DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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 Norbrook Laboratories, Ltd. The supplemental ANADA provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of fever associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia.

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

FOR FURTHER INFORMATION CONTACT: Christopher Melluso, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *christopher.melluso@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed supplemental ANADA 200–308 that provides for veterinary prescription use of Flunixin Injection intravenously in lactating dairy cattle for control of fever associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. The supplemental ANADA is approved as of March 1, 2006, and the regulations

are amended in 21 CFR 522.970 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.

FDA 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 revising paragraph (e)(2)(iii) to read as follows:

§ 522.970 Flunixin.

* * * * *

(e) * * *

(2) * * *

(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 Nos.

000061, 055529, and 059130: 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 No. 057561: Not for use in lactating or dry dairy cows.

Dated: March 20, 2006.

Steven D. Vaughn,

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

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