

pipeline must file revised tariff sheets to implement this subpart J.

(3) The effective date of a blanket certificate issued under this section will be the effective date of a pipeline's filing to implement this subpart J.

(j) *Reporting requirements.* An interstate pipeline that engages in a sales transaction under a certificate granted by this section is subject to the reporting requirements of § 284.223(f), except for § 284.223(f)(1) (iii) and (iv), with the words "sales" and "sold" substituted for the words "transportation" and "transported" in § 284.223(f).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 81N-0022]

RIN 0905-AA06

Phenylpropanolamine Hydrochloride for Over-the-Counter Weight Control Use; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to September 6, 1991, the comment period on the safety and effectiveness of phenylpropanolamine hydrochloride for over-the-counter (OTC) weight control use. FDA is taking this action in response to a request to reopen the comment period to allow additional time to submit new data and information on the safety and effectiveness of phenylpropanolamine hydrochloride for OTC weight control use subsequent to the May 9, 1991 public meeting and reopening of the administrative record (April 1, 1991 (56 FR 13295)).

DATES: Written comments by September 6, 1991.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 1, 1991 (56 FR

13295), FDA published a notice of the reopening of the administrative record for OTC weight control drug products and announced a public meeting to be held on May 9, 1991 to discuss the safety and effectiveness of

phenylpropanolamine hydrochloride for OTC weight control use. The notice contained a detailed list of questions related to phenylpropanolamine hydrochloride for OTC weight control use and requested data and comments on these issues. The agency considers it necessary to resolve these issues before publishing its tentative final monograph for OTC weight control drug products in the Federal Register. Interested persons were given until August 7, 1991 to submit comments regarding matters raised at the public meeting.

On July 26, 1991, the Nonprescription Drug Manufacturers Association (NDMA), a trade association, requested a 45-day extension of time beyond the August 7, 1991 deadline for the submission of data. NDMA contended that the database supporting the safety and effectiveness of phenylpropanolamine hydrochloride is quite extensive and, in relation to the questions asked by FDA, covers virtually every aspect of phenylpropanolamine hydrochloride's safety and effectiveness profile. In addition, NDMA member companies have had to generate new data, analyze these data, and prepare written reports concerning these data. More importantly, NDMA mentioned an FDA request made at a July 23, 1991 meeting (Ref. 1), for industry to reanalyze certain data in multiple ways. That meeting included a discussion of hospital discharge data to determine the background rate of cerebrovascular accidents in the general population and specifically as a result of ingestion of phenylpropanolamine hydrochloride in OTC drug products (Ref. 1). NDMA stated that reanalysis of the data will require substantial additional efforts in order to assure a full development of the database. NDMA contended that because of the short notice for this additional analysis, it is difficult to reschedule the calendars of certain key consultants to NDMA member companies as well as prepare new tabulations of data suitable for submission to the agency.

FDA has carefully considered the request and believes that an extension of time for 30 days is an appropriate time period and in the public interest. The agency notes that NDMA intends to answer questions raised by FDA in the Federal Register of April 1, 1991 and at the July 23, 1991 meeting, and the agency

believes that additional time will allow for more useful comments and data analysis to be developed. Thus, the agency considers a limited extension of the comment period to be appropriate.

Interested persons may, on or before September 6, 1991, submit to the Dockets Management Branch (address above) written comments and new data and information regarding the safety and effectiveness of phenylpropanolamine hydrochloride for OTC weight control use. 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. Comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Reference

(1) Minutes of meeting between FDA and NDMA, July 23, 1991, coded MM9, Docket No. 81N-0022, Dockets Management Branch.

Dated: August 7, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[PS-4-73]

RIN 1545-AC37

One Class of Stock Requirement

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the requirement that a small business corporation have only one class of stock. Changes to the applicable law were made by the Subchapter S Revision Act of 1982. These regulations affect corporations and their shareholders and are necessary to provide them with guidance needed to comply with the applicable tax law.

DATES: Written comments and requests to appear at a public hearing scheduled for October 31, 1991, at 10 a.m. must be received by October 17, 1991. Outlines of oral comments must be received by October 17, 1991. See the notice of hearing published elsewhere in this issue of the Federal Register.