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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; Iron Dextran 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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of iron dextran injection in baby pigs for prevention or treatment of iron deficiency anemia.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-256 that provides for use of iron dextran injection-200 in baby pigs for prevention or treatment of iron deficiency anemia.

Approval of Phoenix Scientific, Inc.'s ANADA 200-256 for iron dextran injection is as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s NADA 134-708 iron dextran complex injection. The ANADA is approved as of August 17, 1998, and the regulations are amended in 21 CFR 522.1182(b)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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)(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.

List of Subjects in 21 CFR Part 522

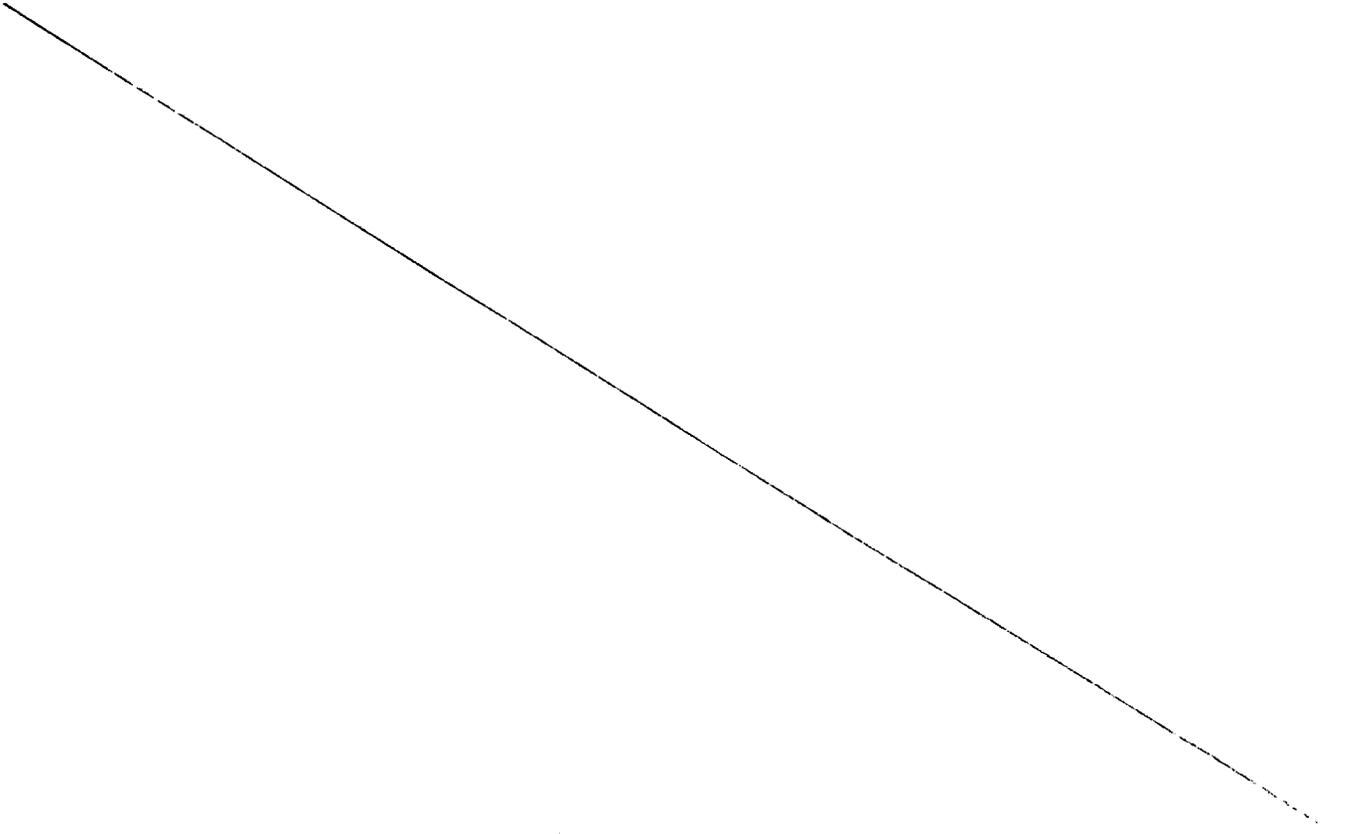
Animal drugs.

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:

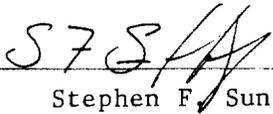
Authority: 21 U.S.C. 360b.



§ 522.1182 [Amended]

2. Section 522.1182 *Iron dextran complex injection* is amended in paragraph (b)(2)(i) by removing “No. 000010” and adding in its place “Nos. 000010 and 059130”.

Dated: 9/23/98
September 23, 1998



Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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