

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 111 and 112

[Docket No. 96N-0417]

RIN 0910-AB88

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 11, 2003, the comment period for a proposed rule published in the **Federal Register** of March 13, 2003. The proposed rule would establish the minimum current good manufacturing practices (CGMPs) necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. This action is being taken in response to requests for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by August 11, 2003.

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

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FOR FURTHER INFORMATION CONTACT: Karen Strauss, Center for Food Safety and Applied Nutrition (HFS-821), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 02740-3835, 301-436-2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 13, 2003 (68 FR 12158), FDA published a proposed rule that, if finalized, would establish the minimum CGMPs necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The proposed provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of the dietary ingredients and dietary supplements.

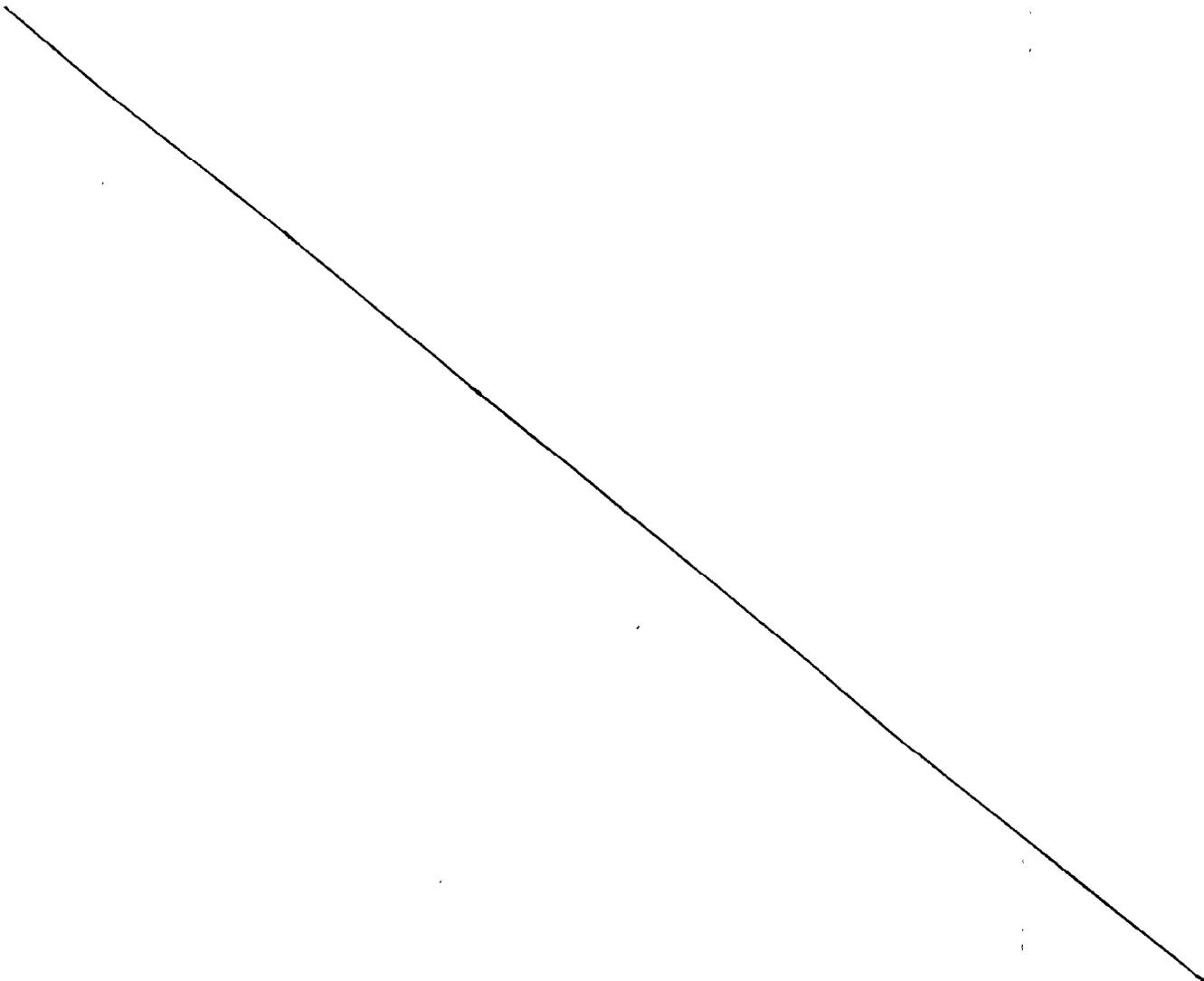
In the March 13, 2003, proposed rule, FDA announced that the time period for public comment would be 90 days from the date of the publication in the **Federal Register**. On April 21, 2003, FDA received a request to allow an additional 60 days for interested persons to comment. In addition, on April 25, 2003, FDA received a request to allow an additional 90 days for interested persons to comment. The requesters assert that the time period of 90 days is insufficient to respond fully to FDA's multiple requests for comments and analyses and to enable all potential respondents adequate time to conduct the research necessary to provide complete scientific responses to questions posed in the proposed rule.

FDA believes that an extension of the comment period is appropriate, given the variety of issues raised by the proposed rule. However, because the agency wants to move forward on finalizing the rule as quickly as possible,

FDA is extending the comment period only for an additional 60 days, until August 11, 2003. This extension will provide the public with a total of 150 days to submit comments. FDA does not intend to grant any additional time for extensions of the comment period.

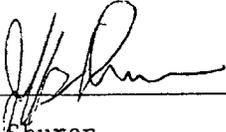
II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the proposal. 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 numbers found in brackets in the heading of



this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/10/03
May 10, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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