

Dated: December 2, 2010.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2010-N-0002]

Implantation or Injectable Dosage Form 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 abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The supplemental ANADA provides for use of flunixin meglumine solution by intravenous injection in lactating dairy cows for control of pyrexia associated with acute bovine mastitis.

DATES: This rule is effective December 8, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200-061 that provides for veterinary prescription use of FLU-NIX (flunixin meglumine) Injectable Solution. The supplemental ANADA provides for use of flunixin meglumine solution by intravenous injection in lactating dairy cows for control of pyrexia associated with acute bovine mastitis. The supplemental application is approved as of September 27, 2010, and the regulations are amended in 21 CFR 522.970 to reflect the approval.

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.

The agency has determined under 21 CFR 25.33 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. In § 522.970, revise paragraphs (b), (e)(1)(iii), and (e)(2) to read as follows:

§ 522.970 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, 055529, and 061623 for use as in paragraph (e) of this section.

(2) See No. 000856 for use as in paragraph (e)(1) of this section.

(3) See Nos. 057561 and 059130 for use as in paragraphs (e)(1) and (2) of this section.

* * * * *

(e) * * *
 (1) * * *

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle—(i) Amounts and indications for use—(A)* Administer 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day intravenously, as a single dose or divided into two doses administered at 12-hour intervals, for up to 3 days for control of pyrexia associated with bovine respiratory disease and endotoxemia or for control of inflammation in endotoxemia.

(B) Administer 2.2 mg/kg (1.0 mg/lb) of body weight once intravenously for control of pyrexia associated with acute bovine mastitis.

(ii) *Limitations.* Cattle must not be slaughtered for human consumption within 4 days of last treatment. Milk that has been taken during treatment

and for 36 hours after the last treatment must not be used for food. Do not use in 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.

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Dated: December 1, 2010.

Elizabeth Rettie,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 84, and 85

[Docket No. FR-5350-F-02]

RIN 2501-AD50

Conforming Changes to Applicant Submission Requirements; Implementing Federal Financial Report and Central Contractor Registration Requirements

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule follows publication of a July 15, 2010, interim rule that revised HUD regulations to reference the new governmentwide Federal Financial Report (FFR) approved by the Office of Management and Budget (OMB). The FFR consolidates requirements from the OMB-issued Standard Forms SF-269, SF-269A, SF-272, and SF-272A into a single governmentwide form. In incorporating reference to the new FFR in its regulations, HUD amended its regulations to remove references to old and outdated forms that are no longer in use. The July 15, 2010, interim rule also codified the requirement that applicants for HUD assistance possess an active Central Contractor Registration (CCR). HUD is adopting the interim rule without change.

DATES: *Effective Date:* January 7, 2011.

FOR FURTHER INFORMATION CONTACT: Barbara Dorf, Director, Office of Departmental Grants Management and Oversight, Office of Administration, Chief Human Capital Officer, Department of Housing and Urban Development, 451 7th Street, SW., Room 3156, Washington, DC 20410-0500, telephone number 202-708-0667. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800-877-8339.