DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 331

[Docket No. 90N–0309]

RIN 0910–AA63

Drug Labeling; Sodium Labeling for Over-the-Counter Drugs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to September 20, 1996, the period for comments on amending the final rule for sodium labeling for over-the-counter (OTC) drug products that was published in the Federal Register of April 22, 1996. In the document, FDA asked for comments on whether the final rule should be amended to include sodium content labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products. FDA is taking this action in response to a request to extend the period for comments to allow interested persons additional time to comment on this matter.

DATES: Written comments 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 17798), FDA issued a final rule on sodium labeling for OTC drug products with opportunity for comments on whether the final rule should be amended to include sodium content labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products. Interested persons were given until July 22, 1996, to submit comments on labeling for those products. The final rule amends the general labeling provisions for OTC drug products to: (1) Require that the sodium content of all OTC drug products intended for oral ingestion be included in labeling when the product contains 5 milligrams (mg) or more sodium per a single dose; (2) require that all OTC drug products intended for oral ingestion containing more than 140 mg sodium in the labeled maximum daily dose bear a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor; and (3) provide for the voluntary use of certain terms (''sodium free,'' ''very low sodium,'' and ''low sodium'') relating to an OTC drug product's sodium content per labeled maximum daily dose. FDA issued the final rule in order to provide uniform sodium content labeling for all OTC drug products intended for oral ingestion (whether marketed under an OTC drug monograph, an approved application, or no application), and to provide for the voluntary use in OTC drug product labeling of the same terms used to describe sodium content in food labeling.

On June 18, 1996, Nonprescription Drug Manufacturers Association (NDMA), a trade association of nonprescription drug manufacturers, requested a 60-day extension to file comments and new information. NDMA stated that to fully address the issue of sodium labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products, its members needed this additional time because six different task groups needed to look at these drug classes in coordination with task groups from the Cosmetic, Toiletry and Fragrance Association. NDMA also raised a number of questions on the final rule, which FDA has answered in a recent feedback letter (Ref. 1).

FDA has carefully considered the request and acknowledges the broad scope of the proposal. The agency considers an extension of time for comments to be in the public interest. This will allow all interested persons additional time to evaluate whether products other than those intended for oral ingestion should be covered by the sodium labeling regulation. The agency is therefore extending the time for comment for an additional 60 days.

Interested persons may, on or before September 20, 1996, submit to the Dockets Management Branch (address above) written comments regarding sodium labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products. 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.

Reference

The following reference has been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Letter from D. Bowen, FDA, to R. W. Soller, NDMA, July 15, 1996, in Docket No. 90N–0309 Dockets Management Branch.

Dated: July 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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