open automatically by hand pressure applied to a button or device in the handle of the knife or by operation of inertia, gravity, or both.

(2) Knives with a detachable blade that is propelled by a spring-operated mechanism and which are referred to as ballistic knives, or components thereof.

* * * * *

§ 12.96 [Amended]

4. In § 12.96(b) remove the words "the Act of August 12, 1958 (15 U.S.C. 1241–1244)" and add, in their place, the words "15 U.S.C. 1241–1245".

5. Section 12.97 is revised to read as follows:

§ 12.97 Importations contrary to law.

Importations of switchblade knives, except as permitted by 15 U.S.C. 1244, are importations contrary to law and are subject to forfeiture under 19 U.S.C. 1595a(c).

6. Section 12.98 is amended by revising the introductory text and revising paragraph (c) to read as follows:

§ 12.98 Importations permitted by statutory exceptions.

The importation of switchblade knives is permitted by 15 U.S.C. 1244, when:

* * * * *

(c) A switchblade knife, other than a ballistic knife, having a blade not exceeding 3 inches in length is in the possession of and is being transported on the person of an individual who has only one arm.

§ 12.100 [Amended]

7. In § 12.100(b) remove the words "§ 4 of the Act of August 12, 1958".

§ 12.101 [Amended]

8. In § 12.101(a) remove the words "section 545, title 18, United States Code" and add, in their place, the words "19 U.S.C. 1595a(c)".

§ 12.103 [Amended]

9. In § 12.103 remove the words "the Act of August 12, 1958 (15 U.S.C. 1241–1244)" and add, in their place, the words "15 U.S.C. 1241–1245".

Michael H. Lane,

Acting Commissioner of Customs.

Approved: August 14, 1989.

John P. Simpson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 89–19492 Filed 8–17–89; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333 and 448

[Docket No. 76N–0482]

RIN 0905–AA06

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for OTC First Aid Antibiotic Drug Products

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) first aid antibiotic drug products in 21 CFR Part 333 that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded. The amendment would allow bacitracin-polymyxin B sulfate topical aerosol to include a suitable local anesthetic as an active ingredient. FDA is concurrently amending the antibiotic regulations in 21 CFR part 448 to be consistent with the monograph for OTC first aid antibiotic drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by October 17, 1989. Requests for an informal conference on proposed change in § 448.510f(a)(1) by September 18, 1989.

ADDRESSES: Written comments or requests for conference on proposed change in § 448.510f(a)(1) 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 December 11, 1987 (52 FR 47312), FDA issued a final monograph for OTC first aid antibiotic drug products (21 CFR Part 333 Subpart B). The monograph providers for combinations of bacitracin-polymyxin B sulfate topical aerosol (§ 333.120(a)(3)) and bacitracin or bacitracin-neomycin sulfate-polymyxin B sulfate ointment and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient (§ 333.120(b)(1) and (2)).

On January 27, 1989, FDA received a citizen petition (Docket No. 76N–0482/CP0002) requesting the amendment of CFR Part 333 and 21 CFR 448.510f to include a suitable local anesthetic in the combination bacitracin-polymyxin B sulfate topical aerosol. Specifically, the petition requested that the following paragraph be added to § 333.120(b):

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle, packaged in a pressurized container with inert gases: *Provided*, that it meets the tests and methods of assay in § 448.510f(b).

The petition also requested that the following sentence be added to § 448.510f(a)(1): "It may contain a suitable local anesthetic."

After reviewing the citizen petition, the agency concludes that there is sufficient evidence to generally recognize the requested combination as safe and effective and not misbranded for OTC first aid antibiotic-anesthetic use. The citizen petition pointed out that FDA, in its final monograph for OTC first aid antibiotic drug products, accepted the appropriateness of the combination of OTC topical products containing antibiotics and a local analgesic, and expressly permitted the combination of certain antibiotic active ingredients with any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient (52 FR 47312 at 47323). This acceptance was based, in part, on the facts that combination topical antibiotic products containing a local anesthetic have a marketing history that predates the OTC drug review and the antibiotic regulations in §§ 448.510a and 448.510e (21 CFR 448.510a and 448.510e) allow certain antibiotic-anesthetic combinations.

In the advance notice of proposed rulemaking for OTC external analgesic drug products (December 4, 1979; 44 FR 69768), the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products recommended as Category I combinations containing certain external analgesic active ingredients and Category I antimicrobial active ingredients provided the product was labeled for the concurrent symptoms involved (44 FR 69865). In the *tentative* final monograph for OTC external analgesic drug products, agency proposed such combinations as

Category I (February 8, 1983; 48 FR 5852 to 5868). That rulemaking has not been finalized to date. However, in the final monograph for OTC first aid antibiotic drug products, the agency stated that the combination of a first aid antibiotic and an external analgesic, anesthetic, or antipruritic is similar in action and intended use to the combination of a topical antimicrobial and an external analgesic, anesthetic, and antipruritic (52 FR 47312 at 47319).

In addition, the agency stated that combinations of first aid antibiotic and local anesthetic ingredients provide rational concurrent therapy for a significant proportion of the target population and that the combination is suitable for OTC use under adequate directions for use and warnings against unsafe use, as required under § 330.10(a)(4)(iv) (52 FR 47319).

In the final monograph for OTC first aid antibiotic drug products, the agency included only those topical antibiotic-anesthetic combinations that included Category I ingredients from both the external analgesic and first aid antibiotic rulemakings and that are the subject of a current CFR antibiotic monograph (52 FR 47319). Bacitracin-polymyxin B sulfate topical aerosol in combination with a local anesthetic was not the subject of an existing antibiotic regulation and, consequently, such a combination was not included in the final monograph.

Therefore, the agency is proposing to amend the existing antibiotic regulation in § 448.510(a)(1) to provide for such a combination and to include this combination in § 333.120(b) of the final monograph for OTC first aid antibiotic drug products. The product would be labeled in accordance with § 333.160 (21 CFR 333.160).

The agency advises that any final rule resulting from this proposed rule will be effective 12 months after its date of publication in the **Federal Register**. On or after that date, any OTC drug product that is not in compliance may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date the product was initially introduced into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

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 first aid antibiotic 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 first aid antibiotic drug products is not expected to pose such an effect 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 first aid antibiotic drug products. Comments regarding the impact of this rulemaking on OTC first aid antibiotic drug products should be accompanied by appropriate documentation.

It has been determined that 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 October 17, 1989, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

Interested persons may, on or before September 18, 1989, submit to the Dockets Management Branch a request for an informal conference on the proposed change in § 448.510f(a)(1). The participants in an informal conference, if one is held, will have until October 17, 1989, or 30 days after the day of the conference, whichever is later, to submit their comments.

List of Subjects

21 CFR Part 333

First aid antibiotic drug products, Labeling over-the-counter drugs.

21 CFR Part 448

Antibiotics.

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 as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 333 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. A new paragraph (b)(3) is added to § 333.120 to read as follows:

§ 333.120 Permitted combinations of active ingredients.

* * * * *

(b) * * *

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle, packaged in a pressurized container with inert gases: *Provided,* That it meets the tests and methods of assay in § 448.510f(b) of this chapter.

PART 448—PEPTIDE ANTIBIOTIC DRUGS

3. The authority citation for 21 CFR Part 448 continues to read as follows:

Authority: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357); 21 CFR 5.10.

4. Section 448.510f is amended by revising paragraph (a)(1) to read as follows:

§ 448.510f Bacitracin-polymyxin B sulfate topical aerosol.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin-polymyxin B sulfate topical aerosol is bacitracin and polymyxin B sulfate in a suitable and

harmless vehicle, packaged in a pressurized container with a suitable and harmless inert gas. Each gram contains 500 units of bacitracin and 5,000 units of polymyxin B. It may contain a suitable local anesthetic. Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. Its moisture content is not more than 0.5 percent. The bacitracin used conforms to the standards prescribed by § 448.10(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

* * * * *

Dated: June 14, 1989.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 89-19392 Filed 8-17-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

Missouri Permanent Regulatory Program

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

ACTION: Proposed rule; Public Comment Period and Opportunity for Public Hearing on Proposed Amendment.

SUMMARY: OSMRE is announcing receipt of a proposed amendment to the Missouri permanent regulatory program (hereinafter, the "Missouri program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment pertains to previously mined areas, fish and wildlife, maps and plans, steep slope mining, subsidence, definitions, financial interests of State employees, and individual civil penalties. The amendment is intended to revise the State program to be consistent with the corresponding Federal standards.

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

DATES: Written comments must be received by 4:00 p.m., c.d.t. September 18, 1989. If requested, a public hearing on the proposed amendment will be held on September 12, 1989. Requests to present oral testimony at the hearing must be received by 4:00 p.m., c.d.t. on September 5, 1989.

ADDRESSES: Written comments should be mailed or hand delivered to Mr. William J. Kovacic at the address listed below.

Copies of the Missouri program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSMRE's Kansas City Field Office:

Mr. William. J. Kovacic, Director, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 1103 Grand Avenue, Room 502, Kansas City, MO 64106, Telephone: (307) 758-6405.

Missouri Department of Natural Resources, Land Reclamation Program, 205 Jefferson Street, P.O. Box 176, Jefferson City, MO 65102, Telephone: (314) 951-4041.

FOR FURTHER INFORMATION CONTACT: Mr. William J. Kovacic, Director, Kansas City Field Office, (307) 758-6405.

SUPPLEMENTARY INFORMATION:

I. Background on the Missouri Program

On November 21, 1980, the Secretary of the Interior conditionally approved the Missouri program. General background information on the Missouri program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Missouri program can be found in the November 21, 1980, **Federal Register** (45 FR 77017). Subsequent actions concerning Missouri's program and program amendments can be found at 30 CFR 925.12, 925.15, and 925.16.

II. Proposed Amendment

By letter dated August 3, 1989, (Administrative Record No. MO-454), Missouri submitted a proposed amendment to its program pursuant to SMCRA. Missouri submitted the proposed amendment in response to a November 3, 1988, letter from OSMRE in accordance with 30 CFR 732 requiring certain provisions of the State program to be updated for consistency with the Federal regulations through June 15, 1988.

The regulations that Missouri proposes to amend are: 10 CSR 40-4.060 (1) and (2), Previously Mined Areas; 10 CSR 40-6.040(11)(E), Fish and Wildlife Resource Information; 10 CSR 40-6.050(5)(C), Operations Maps and Plans; 10 CSR 40-6.060 (2)(B) and (2)(C), Steep Slope Mining; 10 CSR 40-6.070 (7)(A)3, Review of Permit Applications; 10 CSR 40-6.070(8)(M), Criteria for Permit Approval or Denial; 10 CSR 40-6.120(11), Subsidence Control Plan; 10 CSR 40-8.010(1)(A) 5, 18, and 71, Definitions; 10 CSR 40-8.045 (1), (2), (3), (4), (5), and (6), Individual Civil Penalty Assessment to the Directors, Officers, or Agents of a Corporation; and 10 CSR 40-8.060(8)(B), Resolving Prohibited Interest.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSMRE is now seeking comment on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Missouri program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "**DATES**" or at locations other than the Kansas City Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by 4:00 p.m., c.d.t. September 5, 1989. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSMRE officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to