DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Mepivacaine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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. The supplemental NADA provides for revised food safety labeling for mepivacaine injectable solution used in horses for local anesthesia.

DATES: This rule is effective July 13, 2006.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, 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 100 703 for CARBOCAINE-V (mepivacaine hydrochloride) Sterile Aqueous Solution. The supplemental NADA provides for revised food safety labeling for mepivacaine injectable solution used in horses for local anesthesia. The application is approved as of June 2, 2006, and the regulations are amended in § 522.1372 (21 CFR 522.1372) to reflect the approval.

In addition, FDA has found that the April 1, 2005, edition of parts 500 to 599 of title 21 of the Code of Federal Regulations (CFR) does not accurately reflect the approved conditions of use for mepivacaine solution used in horses. These conditions of use were inadvertently deleted as a publication error. At this time, the regulations are being amended in § 522.1372 to correct this error and to format portions of this section to reflect a current format. This action is being taken to improve the accuracy of the regulations.

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(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.

■ 2. Revise § 522.1372 to read as follows:

§ 522.1372 Mepivacaine.

(a) *Specifications*. Each milliliter (mL) of solution contains 20 milligrams mepivacaine hydrochloride.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For nerve block, 3 to 5 mL; for epidural anesthesia, 5 to 20 mL; for intra-articular anesthesia, 10 to 15 mL; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to ventriculectomy, by topical spray, 25 to 40 mL, by infiltration, 20 to 50 mL.

(2) *Indications for use*. For use as a local anesthetic for infiltration, nerve block, intra-articular and epidural anesthesia, and topical and/or infiltration anesthesia of the laryngeal mucosa prior to ventriculectomy.

(3) *Limitations*. Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 30, 2006.

Steven D. Vaughn,

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

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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; Furosemide

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 Intervet Inc. The supplemental NADA provides for the revision of a food safety warning on labeling of furosemide injectable solution for use in horses.

DATES: This rule is effective July 13, 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: Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 34–478 for SALIX (furosemide) Injection 5%. The supplemental NADA provides for the revision of a food safety warning on labeling of furosemide injectable solution for use in horses. The supplemental application is approved as of June 20, 2006, and the regulations are amended in 21 CFR 522.1010 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(a)(1) that these actions are of a type that do 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