

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. 2003N-0496]

RIN 0910-AF09

### Food Labeling: Health Claims; Dietary Guidance; Extension of Comment Period

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

**ACTION:** Advance notice of proposed rulemaking; extension of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is extending to February 25, 2004, the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the **Federal Register** of November 25, 2003 (68 FR 66040). In the ANPRM, FDA requested comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional foods and dietary supplement labels. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written and electronic comments by February 25, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Nancy T. Crane, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1456, or e-mail: *Nancy.Crane@cfsan.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of November 25, 2003 (68 FR 66040), FDA published an ANPRM with a 60-day comment period to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional foods and dietary supplement labels. Comments on the regulatory alternatives and the additional topics will inform FDA's rulemaking to establish regulations for qualified health claims, as well as any policy initiative(s) that FDA may undertake to provide information to consumers to help them make wise food choices.

The agency has received multiple requests for either a 30-day or 60-day extension of the comment period for the ANPRM. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the ANPRM. In addition, two requests noted that the current comment period occurred during a period of time that included the Thanksgiving and year-end holidays. All of the requests explained that an extension is necessary due to the complexity, implications, and/or importance of the rulemaking on health claims and dietary guidance in food and dietary supplement labeling.

FDA has considered the requests and is extending the comment period for the ANPRM for 30 days, until February 25, 2004. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

**II. Request for Comments**

Interested persons may, on or before February 25, 2004, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this ANPRM. Submit two copies of any comments, except that individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. Interested persons may review received comments in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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