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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket Nos. 1994P-0390 and 1995P-0241]

Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for the proposed rule entitled “Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims” (60 FR 66206, December 21, 1995) (the 1995 proposal). In that document, FDA proposed to amend its existing nutrient content claims and health claims regulations to provide additional flexibility in the use of these claims on food products. FDA reopened the comment period for the 1995 proposal to seek comment on the proposed amendments to permit unqualified health claims on certain foods that do not contain 10 percent or more of one of certain required nutrients, the proposed amendments to provide criteria that FDA would consider in determining whether to grant an exemption from disqualifying nutrient levels related to unqualified health claims of certain nutrients, and the proposed amendments to retain the word “may” or “might” in unqualified health claims. In addition, FDA sought comment on the proposed use of unlisted synonyms

and abbreviated health claims. The comment period for the 1995 proposal closed on July 6, 2004. FDA is reopening the comment period again in response to four requests for additional time to submit comments to FDA.

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: You may submit comments, identified by Docket Nos. 1994P-0390 and 1995P-0241, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket Nos. 1994P-0390 and 1995P-0241 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and

insert the docket numbers, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 21, 1995, FDA proposed to amend its existing regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products. Specifically, FDA proposed the following: (1) To allow additional synonyms for nutrient content claims without specific preclearance by the agency (i.e., unlisted synonyms), (2) to permit health claims on certain foods that do not currently qualify to bear a claim because they do not contain 10 percent of one or more of certain required nutrients, (3) to permit the use of shortened versions of authorized health claims (i.e., abbreviated health claims) under certain circumstances, (4) to eliminate and/or make optional some of the specific health claim elements required by regulation, and (5) to provide criteria that FDA would consider in determining whether to grant an exemption from disqualifying nutrient levels to permit some foods to bear an unqualified health claim even though they contain high levels of one or more of certain nutrients. FDA proposed these amendments in response to petitions submitted by the National Food Processors Association (NFPA) (Docket No. 1994P-0390) and the American Bakers Association (ABA) (Docket No. 1995P-0241). FDA requested comments on the 1995 proposal by March 20, 1996, which was later

extended to July 18, 1996 (61 FR 11793, March 22, 1996). The comment period was reopened in 1997 to obtain comment on an FDA study and two consumer research studies submitted by industry (62 FR 3635, January 24, 1997), and then extended to allow interested persons more time to review the studies and submit comments (62 FR 11129, March 11, 1997).

In the **Federal Register** of May 4, 2004 (69 FR 24541), FDA reopened for 60 days the comment period for the 1995 proposal. In the May 4, 2004, notice reopening the comment period, FDA noted that since the publication of the 1995 proposal, FDA established a task force for the Consumer Health Information for Better Nutrition Initiative (the task force). The purpose of the initiative is to make available more and better information about conventional foods and dietary supplements to help American consumers improve their health and decrease their risk of contracting diseases by making sound dietary choices. The task force issued a final report on July 10, 2003 (68 FR 41387, July 11, 2003), which recommended that FDA seek public comment on several topics related to qualified health claims (i.e., claims that do not meet the significant scientific agreement (SSA) standard of evidence required by the Federal Food, Drug, and Cosmetic Act and FDA regulations to evaluate the scientific validity of health claims) and unqualified health claims (i.e., health claims that are supported by SSA and authorized by FDA by regulation). Some of the topics identified in the task force report were specifically addressed in the 1995 proposal. FDA reopened the comment period on the 1995 proposal to seek comment on these topics, which include the following: (1) The proposed amendments to permit unqualified health claims on certain foods that do not contain 10 percent or more of one of certain required nutrients; (2) the proposed amendments to provide criteria that FDA would consider in

determining whether to grant an exemption from disqualifying nutrient levels related to unqualified health claims of certain nutrients; and (3) the proposed amendments to retain the word “may” or “might” in unqualified health claims to describe the relationship between a substance and a disease or health-related condition. In addition, FDA sought comment on the proposed use of unlisted synonyms and abbreviated health claims. Specifically, for unlisted synonyms (i.e., terms not defined by regulation), FDA repeated its request for data or other information demonstrating that unlisted synonyms that are anchored to defined terms in nutrient content claims are reasonably understood by consumers to be synonyms of the defined terms. FDA also sought comments on the petition process in 21 CFR 101.69(n) for synonyms and examples of synonyms that industry may be seeking to use. For abbreviated health claims, FDA sought comments and requested data or other information regarding whether abbreviated health claims would mislead consumers.

Following publication of the May 4, 2004, notice reopening the comment period, FDA received four requests for an extension of the comment period to allow interested persons additional time to comment. Two of the requests were submitted by NFPA and ABA, the petitioners. The requesters asserted that more time is needed, given the complexity of the issues, to thoroughly review the specific elements of the 1995 proposal. Some requesters further supported their requests for additional time by noting that more than 7 years have passed since the 1995 proposal was last considered in comments and FDA’s May 4, 2004, notice reopening the comment period. NFPA and ABA, which are trade associations, specifically stated that, over the intervening years, many of their member companies’ representatives who were responsible for consideration of the technical aspects of the 1995 proposal have left their

companies and have been replaced by staff that are less familiar with the 1995 proposal, subsequent comments, and underlying petitions. In addition, NFPA and ABA asserted that because the character of their membership has changed and current members may advocate different views of the issues raised in the 1995 proposal and in comments on the 1995 proposal received through 1997, additional time is needed to ensure that all members' concerns are addressed to accurately comment and respond to FDA. Another requester, also a trade association, also requested more time to ensure that all of its members' concerns are addressed to accurately comment and respond to FDA.

FDA has considered the requests for additional time to submit comments and, because the comment period for the 1995 proposal closed on July 6, 2004, FDA is again reopening the comment period on the 1995 proposal for an additional 60 days to provide interested persons an opportunity to comment on the issues identified herein and in FDA's May 4, 2004, notice reopening the comment period for the 1995 proposal.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments in response to FDA's request for comments and available data or other information identified in FDA's May 4, 2004, notice reopening the comment period on the 1995 proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify

comments with the docket numbers found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/8/04
November 8, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy,



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