

§ 101.71

21 CFR Ch. I (4-1-08 Edition)

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 "B. Summary of Scientific Data" if the information in "A. Preliminary Requirements" is inadequate in explaining how the substance conforms to the requirements of §101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. A petition that has been denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

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

(i) Deny the petition, or

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

(iii) If FDA does not act within 90 days of the date of filing, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(4)(i) Within 270 of the date of publication of the proposal, FDA will publish a final rule that either authorizes use of the health claim or explains why the agency has decided not to authorize one.

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the FEDERAL REGISTER. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published, which date shall be within 540 days of the date of receipt of the petition.

[58 FR 2534, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993, as amended at 59 FR 425, Jan. 4, 1994; 62 FR 28232, May 22, 1997; 62 FR 40599, July 29, 1997; 63 FR 26719, May 14, 1998; 63 FR 40024, July 27, 1998; 66 FR 56035, Nov. 6, 2001]

§101.71 Health claims: claims not authorized.

Health claims not authorized for foods in conventional food form or for dietary supplements of vitamins, minerals, herbs, or other similar substances:

(a) Dietary fiber and cardiovascular disease.

(b) Zinc and immune function in the elderly.

[58 FR 2534, Jan. 6, 1993, as amended at 58 FR 2548, 2578, 2620, 2639, 2664, 2714, Jan. 6, 1993; 58 FR 17100, Apr. 1, 1993; 59 FR 437, Jan. 4, 1994; 65 FR 58918, Oct. 3, 2000]

§101.72 Health claims: calcium and osteoporosis.

(a) *Relationship between calcium and osteoporosis.* An inadequate calcium intake contributes to low peak bone mass and has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. An adequate intake of calcium is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which an adequate calcium intake and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of an adequate intake of calcium later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause.

(b) *Significance of calcium.* Calcium intake is not the only recognized risk factor in the development of osteoporosis, a multifactorial bone disease. Other factors including a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices such as smoking and excess al-

cohol consumption affect the risk of osteoporosis.

(1) Heredity and being female are two key factors identifying those individuals at risk for the development of osteoporosis. Hereditary risk factors include race: Notably, Caucasians and Asians are characterized by low peak bone mass at maturity. Caucasian women, particularly those of northern European ancestry, experience the highest incidence of osteoporosis-related bone fracture. American women of African heritage are characterized by the highest peak bone mass and lowest incidence of osteoporotic fracture, despite the fact that they have low calcium intake.

(2) Maintenance of an adequate intake of calcium throughout life is particularly important for a subpopulation of individuals at greatest risk of developing osteoporosis and for whom adequate dietary calcium intake may have the most important beneficial effects on bone health. This target subpopulation includes adolescent and young adult Caucasian and Asian American women.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements—(i) Nature of the claim.* A health claim associating calcium with a reduced risk of osteoporosis may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim makes clear that adequate calcium intake throughout life is not the only recognized risk factor in this multifactorial bone disease by listing specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stating that an adequate level of exercise and a healthful diet are also needed;

(B) The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term "Caucasian") women and Asian women in their bone forming years (approximately 11 to 35 years of age or the phrase "during teen or early adult years" may be used). The claim may