Collegeville, PA, Perkiomen Valley, RNAV (GPS) RWY 9, Amdt 1
Du Bois, PA, Du Bois-Jefferson County, RNAV (GPS) RWY 7, Orig
Du Bois, PA, Du Bois-Jefferson County, VOR/DME RNAV OR GPS RWY 7, Amdt 1, CANCELLED
Du Bois, PA, Du Bois-Jefferson County, Takeoff Minimums and Obstacle DP, Orig
Cotulla, TX, Cotulla-La Salle County, VOR–A, Amdt 13
Cotulla, TX, Cotulla-La Salle County, Takeoff Minimums and Obstacle DP, Orig
Farmville, VA, Farmville Regional, Takeoff Minimums and Obstacle DP, Orig
Huntington, WV, Tri-State/Milton J. Ferguson Field, ILS OR LOC RWY 12, Amdt 12
Huntington, WV, Tri-State/Milton J. Ferguson Field, ILS OR LOC RWY 30, Amdt 5
Huntington, WV, Tri-State/Milton J. Ferguson Field, RNAV (GPS) RWY 12, Amdt 1
Huntington, WV, Tri-State/Milton J. Ferguson Field, RADAR–1, Amdt 6
Huntington, WV, Tri-State/Milton J. Ferguson Field, Takeoff Minimums and Obstacle DP, Orig

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 a revised food safety warning on labeling for an injectable solution of polysulfated glycosaminoglycan used in horses.

DATES: This rule is effective October 5, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967, filed a supplement to NADA 140–901 for ADEQUAN i.m. (polysulfated glycosaminoglycan), an injectable solution approved for use in horses and dogs by veterinary prescription for noninfectious degenerative and/or traumatic joint disease. The supplemental NADA provides for a revised food safety warning for use in horses. The application is approved as of September 10, 2007, and the regulations are amended in 21 CFR 522.1850 to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under § 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Parts 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: 21 U.S.C. 360b.

■ 2. Revise § 522.1850 to read as follows:

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications*. Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan; each 5-mL ampule or vial contains 500 mg polysulfated glycosaminoglycan.

(b) *Sponsor*. See No. 010797 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Indications for use*. For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) *Amount*—(A) *Intra-articular use (carpal)*: 250 mg once a week for 5 weeks.

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

(iii) *Limitations*. Do not use in horses intended for human consumption.

(2) *Dogs*—(i) *Indications for use*. For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(ii) *Amount*. 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

Dated: September 26, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–19729 Filed 10–4–07; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs; Ractopamine

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 Elanco Animal Health. The supplemental NADA provides for an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter, a revision to bacterial pathogen nomenclature, and an increase in liver tolerance.

DATES: This rule is effective October 5, 2007.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0221, e-mail: *suzanne.sechen@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–233 that provides for use of OPTAFLEXX (ractopamine hydrochloride), MGA (melengestrol acetate), RUMENSIN (monensin), and TYLAN (tylosin phosphate) Type A medicated articles to