DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333, 444, and 448

[Docket No. 76N-482B]

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 allows several antibiotic combinations of bacitracin zinc, polymyxin B sulfate, and neomycin sulfate to include a suitable local anesthetic as an active ingredient. FDA is concurrently amending the antibiotic regulations in 21 CFR parts 444 and 448 to be consistent with the monograph 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 December 5, 1991; a written notice of participation and request for hearing on the amendments to 21 CFR 444.542l, 448.513a, and 448.513c by January 4, 1991; data, information, and analyses to justify a hearing on the amendments to 21 CFR 444.542l, 448.513a, and 448.513c by February 4, 1991.

ADDRESSES: Written comments or requests for a hearing on the amendments to 444.542l, 448.513a, and 448.513c to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 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 in subpart B of 21 CFR part 333. The monograph provided for combinations of bacitracin ointment 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 (21 CFR 333.120(b)(1) and (2)). In the **Federal Register** of August 18, 1989 (54 FR 34188), FDA issued a proposed amendment, and in the **Federal Register** of March 15, 1990 (55 FR 9721), FDA issued a final amendment to the final monograph for OTC first aid antibiotic drug products to allow bacitracin-polymyxin B sulfate topical aerosol to include a suitable local anesthetic as an active ingredient (§ 333.120(b)(3)).

On October 30, 1989, FDA received three citizen petitions (Docket Nos. 76N-482B/CP0001, CP0002, and CP0003), requesting the amendment of 21 CFR part 333 to include a suitable local anesthetic in several antibiotic combinations containing bacitracin zinc, polymyxin B sulfate, and neomycin sulfate. Specifically, the petitions requested that the following paragraphs be added to § 333.120(b):

(3) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin zinc, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin zinc, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iii) 500 units of bacitracin zinc, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient;

Provided, that it meets the tests and methods of assay in § 448.513c(b).

(4) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin zinc, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base: *Provided*, that it meets the tests and methods of assay in § 448.513a(b).

(5) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin, 10,000 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: *Provided*, That it meets the tests and methods of assay in § 444.542l(b).

The citizen petitions noted that each of the combinations of first aid antibiotic active ingredients and local anesthetic active ingredients listed under 21 CFR 333.120(b) contain the ingredient bacitracin. The petitions contended that formulations containing bacitracin and formulations containing bacitracin zinc may be interchanged freely with no adverse effects on safety or efficacy. The petitions noted that bacitracin zinc, as well as bacitracin, have been utilized in OTC drug products for many years, and the petitions argued that it is unnecessary to restrict the usage of the combination together with a topical anesthetic to the bacitracin base alone.

After reviewing the citizen petitions, the agency concluded that there was sufficient evidence to generally recognize the requested combinations 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 June 8, 1990 (55 FR 23450). In that document, the agency proposed to amend 21 CFR 333.120, 444.542l, 448.513a, and 448.513c to allow several antibiotic combinations of bacitracin zinc, polymyxin B sulfate, and neomycin sulfate to include a suitable local anesthetic as an active ingredient.

One of the petitions requested three ointment combinations containing various potencies of bacitracin zinc-neomycin sulfate-polymyxin B sulfate. Two of the potencies corresponded to the potencies listed in § 333.120 (a)(5)(ii) and (a)(5)(iii) (21 CFR 333.120 (a)(5)(ii) and (a)(5)(iii)) for bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment. However, the petition did not request a local anesthetic be allowed with the monograph combination in § 333.120(a)(5)(i) and requested another combination not included in the monograph. That combination contained 500 units of bacitracin zinc, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B. The agency considered this additional potency to be sufficiently similar to those included in the monograph and proposed to add it to the monograph as new § 333.120(a)(5)(iii). The agency proposed to redesignate § 330.120(a)(5)(iii) as paragraph (a)(5)(iv) and to add bacitracin zinc-neomycin sulfate-polymyxin B sulfate-local anesthetic combinations in § 333.120(b)(1) (21 CFR 333.120(b)(1)) that correspond to the bacitracin zinc-neomycin sulfate-polymyxin B sulfate combinations without a local anesthetic in § 333.120(a)(5). Because a previous amendment to the final monograph added paragraph (3) to § 333.120(b) (55 FR 9721 at 9722; March 15, 1990), the agency numbered the new sections

being proposed for addition to § 333.120 as paragraphs (b)(4) through (b)(6) instead of paragraphs (b)(3) through (b)(5) as requested by the petitions. The potency of bacitracin zinc in these new sections will be listed as 500 units of bacitracin, not 500 units of bacitracin zinc as requested by the petitions, for consistency with other portions of the monograph. The agency also proposed to amend § 448.513c(a)(1) to list all of the potencies of these various combinations. Finally, the agency proposed to amend §§ 444.542l(a)(1), 448.513a(a)(1), and 448.513c(a)(1) to provide for the inclusion of a local anesthetic in these products. Interested persons were invited to submit written comments by August 7, 1990, and to submit requests for an informal conference on the proposed changes in 21 CFR 444.542l, 448.513a, and 448.513c by July 9, 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 amendments to 21 CFR 444.542l, 448.513a, and 448.513c.

As discussed in the proposal (55 FR 23450 at 23452), 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 December 5, 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 (55 FR 23450 at 23452). 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 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 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 amendments to 21 CFR 444.542l, 448.513a, and 448.513c may file objections to them 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 January 4, 1991, a written notice of participation and request for hearing, and (2) on or before February 4, 1991, 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 444

Antibiotics.

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, 444, 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 redesignating paragraph (a)(5)(iii) as paragraph (a)(5)(iv) and by adding new paragraphs (a)(5)(iii), (b)(4), (b)(5), and (b)(6) to read as follows:

§ 333.120 Permitted combinations of active ingredients.

* * * * *

(a) * * *

(5) * * *

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

* * * * *

(b) * * *

(4) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, 8,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iv) 500 units of bacitracin, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredieint;

Provided, That it meets the tests and methods of assay in § 448.513c(b) of this chapter.

(5) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base: *Provided,* That it meets the tests and methods of assay in § 448.513a(b) of this chapter.

(6) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin, 10,000 units polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle: *Provided,* That it meets the tests and methods of assay in § 444.542l(b) of this chapter.

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

3. The authority citation for 21 CFR part 444 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

4. Section 444.542l is amended by revising paragraph (a)(1) to read as follows:

§ 444.542l Neomycin sulfate-polymyxin B sulfate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate cream is a cream containing, in each gram, neomycin sulfate equivalent to 3.5 milligrams of neomycin and polymyxin B sulfate equivalent to 10,000 units of polymyxin B in a suitable and harmless vehicle. It may contain a suitable local anesthetic. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams neomycin that it is represented to contain. Its polymyxin B sulfate 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. The neomycin sulfate used conforms to the standards prescribed by § 444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1) of this chapter.

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PART 448—PEPTIDE ANTIBIOTIC DRUGS

5. 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).

6. Section 448.513a is amended by revising paragraph (a)(1) to read as follows:

§ 448.513a Bacitracin zinc-polymyxin B sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin zinc-polymyxin B sulfate ointment contains bacitracin zinc and polymyxin B sulfate in a suitable and harmless ointment base. It may contain a suitable local anesthetic. Each gram contains 500 units of bacitracin and 10,000 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. 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).

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7. Section 448.513c is amended by revising paragraph (a)(1) to read as follows:

§ 448.513c Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment; bacitracin zinc-neomycin sulfate-polymyxin B sulfate hydrocortisone ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* This drug, in a suitable and harmless ointment base, contains in each gram the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, and 8,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B, with or without 10 milligrams of hydrocortisone; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iv) 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B.

It may contain a suitable local anesthetic except for combinations in paragraph (a)(1)(ii) of this section that contain hydrocortisone. 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 neomycin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin 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 zinc used conforms to the standards prescribed by § 448.13(a)(1). The neomycin sulfate used conforms to the standards prescribed by § 444.42(a)(1) of this chapter. The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

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Dated: November 1, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-28526 Filed 12-4-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 235

[Docket No. R-90-1505; FR-2940-F-01]

Mortgage Insurance—Changes in Interest Rates

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

ACTION: Final rule.

SUMMARY: This change in the regulations reduces the maximum allowable interest rate on section 235 (Homeownership for Lower Income Families) insured loans. This final rule is intended to bring the maximum permissible financing charges for this

program into line with competitive market rates.

EFFECTIVE DATE: November 19, 1990.

FOR FURTHER INFORMATION CONTACT: James B. Mitchell, Director, Financial Services Division, Office of Financial Management, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Telephone (202) 708–4325. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The following amendments to 24 CFR chapter II have been made to decrease the maximum interest rate which may be charged on loans insured by this Department under section 235 of the National Housing Act. The maximum interest rate on the HUD/FHA section 235 insurance programs has been lowered from 10.00 percent to 9.50 percent.

Until recently, HUD regulated interest rates not only for the section 235 Program, but also for fire safety equipment loans insured under section 232 of the National Housing Act. However, section 429(e)(2) of the Housing and Community Development Act of 1987 (Pub. L. 100–242, approved February 5, 1988) amended the National Housing Act to provide that interest on fire safety equipment loans under section 232(i) of the Act will be "at such rate as may be agreed upon by the mortgagor and the mortgagee." Accordingly, these loans, like most other National Housing Act-authorized loans, now have their interest rates determined by negotiation. Accordingly, this announcement of a change in interest rate ceilings for FHA-insured mortgages is limited to the section 235 Program. The Secretary has determined that this change is immediately necessary to meet the needs of the market and to prevent speculation in anticipation of a change.

As a matter of policy, the Department submits most of its rulemaking to public comment, either before or after effectiveness of the action. In this instance, however, the Secretary has determined that advance notice and public comment procedures are unnecessary and that good cause exists for making this final rule effective immediately. HUD regulations published at 47 FR 56266 (1982), amending 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, contain categorical exclusions from their requirements for the actions, activities, and programs specified in § 50.20. Since the amendments made by this rule fall within the categorical exclusions set forth in paragraph (*l*) of § 50.20, the preparation of an Environmental Impact Statement or Finding of No Significant Impact is not required for this rule. This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 on Federal Regulation issued on February 17, 1981. Analysis of the rule indicates that it does not (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local governmental agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the provisions of 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule provides for a small adjustment in the mortgage interest rate in programs of limited applicability, and thus of minimal effect on small entities. This rule was not listed in the Department's Semiannual Agenda of Regulations published on October 29, 1990 (55 FR 44530) pursuant to Executive Order 12291 and the Regulatory Flexibility Act. The Catalog of Federal Domestic Assistance Program numbers are 14.108, 14.117, and 14.120.

List of Subjects in 24 CFR Part 235

Condominiums, Cooperatives, Low- and Moderate-Income housing, Mortgage insurance, Homeownership, Grant programs; Housing and community development.

Accordingly, the Department amends 24 CFR part 235 as follows:

PART 236—MORTGAGE INSURANCE AND ASSISTANCE PAYMENTS FOR HOMEOWNERSHIP AND PROJECT REHABILITATION

1. The authority citation for 24 CFR part 235 continues to read as follows:

Authority: Sections 211, 235, National Housing Act (12 U.S.C. 1715b, 1715z); section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

2. In § 235.9, paragraph (a) is revised to read as follows:

§ 235.9 Maximum interest rate.

(a) The mortgage shall bear interest at the rate agreed upon by the mortgagee and the mortgagor, which rate shall not exceed 9.50 percent per annum, except that where an application for commitment was received by the Secretary before November 19, 1990, loan may bear interest at the r rate in effect at the time of applicatio

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3. In § 235.540, paragraph (a) is revised to read as follows:

§ 235.540 Maximum interest rate.

(a) On or before November 19, 1990, the loan shall bear interest at the rate agreed on by the lender and the borrower, which rate shall not exceed 9.50 percent per annum, with the exception of applications submitted pursuant to feasibility letters, or outstanding conditional or firm commitments, issued prior to the effective date of the new rate. In these instances, applications will be processed at a rate not exceeding the applicable previous maximum rates, if the higher rate was previously agreed upon by the parties. Notwithstanding these exceptions, the application will be processed at the new lower rate if requested by the mortgagee.

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Dated: November 19, 1990.

Arthur J. Hill,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 90–28458 Filed 12–4–90; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[T.D. 8320]

RIN 1545–AM55

Treatment of Certain Losses Attributable to Periods After October 31 of a Taxable Year of a Regulated Investment Company

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning the treatment by a regulated investment company (RIC) of a net capital loss, a net long-term capital loss, or a net foreign currency loss attributable to periods after October 31 of its taxable year (a "post-October loss"). The applicable tax law was amended by the Tax Reform Act of 1986 and the Technical and Miscellaneous Revenue Act of 1988. The final regulations provide guidance relating to the treatment of a post-October loss in determining a RIC's