about the way in which FDA should use the flexibility it has, the agency believes that it is appropriate to propose the same scientific standard and procedure for supplements as is mandated for conventional foods. If the agency were to adopt a more lenient standard and procedure for supplements, FDA believes that there would 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. Furthermore, FDA believes that a standard and procedure that is more lenient than that provided in section 403(r)(3)(B)(i) would not provide a basis on which to evaluate the validity of claims, which both the House Managers (Ref. 3) and at least one Senate author (Ref. 2) stated should be the goal of the approach that the agency adopts.

Nor does FDA consider a more stringent standard to be necessary. The standard that it is proposing for dietary supplements is the same as that which it proposed for all foods in 1990. FDA believes that this standard strikes an appropriate balance between the desire to make information available and the desire to ensure that that information is truthful, usable, and not misleading.

For FDA, a significant measure of whether a claim is valid is whether the evidence that supports that claim has stood the test of exposure to scientific scrutiny. Such scrutiny is a critical element in deciding whether any proposition is based on sound science. FDA cannot ignore such a critical element when deciding whether consumers should be advised that a particular diet-disease relationship exists. Such scrutiny is specifically provided for in the standard set forth in section 403(r)(3)(B)(i) of the act. Therefore, FDA believes that this standard should be applied in judging any health claim, whether for conventional foods or dietary supplements.

FDA does not believe that it could have a significant level of comfort, the standard for appraising claims suggested in the House Report (Ref. 1), about the validity of claims if it adopted any of the more lenient approaches suggested in comments to the March 14, 1991 notice. FDA has an obligation under the act to assure not only that claims comply with section 403(r) of the act but also that they are truthful and not misleading under section 403(a) of the act. Suggestions that the agency should delegate the primary responsibility for evaluating the validity of claims for herbs to industry committees are not consistent with this agency's responsibility. Of course, industry may, if desired, work through committees to prepare well-supported petitions for submission to FDA. However, FDA would still have the ultimate obligation of ensuring that there is compliance with the act.

FDA also does not agree with comments that suggested that it should adopt a regulatory framework for evaluating health claims for supplements that establishes three categories of claims, each of which would be subject to a different level of validity substantiation and different procedures. As suggested, Category I claims would be subject to the same validity requirements as established for conventional food. Category II claims would pertain to claims for which there is substantial scientific evidence but not yet significant scientific agreement. Category III claims would pertain to claims for which there is sound scientific evidence, which on balance supports the claim but is more preliminary in nature. Categories II and III claims would be subject to a certification and notification procedure and would not have to be affirmatively authorized by regulation.

FDA does not believe that the suggested certification and notification procedure for Categories II and III claims are adequate or appropriate under section 403(r)(5)(D) of the act. As discussed above, the legislative history from both the Senate and the House points to the fact that the procedure and standard that FDA is to establish under this section should evaluate the validity of health claims. Yet, the procedure suggested in the comment would not provide the agency with a full opportunity to do so. Under the procedure suggested in the comment, the greater the question about the validity of the claim, the less opportunity that FDA would have to review it. Such a system would not be fair to consumers, who would be exposed to claims whose validity had not been evaluated by FDA, or the manufacturers of conventional foods, who would be subject to the much higher congressionally mandated standard. For these reasons, under the discretion granted the agency by section 403(r)(5)(D), FDA is rejecting the comment.

E. FDA Requests For Data

In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the ten nutrient-disease topics that paragraphs (vi) and (x) of

section 3(b)(1)(A) of the 1990 amendments require FDA to consider. FDA established ten dockets for information relating to these topics, as follows: Calcium and osteoporosis, 91N-0094; sodium and hypertension, 91N-0095; lipids and cardiovascular disease, 91N-0096; lipids and cancer, 91N-0097; dietary fiber and cancer, 91N-0098; dietary fiber and cardiovascular disease, 91N-0099; folic acid and neural tube defects, 91N-0100; antioxidant vitamins and cancer, 91N-0101; zinc and immune function in the elderly, 91N-0102; and omega-3 fatty acids and heart disease, 91N-0103. The compiled scientific data and information were considered by FDA in its development of the proposed regulations pertaining to specific health claims that are published elsewhere in this issue of the **Federal Register**. FDA generally will address that data and information that it received in response to the March 1991 notice in the documents on those proposed regulations.

F. How Claims Are Made

When FDA determines on the basis of its review of the evidence on a nutrient-disease relationship, as it has with respect to some of the topics that are the subject of the specific documents published elsewhere in this issue of the **Federal Register**, that a health claim should be authorized, the agency will propose a specific regulation permitting a claim in subpart E of 21 CFR part 101. (FDA is proposing to create subpart E in this document.) The proposal will clearly identify the elements that must be included in the claim to assure its validity. In addition, the agency will illustrate the claim that is permitted through an example of an appropriate claim (referred to as a "model health claim"). If, after its review of comments, FDA decides to issue a final regulation based on that proposal, firms will be able to make claims that comply with that regulation on appropriate foods. Firms will not be required to use the language in the model claim but will be free to develop their own specific claims within the terms of the regulation.

In the authorizing regulation, FDA will set out requirements to ensure that any claim made under it will fully reflect the scientific facts justifying the claim. These requirements will not only describe the nutrient-disease relationship but will define other relevant factors, such as nondietary elements (e.g., the need for exercise) and relevant nutrient interactions (e.g., calcium and phosphorus levels in a food).

For conventional foods, many of the elements that will be included in the authorizing regulations will reflect the requirements of the 1990 amendments. As discussed previously, section 403(r)(3)(B)(ii)(I) of the act, which was added by the 1990 amendments, requires that regulations authorizing claims require that those claims describe the relationship between the nutrient and the disease or health-related condition. FDA is applying this requirement in the proposed regulations on health specific claims published elsewhere in this issue of the **Federal Register**. For example, the proposal authorizing a health claim on the relationship between calcium and osteoporosis requires, in part, 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 proposed § 101.72(d)(3)).

Section 403(r)(3)(B)(ii)(II) of the act requires that regulations authorizing health claims require that claims describe the significance of the nutrient in affecting the disease or health-related condition. Thus, the proposal concerning calcium and osteoporosis requires, in part, that a claim explain the various factors other than calcium intake that bear on the risk of developing osteoporosis, that is that being a white female or having a family history of fragile bones with aging, places an individual at risk for the development of osteoporosis in later life (see proposed § 101.72(d)(2)).

Further, section 403(r)(3)(B)(iii) of the act requires that the public be able to comprehend the information in the claim and to understand the significance of the information in the context of the total daily diet. Under this requirement, a wide variety of factors may need to be addressed in the claim. For example, the proposal concerning calcium and osteoporosis requires, in part, that claims point out that adequate calcium intake is not enough. The proposal provides that the claim must advise that adequate calcium intake should be accompanied with exercise and maintenance of a balanced diet.

As stated above, section 403(r)(5)(D) [1] of the act directs FDA to establish a procedure and standard to assure the validity of health claims for dietary supplements. In section III.D. of this document, FDA discussed why dietary supplements should be subject to the same scientific standard, and procedure for assessing conformity with the standard, that is used for conventional foods. The agency has tentatively determined that it is also appropriate to subject dietary supplements to the same procedures with respect to how claims are made and how they are petitioned for as those that apply to conventional foods. The agency has reached this tentative conclusion based on three factors:

1. FDA has an obligation to ensure that food labeling is truthful and not misleading. Under the act, a claim can be misleading, and thereby misbrand the food, based on the information that it does not include as well as the information that it does include. The agency believes that the procedures that it is proposing are necessary to ensure that claims that are made are fully informative to consumers. Because claims for dietary supplements must be as informative as claims for conventional foods, FDA believes that it is appropriate to subject the former claims to the same procedures as the latter.

2. As stated above, FDA has an obligation to treat all segments of the regulated food industry with fairness. If dietary supplements were subject to different rules, whether with respect to the procedure for assessment of conformity with the scientific standard or to the manner in which claims are made, there is a possibility that supplements could be made to appear somehow superior to conventional foods that contain the same nutrient. Such an appearance would not only be untrue, it would be unfair to firms producing conventional foods. FDA knows of no differences in the marketing or use of dietary supplements and conventional foods that would compel a different result.

3. As stated previously in the discussion of the scientific standard in section III.D. of this document, some consumers seek to ensure that the nutrient content of their diet is adequate through conventional foods, others through dietary supplements. Ultimately however, it is the nutrient content of the diet that is significant, not its source. For this reason also, the pace of scientific advances with respect to nutritional

[1] FDA notes that section 403(r)(3)(A) of the act states "Except as provided in paragraph (5)," and that that provision relates to only "a procedure and standard." Thus, it is possible that various aspects of how health claims on dietary supplements are made are governed by section 403(r)(3) of the act. However, because FDA, in exercising its discretion, has tentatively decided under section 403(r)(5)(D) of the act that dietary supplements should be subject to the same requirements that conventional foods are subject to under section 403 (r)(3) and (r)(4), FDA finds that the question of the extent to which the latter sections apply to dietary supplements is moot.

substances does not justify different treatment for dietary supplements than for conventional foods.

In sum, it is the nutrient that is significant, not its source. To ensure that labeling is truthful and not misleading, the same substantive rules should thus be applied to conventional foods and to dietary supplements.

IV. Proposed Provisions

A. Definitions

FDA is proposing the following definitions in § 101.14(a) to clarify the meaning of specific terms used in this proposed rule.

1. Health Claim

FDA is proposing to define "health claim" as any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition. Such claims could include "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes. This definition is derived almost directly from section 403(r)(1)(B) of the act, although it has been modified slightly to incorporate that section's reference to section 403(r)(5)(D) of the act.

The definition includes examples of implied claims and expressly limits them to 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. The definition is intended to make clear that vignettes or other forms of communication that depict the general wholesomeness of a product or other attributes that do not involve more specifically the relationship between a substance in the food and a health or disease-related condition are not health claims for the purpose of this regulation.

FDA recognizes that there is often ambiguity in the message conveyed by a logo or symbol, such as the heart symbol that is often used on labels and restaurant menus. FDA specifically invites comment on the appropriate meaning or warnings to be attributed to the heart symbol and other currently used logos and symbols. Should they be regarded as nutrient content descriptors, health claims, or both? Should they be defined as such by FDA and, if so, how? FDA's goal in considering these questions will be to retain the use of logos and symbols where they are useful in communicating health-related information to consumers but to guard against their use in a manner that would be confusing or misleading to consumers.

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. For example, the recent National Cancer Institute "Five-A-Day" program constitutes dietary guidance and not a health claim (Ref. 1). It could appear on the label of foods that appropriately fall within the terms of the dietary guidance. FDA requests comments on what regulatory approaches, if any, with respect to these types of claims would be most consistent with the act's and the agency's goals of assuring both that useful nutritional information is available to consumers, but that the information is scientifically valid and not misleading. The agency also requests comments on whether, if the agency should regulate such claims, it should do so under proposed § 101.14 or under the general regulatory regime of a label needing to be truthful and not misleading.

2. Substance

In proposed § 101.14(a)(2), FDA is proposing to define the term "substance" to facilitate identification, within the proposed regulation and in this document, of all food components that are candidates to be the subject of a health claim. Thus, FDA is proposing to define the term "substance" to include any component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances. Reference in the definition to "a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances" incorporates the statutory language in section 403(r)(5)(D) of the act, which directs the agency to establish a procedure and standard for claims for dietary supplements.

3. Nutritive Value

FDA is proposing to define the term "nutritive value" to facilitate use of one of the criteria under which a substance is a food and thus appropriately the subject of a health claim. FDA proposes to define the term "nutritive value" as value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy. FDA developed this definition based on the common meaning of the words that make up this term.

"Nutrient" is defined in the *Random House Dictionary of the English Language* as "* * * [a substance capable of] providing nourishment or nutriment." This dictionary defines "nutriment" as "any substance or matter that, taken into a living organism, serves to sustain it in its existence, promoting growth, replacing loss, and providing energy." The dictionary defines "nourishment" as "something that nourishes; food, nutriment, or sustenance." Further, the dictionary defines "nourish" as "to sustain with food or nutriment; supply with what is necessary for life, health, and growth." The agency's proposed definition for "nutritive value" encompasses these common definitions except that the definition is specific for humans, for consistency with section 403(r)(1) of the act.

Use of the phrase "such processes as" in the proposed definition conveys a measure of flexibility that the agency believes is necessary for evaluating future petitions. Within the context of the daily diet, there may be a wide array of substances that could logically supply nutritive value. For example, if a substance as a component of a food is of value for cellular functions by providing catalytic support for protective reactions (e.g., inhibiting harmful processes), that substance could be viewed by FDA as providing nutritive value. FDA also advises that any substance that is identified as a nutrient in section 403(q)(1)(C), (q)(1)(D), or (q)(1)(E) of the act conforms to the proposed definition of "nutritive value."

4. Dietary Supplement

FDA is proposing to define "dietary supplement" as a food, other than a conventional food, that supplies a component with nutritive value to supplement the diet by increasing the

total dietary intake of that substance. A dietary supplement includes a food for special dietary use within the meaning of § 101.9(a)(2) that is in conventional food form.

This term, although used in section 403(r)(5)(D) of the act, is not defined in the 1990 amendments. In the past, FDA has taken a position that the term "dietary supplement" applied only to supplements composed of essential nutrients. However, FDA is not proposing to limit the definition in § 101.14(a) in this way because section 403(r)(5)(D) of the act includes dietary supplements of "herbs" which, as foods, are generally used for flavor or aroma rather than for nutritive value. Herbs contain few essential nutrients, and those essential nutrients that are present are seldom present in significant amounts on a per serving basis. In addition, the legislative history indicates that the term "other nutritional substances" could include a number of substances that have not been shown to be essential (Ref. 2).

5. Disqualifying Nutrient Levels

Section 403(r)(3)(A)(ii) of the act provides that a health claim may only be made for a food that does not contain, as determined by regulation, a nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related, taking into account the significance of the food in the total daily diet. There is no indication in the legislative history of this provision as to what Congress considered to be an amount of a nutrient in a specific food that would increase the risk of a disease.

The statute provides the same standard in section 403(r)(2)(B)(ii) of the act for nutrient content claims, with the requirement that the label or labeling of any food that contains a nutrient at a level that increases the risk of a diet-related disease or health condition shall identify that nutrient in immediate proximity to the claim. A similar requirement for a cholesterol content claim is in section 403(r)(2)(A)(iii)(II) of the act. In referring to these levels for nutrient content claims, FDA uses the term "disclosure levels" (see companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**). The disclosure level for a nutrient for a content claim is the same as the disqualifying level for the nutrient for a health claim.

FDA is defining "disqualifying nutrient levels" (referred to in this document as "disqualifying levels") in proposed § 101.14(a)(5). FDA is proposing to define "disqualifying nutrient levels" as 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. The agency is proposing that the disqualifying 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 labeled serving size, and per 100 g. Any one of the levels, on a per reference amount commonly consumed, a per labeled serving size, or a per 100 g basis, will disqualify a food from making a health claim.

These disqualifying levels are intended to ensure that a food that bears a health claim does not at the same time contain a nutrient at a level that increases the risk of a disease. Because Congress did not identify any specific nutrients that were of concern, consistent with section 403(r) of the act, FDA considered the risk presented by nutrients of the type required by section 403(q)(1) and (q)(2) of the act to be in the label or labeling of food. Of these, nutrients, total fat, saturated fat, cholesterol, and sodium have been associated with increased risk of disease. For maintenance of good health, recommended limits for dietary intake levels have been identified for each of these nutrients (Refs. 5 through 7).

Excessive intake of sugars has been associated with increased risk of tooth decay. However, the specific dietary level at which this increased risk occurs is uncertain, and there is, therefore, no recommended level for dietary intake for sugars. In addition, excessive intake of calories is associated with obesity which is a positive risk factor for a number of diseases. "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7, hereinafter referred to as "Dietary Guidelines for Americans") recommends that all Americans maintain a healthy body weight. However, the level of calories needed to maintain a healthy weight can vary widely among individuals depending on age, sex, build, and physical activity, and there is no specific recommended level for calories in terms of an absolute number or as a function of the intake of other nutrients. Therefore, FDA cannot identify any single level of calories or sugar in a food that would increase the risk of disease.

Although there are recommended levels for dietary intake for total fat, saturated fat, cholesterol, and sodium, there are no generally recognized levels at which these nutrients in an individual food pose an increased risk of disease. Thus, FDA knows of no established or accepted approach for identifying disqualifying levels for these nutrients. FDA has, therefore, used an approach that is based upon the recommended levels for dietary intake of these nutrients in setting the proposed disqualifying levels because deviation from the recommended levels has been associated with an increased risk of disease.

As discussed in the supplementary proposal on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is proposing to codify the recommended dietary levels for fat, saturated fat, cholesterol, and sodium, as well as for several other nutrients, as Daily Reference Values (DRV). The DRVs reflect current and established scientific evidence related to overall nutrient intake and risk of diet-related disease. They are intended to reflect total dietary intake, not intakes from individual foods. Therefore, to derive disqualifying levels for health claims, FDA had to find a way of translating total dietary intake into nutrient levels in individual foods that could be considered to increase the risk of disease.

To determine the appropriate disqualifying levels based on the DRVs for total fat, saturated fat, cholesterol, and sodium, FDA used an approach based on the number of servings of food in a day and available information on food composition. An estimate for the number of servings of food in an average daily meal pattern is approximately 16 to 20 servings (Refs. 8 through 10). If the nutrients under consideration were evenly distributed, then each food serving in a recommended diet would contain 5 to 6.25 percent of each DRV. However, as expected, analyses of FDA's Regulatory Food Composition Data Base (Ref. 11) revealed that these nutrients are not evenly distributed within foods.

In this approach, FDA considered that a nutrient is found in a food category if over half of the foods in the category contained 2 percent or more of the proposed Reference Daily Intake (RDI) or DRV, as appropriate, for the nutrient. Two percent of the label reference value has been used by the agency in the past as a measurable level of a nutrient in a food. The agency further considered a nutrient to be: (1) ubiquitously distributed if it was found in more than 75 percent of the food categories; (2) moderately distributed if it was found in 51 to 70 percent of the food categories; and (3) not widely distributed if it was found in 50 percent or fewer of the food categories. Total fat, saturated fat, cholesterol, and sodium were found to be in 50 to 70 percent of the food

categories (Ref. 12). If the nutrient is available from approximately 50 to 75 percent of food categories, then it is reasonable to expect that it may be available from perhaps as few as half of the foods/beverages consumed. That is, assuming that as many as 20 foods/beverages are consumed in a day (Ref. 10), it is reasonable to expect that the nutrient may be available from perhaps as few as 10 of the foods/beverages. Consequently, if these nutrients are not available in up to half of the food in a balanced diet, then the remaining half of the foods can contain an average of twice the 5 to 6.25 percent, or 10 to 12.5 percent, of the DRV without causing the daily intake to exceed the DRV for any nutrient. The agency used this result as a starting point for determining the appropriateness of 10 percent of the DRV as the disqualifying level for nutrients in foods.

As an initial calculation, the agency determined that the consumption of 10 foods per day containing 10 percent of the DRV would result in a consumption of 100 percent of the DRV in a day. This level of intake is not considered to constitute a risk for diet-related diseases and suggests that the level of 10 percent is too low as a criterion. The agency then doubled the 10 percent value to 20 percent and determined that, assuming the consumption of 10 foods per day at the level of 20 percent of the DRV, the 20 percent criterion results in consumption of twice the DRV. This level of intake is more than sufficient to constitute risk. Thus, the agency tentatively concluded that the appropriate percent of DRV constituting a risk for individual foods was likely to be found between 10 and 20 percent of the DRV.

Accordingly, with the data base available to the agency, FDA evaluated 10, 15, and 20 percent using two criteria to determine whether the consequences of each as the disqualifying level would be reasonable (Ref. 13). The agency analyzed a list of foods to see which foods would be disqualified from bearing a health claim and which would not, and whether the results made sense from a nutritional standpoint. Foods that contain relatively high levels of one or more nutrients that should be consumed less frequently to maintain a diet that meets the guidelines, should be disqualified by an appropriate criterion. On the other hand, foods that would be helpful in a recommended diet should not be disqualified.

Using this analytic strategy, the agency found that the 10 percent level was too low. A number of foods thought to be useful in maintaining a balanced diet would be disqualified at this level, including many vegetable and cereal products. The 20 percent level was too high. Under it, some foods would be permitted to bear health claims that should not be consumed frequently in a healthy diet, including some shortenings and candies. The results of testing the three different levels demonstrated that a level of 15 percent of the DRV was the most reasonable.

Based on these analyses, FDA is proposing that 15 percent of the DRV per reference amount commonly consumed and per labeled serving size (as discussed in the proposal on serving sizes published elsewhere in this issue of the **Federal Register**) of a food be the disqualifying/disclosure level (i.e., 11.5 g of fat, 4.0 g of saturated fat, 45 mg of cholesterol, and 360 mg of sodium for the subject nutrients). These levels are those above which total fat, saturated fat, cholesterol, and sodium will be deemed to increase risk of a diet-related disease or health condition.

However, an analysis (Ref. 14) also showed that there were some foods that do not exceed the 15 percent DRV level on a per serving basis because of small serving sizes but that contain relatively high concentrations of one or more of the subject nutrients on a caloric basis. The agency believes that nutrient-dense foods like these should not be promoted for increased use in a diet because they do not conform to national guidelines, and that these foods should not bear health claims. Therefore, the agency is proposing to also disqualify a food from bearing a health claim (or require nutrient disclosure for content claims) if the food contains more than 15 percent of the DRV for fat, saturated fat, cholesterol, or sodium per 100 g. Based on analyses using FDA's Regulatory Food Composition Data Base (Ref. 14), foods that might be disqualified from bearing health claims because of this criterion include some dessert toppings, gravies, crackers, cookies, and chocolate candies.

The agency recognizes that the nutrients fat, saturated fat, cholesterol, and sodium are not found in the same number of foods nor are they present in foods at the same level. For instance, sodium is more ubiquitous than cholesterol among food categories, but cholesterol is generally found to be present in a food at higher levels of the DRV than is sodium. Therefore, the agency specifically requests comments on this approach for determining the disqualifying/disclosure levels particularly as it relates to the variations in nutrient distributions among foods and to the appropriateness of establishing different levels for different nutrients.

The agency stresses that disqualification of a food from bearing a health claim does not, and should not, imply that the food cannot be incorporated into a balanced diet. To illustrate this point, one of the dietary guidelines advises American consumers to choose a diet that is low in fat, saturated fat, and cholesterol to achieve the benefit of lowered risk for several diet-related diseases (Ref. 7). It is recognized, however, that some foods containing these dietary lipids, such as meats, milk, cheese, and eggs, are also good sources of high quality protein, certain vitamins, and essential minerals. Although such foods when modified to be low in fat may make it easier for consumers to comply with the dietary guidelines, the unmodified foods can still be part of a healthy diet with judicious selection.

FDA does not intend that the establishment of disqualifying levels, as required by the 1990 amendments, be perceived as the creation of a good-food/bad-food concept. It is not true that a food that qualifies for a health claim is good, while one that does not is bad. Rather, 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.

The agency also notes that under section 403(r)(3)(A)(ii) of the act, a claim that would otherwise be disallowed because of a disqualifying level of a nutrient may be permitted by regulation for a food based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the presence of the nutrient that would otherwise be disqualifying be prominently disclosed on the label or labeling in proximity to the health claim. The agency is not, however, aware of information to support such a regulation. FDA will address such situations on a case-by-case basis when evaluating potential health claim topics. If there is information to support permitting a claim on this basis, it should be submitted as part of a petition requesting a regulation authorizing a health claim.

The agency requests comments on how it should exercise its authority under section 403(r)(3)(A)(ii) of the act. For example, the agency notes that whole milk will be disqualified from making a claim about calcium and osteoporosis because it contains fat in

an amount that exceeds the disqualifying level. FDA is not proposing to make an exception for whole milk because low fat milk and skim milk could bear such a claim. Thus, the agency believes that there is no basis to make a finding that permitting such a claim on whole milk would assist consumers in maintaining health dietary practices. The agency requests comments on the appropriateness of its approach to this issue. It has been suggested that the agency should consider the net public health benefit in deciding whether to permit a claim on a food that contains a nutrient at a level that exceeds the disqualifying level (e.g., an osteoporosis claim on a food high in fat). This suggestion is that there are advantages in allowing such claims with full and prominent disclosure regarding other nutrients, similar to the requirements for nutrient claims, because the public health gain from consuming the nutrient that is the subject of the health claim would outweigh the risks from consuming the nutrient that would otherwise disqualify the food. A benefit would derive from consuming the nutrient that is the subject of the claim, and a person could balance his or her intake of the disqualifying nutrient by other food selections as part of a total diet. FDA requests comments on this and other approaches in implementing section 403(r)(3)(A)(ii) of the act.

FDA requests comments, including data or other information, on the proposed disqualification levels. If the agency is persuaded by comments that other disqualifying levels, or that modifications in the proposed disqualifying levels, would be more appropriate, FDA will consider making any appropriate changes in the final rule that is based on this proposal.

The agency recognizes that dietary supplements are not subject to the provisions of section 403(r)(3) of the act. However, as explained previously, FDA has tentatively determined that supplements are appropriately subject to the same rules as conventional foods. As a practical matter, however, FDA doubts that disqualifying levels will have any significant impact on supplements because supplements are formulated products that are being promoted as healthful. It would not be logical for such products to be formulated with significant levels of nutrients with known adverse effects.

B. Preliminary Requirements

Congress and FDA, in proposed § 101.14(a)(2), have broadly defined the substances that may be the subject of a health claim. Consequently, FDA anticipates receiving a wide range of petitions for health claims. However, based on the act as a whole, FDA believes that there are certain criteria that must be met before a substance would qualify as the subject of a health claim. The agency is proposing these criteria in § 101.14(b). They reflect not only the requirements of section 403(r) of the act but also the fact that FDA is charged with ensuring the safety of the food supply, and that the food label is not misleading. Given that agency evaluations of the validity of a health claim will be resource intensive, FDA is proposing not to make such an evaluation unless a petition for a health claim demonstrates that the preliminary requirements in proposed § 101.14(b) are met.

1. Effect on General U.S. Population

Section 403(r)(3)(b)(iii) of the act requires that a health claim be stated in a manner "* * * so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet." FDA believes that, for this requirement to be satisfied, the general U.S. population or some identified subgroup must be at risk with respect to the particular diet-related diease or condition, or, if that is not the case, the proponent of the health claim and any claim approved by FDA 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. This would permit claims to be evaluated even if no showing was made that any particular population group is currently at risk, but it would require that such information be provided as part of any resulting health claim. In addition, the label or labeling would be required to include any potential risks posed by the nutrient for which the claim is made.

2. Components in Food Within Context of Daily Diet

As stated above, Congress and FDA have provided for a wide variety of food components as potential subjects of health claims. These components range from desirable components, such as essential nutrients, to components whose intake should be limited, such as saturated fat, and even to components that have traditionally served primarily as sources of flavor or aroma, such as herbs.

However, the agency does not believe that Congress intended that everything that can be formulated into a form in which it could be consumed enterally should qualify for health claims. To the contrary, a firm could not add a drug to a food to justify a health claim (e.g., addition of aspirin or an herb whose only known use is for medicinal effects such as belladonna, rauwolfia, or yellow dock). Such addition would make the food a drug within the meaning of section 201(g) of the act. Any substance that is to be the subject of a claim must meet the definition of a "food" under section 201(f) of the act. Consequently, the agency is proposing § 101.14(b)(2) and (b)(3) to assure that claims are made only for substances that are food.

With respect to what constitutes food, FDA advises that section 201(f) of the act states that the term "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article." This statutory definition has been interpreted by case law (*Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)) to include "common sense foods," that is, articles used primarily for taste, aroma, or nutritive value, as well as components of food, both inherent and added.

Consistent with the statute and applicable case law, FDA is proposing in § 101.14(b)(3)(i) that a substance that is the subject of a suggested claim that explains the advantages of consuming the substance at other than decreased levels must contribute taste, aroma, or nutritional value to a food, or serve one or more of the technical effects listed in 21 CFR 170.3(o) (e.g., nutrient supplement). In addition, Congress explicitly directed in section 403(r)(3)(B)(iii) of the act that regulation permitting health claims allow the public to comprehend the significance o the health benefit within the context of the total daily diet so that consumers may modify their diets to achieve public health goals. Obviously a substance must be a food for it to have any significance in the diet.

For consumption of a substance to have significance within the context of the daily diet, FDA is also proposing in § 101.14(b)(3)(i) that the substance must retain its food attributes at the levels that are necessary to justify the claim. For example, if the substance is a vitamin that must be present at a therapeutic level for a health benefit to occur, the supplement would not qualify for a health claim under this proposal. A therapeutic level of a vitamin would be far above that level that is normally characteristic of food, and, consequently, the vitamin would not retain its food attributes. However, FDA is not proposing a specific definition in the general provisions of this proposal

for an upper limit of any substance based on the context of the daily diet. Instead, the agency intends to leave it to the petitions that are submitted to demonstrate on a case-by-case basis that the substance is a food component and is appropriately the subject of a health claim regulation.

FDA is proposing that this provision apply to dietary supplements as well as conventional foods. Section 403 of the act applies to foods, and thus FDA considers it appropriate to require that the substances that are to be the subject of a health claim under the authority of section 403(r)(5)(D) of the act, as well as section 403(r)(3) of the act, satisfy the definition in section 201(f) of the act. This provision is fully consistent with section 411 of the act. The proposed provision places no limits on the potency of safe vitamins and minerals. However, if a claimed effect can only be achieved at a level of a vitamin, mineral, or other substance that scientifically cannot be characterized as nutritional, but rather as therapeutic, then that fact will be considered by the agency in deciding whether the claim is appropriate for a food, or whether it is in fact a claim that would make the product a drug under section 201(g)(1)(B) of the act.

Under proposed § 101.14(b)(3)(i), food components that are modified to such an extent that they no longer retain their food attributes will also not be eligible to be the subject of a health claim. If claims are made for such components, the agency may well regard the components as drugs.

In view of the necessity for a substance to be a food to qualify for a health claim, FDA disagrees with the comments that it has received that asserted that health claims should be permitted for over-the-counter (OTC) drugs. For example, a comment asserted that a manufacturer of a bulk-fiber laxative product that makes the drug claim "relief from constipation" should not be prohibited from making a cholesterol-lowering health claim on the label of that product.

FDA believes that a food claim on a drug product would be misleading to consumers. On a drug label, the thrust of all the information is toward what the product itself will do. For example, the label states that the product will relieve constipation. Moreover, it lists *active* ingredients. Thus, there is reason to believe that in the example cited in the comment, consumers will read the cholesterol-lowering claim as saying that the product itself will lower cholesterol levels, and not that a properly structured diet would have the effect. This interpretation would be wrong, and it is FDA's obligation to try to structure the rules for health claims to minimize the possibility that such misunderstandings will occur. Therefore, FDA believes that it would be inappropriate to put a health claim on a drug product.

Moreover, in a 1934 Senate report for a predecessor bill of the act, there was a discussion on the need for a provision to the effect that the definitions of food, drug, and cosmetic should not be construed to be mutually exclusive (Ref. 15). It was concluded that such language would be superfluous:

> The use of which the product is to be put will determine the category into which it will fall * * *. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product. (Ref. 15).

A product that is labeled for relief from constipation has been fairly and unequivocally represented by its manufacturer as a drug. Thus, under this legislative history, the product is subject to regulation only as a drug. As such it would not be eligible to bear a health claim. This is not to suggest, however, that a fiber supplement would not in appropriate circumstances be a food and an appropriate candidate for a health claim. A determination as to whether a claim would be appropriate must be based on the factors proposed in this document and on any specific factors in the regulations in part 101, subpart E.

Further, the comment stated that "dual labeling" of OTC drug products (i.e., drug claims and food health claims in the same labeling) should be permitted to avoid excess proliferation of similar products with different labeling in the marketplace and to be consistent with well-established precedents for dual labeling for drug and cosmetic claims on drug products (e.g., a cosmetic claim, such as "promoting white teeth," and a caries prevention claim for toothpaste).

FDA also rejects this aspect of the comment. The agency believes that the potential for consumer confusion outweighs any concerns about a proliferation of products with health claims. That part of the comment on precedents for drug and cosmetic claims in labeling of the same article is not pertinent to this proposal because of the differences in the substantive requirements for a food health claim compared to those for a cosmetic claim.

3. Safety

As discussed in section IV.A.5 of this document, section 403(r)(3)(A)(ii) of the act states that a health claim may only be made for a food that does not contain any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related, 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.

This fact is particularly significant because the agency will be specifically providing for the health claims that will be made. The agency believes, given its responsibilities under the act, that it would be inappropriate for it to provide for a claim for a substance without assurance that the levels at which the substance will be consumed, or will likely be consumed, in response to the health claim will be safe and in compliance with the food safety provisions of the act.

Accordingly, FDA is proposing in § 101.14(b)(3)(ii) that the substance must be a food ingredient, or a component of a food ingredient, that the proponent of the claim can demonstrate to FDA's satisfaction to be safe and lawful when used at the level that is likely under the claim. 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

claims 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. Given the timeframes that FDA is proposing in response to the act for action on petitions for health claims, the agency anticipates that it may be necessary in many cases to deny the health claim petition without prejudice until the agency has completed its review of the petition for safety of the use of the food ingredient.

By way of explanation, FDA has recognized that it is impracticable to list all substances that are GRAS for their intended use based on their common use in food prior to 1958. For example, FDA regards food ingredients such as salt, pepper, vinegar, and baking powder that were in common use before January 1, 1958, as safe for their intended use. Similarly, § 170.30(d) pertains to food ingredients of natural biological origin that have not been listed by the agency as GRAS and states that such an ingredient will ordinarily be considered to be GRAS if it has been widely consumed for its nutrient properties prior to January 1, 1958, without known detrimental effects, is subject only to conventional processing as practiced prior to January 1, 1958, and no known safety hazard exists. The GRAS ingredients listed in part 182 include manmade ingredients and ingredients of natural origin that were listed in most cases during 1958 through 1962 without a detailed scientific review of all available data and information relating to their safety, and thus their GRAS status is likewise based primarily upon common use in food before January 1, 1958.

In the case of ingredients used in accordance with a food additive regulation, a GRAS affirmation regulation under part 184, or a prior sanction, use of the claim within the provisions of the regulation or sanction will ensure that the ingredient is used under conditions found by the agency to be safe, particularly in the case of food additives and substances affirmed as GRAS because these two classes of ingredients have been subjected to extensive safety review by the agency.

The agency recognizes that health claims are likely to have a significant impact on the level of total consumption of food substances within the U.S. population (e.g., where the total number of foods consumed containing the substance increases without the level of use of the substance within those foods increasing). FDA intends to monitor such consequences closely. To assure that safety is not compromised by changes in consumption patterns, FDA intends to consider whether existing GRAS and food additive regulations need to be revised to adequately ensure the safety of the food supply.

For example, the agency is concerned about the changing consumption patterns associated with the development and introduction into the marketplace of new sources of dietary fiber, along with the increased use of fiber sources as food ingredients or as supplements of fiber, that has occurred in recent years and that could be exacerbated if a claim is ultimately authorized for fiber. FDA intends to update its GRAS regulations for sources of fiber in the near future. To deal with this issue, the agency intends to initiate a review of the existing types of isolated dietary fibers and their use as a broad class of foods to identify and assess scientific information on the safety of this use. This review will include consideration of the biological effects of different fibers, the extent to which such effects are significantly different for subclasses of dietary fiber, and whether biological effects are significantly altered by chemical or physical changes and by processing. FDA may use the results of this or other reviews to develop a new strategy for assessing food safety.

Because sections 201(s) and 409 of the act apply to substances that become components of food by virtue of their intended use, and not to naturally occurring components of food such as cholesterol, these statutory provisions do not apply in instances in which the substance for which a claim is made is a nutrient identified in section 403(q)(1)(C) or (D) of the act that is a component of a whole food (not a food ingredient). However, the previously discussed disqualifying levels proposed under authority of section 403(r)(3)(A)(ii) of the act should provide an appropriate measure of safety for these substances.

C. Validity Requirements

1. The Scientific Standard

FDA is proposing in § 101.14(c) that health claims for all substances, including vitamins, minerals, herbs, and other similar nutritional substances in dietary supplements, be required to meet the following scientific standard:

> 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.

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).

As Congress recognized (Ref. 1), this standard has essentially the same content as the standard proposed by the agency in the 1990 reproposal. Some of the comments about the appropriate content of the standard favored it as proposed. However, other comments objected to the standard or suggested modifications. Some of these comments expressed concern about the provision of the standard concerning "the *totality* of publicly available scientific evidence." A few comments asserted that this provision should be deleted because new, unreproduced, or controversial findings might not be considered. Other comments asserted that unpublished research findings, including proprietary data, should be considered in assessing conformity with the standard. Many comments objected to the provision requiring "significant scientific agreement" because of a belief that this provision means "consensus" or "unanimity." Several 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.

There is now no basis under the act for the agency to modify any provisions of the proposed standard. The statute ratifies and adopts this proposed standard (section 403(r)(3)(B)(i) of the act). FDA advises, however, that it will consider under this standard the *totality* of publicly available scientific evidence concerning potential health benefits, including new, unreproduced, or controversial findings. Consistent with the intent of Congress in enacting the 1990 amendments (Ref. 1), FDA will use its discretion to give greater weight to those studies that are more persuasive, regardless of the nature or age of the studies.

The agency cannot delete the provision in the standard for the evaluation of validity to be based upon publicly available scientific evidence

because this provision is a requirement of the act (section 403(r)(3)(B)(i)). Any interested party may submit information that is not publicly available in support of a proposed health claim. However, the agency will make all information that is submitted to support a health claim publicly available through its Dockets Management Branch (address above).

In addition, Congress stated that while the studies relied on to support a claim need not necessarily be published in peer reviewed journals, the agency may look to publication as a factor in evaluating the weight to be given the study (Ref. 1). The agency also cannot revise the requirement for "significant scientific agreement" because this requirement is also now a provision of the act. However this provision does not require a "consensus" or "unanimity" of scientific opinion. The requirements of this provision are explained in the legislative history of the 1990 amendments. The House Report (Ref. 1) states:

> The standard is intended to be a strong one. The bill requires that the Secretary have a high level of confidence that the claim is valid. However, the standard does not require a unanimous agreement among experts. Instead, the standard requires that there must be a significant agreement among experts, but it does not require that every expert in the field approve or agree with the claim.
> (H. Rept. 301-538, 101st Cong., 2d sess., 19).

For dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances, the agency has the discretion to propose different requirements for a scientific standard. However, for reasons explained above in section III.D. of this document, FDA is proposing the same standard.

FDA has applied the standard in proposed § 101.14(c) in reading its tentative determinations on the 10 substance-disease topics that are addressed elsewhere in this issue of the **Federal Register.**

2. Assessment of Conformity With the Standard

FDA is proposing no specific provisions pertaining to the agency's assessment of conformity with the standard. However, FDA envisions that to satisfy the scientific standard, a health claim must be supported by a sound body of scientific evidence that establishes the relationship between a substance and a particular disease or health related condition. The data must persuade FDA that the proposed claim is valid, and that the benefits featured in the claim pertain to the general U.S. population or to a significant segment of the U.S. population. Thus, the body of scientific data must be strong. A few unconfirmed studies, incompletely documented data, or significantly contradictory findings do not constitute a sound body of evidence.

Further, the standard also requires that significant agreement exist among qualified experts that the claim is valid. "Qualified experts" include individuals whose training and experience have produced a general or specific scientific expertise in the diet/health topic being considered for a specific claim. FDA is not proposing to define "significant agreement" among these experts because each situation may differ with the nature of the claimed health benefit. The agency believes that any specific definition of such agreement might prove arbitrary when viewed in light of the multiplicity of potential health benefits and the widely variable nature of expertise required to evaluate the significance of these benefits. Instead, FDA intends to use the discretion granted it by the 1990 amendments to assess the degree of agreement on a case-by-case basis. Nevertheless, FDA will take into account the full range of opinions among qualified scientific experts on a specific claim in determining whether significant agreement exists.

FDA is not prescribing a specific set, type, or number of studies as being sufficient to support a health claim. The agency will consider all relevant data on a topic, including clinical studies (human studies conducted in a controlled clinical setting), epidemiological data (data from uncontrolled human populations), and animal studies. However, 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. A full discussion of how to evaluate all types of studies on the impact of intake of a dietary substance on health is contained in chapter two of "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 6). Important aspects from that reference provide part of the basis for the following discussion of how the agency intends to evaluate the quality of a study supporting a health claim. FDA requests comments on this approach.

FDA believes that, for human studies, data relied upon must be generalizable to, and preferably obtained from, the U.S. population. FDA intends to give the greatest weight in its evaluation to well designed studies conducted with human subjects and in conformity with the agency's requirements regarding institutional review (21 CFR part 56) and informed consent (21 CFR part 50). Data from laboratory studies using animals, in vitro tests, and chemical analyses of the food substance will also frequently be required to understand the nature of the relationship between the substance and the disease or health related condition. If nonclinical studies (animal or in vitro laboratory studies) are to be considered, those conducted in conformity with the good laboratory practice provisions in 21 CFR part 58 will be given greater weight.

Among human studies, certain types of designs may carry greater weight in demonstrating the purported substance-to-disease relationship. Ecological studies (correlational studies using grouped population data) of diet-disease relationships relate dietary patterns of whole populations to disease incidence or mortality rates for whole populations. Because these studies do not examine the relationship between diet and disease among individuals, the studies have been traditionally regarded as useful for generating, rather than definitively testing, a scientific hypothesis (i .e., an unproved theory). Such studies are descriptive in nature rather than analytical. Thus, the results of ecological studies would be insufficient to demonstrate a relationship without other types of data to support them.

Analytical epidemiology studies (controlled studies on human populations) include case-control studies and cohort studies. In case-control studies, the relationship of a substance to a disease would be examined retrospectively by comparing persons with the disease to persons without the disease as to their exposure to the substance. Cohort studies, on the other hand, observe prospectively individuals who have been exposed to the substance, and those who have not, to determine if disease develops over time. Case-control studies provide less reliable estimates of the strength of associations than cohort studies because they are subject to bias in the detection and selection of cases and to bias in assessing exposure. Also, case-control studies require careful consideration of the validity of dietary data and of the appropriateness of control groups.

An intervention study is a type of cohort study in which the "exposure," or substance under study, is administered, or controlled, by the study investigators and the subjects for disease occurrence. For example, the study investigators may select a group of people to undergo a life-style modification, such as cessation of smoking, whereas an

additional group would make no changes. Both groups would then be followed over time, and their incidence of disease compared. The study investigators would have more control over an intervention study than a routine prospective cohort study because they can randomly select individuals for each group, thereby controlling for attributes other than the one under study that may affect disease occurrence.

Although intervention studies are the most reliable of epidemiology studies for determining cause-and-effect relationships, FDA recognizes that generalizing from selected populations often presents serious problems in the interpretation of such studies. Furthermore, in some cases, such as with cancers of different sites, intervention dietary studies are not feasible because diseases with lower frequency of occurrence, such as rare forms of cancer, require very large study samples to detect an effect. Moreover, there frequently are long latency periods from dietary exposure to onset of disease, often 20 to 30 years.

In evaluating proposed claims, FDA will take into account the feasibility of obtaining what might be considered to be the best evidence and will weigh issues of feasibility against the scientific merits of available studies. In some situations, scientific or ethical conditions may exist that would preclude the acquisition of data from human studies. Such scientific conditions associated with human research include the length of time needed to show an effect (e.g., years versus months), the ability to measure specific indicators (e.g., tissue samples), and the numbers of subjects required to show an effect. Ethical conditions would include potential risks associated with human studies in situations in which the study design would require removal of an individual from known beneficial treatment for the disease or would have an unreasonable, potentially detrimental impact on control subjects. Consequently, the agency would give data from uncontrolled studies greater consideration when either scientific or ethical conditions prevent more controlled studies.

A combination of various types of studies can frequently compensate for deficiencies in individual studies and thus provide a stronger case to prove or disprove a hypothesis. Where FDA evaluates a meta-analysis (i.e., a reanalysis of pooled data from several distinct human studies), the agency considers such an analysis primarily as supporting evidence, rather than as primary evidence, that can confirm the validity of data concerning a health claim. The agency must carefully scrutinize each meta-analysis to assess the soundness of its design and the quality of the data from individual studies to determine the significance of the data. Such scrutiny requires review of copies of all the original studies used for the meta-analysis.

Data from animal laboratory studies, in vitro tests (tests in an artificial environment outside the living organism), and chemical analyses of the substance are particularly valuable in providing information on mechanism of action and pathogenesis (the development of a diseased or morbid condition) to help in understanding the nature of the relationship between the substance and disease or health-related condition. Experiments in different animal species can examine genetic variability and can permit more intensive observation under controlled conditions than can human studies. However, extrapolation of data from animal studies to humans is limited by the comparability of physiologic and metabolic parameters between animals and humans.

The consistency of the demonstrated association between a substance and the disease or health-related condition is important when considering whether evidence from animal studies supports a health claim. Thus, the strongest animal evidence would be based on data derived from studies on more than one animal species or test system, on data that have been reproduced in different laboratories, and on data that give a statistically significant dose-response relationship.

In assessing the overall data in each topic area, FDA will apply these general considerations but will seek to avoid the pitfalls of inflexible adherence to rigidly defined criteria. The overriding principle will be to determine whether there are consistent results from different types of well-conducted human studies by different investigators in different populations. The strengths and weaknesses of each individual study will be evaluated. When experiments with animal models are appropriate, consistency of results between human and animal studies will also be considered. Such results will be interpreted in the light of any available evidence on the biological mechanism of the substance-disease relationship, evidence of a dose-response relationship, and similarity of the test substance with the nutrient or food component of interest. The significance of the disease from a U.S. public health standpoint will also be evaluated. In sum, FDA intends that its judgments concerning the overall quality of available data, the appropriateness of the study design, the consistency across different types of studies and laboratories, and the conclusions derived from the total body of evidence will be based on those generally recognized scientific procedures and principles that are most appropriate to the issues being addressed.

3. Use of Scientific Summaries

A number of comments on the 1990 reproposal addressed the concept of development of a scientific summary as part of the procedure for regulating health claims. However, FDA no longer intends to use a separate document called a "Scientific Summary." The 1990 amendments require that health claim decisions be made by regulation. The agency will discuss the scientific information substantiating the substance/disease relationship in the **Federal Register** document that proposes a regulation for the health claim. The regulation itself will include a summary of the scientific information and the conclusions supported by the science. Therefore, there is no longer a need for the Scientific Summary document.

The 1990 amendments resolve many other issues raised in the comments. The request that scientific summaries be developed in an open process is met by the rulemaking process for establishing regulations. There is opportunity for public comment on the agency's proposed analysis of the scientific information and conclusions. The petitions process that FDA is proposing in response to the 1990 amendments provides the opportunity requested by some comments for manufacturers to develop a scientific summary for the agency's evaluation.

One comment questioned the agency's ability to keep a health claim scientific summary current with the evolution of new data and information on the subject of the summary.

This point is well taken and indicates a need for the agency and the food industry to be mindful of new scientific information on the association between a substance and disease or health-related condition for which a claim is permitted by regulation. The likelihood of a need for frequent revision of any health claim regulation is greatly diminished, however, by the requirements of the statutory standard. The statute requires that, for each health claim, there be significant agreement among experts qualified by training and

experience that the claim is supported by a sound body of substantive scientific evidence. Accordingly, the likelihood of a regulation for a claim rapidly becoming obsolete is small, although not nonexistent. While resource limitations make it impossible for FDA to commit that it will ensure that its health claim regulations will reflect significant developments, any person who concludes that a revision is appropriate can request the revision in a petition using the procedures established by this rulemaking.

4. PHS Committee

In the reproposal (55 FR 5176), FDA proposed to establish a Public Health Service (PHS) Committee on Health Messages to serve as an advisory body to FDA on issues relating to the use of food labels to communicate information on the relationship between diet and health. This committee would have played a key role in assessing conformity with the scientific standard.

Although FDA still sees merit in the proposed role of this committee, section 403(r)(4)(A)(i) of the act provides short timeframes for an FDA decision on whether to file a petition for a health claim and on whether to issue a proposed regulation in response to the petition. With such short timeframes, it would be difficult to incorporate the committee into the regular procedures for assessing requested claims. The agency would find it difficult to assess the petition; forward that assessment to the committee; provide a reasonable time for the committee to consider FDA's assessment; reevaluate the agency's assessment, if necessary, in light of the committee's conclusions; and publish a proposed rule in the **Federal Register** within the statutorily required 90 days from the filing of the petition. However, the agency reserves the right to convene a panel of experts from within the Public Health Service of the Department of Health and Human Services (DHHS) to consider particular petitions. When such a panel is convened, selected DHHS Nutrition Policy Board representatives and key FDA and PHS scientists, with expertise in the subject under consideration, will review the suggested claim. These reviews will provide comments to FDA on the science relating to the claim.

Because the committee is not being formally established, the agency is not addressing specific comments concerning the committee. (Comments concerning the committee were mixed. Some comments endorsed the establishment of a committee, while other comments opposed it or suggested modifications in its proposed role or its composition.)

D. General Labeling Requirements

As explained previously in this document, FDA will propose a regulation in part 101, subpart E when the agency determines that a health claim is valid. The first proposed provision of § 101.14(d)(1) sets forth this agency commitment. This provision also advises that FDA will propose to provide for the listing in the nutrition label of a substance about which FDA is authorizing a health claim if no provision for listing the substance exists. FDA believes that such a provision is necessary to ensure that consumers can readily obtain specific information concerning how much of the substance is present in at least those foods on which a claim about the substance appears.

The other provisions of proposed § 101.14(d) contain general labeling requirements for the health claims that the agency provides for by regulation to ensure that consumers are provided with valid and reliable information about the value that ingestion (or reduced ingestion) of the particular substance, as part of a total dietary pattern, may have in affecting certain diet-related diseases or conditions. (Proposals concerning specific health claims in part 101, subpart E that appear elsewhere in this issue of the **Federal Register** list additional requirements for specific health claims on food labels.) The following is a description of the general requirements for health claims and FDA's rationale for them:

1. The Claim Must Be Consistent With the Authorizing Regulation

Proposed § 101.14(d)(2)(i) states 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.

This provision reflects the requirement under section 403(r)(3)(A)(i), that a health claim may only be made if it complies with the regulations issued by the Secretary (and by delegation, FDA). The act establishes fairly detailed requirements for such regulations. Section 403(r)(3)(B)(iii) of the act states that a regulation authorizing a health claim shall require that the claim accurately represent the relationship between a nutrient and a disease or health-related condition and the significance of each such nutrient in affecting such disease or health-related condition. Further, under this section of the act, the claim is to be stated in a manner that enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

To facilitate compliance with these requirements, FDA intends to provide in each regulation authorizing a claim a summary of the scientific information on the substance-disease relationship and a model health claim that includes all the required information.

FDA proposed to establish model health claims for each acceptable health claim in the February 1990 reproposal. The model health claims were to serve as examples for acceptable label statements and to provide guidance for manufacturers who chose to use different phrasing in a health claim. The 1990 reproposal stated that the model health claim would include:

(1) A brief capsulized statement (e.g., about 50 words in length) of the relevant conclusions of the appropriate scientific summary;

(2) A statement of the extent to which the food product contains or does not contain the key food component, and how this food product helps the consumer to attain a total dietary pattern or goal associated with reduction in the risk of the relevant chronic disease;

(3) A reference indicating that more complete nutrition/chronic disease information is available from the appropriate consumer health claim summary, and how that summary may be obtained; and

(4) A statement directing the consumer's attention to the nutrition label for further nutrition information.

The above elements for the model health claim are not as comprehensive as the 1990 statutory requirements for a health claim. Much of the information that would provide an understanding of the significance of the claim within the context of the daily diet would have been included in a consumer health claim summary which, under the 1990 reproposal, was not required to be readily available at the point of purchase. However, under the 1990 amendments, the health claim must include all relevant information (see section 403(r)(3)(B)(iii) of the act). The agency will ensure that all model health claims that it prepares, including those on the specific substance disease topics published elsewhere in this issue of the **Federal Register**, will comply with this requirement.

A summary of the comments pertaining to the reproposal's elements for the model health claim follows.

a. Most of the comments on this subject accepted the concept of a model health claim. Many comments, however, focused on the extent to which a claim on a product label or in labeling would be allowed to depart from the model claim. One consumer organization urged that only claims developed by FDA be allowed as health claims on food products. Recommending that deviation from model health claims not be permitted, the comment suggested that allowance could be made for manufacturers to devise their own health claims provided that they are precleared by FDA. Other comments requested that a model health claim serve as an example for a health claim and that it not be prescriptive. Some urged that manufacturers be allowed the flexibility to make changes in a model health claim so as to vary the content of the claim. They contended that after a time, unvarying messages are likely to become unnoticed and, hence, ineffective.

Section 3(b)(1)(A)(vii) of the 1990 amendments, in describing the regulations on health claims to be established by FDA, states that the regulations shall not require a person who proposes to make a claim described in section 403 (r) (1) (B) of the act (health claims) which is in compliance with such regulations to secure the approval of (the agency) before making such claim. This provision prohibits the agency from requiring preclearance of the phrasing of a claim provided the claim meets the criteria established in the regulation.

The principal reason for developing model health claims is to provide examples of health claims that are clear, accurate, and contain all elements that are necessary for consumers to use and understand the claim. Manufacturers may use a model health claim with the assurance that it is consistent with the permissive regulation authorizing the claim. Manufacturers who choose to craft their own version of a claim from a model claim are free to do so under section 3(b)(1)(A)(vii) of the 1990 amendments. However, the claim they use must be fully consistent with all the regulatory requirements for that health claim. If the labeling does not conform to the regulation, the product is subject to regulatory action as a misbranded food and, possibly, as a drug.

b. Several comments stated that the minimum material facts for a health claim, as generally described for the proposed content of a model health claim in the 1990 reproposal, would be too "wordy" to be effective and too extensive to be accommodated on a product label.

FDA recognizes that some model health claims may be "wordy," but the 1990 amendments have imposed new statutory requirements for health claims to ensure that consumers have sufficient information on the label or labeling to permit a fully informed purchasing decision. As explained previously, section 403(r)(3)(B)(iii) of the act requires that the claim for conventional foods be stated in a manner that enables consumers to understand the relationship of the substance to the disease, the significance of the substance in affecting the disease, and the relative significance of the information in the context of the total daily diet. These statutory requirements cannot be ignored even though, in some instances, the requirements may result in "wordy" claims.

Nevertheless, FDA will attempt to craft specific model health claims that are brief but yet include all essential information to meet the requirements of the act. With specific, rather than generalized, model health claims in the documents on the substance-disease topics elsewhere in this issue of the **Federal Register**, the agency will be able to more easily respond to comments on the content of the proposed claims to determine if they can be made less "wordy" while retaining essential information.

c. One comment said that it would be unnecessary to require a statement directing a consumer's attention to the nutrition label because most consumers interested in the nutritional value of a food would be aware of the nutrition label.

The agency agrees that a health claim need not require a statement directing the consumer's attention to the nutrition label for further nutrition information. With the significant changes in the 1990 amendments to expand the use of nutrition information on a food label, and with education activities addressed to consumers about the importance of that information in maintaining healthy dietary practices, an explicit reference in conjunction with a health claim to nutrition information should not be necessary. This position is consistent with the 1990 amendments which do not require a referral statement in conjunction with health claims as they do in section 403(r)(2)(B) of the act for nutrient content claims (but see section 403(r)(3)(A)(ii)).

d. One comment maintained that a model health claim may be inadequate to convey to consumers all that is necessary to understand the claim. The comment suggested that a manufacturer should have the option for providing information related to a health claim in a product or package insert.

As explained previously in this section, the 1990 amendments impose more comprehensive labeling requirements for health claims than FDA proposed for model health claims in the 1990 reproposal. Thus, Congress has ensured that health claims will be adequately informative for consumers to understand the claim. However, the 1990 amendments refer to health claims made in the labeling of a food as well as on the label (21 U.S.C. 343(r)(1)). Consequently, labeling such as a package insert may serve as the means of providing the required information when the label does not contain sufficient space for the complete health claim, so long as the claim is presented in a manner that complies with proposed § 101.14(d)(2)(iv).

Firms may provide information on labeling in addition to that required by FDA that may be helpful to the consumer in obtaining a deeper understanding of the claim. However, any such additional information would need to be truthful and not misleading. Such information would also have to be consistent with the agency's assessment of the scientific information justifying the health claim, as published in **Federal Register** rulemaking proceedings.

2. Claim Shall Describe Only Those Effects Found To Be Substantiated by Evidence

Proposed § 101.14(d)(2)(ii) states that the claim shall be limited to describing the value that ingestion (or reduced ingestion) of a substance, as part of a total dietary pattern, may have on a particular disease or health-related condition.

FDA will evaluate all relevant data when determining whether to authorize a claim on a substance-disease relationship. On finding that a claim is supported by the available evidence, the agency will describe all the effects of ingestion (or reduced ingestion) of a substance on the disease or health-related condition in the regulation authorizing the claim, which will be codified in part 101, subpart E. Proposed § 101.14(d)(2)(ii) limits the effects described in a claim to those that the agency finds are substantiated by the evidence. Any other effect would not have been substantiated, and including such an effect in a claim would be misleading. FDA is proposing this provision under section 403(r)(3)(B)(iii) of the act, which requires that the claim accurately represent the significance of

each substance in affecting the disease or health-related conditions.

3. Claim Shall be Complete, Truthful, and not Misleading

Proposed § 101.14(d)(2)(iii) states that the claim shall be complete, truthful, and not misleading. Where factors other than consumption of the substance affect the health benefit, such factors shall be addressed in the claim.

This criterion is central to the successful implementation of the proposed health claims policy. "Truthful and not misleading" claims are already mandated by section 403(a)(1) of the act, which deems a food misbranded if its labeling is false or misleading in any particular. Labeling claims are also already subject to statutory requirements concerning adequate disclosure of significant information. Under section 201(n) of the act, labeling can be misleading based on what is omitted from, as well as on what appears on, the label. For example, it would be misleading if a claim omitted significant information that is needed to properly interpret the claim. Even though this proposed provision reflects these statutory requirements, FDA believes that it is important to include the provision in the regulations to ensure that manufacturers understand that the claims that they formulate under FDA's regulations must be complete, truthful, and not misleading.

It has been suggested that FDA should allow claims that reflect more preliminary or controversial 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 casual 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.

Related to proposed § 101.14(d)(2)(iii), FDA is proposing to retain § 101.9(i)(1) (redesignated as § 101.9(k)(1)). This regulation states that any claim on a food product that implies that a substance is effective in the cure, mitigation, treatment, or prevention of a disease that is diet related not only makes the product a drug, but is misleading and will render the product a misbranded food. Such claims imply a degree of association between the substance and the disease that is not supportable for any food within the context of a daily diet. The Surgeon General's Report on Nutrition and Health (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).

4. Claim Shall be Presented in One Place

Proposed § 101.14(d)(2)(iv) requires that all information that is required by the authorizing regulation appear in one place without other intervening material. The entire claim must appear on the label or other labeling. However, this provision contains an exception so that when the entire claim appears on other labeling than the label, the label may bear the statement, "See ____ for information about the relationship between ____ and ____," with the blanks filled in with references to the location of the labeling containing the health claim, the name of the substances, and the disease or health-related condition. This statement may be coupled with the use of the relevant nutrient content claim. Thus, the food label could state: "High in calcium. See side panel for nutrition information. See attached pamphlet for information about the relationship between calcium and osteoporosis."

This provision is proposed under sections 201(n), 403(a), and 403(r)(3)(B)(iii) of the act to ensure that consumers are not misled by the omission of any essential elements of the health claim but at the same time to permit manufacturers to make consumers aware of the claim. Because labels may be too small to accommodate the entire claim in some circumstances, FDA is proposing an exception to the requirement for complete listing. However, the exception is not limited to situations where the label is too small because the agency sees no potential for consumer deception under the proposed provisions.

5. Claim Shall Enable Public To Understand Information Presented

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

This provision is a reiteration of the statutory language in part of section 403(r) (3) (B) (iii) of the act. FDA has considered this requirement in developing the content of the proposed model health claims in the proposals to authorize health claims that appear elsewhere in this issue of the **Federal Register.** The model health claims have been written to provide the basis for a consumer to decide whether (and how) the labeled food best fits into his or her diet. Thus, for example when a substance-disease relationship has more significance for a particular segment of the population than for the general population (e.g., a segment defined by age, sex, race, or other determinant), the agency has tried to reflect that fact in the model claim.

Further, the proposed provision requires that the claim permit the consumer to understand the significance of the information that it provides within the context of the total daily diet. For example, where the level of an increasable nutrient in a food is at the upper range of normal dietary levels, there may be no known benefit from further intake of that nutrient. In such circumstances, consumers should be advised of this fact as part of the claim. The proposed regulation on calcium and osteoporosis that appears elsewhere in this issue of the **Federal Register**, for example, requires that foods that make

a claim on this topic bear a label statement indicating that there is no known benefit from intake of more than 200 percent of the RDI for calcium.

6. Claim Shall Be Made on Foods With Appropriate Levels of the Substance

Unless the authorizing regulation provides otherwise, FDA is proposing in § 101.14(d) (2) (vi) that a claim about the effects of a decreased dietary intake of a substance can be made on any food in which the substance is present at a level that meets the definition for the use of a "low" nutrient content claim for that substance, if such a definition has been established under Part 101, or is present in an amount that is consistent with that specified in the regulation. Such levels are appropriate for this purpose because FDA has sought to define "low" as a level of a substance (nutrient) that will be helpful to individuals in attempting to comply with dietary recommendations. FDA is proposing in separate documents published elsewhere in this issue of the Federal Register definitions in part 101, subpart D for the terms "low fat," "low saturated fat," "low cholesterol," and "low sodium."

If a definition for a "low" nutrient content claim does not exist for the substance, in authorizing a claim, the agency will determine the level of the substance that would qualify a food for a health claim. This determination will be based on any relevant dietary recommendations and on the available scientific information on the specific substance/disease relationship. This level will be included in the regulation in part 101, subpart E that authorizes a claim.

To bear a claim that is based on increased dietary intake of a substance, a food must contain that substance in an appropriate form and at a sufficiently high level. FDA is proposing in § 101.14(d) (2) (vii) that to meet this requirement, the food must contain the substance at a level that would meet the definition for a "high" nutrient content claim if such a definition has been established for that substance in part 101, subpart D. If no definition for a "high" nutrient content claim has been established for the substance, then the agency will propose to establish a specific level in the authorizing regulation.

FDA is proposing that a "high" nutrient content claim be defined as 20 percent or more of the RDI or DRV (§ 101.54(b)). Given the fact that nutrients are not ubiquitously distributed in the food supply, the agency believes it is necessary to meet this proposed requirement to ensure that the food carrying a health claim makes a significant contribution to daily intake. For example, since calcium is not ubiquitously distributed in foods, to achieve 100 percent of the RDI, at least five foods containing 20 percent of the RDI would need to be consumed daily. Based on food consumption patterns, this is a reasonable number of servings and could result in a diet that will achieve the level of the nutrient necessary for the claimed benefit.

FDA believes that a claim based on a increased level of a substance in the diet implies that the food contains a level of the food that makes a significant contribution to the daily diet. Thus, if the food fails to comply with proposed § 101.14(d)(2)(vii), its labeling would be misleading and would misbrand the food.

The agency considered alternatives to the criterion that for health claims dealing with decreased or increased dietary intake of a substance, the level of the substance in a food must meet the definition for a "low" or "high" nutrient content claim. It considered whether a food meeting the definition for a "reduced" or "more" nutrient content claim should also be deemed to qualify for a health claim for that nutrient. On the one hand, some have argued that because the claimedbenefits derive from either decreased or increased dietary levels of the substance, any food that would be helpful in achieving those levels should be permitted to bear a claim. For example, the guideline for lowering salt and sodium dietary intake advises consumers to choose foods that are lower in sodium most of the time. On the other hand, others assert that any health claim should be permitted only for those foods that, when incorporated in a daily diet, are fully compatible with public health recommendations for improving dietary practices within the general U.S. population. "Dietary Guidelines for Americans" (Ref. 7), for example, states that diets low in fat, saturated fat, and cholesterol can be attained through appropriate food selection that includes choosing dairy products that are either lowfat or fat-free. Moreover, if a food starts with a high level of a nutrient, it could meet the definition of "reduced" but still contain a large amount of the nutrient (e.g., a reduced-sodium pickle).

The agency has taken these and other factors into account. Because it believes that compliance with dietary recommendations will be facilitated if only foods that conform to the "low" and "high" nutrient content claim definitions, FDA is proposing to require conformity with those definitions in § 101.14(d) (2) (vi) or (d) (2) (vii).

The agency, however, specifically solicits comment on this issue. Its desire is to establish a sound, equitable requirement that will promote public health. The agency requests comment on whether use of claims on foods that meet the definitions of "reduced," "more," or even other comparative claims will be useful to consumers in achieving the efforts that are highlightedby the claim, or whether allowing the claims on such foods will be misleading because the nutrient levels are not low enough, or not high enough, to really contribute to the claimed effect.

7. Nutrition Labeling for Restaurants

Proposed § 101.14(d) (3) requires that a food that bears a health claim be the subject of nutrition labeling in accordance with §§ 101.9 and 101.36.

Under current § 101.9(a), nutrition labeling is required on all products that contain an added vitamin, mineral, or protein or whose label, labeling, or advertising includes any nutrition claim or information. The agency adopted this requirement under sections 403(a) (1), 201(n), and 701(a) of the act (21 U.S.C. 303(a), 321(n), and 371(a)). Under section 403 (a) (1) of the act, a food is misbranded if its label or labeling is false or misleading in any particular. Under section 201(n) of the act, the label or labeling of a food is misleading if it fails to reveal facts that are material in light of representations actually made in the label or labeling. Finally, under section 701(a) of the act, the agency has authority to issue regulations for the efficient enforcement of the act.

The applicability of current regulations to restaurant foods was discussed in rulemaking promulgating § 101.10 *Nutrition labeling of restaurant foods* (21 CFR 101.10) (39 FR 42375, December 5, 1974 and 41 FR 51002, November 19, 1976). In the preamble to the proposed rule, the agency discussed its belief that nutrition education is of prime importance and stated that it will take every opportunity to foster the dissemination of such information to the consumer, including the use of nutrition labeling in restaurants. However, the agency acknowledged that if nutrition information provided in restaurants necessitates the expense of nutrition labeling, the restaurant "may choose not to provide any nutrition information in advertising or labeling, on the basis that the added cost of providing detailed information might cause the project of providing nutrition information not to be worth the expense" (39 FR 42375). Therefore, to encourage the dissemination of nutrition information in

the food service industry, FDA proposed to exempt ready-to-eat foods from the requirement of bearing nutrition labeling on food labels if the required nutrition labeling was displayed prominently on the premises by other means, e.g., counter cards or wall posters, where the information would be readily available to the consumer when he is making a menu selection.

Subsequent action on this proposal led to the issuance of a statement of policy in § 3.207 (recodified as 21 CFR 101.10 in the **Federal Register** of March 15, 1977 (42 FR 14302)) that if any advertising or labeling (other than labels) includes a claim or information about the total nutritional value of a combination of two or more foods (e.g., a combination consisting of a hamburger, french fries, and milkshake), then, as an alternative to providing nutrition information about each separate food on the food label, the restaurant may instead provide information about the total nutritional value of the combination of foods, provided that the statement of total nutritional value follows the nutrition labeling format and provided that the nutrition information is effectively displayed to the consumer both when he/she orders the food, and when he/she consumes the food.

As discussed in the supplementary nutrition labeling proposal published elsewhere in this issue of the **Federal Register**, the 1990 amendments specifically exclude restaurant foods from the requirement for nutrition labeling. However, as stated above, the agency believes that it has the authority to issue regulations requiring restaurants that choose to make health claims to adhere to the requirements for such claims, including nutrition labeling.

FDA is not, at this time, making any specific provisions for the nutrition labeling of restaurant foods. FDA specifically seeks comment on how it should handle this issue. On one hand, many believe that it is important that consumers be given useful and meaningful nutrition information. On the other hand, many continue to be concerned, as FDA was in 1974, that the cost of compliance not be so high that restaurants will not be willing to offer and identify through health claims those foods that will assist consumers in selecting diets that provide health benefits. Therefore, the agency is requesting comments on whether and to what extent it has a basis for nutrition labeling when health claims are made on restaurant foods, or whether a requirement for such labeling would discourage restaurants from making health claims because of the cost associated with nutrition labeling.

If, based on comments received, FDA were to require nutrition labeling of restaurant foods, should the requirement apply only to large restaurant chains with fixed menu items? Additionally, should the content or format of nutrition labeling be different for the food service industry than for packaged foods? If so, how and why?

FDA recognized in its July 19, 1990 (55 FR 29487 at 29504), reproposal on mandatory nutrition labeling that certain restaurant-type food service facilities cannot reasonably be expected to provide information concerning nutrient profiles, and that exemptive provisions should be established for such situations. The proposal advised that comments pointed out that nutrition labeling for foods served in restaurant-type facilities present significant feasibility problems in a number of situations. The comments made the following points: These facilities may not be able to develop consistent nutrient information on the foods that they sell because of frequent menu changes and variations in how the consumer wants the food prepared and served. Without nutrient consistency, frequent nutrient analyses would have to be performed to provide consumers with accurate nutrition labeling information. These analyses could become very burdensome. The cumulative costs of these analyses could place undue restrictions on some establishments. Firms could be inhibited from making frequent menu changes or forced to limit the options that consumers have in ordering a food.

Because of these problems, FDA proposed an exemption under section 201(n), 403(a), and 701(a) of the act for restaurant-type foods in the mandatory nutrition labeling proposal (see proposed § 101.9(h) (2), 55FR 29516). Although the agency wanted to limit the exemptions to only those situations in which it is needed, FDA did not, and still does not, have sufficient indepth knowledge of the food service industry to develop adequate criteria to fairly impose such limitation. The agency therefore requests comments on this issue.

A related question is what to be done with § 101.10. Because § 101.10 was adopted under section 403(a) of the act, it is not subject to state enforcement under section 307. For this reason, and because § 101.10 has not been enforced by FDA, the agency believes that it is appropriate to make an affirmative statement about the continuing need for this provision. Thus, if FDA elects not to make restaurant labeling part of the NLEA implementation, the agency will, in the final rule, delete § 101.10.

8. Dietary Supplements

Because the provisions in § 101.14(d) derive in large part from section 403(r) (3) of the act, an argument can be made that they should not apply to dietary supplements. However, FDA believes that these provisions are necessary to ensure that claims are not misleading, are valid, and are useful to consumers. Therefore, FDA is proposing to adopt these provisions for dietary supplements based on its authority under section 403 (r) (5) (D) of the act to ensure the validity of claims on these foods.

E. Prohibited Claims

1. Claims not Authorized by FDA

Proposed § 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 a health claim specifically provided for in part 101, subpart E; and (2) the claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of part 101, subpart E.

Although the nature of the proposed prohibition may be obvious for explicit claims (e.g., products bearing statements about cholesterol-lowering effects are explicit claims about a health-related condition) because of their forthright nature, the nature of the prohibition is not as obvious for implied claims. Proposed § 101.14 (a) (1) points out that implied claims include a wide variety of forms of expression, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), -symbols (e.g., a heart symbol), and vignettes.

With respect to "third party" endorsements of food, FDA considers this term to refer generally to any type of approval or implied support for the food pertaining to disease or health-related matters, with or without product specific information, by a person or organization that is independent of the product's manufacturer or distributor. When the endorsement is from a professional society or association that has been identified with treatment of a specific disease, consumers may be led to believe that the food may be useful with respect to the disease. Even when the endorsement is not product specific, there is a potential for consumer deception where consumers may be

given a false sense of security that consumption of products that bear labeling references to the organization or the organization's logo or seal will protect them from the disease.

Examples of some of the types of labeling endorsement programs that FDA has considered to be implied health claims include programs that have been sponsored by the American College of Nutrition, the American Heart Association, The American Medical Association ("Campaign Against Cholesterol"), and the American Medical Women's Association. The agency recognizes, however, that professional societies and associations provide a unique service in establishing criteria for assessing diets of both healthy population groups as well as those who require modifications or restrictions in their diets. FDA encourages such organizations to collaborate with the agency in the development of its regulations pertaining to health claims through submission of specific comments on this proposal as well as on the specific proposals on the 10 substance-disease topics that are published elsewhere in this issue of the **Federal Register**. The agency requests comments on whether it should consider all third-party endorsements that imply that a nutrient in a food has an effect on a disease or health-related condition to be health claims, or whether there are some limits on FDA's coverage of third party endorsements that should appropriately be drawn?

Where other Federal agencies have established programs to change dietary patterns to reduce the risk of diet-related diseases (e.g., the National Cholesterol Education Program), FDA recognizes that references to such programs on food labeling may also be perceived by consumers as "third party" endorsements. Although FDA is proposing to regulate labeling references to such Federal programs as implied health claims, the agency believes that the benefits of these programs to consumers may be significant if the labeling messages that are conveyed to consumers about the other Federal programs are properly merged with the specific health claims that are provided for under part 101, subpart E. Without appropriate merging of information about health benefits, consumers could, however, be confused about the significance of the benefits.

FDA believes that the most efficient way to ensure that consumers will not be confused about this significance is to establish, by regulation, the specific types of statements that may be made on food labeling concerning the Federal programs. The agency is requesting that comments concerning what statements about Federal programs would be appropriate on food labeling be submitted for the appropriate specific regulations in part 101, subpart E. Based on these comments, FDA intends to include a listing of the statements that may be used in the final rules on these regulations. FDA advises interested parties that, at this time, the agency believes that labeling references to the programs should not be made through logos because such visual representations may have too wide a variety of meanings to consumers.

A second, related question with respect to implied health claims is how to regulate the use of symbols such as a heart or electrocardiogram. The agency is aware that symbols are particularly useful in conveying information in a simple and efficient manner. Research has demonstrated that heart symbols, for example, on food labeling are perceived by consumers as meaning that the food has special usefulness relative to health and especially with regard to coronary heart or cardiovascular disease (Refs. 22 and 23). FDA has also heard from consumers, however, that symbols have been used in misleading ways.

The threshold problem with symbols is how to regulate them under the scheme established by the 1990 amendments. On the one hand, properly qualified by other statements on the food label, a heart symbol, for example, can be used as an implied nutrient content claim to denote a food that is low in fat, saturated fat, sodium, and cholesterol. On the other hand, as stated above, a heart that is not qualified by other statements on the label would arguably represent a health claim that a nutrient in the food has some special role in promoting coronary or cardiovascular health.

FDA invites comments on the regulatory approach that it should take to symbols for use on the food label.

FDA does not agree with comments that have suggested that statements identifying certain dietary components (e.g., fiber, calcium) constitute implied health claims, even when the label avoids directly mentioning a disease. Such claims are specifically regulated as nutrient content claims under section 403(r)(1)(A) of the act and are addressed in the agency's proposal on nutrient content claims published elsewhere in this issue of the **Federal Register**. After the effective date of the 1990 amendments, such claims are prohibited unless FDA has issued a regulation defining the particular claim.

2. Disqualifying Levels Exceeded

Proposed § 101.14(e) (3) requires that none of the disqualifying levels identified in paragraph (a) (5) of this section 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 would 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 is proposing this provision under the authority of section 403(r)(3)(A)(ii) of the act.

A complete discussion of the disqualifying levels was presented previously in section IV.A.5 of this document.

3. Inappropriate Levels of Other Substances

Proposed § 101.14(e)(4) prohibits claims for any food where a substance, other than one for which a "disqualifying level" is established, is present at an inappropriate level as determined in specific provisions of part 101, subpart E.

This provision implements a number of different provisions of the 1990 amendments. As was stated previously in this document, section 403(r)(3)(A)(ii) of the act prohibits a claim where any nutrient is present 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. In section IV.A.5 of this document, the agency advised that two approaches for implementing this provision include the preliminary requirement that use of the substance at relevant levels have been found to be safe under agency regulations, and that the "disqualifying levels" not be exceeded. A third approach, which the agency is also proposing to adopt, is to prohibit claims for foods containing any level of a substance, other than one for which a disqualifying level is established, where that substance increases such risk. This provision proposed in § 101.14(e)(4), is intended, in part, to provide for a situation in which

such a substance, or a level of a substance, is identified in one of the specific regulations in part 101, subpart E. However, at this time the agency is not aware of any such situations.

In addition, this provision is intended to implement other aspects of the 1990 amendments. Proposed §§ 101.14 (d)(2)(vi) and (d)(2)(vii) require that substances be present at a level sufficient and in an appropriate form to justify the claim. Proposed § 101.14(e)(4) supplements paragraphs (d)(2)(vi) and (d)(2)(vii) by providing the basis by which FDA can assure through provisions in specific regulations in part 101, subpart E that the appropriate form of the substance is used in light of levels of other nutrients or food components that may counter the effect of the substance for which the health claim is made. Counter effects may include interference with the substance to reduce its absorption, metabolism, or utilization by the body, thereby reducing or negating the substance's value.

For example, the proposed health claim concerning calcium and osteoporosis, published elsewhere in this issue of the **Federal Register**, contains a provision (proposed § 101.72(c)(5)) providing that a serving or recommended total daily intake of a food shall not contain more phosphorus than calcium on a weight per weight basis. As explained in that proposal, this provision is based primarily on scientific evidence demonstrating that diets high in phosphorus and relatively low in calcium result in osteoporosis in experimental animals.

Similarly, if a health claim were permitted in part 101, subpart E associating increased dietary copper intake with a reduced risk of a disease (although note that no such claim is contemplated at this time), it is conceivable that the interactive effect of dietary zinc intake on copper status would have to be considered to assure that an adequate dietary copper intake is attained for the claimed benefit. The antagonistic effect of high levels of dietary zinc on copper absorption and status has been demonstrated in humans and in a variety of animal species (Ref. 16). Some studies, but not all, have reported subtle negative effects of increased intake of zinc, not much in excess of the Recommended Dietary Allowance (RDA) for zinc, on biological indicators of copper status. For example, a study in men of the effect of zinc intake at 3⅓ times the RDA level reported a decrease in zinc, copper-superoxide dismutase, a red blood cell enzyme that is dependent on copper but not zinc status and that thus serves as an index of tissue copper status (Ref. 17). Accordingly, FDA would prohibit a health claim for copper on a food whose zinc level is above the RDA or RDI level.

4. Representing Food for Infants or Toddlers

Proposed § 101.14(e)(5) provides 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.

The American Academy of Pediatrics, in their comment to the 1990 reproposal, expressed concern that a health claim directed toward adults may be inappropriate or harmful to infants and young children. One example cited was that the link between lipids and cardiovascular disease is not established in young children as it is in adults. Consequently, though diets high in fats may be undesirable for adults, the comment stated that infants and toddlers must ingest a certain amount of fat for their growth and development. Accordingly, the comment recommended that a health claim for adults should indicate that it is not intended to apply to infants and young children.

Furthermore, both "The Surgeon General's Report on Nutrition and Health" (Ref. 5) and "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6) state that, because of the increased nutrient demands of children during the early periods of rapid growth and development, the dietary recommendations are not applicable to persons under 2 years of age. The criteria for health claims being proposed in this and the companion documents are based on dietary recommendations for the U.S. population, excluding very young children. Therefore, the agency has tentatively concluded that health claims are inherently misleading if used on the labels of foods represented or purported to be for infants and for toddlers under 2 years of age. Therefore, under sections 201(n), 403(a), and 403(r) of the act, FDA is proposing in § 101.14(e)(5) to prohibit the use of health claims on foods for these young children.

F. Need for Additional Prohibited Claims

FDA is concerned that under these proposed regulations some foods that are inconsistent with generally recognized medical and nutrition principles for a sound total dietary pattern will be permitted to bear health claims. For example, some diet confections, which have no nutritional value, would be permitted to bear health claims for lipids and cardiovascular disease, lipids and cancer, and sodium and hypertension, if the regulations on these substance-disease relationships are finalized as proposed.

Such a situation seems contrary to one of the stated purposes of the health claims provisions of the 1990 amendments—to reinforce Federal dietary recommendations and help Americans maintain a balanced and healthful diet (Ref. 1). This purpose was reinforced through statutory provisions in section 403(r)(3)(A)(ii) of the act requiring FDA to consider the significance of the food in the total daily diet when determining whether a nutrient that increases the risk of a disease or health-related condition should disqualify a food from bearing a health claim. Congress explained (Ref. 1) that this provision "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, whereas that same amount of fat in a snack food product might trigger it." Thus, FDA believes that provisions permitting health claims on only foods recognized as within a sound dietary pattern would be consistent with the intent of Congress.

However, FDA is not aware of any way to limit health claims to only those foods within a sound dietary pattern at this time. The agency considered, and decided against, proposing a provision prohibiting claims unless there is consistency with generally recognized medical and nutrition principles for a sound total dietary pattern (e.g., consumption of the food is consistent with the current edition of "Nutrition and Your Health: Dietary Guidelines for Americans," Third Edition, 1990 (Ref. 7), and the food is not a snack food such as candies or those low in essential nutrients.

For the general U.S. population, "Dietary Guidelines for Americans" provides guidelines on the relationship between diet and various diseases and conditions such as obesity, hypertension, cancer, and deficiency diseases. The guidelines reflect the dietary recommendations contained in the "The Surgeon General's Report on Nutrition and Health" (Ref. 5) and "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6). The guidelines embody dietary principles for consumption of foods with significant nutritional value and for reduction or control of certain food components associated with diet-related diseases or conditions. Throughout FDA's development of both the specific health

claims proposals for part 101, subpart E, as well as the general provisions of this proposal, FDA has considered these guidelines.

At the present time, the guidelines are: Eat a variety of foods; maintain healthy weight; choose a diet low in fat, saturated fat, and cholesterol; choose a diet with plenty of vegetables, fruits, and grain products; use sugars only in moderation; use salt and sodium only in moderation; and if you drink alcoholic beverages, do so in moderation.

However, FDA believes that the guidelines are too general in nature to serve as binding rules upon which the agency can readily take regulatory action. For example, what foods would clearly fit into an appropriate variety of foods? What portion of foods would constitute a moderate amount of sugars? How would the agency define "snack foods?" The agency requests comments from all affected parties concerning what provisions might effectively permit health claims only on foods that can make a significant contribution to a healthful diet. If the comments suggest appropriate provisions, FDA will include them in any final regulation based on this proposal.

G. Exempted Foods

Medical foods, as defined in section 5(b) of the Orphan Drug Act, and infant formulas subject to section 412(h) (21 U.S.C. 350a) of the act are specifically exempted from requirements for health claims and nutrient content claims by section 403(r)(5)(A) of the ac' FDA is proposing to codify these statutory provisions in § 101.14(f).

In addition, section 403(q)(5)(A)(iv) exempts medical foods from nutrition labeling requirements. To deal with this latter exemption, the agency has incorporated the definition of "medical food" in the supplementary proposal on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register**, to clarify this definition by providing criteria in proposed § 101.9(j)(7) for use in identifying a medical food. As explained in that proposal, minimum criteria to distinguish a medical food from other foods include: The product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended for use under medical supervision (Ref. 18).

The supplementary proposal on mandatory nutrition labeling states that medical foods are not foods that are simply recommended by a physician or health care professional as part of an overall diet to reduce the risk of a disease or medical condition or promoted as weight loss products. Nor do medical foods include dietary supplements for the general population that can be openly purchased from retail outlets or by mail order, even though dietary supplements may be recommended by a physician for a specific condition or disease. The intended use and degree of medical oversight for dietary supplements are not regarded to be sufficient to qualify them as medical foods.

FDA is reevaluating its traditional policy to regulate medical foods as foods for special dietary use in light of the existing definition of foods for special dietary use and the definition of medical food enacted by Congress (21 U.S.C. 350(c) and 360ee(b)(3)). FDA intends to address the issue of medical foods in a future **Federal Register** document.

Infant formulas that are subject to section 412(h) of the act are known as "exempt infant formulas" because they are exempt from the requirements of sections 412(a), (b), and (c) of the act, which pertain to other infant formulas. Instead, exempt infant formulas are subject to regulations established by the Secretary under the authority of section 412(h)(2) of the act. Exempt infant formulas are defined in section 412(h)(1) of the act as any infant formula which is represented and labeled for use by an infant: (1) who has an inborn error of metabolism or a low birth weight, or (2) who otherwise has an unusual medical or dietary problem. Regulatory requirements for exempt infant formulas, including claims, are contained in 21 CFR part 107.

H. Applicability of the Regulation

FDA is reflecting the applicability provisions of section 403(r)(1) of the act in proposed § 101.13(g). This provision states that the requirements of proposed § 101.13 apply to foods for human consumption that are offered for sale. Thus, the proposed health claim regulations apply to foods for human consumption sold in grocery stores and other settings.

I. Other Issues

1. Consumer Summaries

The 1990 reproposal would have required preparation of a consumer summary concerning a health claim on a food label. The summary would have been an extension of the health claim on the label to provide 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 alleviate the potential problem of information overload on the label. A summary was to be developed for each diet and chronic disease relationship for which health claim would be appropriate. The food label bearing the health claim would have been required to reference the summary.

The comments generally focused on the concept of developing the summaries through a process that is open and allows for public comment. Some of the comments expressed interest in the development and testing of the summaries. Other comments expressed concern about the accessibility of consumer information at the point of retail sale.

In view of new statutory requirements for the label or labeling of a food bearing a health claim, FDA believes that consumer summaries may no longer be necessary. Section 403(r)(3)(B)(iii) of the act states that the regulation authorizing a claim shall require that the claim be stated in a manner: (1) That accurately reflects the relationship between the substance and the disease or health-related condition, and the significance of the substance in affecting the disease or health-relate condition, and (2) that 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 provision requires that the claim present the most significant aspects of the information that the agency was considering to require in the consumer summaries. Therefore, FDA fails to see what purpose a consumer summary would serve and is not proposing to require these summaries at this time.

However, FDA solicits comments on whether consumer health claim summaries can still serve a useful purpose. The agency asks that interested persons examine the specific model health claims proposed elsewhere in this issue of the **Federal Register** and the consumer summaries that FDA has prepared and consider whether these summaries, which present in lay language, information about the association between the substance and the disease or health-related condition, are needed. If comments persuade the agency that these summaries should in fact still be required, FDA may include a requirement for the summaries in any final rule that is based on this proposal.

The purpose of a consumer summary would be to provide supplementary information to that on the label about substance-disease relationships for consumers who are interested. Such information may include, among other things, a discussion about the disease or health-related condition, its prevalence in the U.S. population, and the relative degree of risk for specific subpopulation groups. In addition, dietary information on other food sources of the claimed nutrient or substance, information on nondietary risk factors for the disease, and other similar information may be provided.

2. Consumer Guide to Food Labeling

The 1990 reproposal would have required the agency to prepare a consumer guide to food labeling (consumer guide) as an adjunct to the procedure for health claims. The consumer guide would have discussed in general terms how the various types of consumer-oriented information found on the food label are to be used. The consumer guide was intended to address questions such as:

(1) What is a consumer health claim summary, and who is it for?

(2) What is nutrition labeling, and how is it used in dietary planning?

(3) What is the importance of the total diet in maintaining good health?

(4) How do dietary supplements best fit into a total daily diet?

(5) What is the process used to develop label statements and consumer health claim summaries?

(6) Are label statements and consumer health claim summaries applicable to specific groups (e.g., certain statements or claims may not be appropriate for children)?

(7) How can consumers use ingredient statements, common or usual names of foods, and nutrient content claims (e.g., low sodium) to assist them in achieving sound dietary practices? FDA conceived of developing one "umbrella" consumer guide that would be broadly applicable to all health claim subject areas.

All comments on the 1990 reproposal endorsed development of the guide. Most of the comments addressed the availability of the consumer guide, stating that it should be widely distributed, accessible, or available. One comment said that information on availability of the consumer guide should be given on the product label. One comment suggested that the consumer guide should be published in the **Federal Register** for public comment before distribution to consumers. Another comment suggested that the consumer guide be developed cooperatively with organizations outside FDA. One consumer organization suggested that the consumer guide should be distributed to beneficiaries of public assistance programs to assure that persons with low incomes have access to nutrition information. Another recommendation was that, in addition to English, the guide should be published in other languages.

Although FDA still intends to issue a consumer guide, the agency believes that such a consumer guide should be issued separately from this proposal. Section 2(c) of the 1990 amendments directs FDA to carry out activities that educate consumers about the availability of nutrition information on the label and in labeling of a food and about the importance of such information in maintaining healthy dietary practices. Inclusion of the consumer guide on health claims as a part of these new educational activities will address the issues and concerns that motivated FDA to propose the consumer guide.

Accordingly, FDA believes that it is not necessary for it to respond more specifically to the comments about the consumer guide at this time. Of course, the agency will consider these comments when a guide or other educational material is being prepared.

J. Petitions for Health Claims

Section 403(r)(4)(A)(i) of the act grants any person the right to petition the agency to issue a regulation authorizing a health claim on a substance-disease relationship. Section 403(r)(4)(B) of the act requires that the petition include an explanation of the reasons why the claim that is the subject of the petition meets the requirements of section 403(r) of the act and a summary of the scientific data that support those reasons. The act also states that if the petition relies on a report from an authoritative scientific body of the United States, the agency shall give particular consideration to such report and shall justify any decision rejecting the conclusions of such report (section 403(r)(4)(C) of the act)

The act requires in section 403(r)(4)(A)(i) that, within 100 days of receipt of a petition for a regulation concerning a health claim, FDA must either issue a final decision denying the petition or file the petition for further action. If the agency denies the petition, it is not made available to the public. If FDA files the petition for further action, the agency must either deny it or publish a proposed regulation responsive to the petition within 90 days of filing.

However, the foregoing provisions do not apply to health claims for dietary supplements. Under section 403(r)(5)(D) of the act, as stated above, these claims are subject to a procedure established by regulation by the Secretary of Health and Human Services (and by delegation, FDA).

On March 14, 1991, the agency published a notice in the **Federal Register** (56 FR 10906) that it is developing procedural regulations that will prescribe the types of information needed to support petitions for health claims and the other types of petitions permitted by the 1990 amendments (including petitions concerning nutrient content claims and State petitions for exemption from Federal preemption granted by the 1990 amendments), the format in which the petitions are to be submitted to the agency, and the procedures that the agency will follow in its review of these petitions. The agency requested comments on these issues and on the following:

(1) Criteria that should be used in evaluating health claim petitions;

(2) The extent, manner, and timing that the agency should use to give public notice of petitions; and

(3) The appropriate procedure for establishing regulations on permissible health claims for dietary supplements.

The agency stated that the most efficient use of its resources would be to establish these procedures in final form before considering, or acting on, any such petitions that are submitted to the agency. The agency, therefore, advised that it would likely deny any petition submitted under the 1990 amendments until final procedural regulations are promulgated.

FDA received comments pertaining to petitions for health claims from the food industry, industry trade associations, and consumer organizations. FDA considered the comments, and many of the recommendations contained therein have been incorporated in, or otherwise used in, the development of this section of the proposed rule.

1. Comments

Some comments objected to the requirement for "publicly available evidence" and stated that unpublished research findings, including proprietary data, should be considered in support of proposed health claims. These comments further stated that firms will be able to justify undertaking research and development activities relating to diet/health relationships only if the regulatory framework allows them to recapture, through competitive marketing, some of the expense of research. They stated that, if regulations are adopted requiring that results be made public to substantiate a health

claim, then this substantiation could be used by other companies to make similar claims. The comments pointed out that the original petitioner would lose its competitive edge and thereby its motivation to perform research. Comments also suggested that the petition process should provide for the strictest confidence in the submission and maintenance of proprietary, unpublished studies.

The agency advises that section 403(r)(3)(B)(i) of the act mandates that "publicly available evidence" be used to support the scientific standard for health claims. Moreover, section 403(r)(A)(i) provides for not making a petition available to the public only if FDA decides to deny it without filing it. Consequently, FDA does not have authority to provide the relief the comments seek. The agency will make all information submitted in support of a health claim publicly available when the petition is filed and thus becomes available to the public.

An approved health claim is a description of a substance-disease relationship. It is not brand specific and, therefore, may appropriately be used by any firm whose food product meets the criteria for the claim.

Another comment stated that, in the past, in evaluating substance-disease relationships, the agency has placed too much reliance on findings published in a few peer-reviewed journals, and that the language in section 403(r)(3)(B) of the act; "totality of publicly available scientific evidence," should not be construed to limit evaluation to such reports. Other comments recommended that petitions should be accompanied by extensive literature reviews and include copies of all animal studies and human epidemiological or clinical trials relevant to the proposed health claim.

The agency advises that under proposed § 101.70(f) the petitioner is required to submit copies of all information, published or unpublished, relied upon for the support of the health claim, as well as information related to the claim that concerns adverse effects in individuals. Further, the petitioner must also submit copies of all information relevant to the claim that is pertinent to the U.S. population. The agency is, therefore, proposing to require that a broad array of information be submitted with the petition. Consequently, the agency's review of the proposed topic will not be limited to peer-reviewed publications, although, 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 intends to give greatest weight, however, to research reports of well-conducted, relevant studies regardless of publication status.

To ensure that submitted information is not biased, one comment recommended that the petition include an assurance statement, such as that required in petitions for the affirmation of the GRAS status of a substance (§ 170.35(c)(1)(v)), whereby the petitioner certifies that the petition contains all favorable and unfavorable scientific data of which he has knowledge. The agency agrees that this requirement is appropriate for a petition that must draw upon the totality of publicly available scientific evidence to support the proposed health claim, and this requirement has been included in the proposed procedural regulations in § 101.70(h).

Several comments addressed format issues for health claims petitions. One comment stated that the format for submission of citizen petitions (§ 10.30) is applicable to health claims petitions.

FDA recognizes the point made in these comments but tentatively concludes that, given the provisions of section 403(r) of the act, it is appropriate to specifically describe the information that should be submitted in support of a health claims petition in a regulation that is separate from § 10.30. The agency believes that a procedural regulation for a health claims petition is necessary so that petitioners will clearly understand what is required, that review will be conducted on an equitable basis, and that the grounds for agency action on the petition will be clearly understood.

A comment stated that the proposed regulations should provide that, for well-substantiated petitions setting forth substance-disease relationships that are widely accepted in the scientific community, the initial agency response time should be reduced from 100 to 60 days, and the agency's proposed regulation should be published within 30 rather than 90 days after the initial response.

The agency's ability to meet timeframes is influenced by many factors such as work priorities and availability of personnel. FDA considers the statutory timeframes for assessing the validity of health claims to be extremely short for evaluating the totality of available scientific evidence on a substance and a disease. It would not be practicable to shorten these timeframes further. The agency does agree that a petition for a claim on a well accepted diet/health relationship would probably be reviewed more expeditiously than one for which scientific agreement is equivocal or marginal.

Several comments recommended procedures for the evaluation of health claim petitions. One recommended the development of a multifactorial scoring system to be used to evaluate health impact based on the product's total nutrient content, the level of nationwid consumption, and the scientific validity of the health claim. This system would incorporate a cut-off limit to determine whether a petition is acceptable. Another suggested criterion was that th new health claim be recognized by reputable health organizations or research centers.

As discussed in section IV.C. of this document, the extremely short timeframes provided under the act for FDA to decide if a health claim is to be authorized make significant input from other health organizations impracticabl before a proposed rule is to be issued. However, the agency does expect and encourages other health organizations, public, private, and governmental, to submit comments on all proposed actions on health claims.

With respect to the suggested scoring system, FDA does not believe that such a system would be practicable because of the necessity for the agency to exercise its scientific judgment to give more weight to those studies of greater significance. Such significance may vary greatly from one situation to another, depending upon the nature of the evidence in each study. A scoring system might, under such circumstances not fairly evaluate the merits of the studies.

One comment pertained to section 403(r)(4)(C) of the act which provides that if a petition for a health claim regulation relies on a report from an authoritative scientific body of the United States, the agency must consider such report and must justify any decision rejecting the conclusions of such report. The comment advised that similar consideration should apply with respect to other reputable scientific data that are submitted in support of the petition.

The agency does not agree. Section 403(r)(4)(C) of the act imposes upon FDA an obligation to justify rejection of conclusions of a report from an authoritative scientific body of the United States. Congress obviously believed that FDA should have strong grounds for not agreeing with such reports because of the high credibility of U.S. Government bodies. However, there is no indication in the legislative history of the 1990 amendments of an intent for FDA to have a similar burden

for reports not generated by such Government bodies. For such situations, the agency is only required to state the reasons for the denial of the recommendation. However, FDA intends to fully and fairly evaluate any scientific reports that are submitted to the agency in support of a health claim. The agency intends to consider such reports as part of the totality of evidence on the substance-disease relationship.

Several comments recommended that the agency establish a distinct and separate procedure (and consequently distinct and separate requirements for petitions) for determining the propriety and validity of health claims for dietary supplements. These comments stated that Congress intended that dietary supplements be considered under a more lenient standard than conventional foods and recommended that health claims for dietary supplements be based on significant scientific evidence and not significant scientific agreement. The comments stated that different standards should be applied to foods and dietary supplements because of FDA's disparate treatment of dietary supplements in the past. Some of these comments recommended that health claims be classified in three categories depending on the abundance of the scientific evidence and strength of scientific support.

FDA recognizes that dietary supplements are not subject to section 403(r)(3) and (r)(4) of the act. However, as explained fully above, FDA has carefully considered the discussion of dietary supplements in both the Senate and House, its obligations under the act, and the question of what standard and procedure are most appropriate to use in assessing and ensuring the validity of health claims for dietary supplements. Based on this consideration, FDA is proposing to apply the same scientific standard to health claims for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances as for conventional foods because the agency considers this standard to be the appropriate standard for ensuring the validity of all such claims. For the same reasons, as discussed above, FDA finds it appropriate under section 403(r)(5)(D) of the act and section 3(b)(1)(A)(x) of the 1990 amendments to make petitions to authorize claims on dietary supplements subject to the same requirements that apply to petitions for claims for conventional foods. FDA is proposing these requirements for dietary supplements because they will ensure that the agency has the information that it needs to assess the validity of claims for substances in these foods. Because FDA is proposing the same requirements for petitions on substances in dietary supplements as for substances in conventional foods, it is not distinguishing between dietary supplements and conventional foods in proposed § 101.70.

2. General Requirements and Provisions for Petitions

The agency is proposing to establish § 101.70 as the general procedural regulation for petitions for health claims. Section 101.70(a) through (d) address general issues and requirements such as the incorporation of various types of information into the petition and standard agency requirements pertaining to clinical and nonclinical studies submitted to the agency for review. Section 101.70(e) provides that all types of data and information in petitions for health claims are available for public disclosure after a petition is filed except for information that would identify a person or a third party, such as a physician or hospital, involved in a report. FDA is proposing no other exceptions to full disclosure because the statute does not provide for any exceptions, and because, as the agency explained above, it has tentatively concluded that the best way to assure the validity of a claim, either for a nutrient or for substance in a dietary supplement, is on the basis of publicly available scientific evidence. However, when FDA denies a petition before it is filed, the agency is proposing in § 101.70(j)(2) that no part of the petition will be made available to the public. This provision conforms to the requirements of section 403(r)(4)(A)(i) of the act and provides the same protection for petitions for substances in dietary supplements. FDA is also proposing to amend § 20.100, by adding § 20.100(c)(34), to reflect the provisions on the availability of records in proposed § 101.70.

Elsewhere in this issue of the **Federal Register**, FDA is publishing several documents that propose to find that certain substance and disease relationships are not valid. (In this document, FDA is proposing to establish § 101.17 in which the agency will list the topics for which it makes such a determination.) Those determinations are being processed through rulemaking proceedings because the 1990 amendments specifically directed the Secretary of Health and Human Services (and by delegation, FDA) to make the determinations (section 3(b)(1)(A)(vi) and (b)(1)(A)(x) of the 1990 amendments). With such specific direction, the agency believes that it is more appropriate to formalize its determinations through rulemaking rather than informally announcing its findings. However, while this course of action may be practicable for the 10 determinations mandated by the 1990 amendments, FDA does not believe it would be so for the many determinations that the agency may have to make in response to future petitions. Instead, FDA believes that its responses to petitions need to be made in the same manner as other petitions to change its food regulations. Specifically, the agency intends to advise firms of the specific reasons for denials without instituting a rulemaking proceeding.

FDA recognizes that in some circumstances there may be considerable interest in the agency's reasons for issuing denials, and that some firms may want to submit additional data that might result in a different FDA finding. Such firms may wish to consult the public listing of those health claims petitions that have been accepted for filing for issues of particular concern. Although denials of petitions not accepted for filing will not be released to the public, filed petitions will be fully available for public disclosure. Where the agency has denied a filed petition, interested parties may wish to review FDA reasons for denial before submitting an additional petition concerning a health claim.

Section 101.70(f) sets forth the proposed format for a health claim petition. It specifies the types of data and other requirements that the agency believes are necessary to provide for an efficient review and to demonstrate that the proposed substance-disease relationship complies with the requirements established under the 1990 amendments.

As proposed in format item A, the petition must include one or more model health claims that may be used on a food label or in labeling for a food to characterize the relationship of the substance in the food to a disease or health-related condition. This item is included among the petition requirements because FDA has tentatively concluded that it is valuable to include a model health claim in any authorizing regulation. Given the short timeframes under which FDA must review a petition, it would be difficult for the agency to prepare a model claim. Therefore, FDA is proposing to require that a model health claim be submitted as part of the petition.

In proposed format item B, the petitioner is to address how the substance conforms to the requirements in proposed § 101.14(b). These

requirements are discussed in section IV.B. of this document. One requirement is that the use of the substance, or the food ingredient of which the substance is a component, at the levels necessary to justify a claim be demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act.

For petitions where the subject substance is a component of a food ingredient, the agency is proposing to require that the petitioner compile a comprehensive list of the specific ingredients that could be added to food to supply the substance in the food bearing the health claim. The agency is also proposing to require that, for each ingredient listed, the petitioner demonstrate that the use of the ingredient is safe and lawful under the applicable food safety provisions of the act. This showing can be made by a showing that the use of the ingredient is GRAS, listed as a food additive, or authorized by a prior sanction. Where the GRAS status is addressed in agency regulations (e.g., listed in Part 182 or affirmed in Part 184), the petition can cite the specific regulation. Where the GRAS status is not specifically addressed in agency regulations (e.g., where the GRAS status is based on common use in food prior to January 1, 1958 or based on conformance with the general principles stated in § 170.30(d)), or where there is a prior sanction, the petitioner must demonstrate, to the agency's satisfaction, that this requirement is met.

With respect to the requirement in proposed § 101.14(b)(1) that the U.S. population must be at risk for a disease or condition to permit a health claim, or that 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, proposed format item C requires that the necessary information be provided. It should be noted that the prevalence of the disease or health-related condition is of greater importance than the extent of the population's inadequate dietary intake of a substance. In particular, there may be data supporting that all or a significant part of the population has, or may have, an inadequate dietary intake of a substance. Such data are of value in justifying authorizing a health claim only in cases where the relationship of inadequate intake of a substance to the condition or disease has been satisfactorily established.

Information on the prevalence of a disease or condition is necessary because data from food intake surveys are commonly interpreted as showing that some segments of the population consume inadequate levels of nutrients. However, such surveys are generally poor predictors of nutritional status. There are several reasons for this apparent inconsistency. It is generally accepted, and controlled studies show (Ref. 19), that consumers who participate in a survey tend to underreport information on food consumption. Further, use of RDAs as criteria for assessing adequate or inadequate nutritional status fails to account for the large safety factor built into the RDAs for adequate nutrient intake by individuals in a population (Ref. 20). In addition, survey data show that a large segment of the population regularly consumes vitamin, mineral, and other dietary supplements that are not adequately recorded in surveys or studies of food consumption (Ref. 21).

For these reasons, the agency has had a longstanding policy that the only reliable means of determining the nutritional adequacy of diets of the population is through the use of clinical and biochemical measures to assess nutritional status. Data from the National Health and Nutrition Examination Survey have frequently been used and generally indicate that the level of nutrient deficiencies is very low or nonexistent for most nutrients. Iron is an exception based on observations of how iron stores in women of childbearing ages and among young children during rapid growth.

Proposed format item C also specifies the requirements to be addressed in the summary of scientific data in support of the claim. This summary must establish that the proposed claim meets the scientific standard provided for in proposed § 101.14(c).

If the claim is intended for a specific group within the population, the petitioner's 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).

Proposed format item D requires the submission of analytical data showing the amount of a substance present in representative foods that would be candidates to bear the claim and specifies that the data be obtained using the Association of Official Analytical Chemists (AOAC) methods, where available, or other valid methodology along with submission of the methodology and its validation. Data on the amount of the substance in various foods will enable the agency to evaluate the usefulness of the claim in the context of the total diet.

Proposed format item E specifies the attachments to be submitted with the petition. These attachments include the scientific reports, studies, and other data and literature searches used to support the petition.

Proposed format item F requires that the petitioner include either a claim for a categorical exclusion under § 25.24 or an environmental assessment under § 25.31.

Proposed § 101.70(g) sets forth how the submitted data in the petition are to be organized and identified and permits the petitioner to incorporate by reference any data from an earlier petition.

Proposed § 101.70(h) requires that the petition include a statement signed by the person responsible for the petition that, to the best of his or 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.

Proposed § 101.70(i) requires that the petition be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

The proposed procedures for agency action on the petition in § 101.70(j) (1), (j) (2), and (j) (3) reflect the requirements of section 403(r) (4) (A) (i) of the act. For fairness, FDA is proposing to apply the same procedures in its review of petitions involving substances in dietary supplements. Further, the agency is proposing therein to notify the petitioner of receipt of the petition within 15 days of receipt.

Finally, with respect to petitions, the agency has proposed elsewhere in this issue of the **Federal Register** to amend 21 CFR 5.61 to redelegate from the Commissioner of Foods and Drugs to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition, all the functions of the Secretary concerning petitions for label claims under section 403(r) of the act for both nutrient content and health claims that do not involve controversial issues. For petitions for health claims, such functions consist of the issuance of notices of proposed rulemaking and final rules concerning authorized health claims and the issuance of letters concerning the filing or denial of a petition. These proposed redelegations will facilitate timely agency action on these petitions given the short timeframes for agency action imposed

by the 1990 amendments. The proposed redelegations are similar to those proposed elsewhere in this issue of the Federal Register in the proposal concerning nutrient content claims which, like health claims, were designated by section 403(r) of the act to be used on food labels and in labeling only in conformity with regulations promulgated by the agency.

V. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the Federal Register. The agency requests comments on the RIA.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. The proposed requirements pertaining to health claims on food labeling qualify for a categorical exclusion under 21 CFR 25.24(a) (11) and the proposed requirements pertaining to petitions requesting approval for the use of health claims for specific substances in food qualify for exclusion under 21 CFR 25.21(a) (8).

VII. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VIII. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 pm., Monday through Friday.

The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet the statutory timeframe for the issuance of final regulations on health claims. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

IX. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 100.70 *Petitions for health claims* relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the Federal Register as part of any final rule that is based on this proposal.

X. 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. Congressional Record-Senate, S16607-16612, October 24, 1990.
3. Congressional Record-House, H12951-12955, October 26, 1990.
4. Congressional Record-House, H5836-5845, July 30, 1990.
5. U.S. Department of Health and Human Services, 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, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.
7. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "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, Food and Drug Administration, December 3, 1981.
9. U.S. Department of Agriculture, Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food Intakes by Individuals, Report No. 86-3, Hyattsville, MD, September 1988, p. 168.
10. Buzzard, I. M., Letter to Virginia Wilkening, Food and Drug Administration, 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, 73rd Cong., 2nd 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, Food and Drug Administration, 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. Food and Drug Administration, "Compliance Program Guidance Manual," Chapter 21, Program No. 7321.002 (1988-1991), Food and Drug Administration, 1990.
19. Schoeller, D. E., "How Accurate is Self-Reported Dietary Energy Intake?", Nutrition Reviews, 48:373-379, 1990.
20. Food and Nutrition Board, National Research Council, "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, 1989, Food and Nutrition Press, Inc., Trumbull, CT.
22. Burke Marketing Research, "Analysis: Restaurant Users Focus Group Session," Study-BMR# 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# 39-651 conducted for the American Heart Association, Dallas, TX, June 1989.

List of Subjects

21 CFR Part 20

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

21 CFR 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, it is proposed that 21 CFR parts 20 and 101 be amended as follows:

Part 20—PUBLIC INFORMATION

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

Authority: Section 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 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 adding a new paragraph (c)(34) to read as follows:

§ 20.100 Applicability; 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 is revised 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, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

4. Section 101.9 is amended by adding 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 property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and subpart E of part 101.

* * * * *

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" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, that 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 or direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition.

(2) *Substance* means a component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances.

(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) *Dietary supplement* means a food, other than a conventional food, that supplies a component with nutritive value to supplement the diet by increasing the total dietary intake of that substance. A dietary supplement includes a food for special dietary use within the meaning of § 101.9(a) (2) that is in conventional food form.

(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 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.

(b) For a substance to be eligible for a 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 (D), or one that FDA has required to be included in the label or labeling under 21 U.S.C. 343 (q) (2) (A); and

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

(i) The substance must be consumed as a component of a conventional food or of a dietary supplement and contribute taste, aroma, or nutritive value, or any other 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; and

(ii) The substance must be a food ingredient or a component of a food ingredient whose use at 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 act.

(c) *Validity requirements.* 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.

(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.

(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 or 101.36, FDA will propose amending these regulations to include declaration of the substance.

(2) When a regulation has been established 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 summary of scientific information and model health claims provided in regulations 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 health benefit, 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, in the same type size, without other intervening material: Except that the label may bear the statement, "See ___ for information about the relationship between ___ and ___," with the blanks filled in with references to the location of the labeling containing the health claim, the name of the substance, and the disease or healthrelated condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing on the other labeling;

(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 in the food 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, the level of the substance must meet the level established in the regulation authorizing the claim.

(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 and 101.36.

(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 provided for in subpart E of this part; and

(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 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) No substance, other than one for which a "disqualifying nutrient level" is established, is present at an inappropriate level as determined in specific provisions of subpart E of this part; and

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age.

(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.

101.70 Petitions for health claims.

101.71 Health claims: Claims not authorized.

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. The petition shall be submitted in quadruplicate. 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. 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 this 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 petition 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 investigation 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 403(r) (s) (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. 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.

B. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of § 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 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.

C. 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 paragraph (a) (2) of § 101.14.

D. 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.

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.

(i) 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 C. *Summary Scientific Data* if the information in B. *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 will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (k) 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 request 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 no basis for claims about the following:

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27151 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 101

[Docket No. 91N-0098]

RIN 0905-AD03

Food Labeling: Health Claims; Dietary Fiber and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that after reviewing the available evidence, it tentatively finds that a basis does not exist on which to authorize the use on foods, including dietary supplements, of health claims relating to an association between ingestion of dietary fiber and reduction in risk of cancer. While data support an association between consumption of fiber-rich plant foods and reduced risk of cancer, FDA tentatively finds that it cannot attribute this effect to the fiber itself. Therefore, FDA specifically requests comments on this topic. FDA has reviewed the relationship between this dietary component and this disease under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0316.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amend the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (and FDA by delegation) to issue regulations authorizing claims on the label or labeling of foods characterizing the relationship between a food component and a disease or health-related condition. With respect to health claims, the new provisions provide 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 the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule "Food Labeling: General Requirements for Health Claims for Food" to establish general requirements for health claims on food labels and labeling that characterize the relationship of nutrients, including vitamins or minerals, herbs, or other nutritional substances (referred to generally as "substances") in food to a disease or health-related condition. In this companion document, FDA has tentatively concluded that such claims would only be justified for substances in conventional foods as well as in dietary supplements if the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) supports a claim, and if there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, about such support.

The 1990 amendments also require (section 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act, and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including dietary fiber and cancer, meet the requirements of the act. In this document, the agency will consider whether a claim on the label or labeling of food or food products on the relationship between dietary fiber and cancer would be justified under the standard proposed in the companion document.

B. Basis for Considering a Claim Relating Dietary Fiber and Cancer

1. Cancer

Cancer accounts for about one of every five deaths and is the second leading cause of death in the United States (DHHS/PHS, 1990). Deaths from cancer numbered more than 475,000 in 1987. The overall economic cost of cancer, including direct health care costs and losses due to morbidity and mortality, was estimated to be $72.5 billion. In addition, the social impact of cancer can be measured in part by potential years of life lost by death before age 65. Potential years of life lost were 18 million for cancer compared to 15 million for heart disease (Ref. 46).

The risk of occurrence of cancer differs markedly for various sites. In 1990, lung cancer accounted for 35 percent of all cancer deaths in men. Colorectal cancer and prostate cancer each accounted for 11 percent of cancer deaths in men. The leading causes of cancer deaths among women were lung cancer (21 percent of cancer deaths), breast cancer (18 percent), and colorectal cancer (13 percent) (Ref. 46).

2. Dietary Fiber

Dietary fiber is comprised of components of plant materials that are resistent to human digestive enzymes (Refs. 12 and 24). These components are predominantly nonstarch polysaccharides and lignin and may include, in addition, associated substances (Ref. 12). To date, the best documented and most widely accepted nutritional role for dietary fibers is for normal bowel function and health (Ref. 24). It is estimated that current dietary fiber intakes of 10 to 15 grams (g) per day (6 to 7 g per 1000 kilocalories) in the United States are less than optimal for meeting needs for normal bowel function and health (Refs. 22 and 24). Significant increases in this level of intake have been recommended frequently (Ref. 24).

Based on currently available analytical methods, dietary fiber is measured both as total dietary fiber and as the subcomponents of soluble and