EPARTMENT OF HEALTH AND
UMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 82N-0166]

Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Alcohol and Food for Over-the-Counter Human Use; Advance Notice of Proposed Rulemaking; Extension of Time for Comments and Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 28, 1983, the comment period and to February 28, 1983, the reply comment period for the advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food. FDA is taking this action in response to a request to allow more time for interested persons to review the advance notice of proposed rulemaking in order to prepare and provide useful comments.

DATES: Written comments by January 28, 1983, and reply comments by February 28, 1983.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 1, 1982 (47 FR 43540), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food for OTC human use. This advance notice of proposed rulemaking, which was based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, is part of the ongoing review of OTC drug products conducted by FDA. Interested persons were given until December 30, 1982, to comment on the advance notice of proposed rulemaking and until January 31, 1983, for reply comments.

Miles Laboratories, Inc., has requested a 29-day extension of the comment and reply comment periods in order to produce more useful comments to the advance notice of proposed rulemaking. Miles Laboratories, Inc., has pointed out that it was one of five companies that submitted data and information on these drug products to the Panel and that it has an active interest in the products that will be covered by this monograph. The company has explained that for the past several months its employees' time has been preempted by the need to take steps promptly and effectively to prevent tampering with its OTC products. Also, two major national holidays, Thanksgiving and Christmas, fall within the comment period and have decreased the time for its employees to review the notice and to prepare thoughtful comments.

FDA has carefully considered the request. The agency believes that an extension of the comment and reply comment periods may be of assistance in establishing the safety and effectiveness of OTC orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food and is in the public interest. The agency considers an extension of the comment period to January 28, 1983, as requested, to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to January 28, 1983, and the reply comment period is extended to February 28, 1983. Interested persons may submit written comments to the Dockets Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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