DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 82N-0214]

Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis 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 April 4, 1983, the comment period and to May 4, 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) drug products for the control of dandruff, seborrheic dermatitis, and psoriasis. This action is being taken in response to a request to allow more time for interested persons to address adequately several important issues raised by the Panel and to consult experts so that more informed comments may be submitted to FDA.

DATES: Written comments by April 4, 1983, and reply comments by May 4, 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 December 3, 1982 (47 FR 54646), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis. This advance notice of proposed rulemaking, which was based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until March 3, 1983, to comment on the advance notice of proposed rulemaking and until April 4, 1983, for reply comments.

In response to the proposal, The Proprietary Association requested a 30-day extension of the comment period to study the issues adequately and to confer with outside consultants. Because of the large number of ingredients the Panel placed in Category II (not generally recognized as safe and effective or misbranded) and Category III (available data insufficient for classification), the association stated its need to coordinate comments from a large number of subgroups of its member companies. The association also stated that it needs time to coordinate its comments on coal tar with those of a joint industry group that has sponsored new research on coal tar products for several years. The association pointed out that industry scientists have been heavily burdened recently with the need to respond to advance notices of proposed rulemaking that were published simultaneously for a number of OTC product categories, and with the tamper-resistant packaging issue, which is still requiring a heavy commitment of time and manpower.

FDA has carefully considered the request. The agency believes that information described by the request may be of assistance in establishing the safety and effectiveness of OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis and is in the public interest. Because of the length of the Panel's report, the agency considers a general extension of the comment period for 30 days to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to April 4, 1983, and the reply comment period is extended to May 4, 1983. Comments may be seen in the Dockets Management Branch, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 1, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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