

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 331**

[Docket No. 93N-0164]

RIN 0905-AA06

Antacid Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph; Reopening of Comment Period**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of proposed rulemaking; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to May 4, 1994, the comment period on the notice of proposed rulemaking that would require specific indication, warning, and direction statements in the labeling of over-the-counter (OTC) antacid drug products containing sodium bicarbonate as an active ingredient (February 2, 1994, 59 FR 5060). FDA is taking this action in response to a request to extend the comment period for an additional 30 days to allow more time to comment on this proposal. The comment period for these issues closed on April 4, 1994. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by May 4, 1994.**ADDRESSES:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.**FOR FURTHER INFORMATION CONTACT:** William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 2, 1994 (59 FR 5060), FDA issued a notice of proposed rulemaking to amend the final monograph for OTC antacid drug products to require specific indication, warning, and direction statements in the labeling of products containing sodium bicarbonate as an active ingredient (hereinafter referred to as the February 1994, proposal). The new labeling would be required only for oral dosage forms intended to be dissolved in liquid prior to administration, such as powders and effervescent granules or tablets. As proposed, no such oral dosage forms

containing sodium bicarbonate as an active ingredient would be allowed to make a claim for "relief of overindulgence in food and drink." The proposed warnings would alert consumers to avoid antacid drug products containing sodium bicarbonate when the stomach is overly full from eating and drinking. The proposed directions would inform consumers that sodium bicarbonate should be completely dissolved before drinking and that the recommended dose should not be exceeded. FDA issued the February 1994, proposal after receiving reports of gastric (stomach) rupture following ingestion of sodium bicarbonate to relieve gastrointestinal distress. Interested persons were given until April 4, 1994, to submit comments on the proposal.

On March 28, 1994, the Nonprescription Drug Manufacturers Association (NDMA), a trade association representing the manufacturers and distributors of OTC medicines, requested that the comment period be extended for at least 30 days. NDMA stated that the extension is necessary to provide sufficient time to develop comprehensive comments to submit to the agency. NDMA explained that most companies that distribute OTC drug products containing sodium bicarbonate as an active ingredient were not anticipating changes in the antacid final monograph and the February 1994, proposal provided the first opportunity for many affected parties to become aware of the agency's concerns and intentions for amending the monograph. NDMA stated that interested parties have had insufficient time to acquire the reference materials cited by FDA, to retrieve relevant product experience reports, and to research thoroughly the issues raised in FDA's February 1994, proposal. NDMA also mentioned that the time period for the comments includes several days on which many company employees will not be working because of religious holidays.

FDA has carefully considered the request and believes that this additional time for comment is in the public interest. Accordingly, the comment period is reopened to May 4, 1994.

Interested persons may, on or before May 4, 1994, submit to the Dockets Management Branch (address above) written comments regarding OTC antacid drug products containing sodium bicarbonate as an active ingredient. Three copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 8, 1994.
 Michael R. Taylor,
 Deputy Commissioner for Policy.
 [FR Doc. 94-9045 Filed 4-13-94; 8:45 am]
 BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[PS-106-91]

RIN 1545-AQ41

State Housing Credit Ceiling and Other Rules Relating to the Low-Income Housing Credit; Hearing Cancellation**AGENCY:** Internal Revenue Service, Treasury.**ACTION:** Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed Income Tax Regulations concerning the low-income housing credit.

DATES: The public hearing originally scheduled for Tuesday, April 26, 1994, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622-7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed amendments to the Income Tax Regulations under section 42 of the Internal Revenue Code of 1986. A notice of proposed rulemaking, and public hearing appearing in the *Federal Register* for Wednesday, December 29, 1993 (58 FR 68799), announced that a public hearing on the proposed regulations would be held on Tuesday, April 26, 1994, beginning at 10 a.m., in the IRS Auditorium, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, DC.

The public hearing scheduled for Tuesday, April 26, 1994, is cancelled.
 Cynthia E. Grigsby,
 Chief, Regulations Unit, Assistant Chief Counsel (Corporate).
 [FR Doc. 94-8936 Filed 4-13-94; 8:45 am]
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