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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 1995N-0309]

RIN 0910-AA04

Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula; Extension of Reopened Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of reopened comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to *[insert date 60 days after date of publication in the Federal Register]*, the comment period, reopened on April 28, 2003, for the proposed rule published in the **Federal Register** of July 9, 1996 (61 FR 36154). The proposed rule would establish requirements for current good manufacturing practice (CGMP) and audits, establish requirements for quality factors, and amend quality control procedures, notification, and records and reports requirements for infant formula. 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 *[insert date 60 days after date of publication in the Federal Register]*.

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: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1491, or e-mail: Shellee.Anderson@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

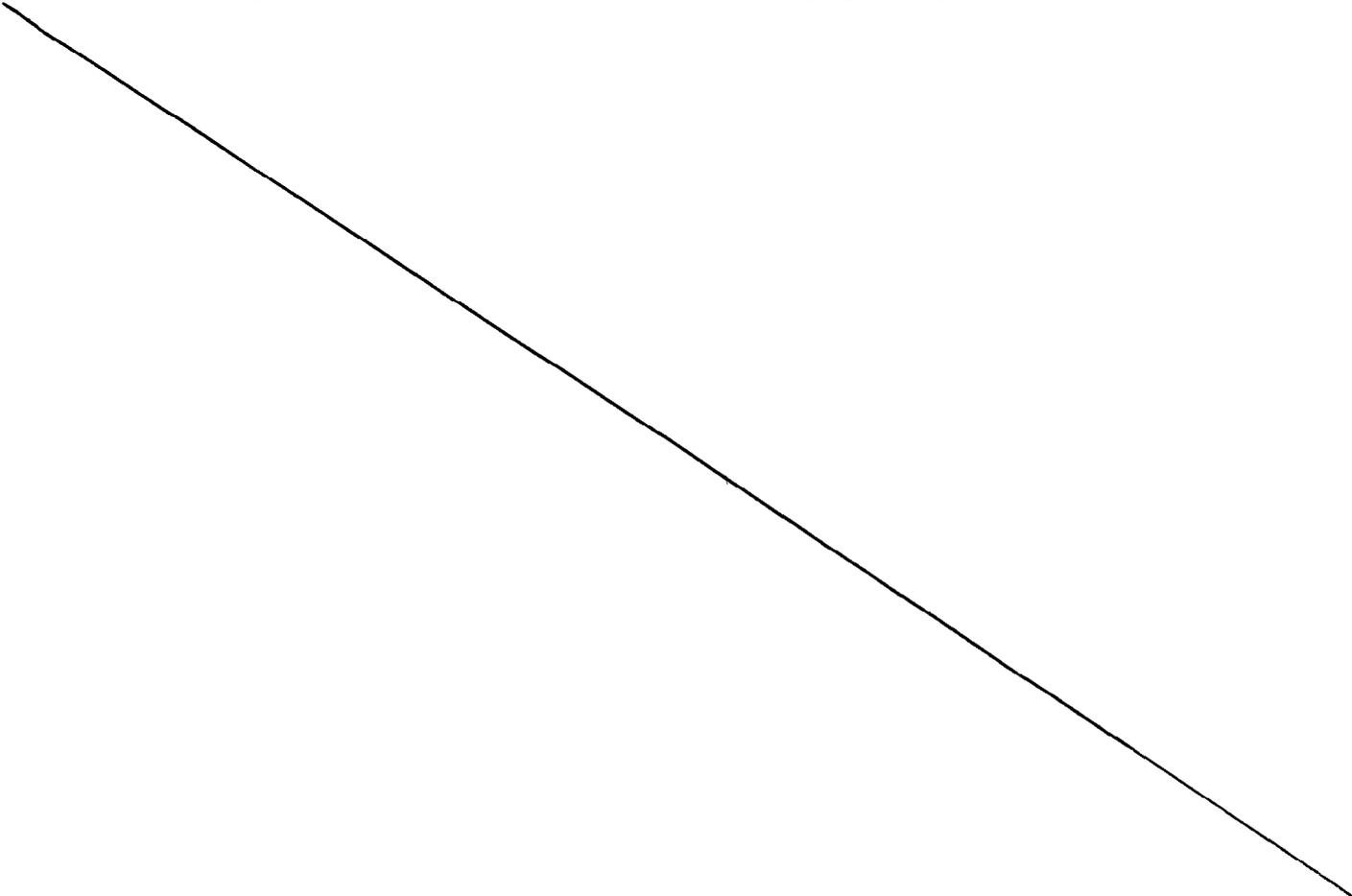
In the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed regulations to revise its infant formula regulations to establish requirements for quality factors and CGMP; to amend quality control procedure, notification, and records and report requirements for infant formulas; to require that infant formulas contain, and be tested for, required nutrients and for any nutrient added by the manufacturer throughout their shelf life, and that they be produced under strict microbiological controls; and to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design.

In the **Federal Register** of April 28, 2003 (68 FR 22341), FDA announced that the time period for public comment would be reopened to June 27, 2003. On May 6, 2003, FDA received a request to extend the reopened comment period to allow interested persons additional time to comment. The requester asserts that the time period of 60 days is insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address the original proposal in light of new issues that have arisen since 1996.

FDA believes that an extension of the reopened comment period is appropriate, given the variety of issues raised by the proposed rule and the April 28, 2003, document. 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 [*insert date 60 days after date of publication in the **Federal Register***]. This extension will provide the public with a total of 120 days to submit comments during the reopened comment period.

II. Comments

Interested persons may submit to the Division of Dockets Management (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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/23/03
June 23, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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