DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 331

[Docket No. 95N–0254]

RIN 0910–AA63

Labeling of Orally Ingested Over-the-Counter Drug Products Containing Calcium, Magnesium, and Potassium; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to September 20, 1996, the comment period on the notice of proposed rulemaking to amend the general labeling provisions for over-the-counter (OTC) drug products intended for oral ingestion to require the content per dosage unit and warning labeling when the product contains certain levels of calcium, magnesium, or potassium. The notice of proposed rulemaking was published in the **Federal Register** of April 22, 1996 (61 FR 17807). FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to comment on the notice of proposed rulemaking.

DATES: Written comments by September 20, 1996. Written comments on the agency's economic impact determination by September 20, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 22, 1996 (61 FR 17807), FDA published a notice of proposed rulemaking to amend the general labeling provisions for OTC drug products to require that the labeling of all OTC drug products intended for oral ingestion include: (1) The calcium content per dosage unit when the product contains 20 milligrams (mg) or more per single dose; (2) a warning statement that persons with kidney stones and persons on a calcium-restricted diet should not take the product unless directed by a doctor when the product contains more than 3.2 grams of calcium in the labeled maximum daily dose; (3) the magnesium content per dosage unit when the product contains 8 mg or more per single dose; (4) a warning statement that persons with kidney disease and persons on a magnesium-restricted diet should not take the product unless directed by a doctor if the product contains more than 600 mg magnesium in the labeled maximum daily dose; (5) the potassium content per dosage unit when the product contains 5 mg or more per single dose; and (6) a warning statement that persons with kidney disease and persons on a potassium-restricted diet should not take the product unless directed by a doctor if the product contains more than 975 mg potassium in the labeled maximum daily dose. FDA issued the notice of proposed rulemaking in order to provide uniform calcium, magnesium, and potassium content and warning labeling for all OTC drug products intended for oral ingestion whether marketed under an OTC drug monograph, an approved application, or no application.

On June 18, 1996, Nonprescription Drug Manufacturers Association (NDMA), a trade association of nonprescription drug manufacturers, requested a 60-day extension in which to file comments and new information. NDMA noted FDA's request for comments on recent scientific information to consider in setting requirements for OTC drug product labeling for products containing these ingredients (cations), the potential far-reaching nature of the proposal, and what NDMA termed "possible substantial economic impact" as a basis for its request for an extension of the comment period. NDMA also had a number of questions on a related final rule for sodium labeling for OTC drug products published in the **Federal Register** of April 22, 1996 (61 FR 17798), which FDA has addressed in a recent feedback letter (Ref. 1).

FDA has carefully considered the request and acknowledges the broad scope of the notice of proposed rulemaking, which would affect products in several therapeutic categories. Manufacturers may require additional time to obtain information, including scientific information, and comment on the notice of proposed rulemaking. Although the agency has a policy of generally not extending such comment periods, FDA considers an extension of time for comments in this case to be in the public interest and is therefore extending the comment period for an additional 60 days.

Interested persons may, on or before September 20, 1996, submit to the Dockets Management Branch (address above) written comments on the notice of proposed rulemaking. 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 the 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.

Reference

1. Letter from Debra Bowen, FDA, to R. W. Soller, NDMA, July 15, 1996, in Docket No. 95N–0254, Dockets Management Branch.

Dated: July 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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