

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N-384H and 96P-0500]

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Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term "Healthy"; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 5, 2003, the comment period for a proposed rule published in the **Federal Register** of February 20, 2003. The proposed rule would amend the regulation for sodium levels for foods that use the nutrient content claim "healthy." This action is being taken in response to a request for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by July 5, 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>.

FOR FURTHER INFORMATION CONTACT: Constance B. Henry, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 02740-3835, 301-436-1450.

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SUPPLEMENTARY INFORMATION:**I. Background**

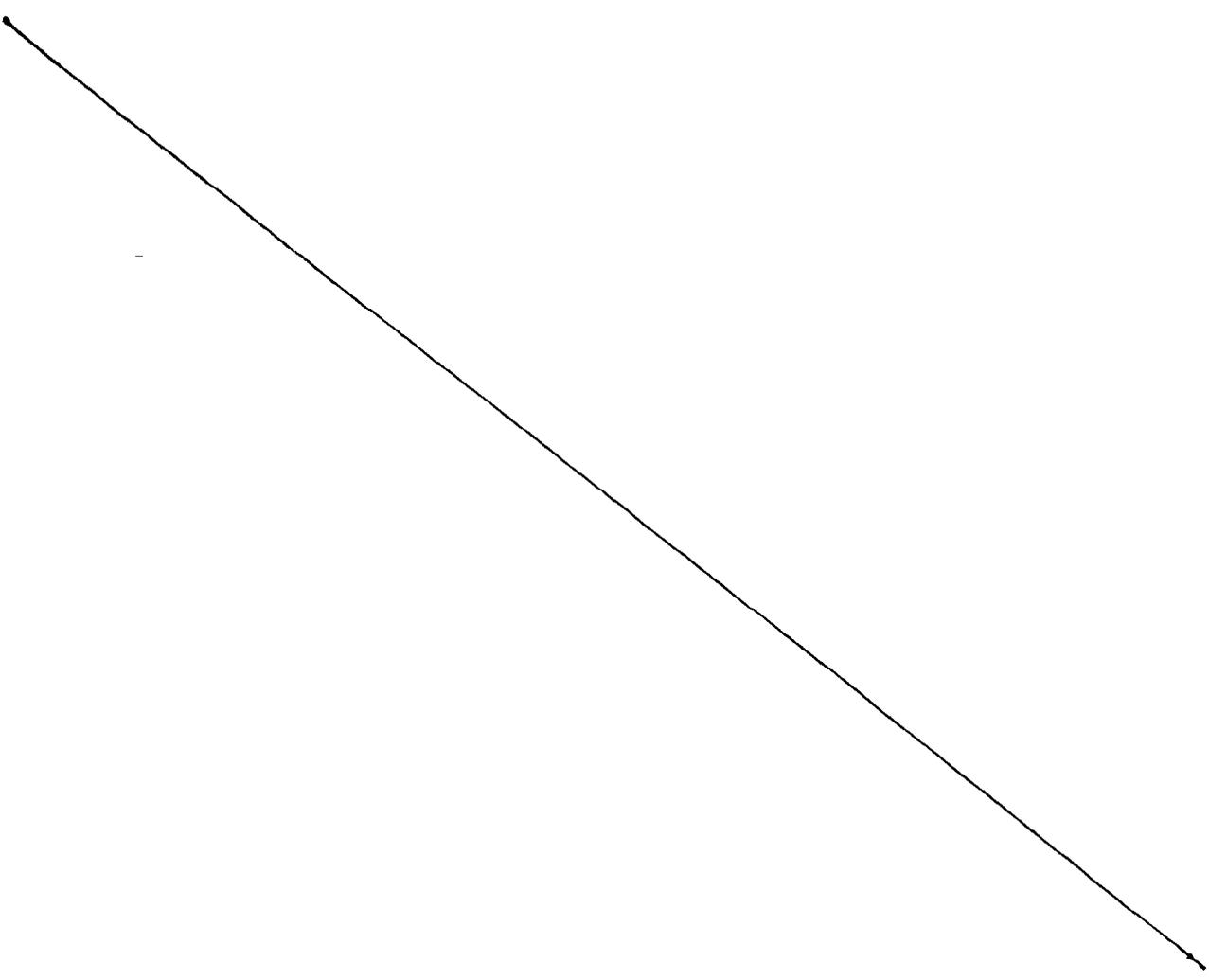
In the **Federal Register** of February 20, 2003 (68 FR 8163), FDA published a proposed rule that, if finalized, would amend the regulation for sodium levels for foods that use the nutrient content claim “healthy.” The agency proposed that a previously established, but not yet implemented, more restrictive second-tier sodium level would be permitted to take effect as a criterion that individual foods must meet to qualify to bear the term “healthy.” The agency proposed to retain the current first-tier sodium levels for meal and main dish products because implementing the more restrictive second-tier sodium level could result in the substantial elimination from the marketplace of meal and main dish products bearing the claim “healthy.”

In the February 20, 2003, proposed rule, FDA announced that the time period for public comment would be 75 days from the date of the publication in the **Federal Register**. On April 9, 2003, FDA received a request to allow an additional 60 days for interested persons to comment. In the requester’s view, the time period of 75 days was 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. Therefore, FDA is extending the comment period for an additional 60 days, until July 5, 2003. This extension will provide the public with a total of 135 days to submit comments.

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: 5/1/03
May 1, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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