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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 170

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Certifier A. Cerbin

[Docket No. 2002P-0122] (formerly 02P-0122)

**Conventional Foods Being Marketed as "Functional Foods"; Extension of Comment Period**

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

**ACTION:** Notice of public hearing; extension of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is extending to March 5, 2007, the comment period for the notice of public hearing that appeared in the **Federal Register** of October 25, 2006 (71 FR 62400). In the notice of public hearing, FDA requested comments on how the agency should regulate conventional foods marketed as "functional foods" under its existing legal authority. 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 March 5, 2007.

**ADDRESSES:** You may submit comments, identified by Docket No. 2002P-0122, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

- 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.

### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:

Division of Dockets Management (HFA-305), Food and Drug Administration,  
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, 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 number, 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:** Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-555), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1731.

**SUPPLEMENTARY INFORMATION:**

## **I. Background**

In the **Federal Register** of October 25, 2006, FDA published a notice of public hearing with a 72-day comment period to request comments on the regulation of conventional foods marketed as “functional foods,” specifically the issues and questions presented in section III of the notice (see 71 FR 62400 at 62403). Comments will inform FDA’s approaches to the regulation of conventional foods marketed as “functional foods.”

The agency has received requests for a 60-day extension of the comment period for the notice of public hearing. Each request conveyed concern that the current 72-day comment period, which closes 30 days subsequent to the public hearing held December 5, 2006, does not allow sufficient time to develop a meaningful or thoughtful response to the request for comments on the issues and questions presented in section III of the notice.

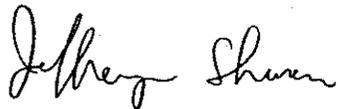
FDA has considered the requests and is extending the comment period for the notice of public hearing for 60 days, until March 5, 2007. The agency believes that a 60-day extension allows adequate time for interested persons to submit comments on the issues and questions presented in section III of the notice without significantly delaying the agency’s consideration of how FDA should regulate conventional foods marketed as “functional foods” under its existing legal authority.

## **II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number 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: 12/29/06  
December 29, 2006.



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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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