interaction having occurred to provide that information to the agency.

Because of the relative nature of the selectivity of selegiline, the lack of knowledge about the precise mechanism of the MAOI-sympathomimetic amine drug interaction, and a lack of data on the effects of MAO B inhibitors on the pharmacokinetics and dynamics of sympathomimetic amine drugs, the agency believes there is a need to consider whether the drug interaction precaution statement should be expanded to include MAO B drugs such as selegiline. If the warning statement were to be expanded, it would be revised to read: "Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

The agency is inviting specific additional comments on whether, from a public health perspective, it would be appropriate to expand the nasal decongestant drug interaction precaution as indicated above. In order to fully consider this aspect of the proposed labeling, the agency is extending the comment period for this notice of proposed rulemaking an additional 60 days.

Interested persons may, on or before October 5, 1992, submit to the Dockets Management Branch (address above) written comments on the possible expansion of the drug interaction precaution statement proposed for OTC nasal decongestant drug products containing sympathomimetic amines. 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 29, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-18625 Filed 8-5-92; 8:45 a.m.]

BILLING CODE 4160-01-F

21 CFR Part 341

[Docket No. 90N-0420]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for OTC Antitussive Drug Products; Request for Additional Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; request for additional comment; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 5, 1992, the comment period for the notice of proposed rulemaking amending the final monograph for over-the-counter (OTC) antitussive drug products to require a drug interaction precaution statement in the labeling of OTC antitussive (relieves cough) drug products containing dextromethorphan or dextromethorphan hydrobromide (57 FR 27666, June 19, 1992). This action is being taken because the agency would like additional comments on a possible addition to the proposed drug interaction precaution statement. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by October 5, 1992.

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-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 19, 1992 (57 FR 27666), FDA published a notice of proposed rulemaking to amend the final monograph for OTC antitussive drug products to include the following drug interaction precaution statement for OTC antitussive drug products containing dextromethorphan or dextromethorphan hydrobromide: "Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression or psychiatric or emotional conditions), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product." The closing date for comments on the proposal is August 18, 1992.

In the notice of proposed rulemaking, the agency discussed reports of adverse reactions, including fatalities, following the ingestion of prescription MAOI drugs and OTC drug products containing the ingredient dextromethorphan or dextromethorphan hydrobromide (referred to generally as dextromethorphan). The agency mentioned that there has been a resurgence in the use of MAOI drugs after a period of decline in the 1970's, and there is evidence that MAOI drugs are also being used to treat a wider variety of conditions, such as bulimia, panic disorders, phobic disorders, anxiety, and obsessive compulsive disorder (57 FR 27666 at 27668). However, the use of MAOI drugs in hypertension has essentially ceased.

There are at least two types of monoamine oxidase (MAO) enzymes: the A form and B form. The two forms are characterized by differential substrate profiles, sensitivity to inhibition by clorgeline, and anatomical locations. MAO A preferentially deaminates norepinephrine and serotonin (5-hydroxytryptamine [5-HT]) and is sensitive to inhibition by clorgeline. MAO A is the unique form located in intestinal mucosa and placenta and predominates in peripheral nerve terminals. In contrast, MAO B preferentially deaminates phenethylamine and benzylamine, is inhibited by selegiline but not clorgeline, and is the unique form located in platelets. Both MAO A and MAO B are found in approximately equal proportions in the liver and brain.

The MAOI drugs marketed in the United States for psychiatric indications are nonspecific. They irreversibly inhibit both MAO A and MAO B. Selegiline is a relatively selective MAO B inhibitor indicated for use in Parkinson's disease treatment. At doses greater than 10 milligrams per day and, perhaps, at lower doses in some people, selegiline's selectivity decreases. Other, apparently more specific, MAO B inhibitors are now under development.

The agency did not address selegiline or MAO B inhibitors in the earlier proposal. The agency has not received any reports of an interaction between selegiline and dextromethorphan or dextromethorphan hydrobromide. The agency invites any interested person with knowledge of such an interaction having occurred to provide that information to the agency.

Because of the relative nature of the selectivity of selegiline, the lack of knowledge about the precise mechanism of the MAOI-dextromethorphan interaction, and a lack of data on the effects of MAO B inhibitors on dextromethorphan's pharmacokinetics and dynamics, the agency believes there is a need to consider whether the drug interaction precaution statement should be expanded to include MAO B drugs such as selegiline. If the warning statement were to be expanded, it would be revised to read: "Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

The agency is inviting specific additional comments on whether, from a public health perspective, it would be appropriate to expand the dextromethorphan drug interaction precaution as indicated above. In order to fully consider this aspect of the proposed labeling, the agency is extending the comment period for this notice of proposed rulemaking an additional 60 days.

Interested persons may, on or before October 5, 1992, submit to the Dockets Management Branch (address above) written comments on the possible expansion of the drug interaction precaution statement proposed for OTC antitussive drug products containing dextromethorphan or dextromethorphan hydrobromide. 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 29, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 5h

[CO-88-90]

RIN 1545-AQ60

Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change; Special Rule for Value of a Loss Corporation Under the Jurisdiction of a Court in a Title 11 Case

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The document contains proposed regulations which provide guidance on determining the value of a loss corporation following an ownership change to which section 382(l)(6) of the Internal Revenue Code of 1986 (the "Code") applies. Under sections 382 and 383, the value of the loss corporation, together with certain other factors, determines the rate at which certain pre-change tax attributes may be used to offset post-change income and tax liability. The proposed regulations are needed to provide guidance to taxpayers concerning compliance with sections 382 and 383.

DATES: Written comments, requests to appear, and outlines of oral comments to be presented at the public hearing scheduled for October 29, 1992, must be received by October 8, 1992. See notice of public hearing published elsewhere in this issue of the **Federal Register.**

ADDRESSES: Send comments, requests to appear at the public hearing, and outlines to: Internal Revenue Service; Attn: CC:CORP:T:R (CO-88-90), room 5228, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the hearing, Carol Savage, Regulations Unit, (202) 622-8452 (not a toll-free number). Concerning the regulation: Victor Penico of the Office of Assistant Chief Counsel (Corporate), Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 (Attention CC:CORP:T:R) or telephone (202) 622-7750 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer T:FP, Washington, DC 20224.

The collections of information in this regulation are in §§ 1.382-3(i) and 1.382-3(p) (ii). This information serves as evidence of an election to apply section 382(l)(6) of the Code in lieu of section 382(l)(5) and an election to apply the provisions of the proposed regulations retroactively. It is required by the Internal Revenue Service to assure that the proper amount of carryover attributes are used by a loss corporation following specified types of ownership changes.

The following estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances.

The following estimates are for the § 1.382-3(1) election:

Estimated total reporting burden: 63 hours.

The estimated burden per respondent varies from 5 to 30 minutes, with an estimated average of 15 minutes.

Estimated number of respondents: 250.

Estimated annual frequency of responses: Once.

The following estimates are for the § 1.382-3(p)(ii) election:

Estimated total reporting burden: 750 hours.

The estimated burden per respondent varies from 5 to 30 minutes, with an estimated average of 15 minutes.

Estimated number of respondents: 3000.

Estimated annual frequency of responses: Once.

Background

This document contains a notice of proposed rulemaking that proposes additions to part 1 of title 26 of the Code of Federal Regulations (CFR) under section 382 of the Internal Revenue Code (Code). The proposed regulations provide guidance under sections 382 and 383 relating to the use of pre-change corporate tax attributes following an ownership change to which section 382(l)(6) applies. Sections 382 and 383