Company, or a copartner in the Limited Partnership Investment Company with any investment adviser of, or principal underwriter for, the company, *provided that* the Limited Partnership Agreement contains in substance the following:

(1) Only general partners who are natural persons shall serve as, and perform the functions of, directors of the Limited Partnership Investment Company.

(2) A general partner shall not have the authority to act individually on behalf of, or to bind, the Limited Partnership Investment Company, except:

(i) In such person's capacity as investment adviser, principal underwriter, or administrator;

(ii) Within the scope of such person's authority as delegated by the board of directors; or

(iii) In the event that no director of the company remains, to the extent necessary to continue the Limited Partnership Investment Company, but only for such limited periods as permitted under the Act to fill director vacancies.

(3) The assignees, transferees, and successors of the limited partners of the Limited Partnership Investment Company shall have all of the rights afforded shareholders under the Act.

(4) A general partner shall not withdraw from the Limited Partnership Investment Company or reduce its Federal Tax Status Contribution without giving one year's prior written notice to the Limited Partnership Investment Company, if such withdrawal or reduction would cause the company to lose its partnership tax classification. This paragraph (a)(4) shall not apply where the general partner is an investment adviser and the company terminates its advisory agreement with such general partner.

(b) *Definitions.*—(1) *Federal Tax Status Contribution* shall mean the interest (including limited partnership interest) in each material item of partnership income, gain, loss, deduction, or credit, as used in section 4 of the Internal Revenue Service's Revenue Procedure 89–12, or any successor provisions thereto.

(2) *Limited Partnership Investment Company* shall mean a registered management company or a business development company that is organized as a limited partnership under state law and for federal income tax purposes.

(3) *Partnership Agreement* shall mean the agreement of the partners of the Limited Partnership Investment Company as to the affairs of the limited partnership and the conduct of its business.

Dated: July 28, 1992.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 92–18360 Filed 8–5–92; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 91N–0323]

RIN 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for OTC Bronchodilator 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) bronchodilator drug products to modify the wording of the drug interaction precaution statement required in the labeling of OTC bronchodilator drug products containing sympathomimetic amines (57 FR 27662, 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 27662), FDA published a notice of proposed rulemaking to amend the final monograph for OTC bronchodilator drug products to revise the drug interaction precaution statement for OTC bronchodilator drug products containing sympathomimetic amines to read: "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 the history of the required drug interaction precaution statement and the reasons for revising its wording. 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 27662). 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 sympathomimetic amines. 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-sympathomimetic amine interaction, and a lack of data on the effects of MAO B inhibitors on the pharmacokinetics and dynamics of sympathomimetic amines, 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 bronchodilator 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 bronchodilator 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. 92-18618 Filed 8-5-92; 8:45 a.m.]

BILLING CODE 4160-01-F

21 CFR Part 341

[Docket No. 76N-052N]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Tentative Final Monograph for OTC Nasal Decongestant 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 tentative final monograph for over-the-counter (OTC) nasal decongestant drug products to modify the drug interaction precaution statement proposed in the labeling of OTC oral nasal decongestant drug products containing sympathomimetic amines (57 FR 27658, 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: Submit 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 27658), FDA published a notice of proposed rulemaking to amend the tentative final monograph for OTC nasal decongestant drug products to include the following drug interaction precaution statement for OTC oral nasal decongestant drug products containing sympathomimetic amines to read: "Do not take 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 **Federal Register** of July 30, 1992 (57 FR 33663), FDA published a correction that changes the wording of the first sentence of the statement to read, "*Drug interaction precaution.* Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor * * *."

In the notice of proposed rulemaking, the agency discussed the history of the drug interaction precaution statement and the reasons for revising its wording. 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 27658). 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 sympathomimetic amines. The agency invites any interested person with knowledge of such an