

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 522

## Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Schering-Plough Animal Health Corp. to Walco International, Inc.

**EFFECTIVE DATE:** May 27, 1997.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., P.O. Box 529, Kenilworth, NJ 07033, has informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 031-971 (cupric glycinate injection) to Walco International, Inc., 15 West Putnam, Porterville, CA 93257. Accordingly, the agency is amending the regulations in 21 CFR 522.518 to reflect the change of sponsor.

## List of Subjects in 21 CFR 522

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 522 is amended as follows:

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

## § 522.518 [Amended]

2. Section 522.518 *Cupric glycinate injection* is amended in paragraph (b) by removing "000061" and adding in its place "No. 049185".

Dated: May 6, 1997.

**Robert C. Livingston,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.* [FR Doc. 97-13822 Filed 5-23-97; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 558

## New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoffmann-La Roche, Inc. The supplemental NADA provides for removal of the international feed number (IFN) for an ingredient in free-choice, lasalocid, liquid Type C feed.

**EFFECTIVE DATE:** May 27, 1997.

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

**SUPPLEMENTARY INFORMATION:** Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110-1199, filed supplemental NADA 96-298, which provides for removing the IFN for the condensed molasses fermentation solubles ingredient of the free-choice, lasalocid, liquid Type C feed. The molasses solubles described by the IFN refer to those solubles from sugar cane molasses. The liquid Type C feed contains beet molasses solubles that do not have an IFN.

The supplemental NADA is approved as of May 27, 1997, and the regulations are amended in 21 CFR 558.311(e)(3)(i) to reflect the approval.

This action does not affect the safety and effectiveness upon which the application was approved. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.24(a)(9) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

## § 558.311 [Amended]

2. Section 558.311 *Lasalocid* is amended in the table in paragraph (e)(3)(i), in the entry for "Condensed Molasses Fermentation Solubles", in the third column by removing "5-25-399" and adding in its place "N/A".

Dated: May 7, 1997.

**Robert C. Livingston,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.* [FR Doc. 97-13825 Filed 5-23-97; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Parts 1 and 601

[TD 8719]

RIN 1545-AU41 and 1545-AV19

## Requirements Respecting the Adoption or Change of Accounting Method; Extensions of Time To Make Elections; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to temporary regulations.

**SUMMARY:** This document contains corrections to the temporary regulations (TD 8719) which were published in the **Federal Register** for Thursday, May 15, 1997 (62 FR 26740). The regulations relate to the procedure for requesting a change in accounting method and the standards for granting an extension of time to request a change in accounting method. The regulations provide for a longer period of time for filing an application for change in accounting method with the Commissioner.

**EFFECTIVE DATE:** May 15, 1997.

**FOR FURTHER INFORMATION CONTACT:** Cheryl L. Oseekey at (202) 622-4970 (not a toll-free number).

## SUPPLEMENTARY INFORMATION:

## Background

The temporary regulations that are the subject of this correction are under section 446 of the Internal Revenue Code.

**Need for Correction**

As published, the temporary regulations contain two errors which may prove to be misleading and are in need of clarification.

**Correction of Publication**

Accordingly, the publication of the temporary regulations which are the subject of FR Doc. 97-12514 is corrected as follows:

**§ 1.446-1T [Corrected]**

**Paragraph 1.** On page 26741, column 1, in § 1.446-1T, paragraph (e)(3)(i)(B) is corrected to read as follows:

\* \* \* \* \*

(e) \* \* \*

(3) \* \* \*

(i) \* \* \*

(B) For any form 3115 filed on or after May 15, 1997, to secure the Commissioner's consent to a taxpayer's change in method of accounting the taxpayer must file the Form 3115 with the Commissioner during the taxable year in which the taxpayer desires to make the change in method of accounting.

\* \* \* \* \*

**§ 601.204T [Corrected]**

**Par. 2.** On page 26741, column 2, in § 601.204T, paragraph (b)(2) is corrected by removing the last sentence.

**Dale D. Goode,**

*Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).*

[FR Doc. 97-13815 Filed 5-23-97; 8:45 am]

BILLING CODE 4830-01-U

**PENSION BENEFIT GUARANTY CORPORATION**

**29 CFR Parts 4003, 4007, 4011, 4041, 4041A, 4043, and 4050**

**Disaster Relief in Response to Severe Weather and Flooding in the Upper Midwest**

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Notice of disaster relief; waiver of certain penalties and extension of certain deadlines.

**SUMMARY:** The Pension Benefit Guaranty Corporation is waiving certain penalties and extending certain deadlines in response to the major disasters declared by the President of the United States on account of severe weather and flooding in the Upper Midwest.

**FOR FURTHER INFORMATION CONTACT:** Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Suite 340, Pension Benefit Guaranty

Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024 (202-326-4179 for TTY and TDD). (These are not toll-free numbers.)

**SUPPLEMENTARY INFORMATION:** The Pension Benefit Guaranty Corporation administers the pension plan termination insurance program under title IV of the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*). Under ERISA and the PBGC's regulations, a number of deadlines must be met in order to avoid the imposition of penalties or other consequences.

In April 1997, the President of the United States issued declarations, under the Disaster Relief Act of 1974, as amended (42 U.S.C. 5121 *et seq.*), that major disasters exist because of recent severe weather and flooding in the Upper Midwest. When this document was prepared, the following counties had been designated by the Federal Emergency Management Agency (pursuant to 44 CFR 206.40(b)) as areas affected by these disasters:

- In the state of South Dakota: all counties;
- In the state of North Dakota: all counties;
- In the state of Minnesota: Aitkin, Anoka, Becker, Beltrami, Benton, Big Stone, Blue Earth, Brown, Carver, Cass, Chippewa, Clay, Clearwater, Dakota, Douglas, Goodhue, Grant, Hennepin, Houston, Hubbard, Kandiyohi, Kittson, Lac Qui Parle, Lake of the Woods, Le Sueur, Lincoln, Lion, Mahanomen, Marshall, McLeod, Morrison, Nicollet, Norman, Otter Tail, Pennington, Polk, Pope, Ramsey, Red Lake, Redwood, Renville, Roseau, Scott, Sherburne, Sibley, Stearns, Stevens, St. Louis, Swift, Todd, Traverse, Wabasha, Wadena, Washington, Wilkin, Winona, Wright, and Yellow Medicine.

The PBGC is providing relief from certain deadlines and penalties. In general, this relief is applicable with respect to plans for which the administrator's or sponsor's principal place of business, or the office of a service provider, bank, insurance company, or other person maintaining information necessary to meet the applicable deadlines, is located in an area that has been or is hereafter designated a major disaster area on account of severe weather and flooding in the Upper Midwest occurring on or after April 15 and before June 30, 1997 (a "designated disaster area"). However, the extension (discussed below) for filing requests for reconsideration or appeals is applicable to any aggrieved person who is residing in, or whose principal place of business is within, a

designated disaster area, or with respect to whom the office of the service provider, bank, insurance company, or other person maintaining the information necessary to file the request for reconsideration or appeal is within such an area.

**Premiums**

The PBGC will waive the late payment penalty charge with respect to any premium payment required to be made on or after April 15, 1997, and before June 30, 1997, if the payment is made by June 30, 1997. The PBGC is not permitted by law to waive late payment interest charges. (ERISA section 4007(b); 29 CFR 4007.7 and 4007.8(b)(3).)

**Section 4071 Penalties**

For any of the following notices that is required to be filed with the PBGC on or after April 15, 1997, and before June 30, 1997, in order to avoid the assessment of section 4071 penalties, the PBGC will not assess a section 4071 penalty if the notice is filed by June 30, 1997:

(1) Post-distribution certification for single-employer plans (PBGC Form 501 or 602; ERISA section 4041 (b)(3)(B) or (c)(3)(B); 29 CFR 4041.27(h) or 4041.48(b)),

(2) Notice of termination for multiemployer plans (ERISA section 4041A; 29 CFR 4041A.11),

(3) Notice of plan amendments increasing benefits by more than \$10 million (ERISA section 307(e)),

(4) Missing participants information for single-employer plans (Schedule MP (including Attachments A and B) to PBGC Forms 501 and 602; ERISA section 4050; 29 CFR 4050.6), and

(5) Premium declarations (PBGC Forms 1 (including Schedule A) and 1-ES; ERISA section 4007; 29 CFR 4007.3).

The PBGC will not assess a section 4071 penalty for a failure to provide certain supporting information and documentation when a notice of failure to make required contributions totaling more than \$1 million (including interest) is timely filed, if the timely filed notice includes at least items 1 through 7 and items 11 and 12 of Form 200; the responses to items 8 through 10, with the certifications in items 11 and 12, may be filed late (PBGC Form 200; ERISA section 302(f)(4); 29 CFR 4043.81). This relief applies to notices required to be filed with the PBGC on or after April 15, 1997, and before June 30, 1997, provided that all supporting information and documentation are filed by June 30, 1997.

The PBGC is not automatically forgoing assessment of penalties under section 4071 for failure to comply with