

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DMB
Display Date 2-28-02
Publication Date 3-1-02
Certifier D. Hawkins

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin Meglumine Solution

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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for use of flunixin meglumine solution by intravenous injection for control of fever and inflammation in beef cattle and nonlactating dairy cattle.

DATES: This rule is effective *[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 Street Ter., P.O. Box 6457, St. Joseph, MO 64506-0457, filed supplemental ANADA 200-124 that provides for veterinary prescription use of Flunixin Meglumine Injection by intravenous administration for control of fever and inflammation in beef cattle and nonlactating dairy cattle. The supplemental ANADA is approved as of November 1, 2001, and the regulations are amended in § 522.970 (21 CFR 522.970) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, §522.970 is being amended to add the drug labeler code (DLC) for Agri Laboratories, Ltd., which is the sponsor of approved ANADA ZOO-061 (62 FR 22888, April 28,

1997), but whose DLC (057561) was inadvertently omitted in a subsequent revision (63 FR 38749, July 20, 1998).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.1 1(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.

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 522.970 is amended by redesignating paragraph (d) as paragraph (e); by adding new paragraph (d); and by revising paragraphs (a), (b), and newly redesignated paragraphs (e)(1)(i), (e)(1)(iii), (e)(2)(i), and (e)(2)(iii) to read as follows:

§ 522.970 Flunixin meglumine solution.

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

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

(1) See Nos. 000061 and 059130 for use as in paragraph (e) of this section.

(2) See Nos. 000856 and 057561 for use as in paragraph (e)(1) of this section.

* * * * *

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) * * *

(1) * * *

(i) *Amount.* 0.5 mg per pound (/lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

* * * * *

(iii) *Limitations.* Not for use in horses intended for food.

(2) * * *

(i) *Amount.* 1.1 to 2.2 mg/kilogram (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into 2 doses administered at 12-hour intervals, intravenously, for up to 3 days.

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(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. Not for use in lactating or dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

Dated: 2/08/2002

February '8, 2002.

Claire M. Lathers

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

JK

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Dawn P. Hawkins