

FEE SCHEDULE FOR FY 1997—Continued

State	County	Rate per acre
	Baker, Crook, Deschutes, Gilliam, Grant, Jefferson, Klamath, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, Wheeler.	11.93
	Coos, Curry, Douglas, Jackson, Josephine	17.91
	Benton, Clackamas, Clatsop, Columbia, Hood River, Lane, Lincoln, Linn, Marion, Multnomah, Polk, Tillamock, Washington, Yamhill.	23.86
Pennsylvania	All counties	23.86
Puerto Rico	All	35.81
South Carolina	All counties	35.81
South Dakota	Butte, Custer, Fall River, Lawrence, Meade, Pennington	17.91
	All other counties	5.96
Tennessee	All counties	23.86
Texas	Culberson, El Paso, Hudspeth	5.96
	All other counties	35.81
Utah	Beaver, Box Elder, Carbon, Duchesne, Emery, Garfield, Grand, Iron, Jaub, Kane, Millard, San Juan, Tooele, Uintah, Wayne.	5.96
	Washington	11.93
	Cache, Daggett, Davis, Morgan, Piute, Rich, Salt Lake, Sanpete, Sevier, Summit, Utah, Wasatch, Weber.	
Vermont	All counties	23.86
Virginia	All counties	23.86
Washington	Adams, Asotin, Benton, Chelan, Columbia, Douglas, Franklin, Garfield, Grant, Kittitas, Klickitat, Lincoln, Okanogan, Spokane, Walla Walla, Whitman, Yakima.	11.93
	Ferry, Pend Oreille, Stevens	17.91
	Callam, Clark, Cowlitz, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, Pacific, Pierce, San Juan, Skagit, Skamania, Snohomish, Thurston, Wahkiakum, Whatcom.	23.86
West Virginia	All counties	23.86
Wisconsin	All counties	17.91
Wyoming	Albany, Campbell, Carbon, Converse, Fremont, Goshen, Hot Springs, Johnson, Laramie, Lincoln, Natrona, Niobrara, Platte, Sheridan, Sublette, Sweetwater, Uinta, Washakie.	5.96
	Big Horn, Crook, Park, Teton, Weston	17.91
All other zones	5.09

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 95N-0062]

RIN 0910-AA01

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 amending the monograph for over-the-counter (OTC) first aid antibiotic drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded). The amendment adds a warning statement concerning allergic reactions resulting from topical antibiotic drug products containing bacitracin, bacitracin zinc, neomycin,

neomycin sulfate, polymyxin B, or polymyxin B sulfate. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: November 17, 1997.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of December 11, 1987 (52 FR 47312), FDA issued a final monograph for OTC first aid antibiotic drug products in part 333 (21 CFR part 333) subpart B. The monograph provides for single ingredient products containing bacitracin, bacitracin zinc, neomycin, or neomycin sulfate and various combinations containing bacitracin, neomycin sulfate, and polymyxin B sulfate. The monograph did not include an allergy warning for products containing bacitracin (zinc), neomycin (sulfate), and polymyxin B (sulfate).

In the *Federal Register* of February 14, 1996 (61 FR 5918), the agency published a proposed amendment of the monograph for OTC first aid antibiotic drug products to add a new warning for

products containing bacitracin (zinc), neomycin (sulfate), and polymyxin B (sulfate). The warning adds the words "or if a rash or other allergic reaction develops. Do not use this product if you are allergic to any of the ingredients." in the middle of the existing warning in § 333.150(c)(2) that has been used for all OTC first aid antibiotic drug products for years. The new warning would read:

Stop use and consult a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops. Do not use this product if you are allergic to any of the ingredients. Do not use longer than 1 week unless directed by a doctor.

The agency included this new warning in proposed § 333.150(c)(3) under the heading *For any product containing bacitracin, bacitracin zinc, neomycin, neomycin sulfate, polymyxin B and/or polymyxin B sulfate*. The agency retained the current warning in § 333.150(c)(2) for products containing chlortetracycline hydrochloride and tetracycline hydrochloride and added the heading *For any products containing chlortetracycline hydrochloride or tetracycline hydrochloride* to § 333.150(c)(2). Combinations containing oxytetracycline hydrochloride and polymyxin B sulfate in § 333.120(a)(11) and (a)(12) would use the new warning in proposed § 333.150(c)(3).

Interested persons were invited to submit comments on the proposal by May 14, 1996, and comments on the agency's economic impact determination by May 14, 1996.

In response to the proposed monograph amendment, one trade association of OTC drug manufacturers submitted a comment. Copies of the comment received are on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

The agency has considered the comment in proceeding with this final rule. A summary of the comment with FDA's response follows.

II. Summary of the Comment Received

The comment supported the warning language proposed by the agency and requested a technical clarification of part of one sentence of the warning. The comment noted that in the preamble to the monograph amendment (61 FR 5918), the agency had stated a new sentence as "Do not use if you are allergic to any of the ingredients," while in proposed § 333.150(c)(3) (61 FR 5918 at 5920), the agency had included the words "this product" after the word "use" in this sentence. The comment stated that the words "this product" were implicitly understood in product labeling and that deletion of these words would conserve label space. The comment supported deletion of these two words and asked the agency to clarify this issue as soon as possible.

The agency concurs with the comment that the words "this product" are implicitly understood in product labeling. While the agency proposed to include these two words for completeness, the agency agrees that the words can be deleted without affecting the meaning of the sentence. Accordingly, § 333.150(c)(3) in this final rule does not include the words "this product."

III. The Agency's Final Conclusions

The agency concludes that addition of a warning statement about the possibility of allergic reactions to the labeling of topical antibiotic drug products containing bacitracin (zinc), neomycin (sulfate), and polymyxin B (sulfate) would benefit consumers who use these OTC drug products. The new warning is supportable based on the

adverse event reports discussed in the proposal (61 FR 5918).

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule will generate a one-time label modification, which can be implemented at very little cost by manufacturers at the next printing of labels. The agency is providing 12 months for this revision to be made. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirement in this document is not subject to review by the Office of Management and Budget because it does not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the warning statement is a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

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.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 333 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), unless otherwise noted.

2. Section 333.150 is amended by adding a heading to paragraph (c)(2) and by adding new paragraph (c)(3) to read as follows:

§ 333.150 Labeling of first aid antibiotic drug products.

* * * * *

(c) * * *

(2) For products containing chlortetracycline hydrochloride or tetracycline hydrochloride. * * *

(3) For any product containing bacitracin, bacitracin zinc, neomycin, neomycin sulfate, polymyxin B, and/or polymyxin B sulfate. "Stop use and consult a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops. Do not use if you are allergic to any of the ingredients. Do not use longer than 1 week unless directed by a doctor."

* * * * *

Dated: November 5, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-29302 Filed 11-14-96; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3500

[Docket No. FR 4148-F-01]

Amendments to Regulation X, the Real Estate Settlement Procedures Act Regulation (Withdrawal of Employer-Employee and Computer Loan Origination Systems (CLOs) Exemptions); Final Rule

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.