published in the **Federal Register** of February 27, 1997 (62 FR 9024). The document proposed to establish a standardized format for the labeling of OTC drug products. The document supersedes the agency's proposed rule regarding the use of interchangeable terms, published in the **Federal Register** of March 4, 1996 (61 FR 8460), and responds to the comments that were submitted to FDA as a result of that proposal (Docket No. 92N–454A). The document also proposes to preempt State and local rules that establish different or additional format or content requirements than those in the proposed rule. FDA is extending the comment period of the proposed rule in response to two manufacturers' associations requests to extend the period for comments to allow interested persons adequate time to assess and respond to the proposal. Elsewhere in this issue of the **Federal Register** the agency is also announcing that the Nonprescription Drugs Advisory Committee will meet to discuss proposed labeling requirements for OTC drug product labeling.

DATES: Written comments by October 6, 1997.

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: Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA published a notice of proposed rulemaking to establish a standardized format for the labeling of OTC drug products. Interested persons were given until June 27, 1997, to submit comments on the proposal.

In the proposal, the agency indicated that because the design and format of labeling information varies considerably among OTC drug products, consumers often have difficulty reading and understanding the information presented on OTC drug product labeling. The proposal is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. The agency had also tentatively determined that to ensure that OTC drug product labeling conveys all material information to the consumer, and that the labeling conveys this information in a manner that is likely to be read and understood by the consumer, State and local rules that would establish different or additional format or content requirements than those in the proposed rule should be preempted.

FDA has received requests from two manufacturers' associations to extend the comment period to permit industry and other interested parties additional time to respond to the proposed labeling requirements. One association requested a 90-day extension of the comment period until September 25, 1997, for the following reasons: (1) To comment on the economic and possible environmental impact of the proposed rule; (2) to obtain, analyze, collate, and summarize data from a survey of OTC drug manufacturers to determine the actual cost and the time involved in major label revisions; (3) to prepare model or prototype labels to illustrate the effect of the proposed rule and to develop solutions to problems that may be encountered; and (4) to provide the agency with quality comments in response to the recently published proposal. The comment added that the proposal is the most far-reaching for, and will have the most universal effect on, OTC drug products of any rule published in the last 20 years.

The other association requested a 120-day extension to the comment period until October 25, 1997, because the proposal would require extensive relabeling of its member companies' products. The comment indicated that additional time is essential to form industry consensus to support useful comments to the agency and to ascertain the long range implication of the labeling proposal for the entire industry and for cosmetic-drug products in particular. The comment also mentioned that the first opportunity for its board of directors to make a recommendation on the labeling proposal would not occur until September 30, 1997. Therefore, the extension request of 120 days is dictated by the scheduling of the meeting of its board and the time needed subsequent to the board meeting to complete comments on the proposed rule.

Recognizing the scope of the proposed labeling requirements on OTC drug products, the agency provided in the February 27, 1997, proposal a comment period of 120 days until June 27, 1997, rather than the 90-day comment period generally provided, to address many of the labeling issues proposed. The agency continues to work closely with a number of companies, associations, and other interested parties, in an effort to improve OTC drug labeling readability and understandability. Based on the far-reaching effect the proposal will have on OTC drug labeling and the reasons provided by the two manufacturers' associations, the agency believes that an extension of the comment period is appropriate. Therefore, the agency is providing an extension of the period for comment until October 6, 1997.

Interested persons may, on or before October 6, 1997, submit to the Dockets Management Branch (address above) written comments on the proposed OTC labeling requirements. Three copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16066 Filed 6–18–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 251

RIN 1010–AC10

Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule;

SUMMARY: This notice announces that MMS will hold a meeting to discuss comments received on the proposed rule entitled Geological and Geophysical Explorations of the Outer Continental Shelf, published on February 11, 1997 (62 FR 6149).

DATES: MMS will hold the meeting on July 10, 1997, from 9:00 a.m. to 5 p.m. at the location listed in the **ADDRESSES** section.

ADDRESSES: We will hold the meeting at the MMS Gulf of Mexico Region Office, 1201 Elmwood Park Boulevard, Room 111, New Orleans, Louisiana. For directions please call (504) 736–0557.

FOR FURTHER INFORMATION CONTACT: Kumkum Ray, Rules Processing Team at (703) 787–1600.

Dated: June 12, 1997.

E.P. Danenberger,

Chief, Engineering and Operations Division.

[FR Doc. 97–16093 Filed 6–18–97; 8:45 am]

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