In response to Congressman Wise's comments, the OIG has established two systems of records. The primary system, containing investigatory materials compiled for law enforcement purposes, will be entitled Office of Inspector General Investigative Files (General). The second system, entitled Office of Inspector General Investigative Files (Criminal), will be maintained and used by the OIG's newly established Criminal Investigations Subunit.

The primary system of records will contain material compiled for law enforcement purposes during the course of non-criminal investigations. These files, the Office of Inspector General Investigative Files (General), will be maintained by the OIG, and will be exempt from certain requirements of the Privacy Act under section (k)(2).

The secondary system will contain information compiled during criminal investigations and will be used and maintained by the OIG's newly established Criminal Investigations Subunit. The sole function of the new subunit will be to conduct investigations into possible criminal violations. Thus the principal function of this subunit would be an activity pertaining to the enforcement of criminal laws. This subunit will maintain the system of records entitled Office of Inspector General Investigative Files (Criminal), and this system will be exempt from certain requirements of the Privacy Act under section (j)(2).

The Commission has determined that this rule does not constitute a major rule under section 1(b) of Executive Order 12291 because it will not result in (1) an annual effect on the economy of at least $100 million or more, (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, or (3) significant adverse effects on competition, employment, investment, productivity, or innovation. In addition, the Regulatory Flexibility Act, 5 U.S.C. 605(b), does not apply since this rule will not have significant impact on a substantial number of small entities. The Privacy Act concerns the rights of individuals, who do not constitute small entities under the Regulatory Flexibility Act.

**List of subjects in 19 CFR part 201**

Privacy, Reporting and Recordkeeping Requirements.

For the reasons set forth above, the U.S. International Trade Commission proposes to amend 19 CFR part 201, subpart D, as follows:

## PART 201—RULES OF GENERAL APPLICATION

### Subpart D—Safeguarding Individual Privacy Pursuant to 5 U.S.C. 552a.

1. The authority citation for subpart D continues to read as follows:

**Authority:** 5 U.S.C. 552a.

2. Part 201, Subpart D, is amended to add §§ 201.32(d) and 201.32(e) as follows:

**§ 201.32 Specific exemptions.**

* * * * *

(d) Pursuant to 5 U.S.C. 552a(k)(2), and in order to protect the effectiveness of Inspector General investigations by preventing individuals who may be the subject of an investigation from obtaining access to the records and thus obtaining the opportunity to conceal or destroy evidence or to intimidate witnesses, records contained in the system titled Office of Inspector General Investiative Files (General), insofar as they include investigatory material compiled for law enforcement purposes, shall be exempt from this subpart and from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of section 3 of the Privacy Act. *Provided, however,* that if any individual is denied any right, privilege, or benefit to which he is otherwise entitled to under Federal law due to the maintenance of this material, such material shall be provided to such individual except to the extent that the disclosure of such material would reveal the identify of a source who furnished information to government investigators under an express promise that the identity of the source would be held in confidence.

(e) Pursuant to 5 U.S.C. 552a(j)(2), and in order to protect the confidentiality and integrity of Inspector General investigations by preventing individuals who may be the subject of an investigation from obtaining access to the records and thus obtaining the opportunity to conceal or destroy evidence or to intimidate witnesses, records maintained in the Office of Inspector General Investigative Files (Criminal), insofar as they contain information pertaining to the enforcement of criminal laws, shall be exempt from this subpart and from the Privacy Act, *except that,* subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11) and (i) shall still apply to these records.

By the Commission.

Dated: September 26, 1990.

**Kenneth R. Mason,**

*Secretary.*

[FR Doc. 90-23374 Filed 10-2-90; 8:45 am]

BILLING CODE 7020-02-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 333 and 448

**[Docket No. 76N-482A]**

**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 part 333 that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded. This amendment revises the standards for bacitracin zinc-polymyxin B sulfate topical aerosol. 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 amendment of the final monograph is a part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Effective October 3, 1991; a written notice of participation and request for hearing on the amendment to 21 CFR 448.513e(a)(1) by November 2, 1990; data, information, and analyses to justify a hearing on the amendment to 21 CFR 448.513e(a)(1) by December 3, 1990.

**ADDRESSES:** Written comments or requests for a hearing on the amendment to § 448.513e(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 provided for bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each 90-gram container, 10,000 units of bacitracin and 200,000 units of polymyxin B (§ 333.120(a)(7)) (21 CFR 333.120(a)(7)).

On June 3, 1988, FDA received a citizen petition (Docket No. 76N–0482/CP) requesting the amendment of § 333.120(a)(7) to delete the "90-gram" specification for the container size so that § 333.120(a)(7) would be consistent with the antibiotic regulation in § 448.513e(a)(1) which does not specify a container size for bacitracin zinc-polymyxin B sulfate topical aerosol.

On October 13, 1989, FDA received an amendment to the citizen petition (Docket No. 76N–0482/AMD1) requesting that § 333.120(a)(7) be revised to state the concentration of antibiotics contained in each gram, rather than designating the concentration of antibiotics contained in each "90-gram" container. The petitioner stated that vehicles and/or inert gases that could be used in the aerosol product vary in specific gravity and/or weight. The petitioner mentioned that if it wished to reformulate the product to change, add, or delete either the "suitable vehicle" or the "suitable inert gases," the final product would still provide the same number of units of antibiotics but the total container content might be at variance from the required 90 grams. Accordingly, the petitioner requested the § 333.120(a)(7) be revised to read "Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin zinc and 2,350 units of polymyxin B * * *." The petitioner concluded that this approach would be consistent with other monograph listings in §§ 333.110 and 333.120.

In developing the final monograph for OTC first aid antibiotic drug products, the agency stated that the dosage forms included in the monograph reflected those dosage forms identified in Subpart F of the specific antibiotic regulations that applied to first aid antibiotics (52 FR 47312 at 47313). Although § 448.513e does not state a container size, as the petitioner noted, that particular section of the antibiotic regulations was based on an approved new drug application (NDA) for an aerosol product in a 90-gram container. When the final monograph for OTC first aid antibiotic drug products was prepared, it was necessary to state therein the size of the container to inform other manufacturers of the amount of antibiotics per total container size. After publication of the final monograph for OTC first aid antibiotic drug products, the agency was notified that the underlying NDA for the aerosol product had been amended to provide for a change in the container size from a 90-gram container to an 85-gram container, as allowed under § 314.70(d) (21 CFR 314.70(d)). The amount of antibiotics per 85-gram container remained the same in accord with § 448.513e(a)(1): 10,000 units of bacitracin and 200,000 units of polymyxin B. These amounts are equivalent to 117.65 units of bacitracin per gram and 2352.94 units of polymyxin B per gram, and are very close to the rounded-off amounts requested by the petitioner.

After reviewing the citizen petition, the agency agreed that it would be appropriate to revise §§ 333.120(a)(7) and 448.513e(a)(1) to state the concentration of antibiotics contained in each gram of the final product. This revision would allow manufacturers to market other size aerosol products containing these antibiotics and would allow greater flexibility in reformulating existing products if the manufacturer elected to change the suitable vehicle and/or inert gases. 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 May 11, 1990 (55 FR 19868). In that document, the agency proposed to amend the final monograph for OTC first aid antibiotic drug products in § 333,120(a)(7) and the exiting antibiotic regulation in § 448.513e(a)(1) to provide for bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin and 2,350 units of polymyxin B. In addition, the agency corrected an error that existed in § 448.513e(a)(1): 120 percent should have read 130 percent. Interested persons were invited to submit written comments by July 10, 1990, and to submit requests for an informal conference on the proposed change in § 448.513e(a)(1) by June 11, 1990.

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 448.513e(a)(1).

As discussed in the proposal (55 FR 19868), 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 October 3, 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 role 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 (55 FR 19868). 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 enviromental impact statement is required.

Any person who will be adversely affected by the amendment to 21 CFR Part 448.513e(a)(1) may file objec[illegible] it and request a hearing. Reasona[illegible] grounds for the hearing must be shown.

Any person who decides to seek a hearing must file (1) on or before November 2, 1990, a written notice of participation and request for hearing, and (2) on or before December 3, 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 judgment 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, and filed with the Dockets Management Branch (address above).

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**

*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, subchapter D of chapter I of title 21 of the Code of Federal Regulations is amended in parts 333 and 448 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 revising paragraph (a)(7) to read as follows:

**§ 333.120 Permitted combinations of active ingredients.**

* * * * *

(a) * * *

(7) Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin and 2,350 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided,* That is meets the tests and methods of assay in § 448.513e(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 448.513e is amended by revising paragraph (a)(1) to read as follows:

**§ 448.513e Bacitracin zinc-polymyxin B sulfate topical aerosol.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin zinc-polymyxin B sulfate topical aerosol is bacitarcin zinc, polymyxin B sulfate in a suitable and harmless vehicle, packaged in a pressurized container with suitable and harmless inert gases. Each gram contains 120 units of bacitracin and 2,350 units of polymyxin B. 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. It contains not more than an average of 10 microorganisms per container. The bacitracin zinc used conforms to the standards prescribed by § 448.13(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

* * * * *

Dated: September 3, 1990

**James S. Benson,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 90–23347 Filed 10–2–90; 8:45 am]

BILLING CODE 4160–01–M

**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; Amendment of Final Monograph for OTC Antitussive Drug Products

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) antitussive drug products in 21 CFR part 341. As amended, only the term "lozenge" is used to describe a solid dosage form oral antitussive drug product intended for dissolution in the mouth. Also, the final monograph is amended to clarify that a systemically acting antitussive drug product can be marketed in a lozenge dosage form. This amendment of the final monograph is part of the ongoing review of OTC drug products conducted by FDA.

**EFFECTIVE DATE:** October 3, 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 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 currently provides for menthol to be used in a "lozenge" or "compressed tablet" dosage form (See §§ 341.3(c) and 341.74(d)(2)(iii).)

After publication of the antitussive final monograph, the United States Pharmacopeia (U.S.P.) (Ref. 1) added a definition for "lozenges." This definition, which became official in January 1990, is 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