75053–4005. This information may be examined at the FAA, Office of the Assistant Chief Counsel, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Monschke, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5116, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to Eurocopter Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters was published in the Federal Register on February 13, 1995 (60 FR 8205). That action proposed to require initial and repetitive inspections of the M/R blade upper and lower surfaces for bulging.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed, except for editorial changes and adding explanatory Note 1, relating to the scope of the applicability statement when modifications, alterations, or repairs have been made in the area subject to the requirements of the AD. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 125 helicopters of U.S. registry will be affected by this AD, that it will take approximately one-half work hour per helicopter to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $3,750.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

AD 95–21–12 Eurocopter Deutschland GmbH (ECD): Amendment 39–9399. Docket No. 94–SW–19–AD.

Applicability: Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To detect movement of a balance weight and to prevent severe vibrations and a subsequent precautionary landing, accomplish the following:

(a) Within the next 5 hours time-in-service (TIS) after the effective date of this AD, and thereafter, at intervals not to exceed 50 hours TIS, visually inspect the upper and lower surfaces of the main rotor blades (blades) in the area of the outboard lead balance weight in the marked inspection area for signs of bulging, in accordance with Paragraph 2.A. of the Accomplishment Instructions of Eurocopter Deutschland GmbH (ECD) Alert Service Bulletin ASB–MBB–BK 117–10–108, Revision 1, dated October 14, 1994.

(b) If a marked inspection area is not visible, mark the area in accordance with Paragraph 2.A. of the Accomplishment Instructions of Eurocopter Deutschland GmbH (ECD) Alert Service Bulletin ASB–MBB–BK 117–10–108, Revision 1, dated October 14, 1994, and then inspect in accordance with paragraph (a) of this AD.

(c) If bulging exceeds 1mm (0.040 inch) in height, remove the blade and replace it with an airworthy blade in accordance with the applicable maintenance manual.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) The inspection and replacement, if necessary, shall be done in accordance with Eurocopter Deutschland GmbH (ECD) Alert Service Bulletin ASB–MBB–BK 117–10–108, Revision 1, dated October 14, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005. Copies may be inspected at the FAA, Office of the Assistant Chief Counsel, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on November 20, 1995.

Issued in Fort Worth, Texas, on October 4, 1995.

Daniel P. Salvano,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 95–25522 Filed 10–13–95; 8:45 am]

BILLING CODE 4910–13–U

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.

* * * * *

Dated: October 2, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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