intersection with the Arcadia city limits; then easterly along the Arcadia city limits to its intersection with the Monrovia city limits; then northerly and easterly along the Monrovia city limits to its intersection with Duarte city limits; then easterly and southerly along the Duarte city limits to its intersection with the Azusa city limits; then easterly and southerly along the Azusa city limits to its intersection with the Glendora city limits; then northerly and easterly along the Glendora city limits to its intersection with the San Dimas city limits; then easterly and southerly along the San Dimas city limits to its intersection with the Angeles National Forest boundary; then easterly along this boundary to its intersection with the La Verne city limits; then northerly, easterly, and southerly along the La Verne city limits to its intersection with State Highway 30; then easterly along this highway to the point of beginning.

* * * * *

Done in Washington, DC, this 9th day of March 1990.

**James W. Glosser,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 90-5976 Filed 3-14-90; 8:45 am]

BILLING CODE 3410-34-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; Amendment of Final Monograph for OTC First Aid Antibiotic Drug Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule that amends the final monograph for over-the-counter (OTC) first aid antibiotic drug products in 21 CFR 333.120 to 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 448.510f(a)(1) to be consistent with the mongraph for OTC first aid antibiotic drug products. This amendment of the final monograph is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Effective March 15, 1991; notice of participation, and request for hearing on the amendment to 21 CFR 448.510f(a)(1) by April 16, 1990; data, information, and analyses to justify a hearing on the amendment to 21 CFR 448.510f(a)(1) by May 14, 1990.

**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 provided 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 21 CFR 333.120 and 21 CFR 448.510f(a)(1) 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 concluded that there was sufficient evidence to generally recognize the requested combination as safe and effective and not misbranded for OTC first aid antibiotic-anesthetic use. The agency's proposed regulation, in the form of a proposed amendment of the final monograph for OTC first aid antibiotic drug products, was published in the **Federal Register** of August 18, 1989 (54 FR 34188). In that document, the agency proposed to amend 21 CFR 333.120 and 448.510f(a)(1) to allow bacitracin-polymyxin B sulfate topical aerosol to include a suitable local anesthetic as an active ingredient. Interested persons were invited to submit written comments by October 17, 1989, and to submit requests for an informal conference on the proposed change in § 448.510f(a)(1) by September 18, 1989.

No comments were received in response to the proposed amendments and no requests for an informal conference were received in response to the proposed amendment to 21 CFR 448.510f(a)(1). However, the agency wants to acknowledge that a second citizen petition (Docket No. 76N-0482/CP0003) making the same request was received on March 14, 1989. The second petition noted the existence of the first petition, stated that it wished to maintain its status as a separate petitioner, and stated its belief that it would be appropriate for the agency to take action on both petitions at the same time. Although the second petition inadvertently was not mentioned in the August 18, 1989 proposed rule, this final rule addresses both petitions simultaneously.

As discussed in the proposal (54 FR 34188), the agency advised that any final rule resulting from the proposal would be effective 12 months after its date of publication in the **Federal Register.** Therefore, on or after March 15, 1991, any OTC drug product that is not in compliance with the final rule 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 or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (54 FR 34188). The agency has examined the economic consequences of this final rule 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 amendment of the final monograph 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 final rule will not have a significant economic impact on a substantial number of small entities.

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.

Any person who will be adversely affected by the amendment to 21 CFR 448.510F(a)(1) may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before April 16, 1990, a written notice of participation and request for hearing, and (2) on or before May 14, 1990, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgement against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order, the filed with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The procedures and requirements governing this order, a notice of participation and request for a hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR**

*Part 333:*

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

*Part 448:*

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations is 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, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 333.120 is amended by adding new paragraph (b)(3) 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 suitable 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 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

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: February 20, 1990.

**James S. Benson,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 90–5864 Filed 3–14–90; 8:45 am]

BILLING CODE 4160–01–M

## DEPARTMENT OF STATE

## 22 CFR Parts 60, 61, 62, 63, and 65

**[Public Notice 1171]**

## South Africa and Fair Labor Standards

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Comprehensive Anti-Apartheid Act of October 2, 1986 (Pub. L. 99–440) contains provisions on the fair labor standards to be implemented by U.S. firms in South Africa. This final rule implements the requirements of the Act to remove Namibia from the scope of application of the standards upon Namibia's independence on March 21, 1990.

**EFFECTIVE DATE:** March 21, 1990.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Bruce, Office of Southern African Affairs, (202) 647–8433, or John R. Byerly or Antonio F. Perez, Office of Legal Adviser, (202) 647–4110, Department of State.

**SUPPLEMENTARY INFORMATION:** Section 2 of Executive Order 12532 of September 9, 1985 (50 FR 36861) deals with labor practices of U.S. nationals and their firms in South Africa. On November 8, 1985 the Department of State published draft implementing regulations as a proposed rule for public comment (50 FR 46455). The final rule was published on December 31, 1985 (50 FR 53308).

The Comprehensive Anti-Apartheid Act of 1986 (Pub. L. 99–440) ("the Act") codified the measures required ur