

but not limited to, the ability of individuals to identify themselves as being at risk for the disease or health-related condition associated with the disqualifying nutrient; and

4. All other evidence demonstrating the public health need for waiving the disqualification requirements.

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5. Section 101.72 is amended by revising paragraph (c)(2)(i); by redesignating paragraphs (c)(2)(ii) and (d)(2) as (c)(2)(iii) and (d)(5), respectively; by adding new paragraphs (c)(2)(ii), (d)(2), (d)(3), and (d)(4); and by revising paragraph (e) to read as follows:

**§ 101.72 Health claims: calcium and osteoporosis.**

\* \* \* \* \*

(c)(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)(iii) of this section, provided that:

(A) The claim makes clear that adequate calcium intake as part of a healthful diet throughout life is essential to reduce the risk of osteoporosis. The claim does not imply that adequate dietary calcium intake is the only recognized risk factor for the development of osteoporosis;

(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 population at particular risk for the development of osteoporosis as women in their bone forming years from approximately 11 to 35 years of age. An optional statement that further characterizes this and other populations at risk for developing osteoporosis may be made in accordance with paragraph (d)(3) of this section;

(C) The claim does not attribute any degree to which maintaining adequate calcium intake throughout life may reduce the risk of osteoporosis; and

(D) The claim states that total dietary intake of calcium greater than 2,000 milligrams (mg) per day (200 percent of the DV for calcium for adults and children 4 or more years of age or 154 percent of the daily value (DV) for pregnant or lactating women) provides no further benefit to bone health in reducing the risk of osteoporosis. This requirement does not apply to a food that provides 1,500 mg or less of calcium per day (150 percent or less of the DV for calcium for adults and children 4 or more years of age or 115 percent or less of the DV for pregnant or lactating women) when used as directed in labeling.

(ii) *Presentation of the claim.* All of the elements listed in paragraph (c)(2)(i) of this section must be included in one presentation of the claim displayed prominently on the label or labeling on which the claim appears. Other presentations of the claim on that label or labeling, including on the principal display panel, need not include the information in paragraphs (c)(2)(i)(B) and (c)(2)(i)(D) of this section provided that, displayed prominently and in immediate proximity to such claim, the following referral statement is used: "See \_\_\_\_\_ for more information" with the blank filled in with the identity of the panel on which is presented the statement of the claim that includes all of the elements in paragraph (c)(2)(i) of this section.

(A) The referral statement "See [appropriate panel] for more information" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(B) The referral statement shall be immediately adjacent to any presentation of the health claim that does not include all of the elements of paragraph (c)(2)(i) of this section, and there may be no intervening material between the claim and the referral statement. If the abbreviated health claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the full health claim where it may be omitted.

\* \* \* \* \*

(d) \* \* \*

(2) The claim may list specific risk factors for osteoporosis, identifying them among the multifactorial risks for the disease. Such factors include a person's sex, age, and race. The claim may state that an adequate amount of exercise is also needed to reduce risk for the disease.

(3) The claim may further identify the population at particular risk for the development of osteoporosis as including white (or "Caucasian") women and Asian women in their bone forming years (approximately 11 to 35 years of age). The claim may also identify menopausal (or the term "middle-aged") women, persons with a family history of the disease, and elderly (or "older") men and women as being at risk.

(4) The claim may state that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase "build and maintain good bone health" may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss.

\* \* \* \* \*

(e) *Model health claims.* The following are examples of model health claims that may be used in food labeling to describe the relationship between calcium and osteoporosis:

(1) *Examples 1 and 2.* Model health claims for a food that does not require the statement specified in paragraph (c)(2)(i)(D) of this section:

Especially for teen and young adult women, adequate calcium in a healthful diet may reduce the risk of osteoporosis later in life.

A healthful diet with adequate calcium and regular exercise help teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

(2) *Example 3.* Model health claims for a food labeled for use by adults and children 4 or more years of age that requires the statement specified in paragraph (c)(2)(i)(D) of this section:

Exercise and a healthful diet with enough calcium may help teen and young adult women reduce their high risk of osteoporosis later in life. Adequate calcium is important for everyone (women and men at all ages) but daily intakes above 2,000 mg (200 percent of the DV) may not provide added benefit.

(3) *Example 4.* Abbreviated model health claim for use with a full health claim and that conforms with the requirements of paragraph (c)(2)(ii) of this section:

Adequate calcium in a healthful diet may reduce the risk of osteoporosis. See [appropriate panel] for more information.

6. Section 101.73 is amended by revising paragraphs (c)(2)(i)(F), (d)(1), and (e)(1) to read as follows:

**§ 101.73 Health claims: dietary lipids and cancer.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) \* \* \*

(F) The claim does not imply that dietary fat consumption is the only