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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N-052G]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Combination Drug Products; Clarification

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; clarification.

SUMMARY: The Food and Drug Administration (FDA) is issuing a clarification of its notice of proposed rulemaking published in the Federal Register of August 12, 1988 (53 FR 30522) in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products (drug products that contain more than one active ingredient and are used for the relief of symptoms such as nasal congestion, runny nose, coughing, watery eyes, sore throat, headache, and fever) are generally recognized as safe and effective and not misbranded.

DATE: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by December 12, 1988.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room. 4-62, 5600 Fishers Lane, 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: This clarification relates to § 341.40(t) of the tentative final monograph (53 FR 30561), which provided that promethazine hydrochloride identified as an antihistamine (if labeled for relief of symptoms of the common cold as identified in § 341.72(b)(2)) may be used in combination with other cough-cold and/or analgesic-antipyretic ingredients as provided for anthihistamine active ingredients in § 341.40 (a) through (f).

Because § 341.40 (a) through (f) each refer to any single antihistamine active ingredient identified in § 341.12, and promethazine hydrochloride is not identified in § 341.12, it might be possible § 341.40(t) could be subject to more than one interpretation. It could be interpreted to mean that promethazine hydrochloride and another antihistamine active ingredient identified in § 341.12 could be combined with other nonantihistamine active ingredients as permitted combinations in § 341.40 (a) through (f), or it could also be interpreted to mean that only promethazine hydrochloride, without any other antihistamine active ingredients, may be combined with other nonantihistamine active ingredients identified in § 341.40 (a) through (f).

In proposing § 341.50(t) the agency intended the latter interpretation of the wording. In order to remove the potential ambiguity and to avoid possible misinterpretation, FDA is revising § 341.40(t) as set forth below.

The agency has determined that this clarification should not necessitate an extension of the December 12, 1988, deadline for written comments, objections, or requests for oral hearing on this proposed rule.

List of Subjects in 21 CFR Part 341

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic combinations; Labeling; Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 341 to read as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 341 continues to read as follows:

Authority: 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); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 341.40 is amended by revising paragraph (t) to read as follows:

§ 341.40 Permitted combinations of active ingredients.

* * * * *

(t) Promethazine hydrochloride identified as an antihistamine (if labeled for relief of symptoms of the common cold as identified in § 341.72(b)(2)) may be used as the antihistamine component of any of the permitted combinations of active ingredients identified in § 341.40 (a) through (f) of this section.

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Dated: November 4, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-26158 Filed 11-10-88; 8:45 am]

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DEPARTMENT OF THE TREASURY

31 CFR Part 103

Proposed Amendments to the Bank Secrecy Act Regulations Regarding the International Transportation and Receipt of Monetary Instruments

AGENCY: Departmental Office, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Anti-Drug Abuse Act of 1986, Pub. L. 99-570, Title I, Subtitle H, section 1358, authorized the Secretary of the Treasury to prescribe regulations defining "at one time" for the purposes of the international transportation and receipt of monetary instruments. This Notice proposes such a definition in order to permit Customs, under a delegation from Treasury, to investigate instances of structuring of international transportation and receipt of monetary instruments to avoid the reporting requirements of the Bank Secrecy Act.

In a related matter, Treasury also is proposing to amend §103.11(k), the definition of "monetary instruments," to include all forms of traveler's checks. This amendment would clarify the status of traveler's checks and conform the definition more closely to the statute.

DATE: Comments should be submitted by January 13, 1989.

ADDRESS: Comments should be addressed to Amy G. Rudnick, Director, Office of Financial Enforcement, Department of the Treasury, Room 4320, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Kathleen A. Scott, Attorney Advisor, Office of the Assistant General Counsel (Enforcement), (202) 566-9947.