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.