Staphylococcus aureus); upper respiratory infections such as rhinitis or pharyngitis (C*pyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations*. Limit treatment to two doses. Not for use within 30 days of slaughter.

3. Section 522.1696b is revised to read as follows.

§ 522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 010515, 053501, and 059130 for use as in paragraph (d) of this section.

(2) Nos. 000864 and 055529 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 000864, 010515, 053501, and 059130: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. Not for use in horses intended for food.

(A) For Nos. 000864, 010515, 053501, and 059130: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7, all other cattle—4, sheep—8, and swine—6.

(B) For No. 055529: Treatment should not exceed 4 consecutive days. Milk that has been taken during treatment and for 72 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7.

Dated: December 12, 2000.

Melanie R. Berson,

Acting Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinatiy Medicine.

[FR Doc. 01–72 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Mometasone Furoate, Clotrimazole Otic Suspension

AGENCY: Food and Drug Administration

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for veterinary prescription use of gentamicin/mometasone/clotrimazole otic suspension to treat otitis externa in dogs.

DATES: This rule is effective January 4, 2001.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 141–177 that provides for veterinary prescription use of Mometamax™ gentamicin sulfate/mometasone furoate/clotrimazole) Otic Suspension for the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs. The NADA is approved as of December 5, 2000, and the regulations are amended in 21 CFR 524 by adding § 524.1044h to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning December 5, 2000, because the application contains substantial evidence of effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1044h is added to read as follows:

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

(a) *Specifications*. Each gram contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3-milligram (mg) gentamicin base, mometasone furoate monohydrate

equivalent to 1-mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsor.* See No. 000061 in § 510.6(c) of this chapter.

(c) *Conditions of use— Dogs*—(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 5- and 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 5- and 30-g bottle into the ear canal (4 drops from the 215-g bottle), twice daily for 7 days.

(2) Indications for use. For the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–140 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8919]

RIN 1545–AY57

Guidance on Filing an Application for a Tentative Carryback Adjustment in a Consolidated Return Context

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to the filing of an application for a tentative carryback adjustment. These temporary regulations provide guidance to determine the time for filing such application by a consolidated group. This document also contains temporary regulations relating to the filing of an application for a tentative carryback adjustment by certain corporations for the separate return year created by their becoming a member of a consolidated group. These temporary regulations may affect all consolidated groups. The text of these temporary regulations also serves as the text of proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date:* January 4, 2001.

Applicability Date: For dates of applicability, see § 1.1502–78T (g)(2)(v) of these regulations.

FOR FURTHER INFORMATION CONTACT: Christopher M. Bass or Frances L. Kelly, (202) 622–7770 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains temporary amendments to the Income Tax Regulations (26 CFR Part 1) under section 1502 of the Internal Revenue Code of 1986 (Code). The amendments provide guidance as to the time for filing an application for a tentative carryback adjustment by a consolidated group. The amendments also extend the time for filing an application for a tentative carryback adjustment by certain corporations for the separate return year created by their becoming new members of a consolidated group.

Section 6411(a) requires that an application for a tentative carryback adjustment be filed on or after the date of filing for the return for the taxable year of the loss (or unused business credit) from which the carryback results and within a period of twelve (12) months after the end of such taxable year. Section 6411(c) provides that if the corporation seeking a tentative carryback adjustment made or was required to make a consolidated return for the year in which the loss or credit arose or for the preceding taxable year affected by such loss or credit, the provisions of Section 6411(a) apply only to such extent and subject to such conditions, limitations and exceptions as the Secretary may by regulations prescribe. Section 1.6411–4 refers taxpayers to the consolidated return regulations, specifically § 1.1502–78, for further rules applicable to consolidated groups filing for a tentative carryback adjustment.

Section 1.1502–78(a) addresses the proper party to file an application for a tentative carryback adjustment. However, there is no provision addressing the time for filing such application. Section 1.1502–78 does not currently alter the statutory rule as to ''when'' the end of a taxable year occurs for purposes of determining whether the twelve-month rule of section 6411 has been satisfied. Under § 1.1502–76, the due date for the separate return of a new member is generally extended until the due date of the return of the consolidated group. In certain instances, however, such separate return cannot be filed before the expiration of the twelve-month period under section 6411(a). Thus, a new member may be prevented from filing an application for a tentative carryback adjustment.

Section 1.1502–76(b)(1)(i) provides that the consolidated return must include the common parent's items of income, gain, deduction, loss, and credit for the entire consolidated year, and each subsidiary's items for the portion of the year for which it is a member. Items of a corporation for the portion of the year not included in the consolidated return must be included in a separate return (including the consolidated return of another group). Thus, the items of a new member of a consolidated group are included in two returns: first, the consolidated return for the period of time it is a member of the group; and second, a separate return (including the consolidated return of another group) for the pre-affiliation period prior to becoming a member of the consolidated group. This pre-affiliation period is a separate return year as defined in § 1.1502–1(e).

The tax returns for the periods that end and begin upon a corporation becoming (or ceasing to be) a member of a consolidated group are separate taxable years for all Federal income tax purposes. Section 1.1502–76(b)(2)(i). Although these periods are separate taxable years, items of income, gain, deduction, loss, and credit (other than extraordinary items) may be ratably allocated between such years if: (1) The corporation is not required to change its annual accounting period or its method of accounting as a result of its change in status as a member; and (2) a timely ratable allocation election is made. Section 1.1502–76(b)(2)(ii)(A). If a ratable allocation cannot be made (or is not made), the corporation must close its books at the close of the day on which its status as a member changes and its items of income, gain, deduction, loss, and credit for the pre-affiliation period are included in its separate return. Section 1.1502–76(b)(2)(ii).

Section 1.1502–76(c) determines the time for filing the new member's separate return. The provisions of this section apply only to a corporation which, immediately prior to becoming a new member of a group, was the common parent of another consolidated group, or was not required to join in the filing of a consolidated return. Under § 1.1502–76(c), the due date of the new member's separate return is dependent upon the filing of the consolidated group's tax return. If the consolidated return for the group has been filed by the due date for the new member's separate return, then the separate return must be filed no later than the due date of the consolidated group's return,