Rules and Regulations

Federal Register
Vol. 69, No. 65
Monday, April 5, 2004

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Furosemide; Technical Amendment

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 the approved salts of injectable furosemide. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective April 5, 2004.

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Punderson, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4109, e-mail: *jeffrey.punderson@fda.gov*.

SUPPLEMENTARY INFORMATION: FDA has found that the animal drug regulations do not correctly identify the monoethanolamine salt of furosemide sponsored by Boehringer Ingelheim Vetmedica, Inc., and approved under NADA 127–034 and NADA 131–538. This error occurred with the approval of NADA 127–034 (49 FR 26715, June 29, 1984). This document amends the regulations in 21 CFR 522.1010 to correct this error.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting a nonsubstantive error.

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. Section 522.1010 is amended by revising paragraphs (a) and (b) to read as follows:

§ 522.1010 Furosemide.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 50 milligrams (mg) furosemide monoethanolamine.

(2) Each mL of solution contains 50 mg furosemide diethanolamine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section for use as in paragraph (d) of this section.

(1) No. 000010 as described in paragraph (a)(1) of this section for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 061623 as described in paragraph (a)(2) of this section for use as in paragraph (d)(2)(ii) of this section.

(3) Nos. 057926 and 059130 as described in paragraph (a)(2) of this section for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

* * * * *

Dated: March 19, 2004.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 04–7534 Filed 4–2–04; 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; Penicillin G Procaine Aqueous Suspension; Technical Amendment

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 the approved preslaughter withdrawal period in cattle following use of a penicillin G procaine injectable suspension. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective April 5, 2004.

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Punderson, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4109, e-mail: *jeffrey.punderson@fda.gov.*

SUPPLEMENTARY INFORMATION: FDA has found that the animal drug regulations do not reflect the preslaughter withdrawal period in cattle for Penicillin G Procaine Aqueous Suspension sponsored by G.C. Hanford Manufacturing Co. and approved under NADA 065–493. This error was introduced into the regulations when sections for certain pencillin-containing products were recodified (57 FR 37318, August 18, 1992). At this time, the regulations are being amended in 21 CFR 522.1696b to correct this error.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting a nonsubstantive error.

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.