

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DDM
Display Date 3-7-08
Publication Date 3-10-08
Certifier SP/SPC

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor; Ferric Oxide Injection; Gleptoferron Injection; Iron Dextran Complex Injection; Iron Hydrogenated Dextran Injection

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 a change of sponsor for two new animal drug applications (NADAs) for injectable iron supplements used in baby pigs from Boehringer Ingelheim Vetmedica, Inc., to Animal Health Pharmaceuticals, LLC. In addition, FDA is taking this opportunity to consolidate injectable iron supplements in a single section of the Code of Federal Regulations (CFR). This is being done to simplify and clarify the regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 106-772 for Iron-GARD Injection 100 milligrams/milliliter (mg/mL) and NADA 134-708 for Iron-GARD Injection 200 mg/mL to Animal Health Pharmaceuticals, LLC,

1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506. Accordingly, the regulations are amended in 21 CFR 522.1182 to reflect these changes of sponsorship.

In addition, FDA is taking this opportunity to consolidate such injectable iron supplements in a single section of the CFR. This is being done to simplify and clarify the regulations.

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.

§ 522.940 [Removed]

■ 2. Remove § 522.940.

§ 522.1055 [Removed]

■ 3. Remove § 522.1055.

■ 4. Revise § 522.1182 to read as follows:

§ 522.1182 Iron injection.

(a) *Specifications.* See § 510.440 of this chapter. Each milliliter (mL) of solution contains the equivalent of:

(1) 100 milligrams (mg) of elemental iron derived from:

(i) Ferric hydroxide;

(ii) Ferric oxide; or

(iii) Elemental iron.

(2) 200 mg of elemental iron derived from ferric hydroxide.

(b) *Sponsors and conditions of use.* It is used in baby pigs by sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 059130 and 068718 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For prevention of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection. Dosage may be repeated in approximately 10 days.

(2) No. 000856 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 mg at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 mg.

(3) Nos. 000061 and 062408 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 mg of elemental iron to animals from 1 to 3 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 mg of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(4) Nos. 051311 and 053501 for use of product described in paragraph (a)(1)(ii) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For treatment of iron deficiency anemia, administer 1 to 2 mL by intramuscular injection at 5 to 28 days of age.

(5) No. 053501 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection up to 4 weeks of age.

(6) Nos. 058005 and 059130 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular injection. Treatment may be repeated in 10 days.

(7) Nos. 059130 and 068718 for use of product described in paragraph (a)(2) of this section as follows:

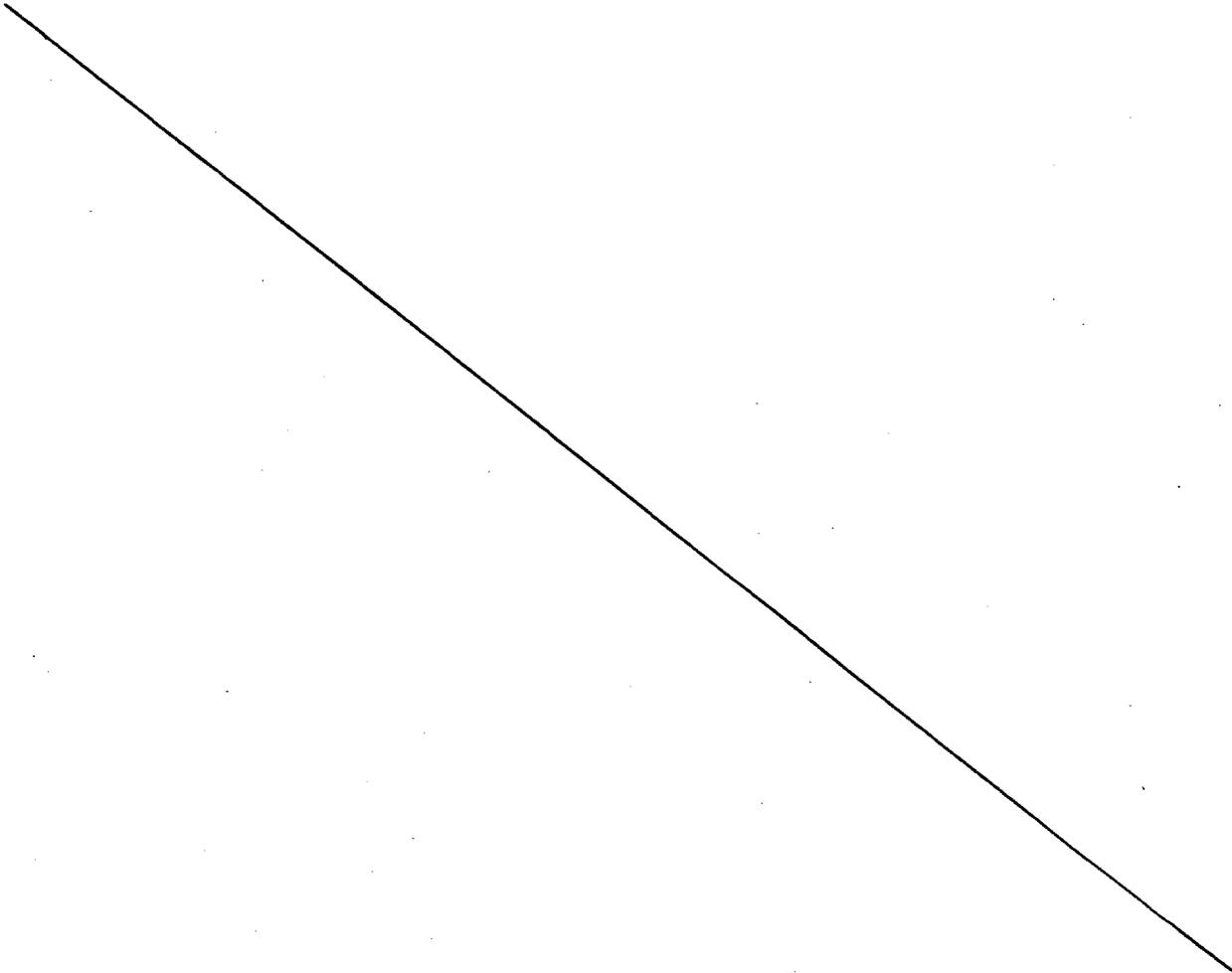
(i) For prevention of baby pig anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron (1 mL) at 1 to 3 days of age.

(ii) For treatment of baby pig anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron at the first sign of anemia.

(8) No. 062408 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 200 mg intramuscularly on or before 3 days of age.

(ii) For treatment of iron deficiency anemia, administer 200 mg intramuscularly.



§ 522.1183 [Removed]

■ 5. Remove § 522.1183.

Dated: 2/27/08

February 27, 2008.

Bernadette Dunham *over [Signature]*

Bernadette Dunham,
Director,
Center for Veterinary Medicine.

JL 2/29/08

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

[Signature]