(1) $2,500 until December 31, 1990;
(2) $8,125 after January 1, 1991 but until December 31, 1991;
(3) $13,750 after January 2, 1992 but until December 31, 1992;
(4) $19,375 after January 1, 1993 but until December 31, 1993;
(5) $25,000 after January 1, 1994.

* * * * *

By the Commission.
Dated: September 15, 1989.
Jonathan G. Katz,
Secretary.

[FR Doc. 89-23022 Filed 9-29-89; 8:45 am]
BILLING CODE 6010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 89N-0411]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment to the 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 final monograph for over-the-counter (OTC) antitussive drug products to use only the term "lozenge" to describe a solid dosage form intended for dissolution in the mouth and to clarify that an oral antitussive drug product can be marketed in a lozenge dosage form. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by December 1, 1989; written comments on the agency's economic impact determination by January 30, 1990.

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: In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published an advance notice of proposed rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. The Panel referred to solid topical dosage forms intended for dissolution in the mouth as either a troche or a lozenge. (See 41 FR 38312 at 38343 to 38353.)

In the **Federal Register** of October 19, 1983 (48 FDR 48576), FDA issued a notice of proposed rulemaking (tentative final monograph) for OTC antitussive drug products. One ingredient (menthol) was proposed as Category I in a lozenge dosage form. (See § 341.74(d)(2)(iii).) In response to a comment's request, the agency also included a "compressed tablet" dosage form for products containing menthol to be dissolved in the mouth. (See comment 20 at 48 FR 485786 at 48588 and proposed § 341.3(k) and § 341.74(d)(2)(iii) at 48 FR 48576, 48593 and 48594.)

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 provided for menthol to be used in a lozenge or compressed tablet dosage form. (See § 341.3(c) and § 341.74(d)(2)(iii) at 52 FR 30042, 30555 and 30056.)

Since the publication of the antitussive final monograph, the United States Pharmacopeial Convention, Inc., in a proposed revision of the United States Pharmacopeia (U.S.P.) (ref. 1), and in the recently published U.S.P. XXII (ref. 2), included a definition for lozenges as follows:

> Lozenges are solid preparations containing one or more medicaments, usually in a flavored, sweetened base which are intended to dissolve or disintegrate slowly in the mouth. They can be prepared by molding (gelatin and/or fused sucrose or sorbitol base) or by compression of sugar based tablets. Molded lozenges are sometimes referred to as pastilles while compressed lozenges are often referred to as troches. They are usually intended for treatment of local irritation or infections of the mouth or throat but may contain active ingredients intended for systemic absorption after swallowing.

Based on the new U.S.P. definition, the agency has reconsidered its position stated in comment 20 of the notice of proposed rulemaking for OTC antitussive drug products (see above) and intends to adopt the new U.S.P. definition. Accordingly, the agency is proposing (1) to amend the final monograph for OTC antitussive drug products to use only the term lozenge to describe a solid dosage form to be dissolved in the mouth for a local effect, and (2) to delete the term "compressed tablet" from the final monograph in § 341.3(c) and § 341.74(d)(2)(iii). In addition, the definition in § 341.3(b) for an "oral antitussive drug" is being revised slightly to clarify that such drugs may also be formulated as lozenges. This revision is being made because the U.S.P. definition of lozenges provides for this dosage form to be dissolved in the mouth and to contain ingredients intended to have a systemic effect and because the agency is aware that antitussive drug products intended for systemic use are currently being marketed as lozenges (ref. 3). Thus, the revised definition in § 341.3(b) will be consistent with the new U.S.P. definition of lozenges.

The agency does not intend to finalize this amendment until the U.S.P. XXII becomes official in January 1990. In addition, the agency intends to use the term "lozenge" for solid dosage forms to be dissolved in the mouth in applicable rulemakings for other OTC drug categories, in future issues of the **Federal Register**. While the various types of lozenges such as compressed tablets, troches, or pastilles will not be described in final monographs, these terms may continue to be used in labeling. Accordingly, this proposed amendment, when finalized will not require any labeling revisions.

References

(1) "Pharmacopeial Forum," In-Process Revision, The United States Pharmacopeial Convention, Inc., 14:4390, 1988.
(2) "The United States Pharmacopeia XXII—The National Formulary XVII," The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1692, 1989.
(3) "Physicians' Desk Reference—For Nonprescription Drugs," 9th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 512. 515, 651, and 652, 1988.

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 actions, including this proposed rule for OTC 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 entitites. However, this particular rulemaking for OTC 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 December 1, 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 January 30, 1990. 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. Section 341.3 is amended by revising paragraphs (b) and (c) to read as follows:

§ 341.3 Definitions.

* * * * *

(b) *Oral antitussive drug.* A drug that either is taken by mouth or is dissolved in the mouth in the form of a lozenge and acts systemically to relieve cough.

(c) *Topical antitussive drug.* A drug that relieves cough when inhaled after being applied topically to the throat or chest in the form of an ointment or from a steam vaporizer, or when dissolved in the mouth in the form of a lozenge for a local effect.

* * * * *

3. Section 341.74 is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(d) * * *

(2) * * *

(iii) *For products containing menthol identified in § 341.14(b)(2) in a lozenge.* The product contains 5 to 10 milligrams menthol. Adults and children 2 to under 12 years of age: Allow lozenge to dissolve slowly in the mouth. May be repeated every hour as needed or as directed by a doctor. Children under 2 years of age: consult a doctor.

* * * * *

Dated: September 12, 1989.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89–23137 Filed 9–29–89; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Kentucky Permanent Regulatory Program; Minor Field Revisions

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

ACTION: Proposed rule.

SUMMARY: OSMRE is announcing the receipt of a proposed amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment concerns new permit revision procedures that will allow minor field revisions to be processed in the Department for Surface Mining Reclamation and Enforcement's (DSMRE) Regional Offices rather than in the central Office in Frankfort. The proposal contains a list of permit revisions defined as minor field revisions.

This notice sets forth the times and locations that the Kentucky program and the proposed amendment are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding a public hearing, if one is requested.

DATES: Written comments must be received on or before 4:00 p.m. on November 1, 1989. If requested, a public hearing on the proposed amendment will be held at 10:00 a.m. on October 27, 1989. Requests to present oral testimony at the hearing must be received on or before 4:00 p.m. on October 17, 1989.

ADDRESSES: Written comments and requests for a hearing should be mailed or hand delivered to: Roger Calhoun, Acting Director, Lexington Field Office Office of Surface Mining Reclamation and Enforcement, 340 Legion Drive, Suite 28, Lexington, Kentucky 40504. Copies of the Kentucky program, the proposed amendment, and all written comments received in response to this notice will be available for review at the addresses listed below, Monday through Friday, 9:00 a.m. to 4:00 p.m., excluding holidays. Each requestor may receive, free of charge, one copy of the proposed amendment by contacting OSMRE's Lexington Field Office.

Office of Surface Mining Reclamation and Enforcement, Lexington Field