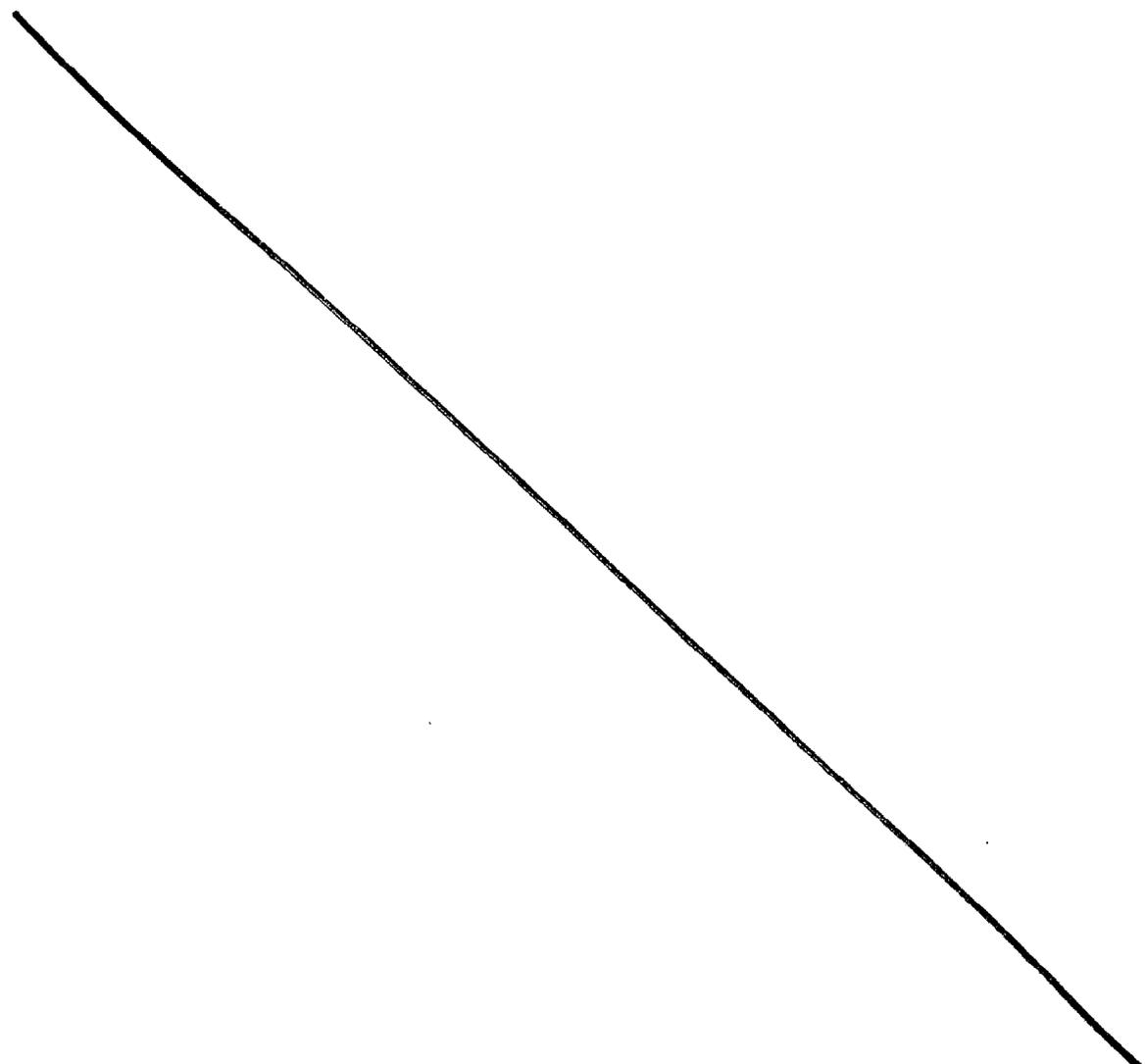


The agency has carefully considered the potential environmental effects of this proposal and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact, and the evidence supporting this finding, is contained in an environmental assessment (under 21 CFR 25.31, proposed in the FEDERAL REGISTER of December 11, 1979; 44 FR 71742), which may be seen in the Dockets Management Branch, Food and Drug Administration.



List of Subjects in 21 CFR Part 341

OTC drugs: Anticholinergics; Expectorants;
Bronchodilators; Antitussives; Nasal Decongestants.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 341 (as set forth in the tentative final monograph that was published in the FEDERAL REGISTER of July 9, 1982 (47 FR 30002)) to read as follows:

1. In Subpart A, § 341.3 is amended by adding new paragraphs (h) and (i) to read as follows:

§ 341.3 Definitions.

* * * * *

(h) Oral nasal decongestant drug. A drug which is taken by mouth and acts systemically to reduce nasal congestion caused by acute or chronic rhinitis.

(i) Topical nasal decongestant drug. A drug which when applied topically inside the nose, in the form of drops, jellies, or sprays, or when inhaled intranasally reduces nasal congestion caused by acute or chronic rhinitis.

2. In Subpart B, new § 341.20 is added, to read as follows:
§ 341.20 Nasal decongestant active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits and in the dosage forms established for each ingredient in § 341.80(d):

(a) Oral nasal decongestants. (1) Phenylephrine hydrochloride.

(2) Pseudoephedrine hydrochloride.

(3) Pseudoephedrine sulfate.

(b) Topical nasal decongestants. (1) 1-Desoxyephedrine.

(2) Ephedrine.

- (3) Ephedrine hydrochloride.
- (4) Ephedrine sulfate.
- (5) Racephedrine hydrochloride.
- (6) Naphazoline hydrochloride.
- (7) Oxymetazoline hydrochloride.
- (8) Phenylephrine hydrochloride.
- (9) Propylhexedrine.
- (10) Xylometazoline hydrochloride.

3. In Subpart C, new § 341.80 is added and § 341.90 is amended by adding new paragraphs (m) and (n) to read as follows:

§ 341.80 Labeling of nasal decongestant drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "nasal decongestant."

(b) Indications. (1) The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the following phrase: "For the temporary relief of nasal congestion due to the common cold (cold), hay fever" (which may be followed by any of the following: "(allergic rhinitis)," "or other upper respiratory allergies," or "or other upper respiratory allergies (allergic rhinitis),") "or associated with sinusitis."

(2) Other allowable indications. In addition to the

required information identified in paragraph (b)(1) of this section, the labeling of the product may contain any of the following statements provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(i) "For the temporary relief of"(select one of the following: "stuffy nose," "stopped up nose," "nasal stuffiness," or "clogged up nose.")

(ii) (Select one of the following: "Reduces swelling of," "Decongests," or "Helps clear") "nasal passages; shrinks swollen membranes."

(iii) "Temporarily restores freer breathing through the nose."

(iv) "Helps decongest sinus openings and passages; relieves sinus pressure."

(v) "Promotes nasal and/or sinus drainage; relieves sinus pressure."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) Oral nasal decongestants--(i) For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate identified in § 341.20(a)(1), (2), and (3) when labeled for adults. (a) "Do not exceed recommended dosage because at higher doses nervousness, dizziness, or

sleeplessness may occur."

(b) "Do not take this product for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a doctor."

(c) "Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(d) "Drug Interaction Precaution. Do not take this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your doctor."

(ii) For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate identified in § 341.20(a)(1), (2), and (3) when labeled for children under 12 years of age. (a) "Do not exceed recommended dosage because at higher doses nervousness, dizziness, or sleeplessness may occur."

(b) "Do not give this product to children for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a doctor."

(c) "Do not give this product to children who have heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor."

(d) "Drug Interaction Precaution. Do not give this

than 3 days. If symptoms persist, consult a doctor."

(b) "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(iv) For products containing naphazoline hydrochloride identified in § 341.20(b)(6) at a concentration of 0.05 percent. "Do not use this product in children under 12 years of age because it may cause sedation if swallowed."

(v) For products containing phenylephrine hydrochloride identified in § 341.20(b)(8) at a concentration of 1 percent. "Frequent use of this product may cause nasal congestion to recur or worsen."

(vi) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for adults. "Do not use this product for more than 3 days. If symptoms persist, consult a doctor."

(vii) For products containing any topical nasal decongestant identified in § 341.20(b) when labeled for children under 12 years of age. The labeling of the product contains the warnings identified in paragraph (c)(2)(i) of this section.

(viii) For products containing l-desoxyephedrine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for children under 12 years of age. "Do not use this product for more than 7 days. If symptoms

persist, consult a doctor."

(ix) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, racephedrine hydrochloride, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(2), (3), (4), (5), (6), (7), (8), and (10) when used as nasal sprays, drops, or jellies and when labeled for children under 12 years of age. (a) "Do not use this product for more than 3 days. If symptoms persist, consult a doctor."

(b) "Do not use this product in children who have heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor."

(x) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for children under 12 years of age. "Do not use this product for more than 3 days. If symptoms persist, consult a doctor."

(xi) For topical nasal decongestant products labeled for both adults and for children under 12 years of age. The labeling of the product contains the applicable warnings identified in paragraphs (c)(2)(i), (ii), (iii), and (vi) of this section.

(d) Directions. The labeling of the product contains the following information under the heading "Directions":

(1) Oral nasal decongestants--(i) For products containing

phenylephrine hydrochloride identified in § 341.20(a)(1).

Adults: 10 milligrams every 4 hours not to exceed 60 milligrams in 24 hours. Children 6 to under 12 years of age: 5 milligrams every 4 hours not to exceed 30 milligram in 24 hours. Children 2 to under 6 years of age: 2.5 milligrams every 4 hours not to exceed 15 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(ii) For products containing pseudoephedrine hydrochloride or pseudoephedrine sulfate identified in § 341.20(a)(2) and (3). Adults: 60 milligrams every 4 to 6 hours not to exceed 240 milligrams in 24 hours. Children 6 to under 12 years of age: 30 milligrams every 4 to 6 hours not to exceed 120 milligrams in 24 hours. Children 2 to under 6 years of age: 15 milligrams every 4 to 6 hours not to exceed 60 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(2) Topical nasal decongestants--(i) For products containing 1-desoxyephedrine identified in § 341.20(b)(1) when used in an inhalant dosage form. The product delivers in each 800 milliliters of air 0.04 to 0.150 milligrams of 1-desoxyephedrine. Adults: 2 inhalations in each nostril not more often than every 2 hours. Children 6 to under 12 years of age (with adult supervision): 1 inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(ii) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in § 341.20(b)(2), (3), (4), and (5)--(a) Nasal drops or sprays--For a 0.5-percent aqueous solution. Adults: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(b) Nasal jelly--For a 0.5-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(iii) For products containing naphazoline hydrochloride identified in § 341.20(b)(6)--(a) Nasal drops or sprays--(1) For a 0.05-percent aqueous solution. Adults: 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.025-percent aqueous solution. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(b) Nasal jelly--(1) For a 0.05 percent water-based

jelly. Adults: place a small amount in each nostril and inhale well back into the nasal passages not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.025-percent water-based jelly. Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(iv) For products containing oxymetazoline hydrochloride identified in § 341.20(b)(7)--(a) Nasal drops or sprays--For a 0.05-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 applications in any 24-hour period. Children under 6 years of age: consult a doctor.

(b) Nasal jelly--For a 0.05-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages not more often than every 10 to 12 hours. Do not exceed 2 applications in any 24-hour period. Children under 6 years of age: consult a doctor.

(v) For products containing phenylephrine hydrochloride identified in § 341.20(b)(8)--(a) Nasal drops or sprays--(1) For a 1-percent aqueous solution. Adults: 2 or 3 drops or

sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.5-percent aqueous solution. Adults: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(3) For a 0.25-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(4) For a 0.125-percent aqueous solution. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children under 2 years of age: consult a doctor.

(b) Nasal jelly--(1) For a 1-percent water-based jelly. Adults: place a small amount in each nostril and inhale well back into the nasal passages not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.5-percent water-based jelly. Adults: place a small amount in each nostril and inhale well back into the nasal passages not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(3) For a 0.25-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(vi) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form. The product delivers in each 800 milliliters of air 0.40 to 0.50 milligrams of propylhexedrine. Adults and children 6 to under 12 years of age (with adult supervision): 2 inhalations in each nostril not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(vii) For products containing xylometazoline hydrochloride identified in § 341.20(b)(10)--(a) Nasal drops or sprays--(1) For a 0.1-percent aqueous solution. Adults: 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.05-percent aqueous solution. Children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Children under 6 years of age: consult a doctor.

(b) Nasal jelly--(1) For a 0.1-percent water-based jelly. Adults: place a small amount in each nostril and inhale well back into the nasal passages not more often than

every 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.05-percent water-based jelly. Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages not more often than every 8 to 10 hours. Children under 6 years of age: consult a doctor.

(viii) Other required statements--For products containing 1-desoxyephedrine or propylhexedrine identified in § 341.20(b)(1) or (9) when used in an inhalant dosage form.

(a) "This inhaler is effective for a minimum of 3 months after first use."

(b) "Keep inhaler tightly closed."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements above.

§ 341.90 Professional labeling.

* * * * *

(m) For products containing oxymetazoline hydrochloride identified in § 341.20(b)(7). Children 2 to under 6 years of age: 2 or 3 drops or sprays in each nostril of a 0.025-percent aqueous solution not more often than every 10 to 12 hours. Do not exceed 2 applications in any 24-hour period.

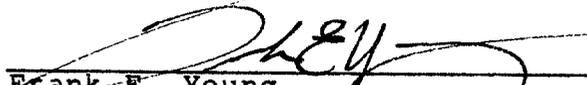
(n) For products containing xylometazoline hydrochloride identified in § 341.20(b)(10). Children 2 to under 6 years of age: 2 or 3 drops or sprays in each nostril of a 0.05-percent aqueous solution not more often than every 8 to 10 hours.

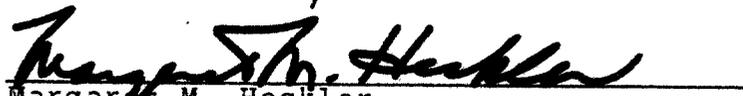
Interested persons may, on or before (insert date 120 days after date of publication in the FEDERAL REGISTER) submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. The agency has provided this 120 day period (instead of the normal 60 days) because of the number of OTC drug review documents being published concurrently. Written comments on the agency's economic impact determination may be submitted on or before (insert date 120 days after date of publication in the FEDERAL REGISTER). Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests 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. Comments, objections, and requests may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the FEDERAL REGISTER.

Interested persons, on or before (insert date 12 months after date of publication in the FEDERAL REGISTER), may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before (insert date 14 months after date of publication in the FEDERAL REGISTER). These dates are consistent with the time

periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the FEDERAL REGISTER of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on (insert date 14 months after date of publication in the FEDERAL REGISTER). Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the FEDERAL REGISTER unless the Commissioner finds good cause has been shown that warrants earlier consideration.


 Frank E. Young
 Commissioner of Food and Drugs


 Margaret M. Heckler
 Secretary of Health and Human Services

Dated: DEC 31 1984

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Robert J. Somers