

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 1994P-0390 (formerly 94P-0390) and 1995P-0241 (formerly 95P-0241)]

**Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Withdrawal in Part**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; withdrawal in part.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it is withdrawing certain proposed amendments of a proposed rule that published in the **Federal Register** of December 21, 1995 (60 FR 66206), related to the calcium and osteoporosis health claim (21 CFR 101.72). FDA is taking action in response to a health claim petition submitted by The Beverage Institute for Health and Wellness to amend the calcium and osteoporosis claim. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the calcium and osteoporosis claim.

**DATES:** The proposed rule that published on December 21, 1995 (60 FR 66206) is withdrawn in part for § 101.72(c)(2)(i)(A), (B), and (E) as of [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1450.

CF0636 1994P-0390

NWL 1

DDM

Display Date

1-4-06<sup>7</sup>

Publication Date

1-5-06<sup>7</sup>

Certifier

A. Corbin

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of December 21, 1995, FDA published a proposed rule entitled "Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims" (60 FR 66206), the 1995 proposal, to amend its regulations on health claims and nutrient content claims to provide more flexibility in the use of these claims on food products, and to amend specific requirements to certain individual health claims. FDA took this action in response to citizen petitions submitted by the National Food Processors Association (NFPA) (Docket No. 1994P-0390) and the American Bakers Association (ABA) (Docket No. 1995P-0241). The agency has extended or reopened the comment period for the 1995 proposal four times in response to requests by stakeholders and other FDA initiatives and developments. The most recent reopening of the comment period was announced in the **Federal Register** of May 4, 2004 (69 FR 24541), and the comment period was open until July 6, 2004.

On July 12, 2004, the agency received a health claim petition submitted by The Beverage Institute for Health and Wellness requesting that the agency amend the calcium and osteoporosis health claim to, among other things, simplify the language used in the claim. In response to this health claim petition, FDA is publishing elsewhere in this issue of the **Federal Register** a proposed rule to, among other things, simplify the language used in the calcium and osteoporosis health claim. Accordingly, the agency is withdrawing certain proposed amendments to the specific requirements in the calcium and osteoporosis health claim.

## II. Withdrawn Proposed Amendments to § 101.72(c)(2)(i)(A), (B), and (E) of the 1995 Proposal

In the 1995 proposal, FDA proposed to simplify § 101.72(c)(2)(i)(A) by limiting the requirement to a balanced statement that reflects the importance of the essential nutrient calcium over a lifetime in a healthful diet to reduce osteoporosis risk, but that does not imply that calcium is the only risk factor for the development of osteoporosis, and to eliminate the provision in § 101.72(c)(2)(i)(A) that the specific risk factors, including sex, race, age, and the need for an adequate level of exercise be stated in any claim. Elsewhere in this issue of the **Federal Register**, FDA is proposing alternative amendments to § 101.72(c)(2)(i)(A). Therefore, FDA is withdrawing this proposed amendment of the 1995 proposal.

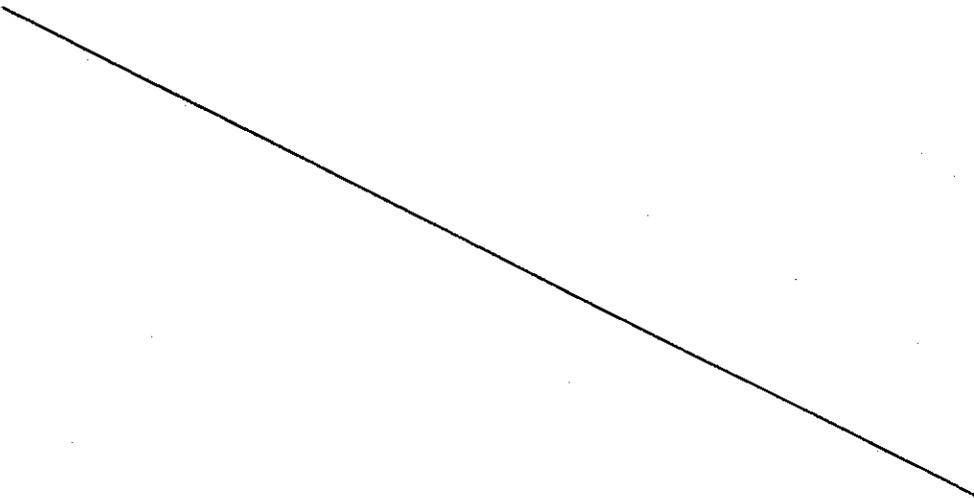
In the 1995 proposal, FDA proposed to revise § 101.72(c)(2)(i)(B) by removing the requirement to identify by race or ethnicity those populations at particular risk for the development of osteoporosis, but to retain identification of teen and young women, irrespective of race or ethnicity, as the focus of the claim. Elsewhere in this issue of the **Federal Register**, FDA is proposing alternative amendments to § 101.72(c)(2)(i)(B). Therefore, FDA is withdrawing this proposed amendment of the 1995 proposal.

In the 1995 proposal, FDA proposed to increase the amount of calcium present in a food that triggers the requirement in § 101.72(c)(2)(i)(E) that the claim include a statement that reflects the limit of the benefits derived from dietary calcium intake. Elsewhere in this issue of the **Federal Register**, FDA is proposing alternative amendments to § 101.72(c)(2)(i)(E). Therefore, FDA is withdrawing this proposed amendment of the 1995 proposal.

### III. Related Action

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend § 101.72 to, among other things: (1) Eliminate the requirement in § 101.72(c)(2)(i)(A) that the claim list sex, race, and age as specific risk factors for the development of osteoporosis; (2) eliminate the requirement in § 101.72(c)(2)(i)(B) that the claim does not state or imply that the risk of osteoporosis is equally applicable to the general U.S. population, and that the claim identify the populations at particular risk for the development of osteoporosis; and (3) eliminate the requirement in § 101.72(c)(2)(i)(E) that the claim include a statement that reflects the limit of the benefits derived from dietary calcium intake, when the level of calcium in the food exceeds a set threshold level.

Comments specific to the proposed amendments in § 101.72(c)(2)(i)(A), (B), and (E) that were submitted in response to the 1995 proposal were considered in the development of the proposed rule that responds to the health claim petition submitted by The Beverage Institute for Health and Wellness.



Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the proposed rule published on December 21, 1995 (60 FR 66206), is withdrawn in part for § 101.72(c)(i)(A), (B), and (E).

Dated: 12/18/06  
December 18, 2006.



---

Michael M. Landa,  
Deputy Director,  
Regulatory Affairs,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

