

## 21 CFR Part 357

[Docket No. 81N-0022]

**Weight Control Drug Products 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 July 26, 1982, the comment period and to August 27, 1982, 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) weight control drug products. This action is being taken in response to a request to allow more time for interested parties to examine background data on the safety of phenylpropanolamine, an active ingredient in weight control drug products, in order to provide more informed comments on the notice.

**DATES:** Written comments by July 26, 1982, and reply comments by August 27, 1982.

**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, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of February 28, 1982 (47 FR 8466), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of weight control drug products for OTC human use. This advance notice of proposed rulemaking, 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 the agency. Interested persons were given until May 27, 1982, to comment on the advance notice of proposed rulemaking and until June 28, 1982, for reply comments.

In response to the proposal, The Proprietary Association requested a 60-day extension of the comment period in order to allow adequate time for the association to examine background data

on the ingredient phenylpropanolamine in order to respond more meaningfully to safety questions regarding this ingredient raised by the agency in this advance notice of proposed rulemaking.

FDA has carefully considered the request and believes that information described in the request may be of assistance to the agency in establishing the safety and effectiveness of OTC weight control drug products and is in the public interest. The agency considers a general extension of the comment period for 60 days to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to July 26, 1982, and the reply comment period is extended to August 27, 1982. 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: April 16, 1982.

William F. Randolph,  
Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 82-11114 Filed 4-20-82; 12:11 pm]

BILLING CODE 4160-01-M

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 942****Abandoned Mine Land Reclamation Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed rule.

**SUMMARY:** On March 24, 1982, the State of Tennessee submitted to OSM its proposed Abandoned Mine Land Reclamation Plan (Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). OSM is seeking public comment on the adequacy of the State Plan.

**DATES:** Written comments on the Plan must be received on or before 5:00 p.m., May 24, 1982.

**ADDRESSES:** Copies of the full text of the proposed Tennessee Plan are available for review during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Region II, 530 Gay Street, Suite 500, Knoxville, Tennessee 37902

State of Tennessee, Department of Conservation, Division of Surface Mining and Reclamation, 305 W.

Springdale, Knoxville, Tennessee 37917

Office of Surface Mining Reclamation and Enforcement, Administrative Record, Rm. 5315; 1100 "L" Street, N.W., Washington, D.C. 20240

Written comments must be mailed or hand carried to: Office of Surface Mining at the first address listed above. Comments received after 5:00 p.m., (30 days from publication) ordinarily will not be considered or included in the administrative record for this rulemaking.

The administrative record will be available for public review at the OSM Knoxville office above, on Monday through Friday, 8:00 a.m. to 4:00 p.m. excluding holidays.

**FOR FURTHER INFORMATION CONTACT:** Richard Ellison, Abandoned Mine Land Reclamation, Office of Surface Mining, 530 Gay Street, Suite 500, Knoxville, Tennessee 37902, Telephone: (615) 971-5290.

**SUPPLEMENTARY INFORMATION:** Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87, 30 U.S.C. 1201 *et seq.*, establishes an abandoned mine land reclamation program for the purposes of reclaiming and restoring lands and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. Lands and water eligible for reclamation are those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977 and for which there is no continuing reclamation responsibility under State or Federal law.

Title IV provides that if the Secretary determines that a State has developed and submitted a program for reclamation of abandoned mines and has the ability and necessary State legislation to implement the provisions of Title IV, the Secretary may approve the State program and grant to the State exclusive responsibility and authority to implement the approved program.

On March 24, 1982, OSM received a proposed Abandoned Mine Land Reclamation Plan from the State of Tennessee. The purpose of this submission is to demonstrate both the intent and capability to assume responsibility for administering and conducting the provisions of SMCRA and OSM's Abandoned Mine Land Reclamation (AMLR) Program (30 CFR Chapter VII, Subchapter R) as published in the Federal Register (FR) on October 25, 1978, 43 FR 49932-49952.