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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Display Date	7-12-06
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Carrier	A. Corbin

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 [*insert date of publication in the Federal Register*].

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.

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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 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. In § 522.1010, revise paragraph (b)(3); and add paragraphs (b)(4) and (d)(2)(iii) to read as follows:

§ 522.1010 Furosemide.

* * * * *

(b) * * *

(3) No. 059130 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(4) No. 057926 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(iii), and (d)(3) of this section.

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(d) * * *

(2) * * *

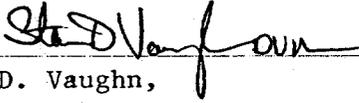
(iii) *Amount.* 250 to 500 mg/animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

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

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Dated: June 30, 2006
June 30, 2006.



Steven D. Vaughn,
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Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
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