

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Flunixin

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 Schering-Plough Animal Health Corp. The supplemental NADA provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk.

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

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 101-479 that provides for the veterinary prescription use of BANAMINE (flunixin meglumine) Injectable Solution by intravenous injection in lactating dairy

cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk. The supplemental NADA is approved as of August 19, 2004, and the regulations are amended in 21 CFR 522.970 and 556.286 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 21 CFR 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 Division of Dockets Management (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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act the act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 19, 2004. The 3 years of marketing exclusivity applies only to the new indication of control of pyrexia associated with acute bovine mastitis.

The agency has determined under 21 CFR 25.33(d)(5) 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 522 and 556 are 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 revising the section heading; by revising paragraph (b)(1); by redesignating paragraph (b)(2) as paragraph (b)(3); by adding new paragraph (b)(2); and by revising paragraphs (e)(2) introductory text, (e)(2)(i), (e)(2)(ii), and (e)(2)(iii) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See No. 000061 for use as in paragraph (e) of this section.

(2) See Nos. 055529, 057561, and 059130 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

* * * * *

(e) * * *

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

(B) 2.2 mg/kg (1.0 mg/lb) of body weight given once by intravenous administration.

(ii) *Indications for use*. (A) For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(B) For control of pyrexia associated with acute bovine mastitis.

(iii) *Limitations*. Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For No. 000061: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For Nos. 055529, 057561, and 059130: Not for use in lactating or dry dairy cows.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. Section 556.286 is amended by revising the section heading; by revising paragraph (b); and by adding paragraph (c) to read as follows:

§ 556.286 Flunixin.

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(b) *Tolerances*—(1) *Cattle*. The tolerance for flunixin free acid (the marker residue) is:

(i) *Liver (the target tissue)*. 125 parts per billion (ppb).

(ii) *Muscle*. 25 ppb.

(iii) *Milk*. 2 ppb.

(2) [Reserved]

(c) *Related conditions of use*. See § 522.970 of this chapter.

Dated: September 27, 2004.

Stephen D. Vaughn,

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

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