

(d) *Optional information.* (1) The claim may include the term “vitamin D” if the food meets or exceeds the requirements for a “high” level of vitamin D as defined in § 101.54(b);

(2) The claim may include information from paragraphs (a) and (b) of this section.

(3) The claim may include information on the number of people in the United States 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.

(4) The claim may state that the role of adequate calcium intake, or when appropriate, the role of adequate calcium and vitamin D 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 intake of calcium or adequate intake of calcium and vitamin D, if applicable, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss.

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

Physical activity and adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis. Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

(f) *Model additional health claims for calcium and vitamin D.* The following model health claims may be used in food labeling to describe the relationship between calcium, vitamin D, and osteoporosis:

Physical activity and adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium and vitamin D as part of a healthful diet, throughout life along with physical activity, may reduce the risk of osteoporosis in later life.

Dated: December 18, 2006.

**Michael M. Landa,**

*Deputy Director, Regulatory Affairs, Center for Food Safety and Applied Nutrition.*

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## 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 January 5, 2007.

**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.

#### **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: December 18, 2006.

**Michael M. Landa,**

*Deputy Director, Regulatory Affairs, Center for Food Safety and Applied Nutrition.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[USCG-2006-25767 formerly CGD09-06-123]

RIN 1625-AB11

### Safety Zones; U.S. Coast Guard Water Training Areas, Great Lakes

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking; withdrawal.

**SUMMARY:** The Coast Guard is withdrawing its notice of proposed rulemaking (NPRM) concerning the establishment of safety zones throughout the Great Lakes for the purpose of conducting gunnery training. The Coast Guard is authorized to conduct training in realistic conditions and in locations including in, on, and over the internal waters of the United States. In order to maximize safety, the NPRM proposed establishing safety zones in order to maintain Coast Guard control over the training area during training periods. This NPRM is being withdrawn, however, because of comments received from the public regarding the number and location of the proposed safety zones, the frequency of use, notification procedures as well as other concerns raised by the public. There will be no further gunnery training on the Great Lakes to satisfy non-emergency training requirements unless we first propose to the public and then publish a final rule. Because the Coast Guard is mandated to provide for the safety and security of the more than 30 million people in Great Lakes region, the critical infrastructure that make up the Great Lakes system, and the vessels that use it, we are evaluating all available options, including a new NPRM for gunnery training.

**DATES:** The notice of proposed rulemaking is withdrawn on January 5, 2007.

#### FOR FURTHER INFORMATION CONTACT:

Commander Gustav Wulfkühle, Enforcement Branch, Response Division, Ninth Coast Guard District, Cleveland, OH at (216) 902-6091.

#### SUPPLEMENTARY INFORMATION:

#### Regulatory History

On August 1, 2006, the Coast Guard published a notice of proposed rulemaking (NPRM) (71 FR 43402) to establish permanent safety zones throughout the Great Lakes which would restrict vessels from portions of

the Great Lakes during live-fire gun exercises that would be conducted by Coast Guard cutters and small boats. The initial comment period for the NPRM ended on August 31, 2006. In response to public requests, the Coast Guard re-opened the comment period (71 FR 53629, September 12, 2006) from September 12, 2006 to November 13, 2006, in order to provide the public more time to submit comments and recommendations. On September 19 and 27, 2006, the Coast Guard published brief documents announcing the dates and other information on public meetings regarding the NPRM and the gunnery exercises. (71 FR 54792, 56420).

On October 12, 2006, the Coast Guard announced the addition of three more public meetings and again stated that more detailed information related to the meetings would be published at a later date. (71 FR 60094). On October 23, the Coast Guard published a document containing detailed information about five additional public meetings. (71 FR 62075).

#### Background

Thirty-four safety zones were to be located throughout the Great Lakes in order to accommodate 56 separate Coast Guard units. The proposed safety zones were all located at least three nautical miles from the shoreline.

The Coast Guard proposed to establish permanent zones on the Great Lakes to provide the public with more notice and predictability when conducting infrequent periodic training exercises of brief duration, and to give the public an opportunity to comment on the proposals. The proposed safety zones would have appeared on National Oceanographic and Atmospheric Administration nautical charts, which would have provided a permanent reference for mariners.

The proposed safety zones would have been utilized only upon notice by the cognizant Captain of the Port for the area involved in the exercise. Under the procedure outlined in the NPRM, the cognizant Captain of the Port would have issued notice of the enforcement of a live-fire exercise safety zone by all appropriate means to effect the widest publicity among the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification would have included, but not been limited to, Broadcast Notice to Mariners or Local Notice to Mariners before, during, and at the conclusion of training exercises.

The coordinates of the proposed safety zones were published on August