Compliance: Required as indicated, unless accomplished previously.

To minimize the potential hazards associated with operating the airplane in severe icing conditions by providing more clearly defined procedures and limitations associated with such conditions, accomplish the following:

(a) Within 30 days after the effective date of this AD, accomplish the requirements of paragraphs (a)(1) and (a)(2) of this AD.

Note 2: Operators must initiate action to notify and ensure that flight crewmembers are apprised of this change.

(1) Revise the FAA-approved Airplane Flight Manual (AFM) by incorporating the following into the Limitations Section of the AFM. This may be accomplished by inserting a copy of this AD in the AFM.

''WARNING

Severe icing may result from environmental conditions outside of those for which the airplane is certificated. Flight in freezing rain, freezing drizzle, or mixed icing conditions (supercooled liquid water and ice crystals) may result in ice build-up on protected surfaces exceeding the capability of the ice protection system, or may result in ice forming aft of the protected surfaces. This ice may not be shed using the ice protection systems, and may seriously degrade the performance and controllability of the airplane.

• During flight, severe icing conditions that exceed those for which the airplane is certificated shall be determined by the following visual cues. If one or more of these visual cues exists, immediately request priority handling from Air Traffic Control to facilitate a route or an altitude change to exit the icing conditions.

— Unusually extensive ice accreted on the airframe in areas not normally observed to collect ice.
— Accumulation of ice on the lower surface of the wing aft of the protected area.
— Accumulation of ice on the propeller spinner farther aft than normally observed.

• Since the autopilot may mask tactile cues that indicate adverse changes in handling characteristics, use of the autopilot is prohibited when any of the visual cues specified above exist, or when unusual lateral trim requirements or autopilot trim warnings are encountered while the airplane is in icing conditions.

• All icing detection lights must be operative prior to flight into icing conditions at night. [NOTE: This supersedes any relief provided by the Master Minimum Equipment List (MMEL).]''

(2) Revise the FAA-approved AFM by incorporating the following into the Procedures Section of the AFM. This may be accomplished by inserting a copy of this AD in the AFM.

''THE FOLLOWING WEATHER CONDITIONS MAY BE CONDUCIVE TO SEVERE IN-FLIGHT ICING

• Visible rain at temperatures below 0 degrees Celsius ambient air temperature.

• Droplets that splash or splatter on impact at temperatures below 0 degrees Celsius ambient air temperature.

PROCEDURES FOR EXITING THE SEVERE ICING ENVIRONMENT

These procedures are applicable to all flight phases from takeoff to landing. Monitor the ambient air temperature. While severe icing may form at temperatures as cold as −18 degrees Celsius, increased vigilance is warranted at temperatures around freezing with visible moisture present. If the visual cues specified in the Limitations Section of the AFM for identifying severe icing conditions are observed, accomplish the following:

• Immediately request priority handling from Air Traffic Control to facilitate a route or an altitude change to exit the severe icing conditions in order to avoid extended exposure to flight conditions more severe than those for which the airplane has been certificated.

• Avoid abrupt and excessive maneuvering that may exacerbate control difficulties.

• Do not engage the autopilot.

• If the autopilot is engaged, hold the control wheel firmly and disengage the autopilot.

• If an unusual roll response or uncommanded roll control movement is observed, reduce the angle-of-attack.

• Do not extend flaps during extended operation in icing conditions. Operation with flaps extended can result in a reduced wing angle-of- attack, with the possibility of ice forming on the upper surface further aft on the wing than normal, possibly aft of the protected area.

• If the flaps are extended, do not retract them until the airframe is clear of ice.

• Report these weather conditions to Air Traffic Control.''

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) 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 airplane to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on November 22, 1996.

Issued in Renton, Washington, on October 10, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–26720 Filed 10–17–96; 8:45 am]

BILLING CODE 4910–13–P

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 a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for use of phenylbutazone injection in dogs for relief of inflammatory conditions associated with the musculoskeletal system.

EFFECTIVE DATE: October 18, 1996.

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 St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed a supplement to ANADA 200–126 which provides for intravenous use of phenylbutazone injection in dogs for relief of inflammatory conditions associated with the musculoskeletal system. The ANADA is currently approved for use of the drug in horses. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of supplemental ANADA 200–126 for Phoenix's phenylbutazone injection 20 percent is as a generic copy of Cooper's NADA 11–575 Butazolidin® Injectable 20 percent (phenylbutazone). Supplemental ANADA 200–126 is approved as of September 6, 1996, and the regulations are amended by revising § 522.1720(b) (21 CFR 522.1720(b)), 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 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, 12420 Parklawn Dr., rm. 1–23, 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 revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 522.1720 Phenylbutazone injection.

* * * * *

(b) *Sponsors.* (1) Approval for use of the 200 milligrams per milliliter drug in dogs and horses: See sponsor Nos. 000031, 011716, 015579, and 059130 in § 510.600(c) of this chapter.

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

* * * * *

Dated: October 4, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–26685 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Polysulfated Glycosaminoglycan

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 Luitpold Pharmaceuticals, Inc. The supplemental NADA provides for intramuscular (i.m.) use of polysulfated glycosaminoglycan in horses for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the hock joint.

EFFECTIVE DATE: October 18, 1996.

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: Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967, is the sponsor of NADA 140–901, which provides for use of Adequan® i.m. (500 milligrams of polysulfated glycosaminoglycan per 5 milliliters of sterile aqueous solution). The NADA provides for the intra-articular and intramuscular use of polysulfated glycosaminoglycan in horses for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint. The firm has filed a supplement to the NADA that provides for intramuscular use of the drug product in horses for treatment of the same conditions of the hock joint. The supplemental NADA is approved as of September 13, 1996, and the regulations are amended in 21 CFR 522.1850 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 522.1850 is amended by revising paragraph (c)(1) and the first sentence of paragraphs (c)(2)(i) and (c)(2)(ii) to read as follows:

§ 522.1850 Polysulfated glycosaminoglycan.

* * * * *

(c) *Conditions of use—horses.* (1) *Indications for use.* Polysulfated glycosaminoglycan is for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(2) *Amount*—(i) *Intra-articular use (carpal)*: 250 milligrams once a week for 5 weeks.

* * * * *

(ii) *Intramuscular use (carpal and hock)*: 500 milligrams every 4 days for 28 days. * * *

* * * * *

Dated: October 4, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–26686 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 91

[OJP No. 1099]

RIN 1121–AA41

Grants program for Indian Tribes; Correction

AGENCY: Office of Justice Programs, Justice.

ACTION: Correction to interim rule.

SUMMARY: This document provides the correct contact telephone number for Dr. Stephen Amos. The number provided for further information in the interim final rule, 28 CFR Part 91, published in the Federal Register on Wednesday, September 24, 1996 (61 FR 49969) was incorrect.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen Amos, the Corrections Program Office at 1–800–848–6325.