## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 522

### Implantation or Injectable Dosage Form New Animal Drugs; Phenylbutazone Injection

**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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of a generic phenylbutazone injection in horses as an anti-inflammatory agent.

**EFFECTIVE DATE:** October 16, 1995.

**FOR FURTHER INFORMATION CONTACT:** Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, is the sponsor of ANADA 200–126 which provides for the use of generic Phenylbutazone 20% Injection (200 milligrams (mg) of phenylbutazone per milliliter (mL) of solution) for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

Approval of ANADA 200–126 for Phoenix Scientific's Phenylbutazone 20% Injection is as a generic copy of Coopers Animal Health's Butazolidin® (200 mg of phenylbutazone per mL) which is covered by NADA 011–575. The ANADA is approved as of September 1, 1995, and the regulations are amended in 21 CFR 522.1720 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulation contains an outdated footnote and superscript references citing the National Academy of Science/National Research Council (NAS/NRC) status of these products. The Generic Animal Drug and Patent Term Restoration Act of 1988 changed that status. The NAS/NRC footnote references are removed at this time.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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).

2. Section 522.1720 is amended by removing the footnote in paragraphs (c) and (d) and by revising paragraph (b)(2) to read as follows:

**§ 522.1720 Phenylbutazone injection.**

* * * * *

(b) * * *

(2) Approval for use of the 200 milligrams per milliliter drug in horses: See sponsor Nos. 000010, 000402, 000864, and 059130 in § 510.600(c) of this chapter.

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Dated: October 2, 1995.

Stephen F. Sundlof,

*Director, Center for Veterinary Medicine.*

[FR Doc. 95–25503 Filed 10–13–95; 8:45 am]

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### 21 CFR Part 558

### New Animal Drugs; 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 Syntex Animal Health, Division of Syntex Agribusiness, Inc., to Hoffman-La Roche, Inc.

**EFFECTIVE DATE:** October 16, 1995.

**FOR FURTHER INFORMATION CONTACT:** Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

**SUPPLEMENTARY INFORMATION:** Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, has informed FDA that it has transferred the ownership of, and all rights and interests in, approved NADA 141–025 (Laidlomycin) to Hoffman-La Roche, Inc., Nutley, NJ 07110–1199.

Accordingly, the agency is amending the regulations in 21 CFR 558.305 to reflect the change of sponsor.

List of Subject 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).

**§ 558.305 [Amended]**

2. Section 558.305 *Laidlomycin propionate potassium* is amended in paragraph (a) by removing ''000033'' and adding in its place ''000004''.

Dated: October 4, 1995.

Robert C. Livingston,

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 95–25504 Filed 10–13–95; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Parts 31 and 602

**[TD 8624]**

**RIN 1545–AT87**

### Reporting of Nonpayroll Withheld Tax Liabilities

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains final and temporary regulations relating to