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

FDA has determined under 21 CFR 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 Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 520.446, revise paragraphs (b)(1) and (b)(2); remove paragraph (c); redesignate paragraph (d) as paragraph (c); and revise newly redesignated paragraph (c) to read as follows:

§ 520.446 Clindamycin capsules and tablets.

* * * * *

(b) * * *

(1) Nos. 000009 and 059130 for use of capsules described in paragraph (a)(1) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(2) of this section.

(c) *Conditions of use in dogs*—(1) Amount. Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

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

Dated: June 27, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–10877 Filed 7–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate Sodium 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 new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for a revised food safety warning on labeling for hyaluronate sodium injectable solution.

DATES: This rule is effective July 12, 2006.

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: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 112–048 for HYLARTIN (sodium hyaluronate) Injection, approved for veterinary prescription use by intra-articular injection for the treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis. The supplemental NADA provides for a revised food safety warning on the labeling. The application is approved as of May 30, 2006, and the regulations are amended in 21 CFR 522.1145 to reflect the approval.

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 21 CFR 25.33(d)(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 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: 21 U.S.C. 360b.

§ 522.1145 [Amended]

■ 2. In § 522.1145, in the heading remove the word ''injection''; and in paragraph (a)(3)(iii) remove the sentence ''Not for use in horses intended for food.'' and add in its place ''Do not use in horses intended for human consumption''.

Dated: June 27, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–10879 Filed 7–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol, Lasalocid, and Tylosin

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 Ivy Laboratories, Div. of Ivy Animal Health, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing melengestrol, lasalocid, and tylosin to make three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective July 12, 2006.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–430 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, BOVATEC (lasalocid), and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make dry and liquid, three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter. Ivy Laboratories' ANADA 200–430 is approved as a generic copy of NADA 138–992, sponsored by Pharmacia and Upjohn Co., a Division of Pfizer, Inc., for combination use of MGA 500 (melengestrol acetate) Liquid Premix, BOVATEC, and TYLAN in cattle feed. The application is approved as of June 1, 2006, and the regulations are amended in 21 CFR 558.342 to reflect the approval. The basis of approval is discussed in freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) 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 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: 21 U.S.C. 360b, 371.

§ 558.342 [Amended]

■ 2. In § 558.342, amend the table in paragraph (e)(1)(iv) in the ''Sponsor'' column by adding in numerical sequence ''021641''.

Dated: June 23, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–10878 Filed 7–11–06; 8:45 am]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4281

RIN 1212–AA55

Duties of Plan Sponsor Following Mass Withdrawal

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule; technical amendment.

SUMMARY: This document amends part 4281 (Duties of Plan Sponsor Following Mass Withdrawal) to make technical changes to conform to amendments made to part 4044 (Allocation of Assets in Single-Employer Plans) in a final rule published in the **Federal Register** on December 2, 2005. That final rule updated PBGC's mortality tables used for certain valuations for single-employer plans. Part 4281, which provides rules for valuing benefits in multiemployer plans following mass withdrawal, refers to the mortality tables in part 4044. Technical amendments are needed to conform the references in part 4281 to the changes in part 4044.

FOR FURTHER INFORMATION CONTACT: John H. Hanley, Director, or James L. Beller, Jr., Attorney, Legislative and Regulatory Department, PBGC, 1200 K Street, NW., Washington, DC 20005–4026; 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

DATES: Effective July 12, 2006.

SUPPLEMENTARY INFORMATION: On December 2, 2005, at 70 FR 72205, PBGC published a final rule modifying part 4044 of its regulations (Allocation of Assets in Single Employer Plans) to update the mortality tables in Appendix A. Part 4281 (Duties of Plan Sponsor Following Mass Withdrawal) refers to those mortality tables. Because conforming changes to those references in part 4281 were inadvertently omitted, those references are no longer accurate. However, the correct references are obvious.

The mortality assumptions used for valuations under part 4281 mirror the assumptions in part 4044. The mortality assumptions in the two parts were updated at the same time in a final rule published in 1993. The preamble to the associated proposed rule stated: ''The multiemployer regulation will be simultaneously amended so that the same mortality, loading, and interest assumptions will be employed to determine the values of benefits under multiemployer plans after a mass withdrawal.'' 58 FR at 5132 (January 19, 1993). Thus, it is clear there was no intent to change this correlation when the mortality tables in part 4044 were updated in 2005. It is necessary to use the updated mortality tables under part 4281 in order to avoid inappropriate benefit valuations under that part.

Because this rule conforms part 4281 in a way that was obviously intended when part 4044 was amended by the final rule published in the **Federal Register** on December 2, 2005, at 70 FR 72206, PBGC finds good cause to issue this technical amendment without prior proposal and opportunity for public comment and without a 30-day delayed effective date.

List of Subjects in 29 CFR Part 4281

Employee benefit plans, Pensions.

■ For the reasons set forth above, PBGC amends part 4281 of 29 CFR chapter XL as follows:

PART 4281—DUTIES OF PLAN SPONSOR FOLLOWING MASS WITHDRAWAL

■ 1. The authority citation for part 4281 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1341a, 1399(c)(1)(D), and 1441.