in the manner specified in § 25.8 within 6 years after the date on which such claim or statement is made.

(b) If the respondent fails to file a timely answer, service of a notice under § 25.10(b) shall be deemed a notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

Wendell L. Willkie, II,

General Counsel, Department of Commerce.

[FR Doc. 89-15651 Filed 7-5-89; 8:45 am]

BILLING CODE 3510-GJ-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 88P-0142]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment to Monograph for OTC Antitussive Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the over-the-counter (OTC) monograph for antitussive drug products by adding a new section that will exempt antitussive drug products containing methol in a lozenge or a compressed tablet dosage form from that part of the accidental overdose warning required by § 330.1(g) (21 CFR 330.1(g)) that states, "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The exemption from the warning above is being provided because OTC antitussive drug products containing methol in a lozenge or a compressed tablet dosage form have been determined to have a low potential for acute toxicity resulting from accidental ingestion. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by September 5, 1989. Written comments on the agency's economic impact determination by November 3, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 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: Under 21 CFR 330.1(g), the following general warning statements are required on all orally administered OTC drug products: "Keep this and all drugs out of the reach of children. In case of accidential overdose, seek professional assistance or contact a poison control center immediately." Section 330.1(g) also states that FDA will grant an exemption from these general warnings where appropriate upon petition.

In the **Federal Register** of August 12, 1987 (52 FR 30042), FDA issued a final monograph for OTC antitussive drug products (21 CFR Part 341) that established conditions under which these products are generally recognized as safe and effective and not misbranded. The monograph provides for menthol to be used in a lozenge or compressed tablet dosage form at a dose of 5 to 10 milligrams (mg).

Since the publication of the antitussive final monograph, two companies have petitioned for an exemption from the general warning statements in § 330.1(g) having to appear on the labeling of OTC antitussive drug products containing methol in cough drops. One company (Ref. 1) requested that its OTC drug product containing 3 mg menthol per cough drop that is to be marketed in pouches containing 21 cough drops and in sticks containing 10 cough drops be exempted from the general warning statements in §330.1(g). Another company (Ref. 2) made a similar request for its OTC antitussive drug products containing 6.1 to 10 mg menthol per drop marketed with 30 drops per package. In support of these requests, the companies asserted that the cough drop products do not present a risk of toxicity or poisoning to children or adults as a result of acute overdose and thus the warnings are not needed.

The agency believes that there is a low potential for acute toxicity from the accidental ingestion of lozenges containing menthol in the quantities mentioned above. In 2 studies evaluated by the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (September 9, 1976; 41 FR 38312 at 38350), 40 healthy subjects who were each asked to dissolve 2 candy-base lozenges, each lozenge containing 1.36 mg of menthol together with other volatile oils, every 20 minutes for 2 hours exhibited no adverse effects with the exception of 1 report of nausea and vomiting. This was attributed to a dislike for the wild cherry flavor of the lozenge (Refs. 3 and 4). In a group of 70 healthy subjects, 50 adults and 20 children ages 8 to 12, half of the subjects dissolved a menthol-eucalyptus lozenge containing 9.62 mg menthol and 5.55 mg eucalyptus oil every 4 to 8 hours on 2 successive days. The other half of the subjects dissolved the cough drop base without the aromatics. In the intensive dosage schedule, a slightly large number of subjects demonstrated mild irritation of the oral mucosa on days one and two, but there were no differences between the two groups in the severity of irritation or residual findings after day two. No systemic complaints were reported (Ref. 5). A similar study using a lozenge formulation containing menthol 8.14 mg and eucalyptus oil 4.625 mg versus a lozenge base without volatile substances produced comparable results (Ref. 6). The Panel stated that the fatal oral dose of menthol itself in man is about 2 grams (41 FR 38349).

Based on the studies discussed above (Refs. 3 through 6) and the Panel's evaluation, the agency agrees with the petitioners that accidental ingestion of menthol lozenges or compressed tablets marketed in the monograph dosage (5 to 10 mg) is highly unlikely to present any degree of acute oral toxicity. Because of this low potential for acute toxicity, the agency believes that antitussive drug products containing menthol in a lozenge or compressed tablet dosage form should be exempted from the accidental overdose warning in the second part of § 330.1(g). Products containing this ingredient must continue to bear the first part of the general warning, which states, "Keep this and all drugs out of the reach of children." The agency believes that this part of the warning is necessary to reinforce and ensure that all drugs, regardless of potential toxicity, are treated by consumers as drugs and kept out of the reach of all children.

Based on the above, the agency has granted an exemption for the cough drop products described above from having to bear the warning in the second part of 21 CFR 330.1(g), i.e., "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." Copies of the petitions and FDA's response (Refs. 1, 2, 7, and 8) are on file in the Dockets Management Branch (address above).

The agency believes that it will receive additional petitions similar to the two discussed above requesting an exemption from the general overdose warnings for OTC antitussive drug products that contain menthol in a lozenge or compressed tablet dosage

form. The agency also believes that it would be unnecessarily burdensome to require separate petitions from each manufacturer for exemption from this warning for every OTC antitussive drug product containing menthol in a lozenge or a compressed tablet that is marketed in accordance with the monograph dosage. Therefore, the agency is proposing to add new § 341.74(f) to provide such an exemption for all comparable products.

The agency proposes that this proposed rulemaking be effective upon publication of the final rule. However, manufacturers of OTC antitussive drug products may adopt the labeling changes proposed in this document as of the date of publication of this proposal, subject to the possibility that FDA may change its position as a result of comments filed in response to this proposal.

References

(1) Comment No. CP, Docket No. 86P–0142, Dockets Management Branch.

(2) Comment No. CP00002, Docket No. 86P–0142, Dockets Management Branch.

(3) Mendoza, J. A., "Clinical Safety Tests on Vicks Cough Drops," draft of unpublished data, OTC Volume 040298, Docket No. 76N–0052, Dockets Management Branch.

(4) Seltzer, S., "Clinical Safety Test on Vicks Cough Drops," draft of unpublished data, OTC Volume 040298, Docket No. 76N–0052, Dockets Management Branch.

(5) Glassman, S., and E.W. Packman, "Menthol-Eucalyptus Cough Drops: Safety: Intensive Use, CRD 71–25," draft of unpublished data, OTC Volume 040298, Docket No. 76N–0052, Dockets Management Branch.

(6) Glassman, S., and E.W. Packman, "Cherry Victors, Safety: Intensive Use, CRD 71–23," draft of unpublished data, OTC Volume 040298, Docket No. 76N–0052, Dockets Management Branch.

(7) Letter from J.M. Taylor, FDA, to D.B. Deck, Joel, Inc., coded PAV2PDN2, Docket No. 86P–0142, Dockets Management Branch.

(8) Letter from J.M. Taylor, FDA, to P.S. Reichertz, Counsel for Ricola, Inc., coded PAV1PDN1, Docket No. 86P–0142, Dockets Management Branch.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC antitussive drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antitussive drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC antitussive drug products. Comments regarding the impact of this rulemaking on OTC antitussive drug products should be accompanied by appropriate documentation.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before September 5, 1989, submit written comments to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before November 3, 1989. Three copies of all 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. Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 341

Antitussive drug products, 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 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. In § 341.74 new paragraph (f) is added to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(f) *Exemption from the general accidental overdose warning.* The labeling for antitussive drug products containing the active ingredient identified in § 341.14(b)(2) marketed in accordance with § 341.74(d)(2)(iii) is exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

Dated: June 23, 1989.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 89–15850 Filed 7–5–89; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 715

Availability of Petition To Initiate Rulemaking; Surface Coal Mining and Reclamation Operations; General Performance Standards for Postmining Use of Land Under Initial Program Regulations

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of availability of a petition to initiate rulemaking and request for comment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) of the United States Department of the Interior (DOI) seeks comments concerning the rule change suggested in