§ 28.25 Change in control.

(a) After-the-fact notice. In cases in which no other filing is required under subpart B of this part, a foreign bank that operates a Federal branch or agency shall inform the OCC in writing of the direct or indirect acquisition of control of the foreign bank by any person or entity, or group of persons or entities acting in concert, within 14 calendar days after the foreign bank becomes aware of a change in control.

(b) Additional information. The foreign bank shall furnish the OCC with any additional information the OCC may require in connection with the acquisition of control.

§ 28.26 Loan production offices.

A Federal branch may establish lending offices, make credit decisions, and engage in other representational activities at a site other than a Federal branch office, subject to the same rights, privileges, requirements and limitations that apply to national banks under 12 CFR 7.1003, 7.1004, and 7.1005.


John D. Hawke, Jr.,
Comptroller of the Currency.

[FR Doc. 03–31342 Filed 12–18–03; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522

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 an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for the veterinary prescription use of flunixin meglumine injectable solution for the control of inflammation in horses, beef cattle, and nonlactating dairy cattle.

DATES: This rule is effective December 19, 2003.

FOR FURTHER INFORMATION CONTACT:
Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200–308 for the use of Flunixin Injection by veterinary prescription for the control of inflammation in horses, beef cattle, and nonlactating dairy cattle. Norbrook Laboratories’ Flunixin Injection is approved as a generic copy of Schering-Plough Animal Health’s BANAMINE (flunixin) Solution, approved under NADA 101–479. The ANADA is approved as of November 17, 2003, and the regulations in § 522.970 (21 CFR 522.970) are amended 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.

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 Subject 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

§ 522.970 [Amended]
2. Section 522.970 Flunixin meglumine solution is amended in paragraph (b)(1) by removing “000061 and 059130” and by adding in its place “000061, 055529, and 059130”.


Linda Tollefson,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 03–31294 Filed 12–18–03; 8:45 am]

BILLING CODE 4160–01–S