

Guidance for Industry

Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis Small Entity Compliance Guide

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

May 2009

FDA-2009-D-0209

G-D2

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Small Entity Compliance Guide

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I. Introduction

On September 29, 2008, FDA published in the Federal Register a final rule (73 FR 56477, corrected at 73 FR 66754, November 12, 2008) that amended its regulations on the calcium and osteoporosis health claim (21 CFR 101.72) to: (1) include vitamin D so that, in addition to a claim for calcium and reduced risk of osteoporosis, a claim can be made for calcium and vitamin D and reduced risk of osteoporosis; (2) eliminate the requirement that the claim list sex, race, and age as specific risk factors for the development of osteoporosis; (3) eliminate the requirement that the claim identify the populations at particular risk for the development of osteoporosis and that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population; (4) eliminate the requirement that the claim identify the mechanism by which calcium reduces the risk of osteoporosis and instead make it optional; and (5) eliminate the requirement that the claim include a statement that a total dietary intake greater than 200 percent of the recommended daily intake of calcium (2,000 milligrams (mg) of calcium) has no further benefit to bone health when the food contains 400 mg or more of calcium per reference amount customarily consumed (RACC) or per total daily recommended supplement intake; and (6) allow reference to the need of physical activity for prevention of osteoporosis as optional rather than required. Manufacturers were permitted to start using the new calcium and osteoporosis and calcium, vitamin D and osteoporosis health claim on the label or in the labeling of their products on September 29, 2008. The final rule is effective on January 1, 2010. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements of the September 29, 2008 final rule set forth in 21 CFR 101.72 concerning the calcium and vitamin D and osteoporosis health claim. That regulation is binding and has the full force and effect of law.

¹ This guidance has been prepared by the Nutrition Assessment and Evaluation Team in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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II. Questions and Answers

1. Must I comply with the general health claim requirements set forth in 21 CFR 101.14 in order to make a claim associating calcium and vitamin D with a reduced risk of osteoporosis?

Yes. (21 CFR 101.72 (c) (1))

2. What specific requirements must be met to make a claim on the label or labeling of food associating calcium or calcium and vitamin D with a reduced risk of osteoporosis?

- The claim must make clear that adequate calcium or calcium and vitamin D intake throughout life in a healthful diet are essential to reducing osteoporosis risk.
- The claim must not imply that adequate calcium or adequate calcium and vitamin D intake is the only recognized risk factor for the development of osteoporosis.
- The claim must not attribute any reduction in risk of osteoporosis to maintaining an adequate dietary calcium and vitamin D intake throughout life.

(21 CFR 101.72(c)(2)(i))

3. What characteristics must a food or dietary supplement have to make a claim associating calcium and vitamin D with a reduced risk of osteoporosis?

- The food for which the claim is being made must contain at least 200 milligrams of calcium, except that meal products as defined in 21 CFR 101.13(l) and main dish as defined in 21 CFR 101.13(m) must be labeled in a way that clearly identifies the food that is the subject of the claim (e.g., the serving of low fat milk in this product is high in calcium) (see 21 CFR 101.54(b) and 101.9 (c) (8)(iv)).
- The calcium content must be digestible.
- The dietary supplement for which the claim is being made must meet the United States Pharmacopeia (USP) standards for disintegration and dissolution applicable to their component calcium salt, except that that dietary supplements that have no USP standard must exhibit appropriate digestibility under the conditions of use stated on the label of the dietary supplement.
- A food or total daily recommended dietary supplement intake must not contain more phosphorous than calcium on a weight per weight basis.

Contains Nonbinding Recommendations

(21 CFR 101.72 (c)(2)(ii))

4. What optional information can be included on the label when I make a health claim associating calcium or calcium and vitamin D with a reduced risk of osteoporosis?
- The claim may include the term “vitamin D” if the food meets or exceeds 80 International Units of vitamin D (see 21 CFR 101.54 (b) and 101.9 (c)(8)(iv)). (21 CFR 101.72(d)(1))
 - The claim may include information on the relationship between calcium, vitamin D, and osteoporosis and the significance of calcium and vitamin D as set forth in 21 CFR 101.72(a) and (b) respectively. (21 CFR 101.72(d)(2))
 - The claim may make reference to physical activity and reduced risk of osteoporosis. (21 CFR 101.72 (d)(3))
 - The claim may include information about the number of people in the United States, including people in certain subpopulations, who have osteoporosis or low bone density. The sources of this information must be identified and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or the National Osteoporosis Foundation. (21 CFR 101.72 (d)(4))
 - The claim may include information about the role of adequate calcium intake, or when appropriate, the role of adequate calcium and vitamin D intake, throughout life and its link to the reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The claim may use the phrase “build and maintain good bone health” in reference to optimizing peak bone mass. The claim may also state that adequate intake of calcium, or when appropriate, calcium and vitamin D, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women. (21 CFR 101.72 (d)(5))

5. What are some examples of model health claims that may be used?

Calcium and osteoporosis health claim: Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis" or "Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life." (21 CFR 101.72(e))

Calcium, vitamin D, and osteoporosis: "Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis" or "Adequate calcium and vitamin D throughout life, along with physical activity, may reduce the risk of osteoporosis in later life." (21 CFR 101.72(f))