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 Agri Laboratories, Ltd. 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 September 2, 2004.

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: *lonnie.luther@fda.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 Flunixin Meglumine Injection by intravenous administration for control of fever and inflammation in beef cattle and nonlactating dairy cattle. The supplemental application is approved as of July 29, 2004, 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.

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.

§ 522.970 [Amended]

■ 2. Section 522.970 is amended in paragraph (b)(1) by removing ''Nos. 000061 and 059130'' and by adding in its place ''Nos. 000061, 057561, and 000856''; and in paragraph (b)(2) by removing ''Nos. 000856 and 057561'' and by adding in its place ''No. 000856''.

Dated: August 18, 2004.

Steven D. Vaughn,

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

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DEPARTMENT OF STATE

22 CFR Part 22

[Public Notice 4809]

RIN 1400–AB95

Schedule of Fees for Consular Services; Exemption From the Nonimmigrant Visa Application Processing Fee for Family Members of Individuals Killed or Critically Injured While Serving the United States

AGENCY: State Department.

ACTION: Interim rule.

SUMMARY: This rule amends the Schedule of Fees for Consular Services (''Schedule of Fees'' or ''Schedule'') to include an exemption from the nonimmigrant visa application processing fee for family members traveling to the United States for the funeral or burial of a U.S. Government employee killed in the line of duty or to visit a U.S. Government employee critically injured in the line of duty.

DATES: *Implementation Date:* This interim rule is effective September 2, 2004. Interested parties are invited to submit written comments by September 24, 2004.

ADDRESSES: Comments may be submitted in writing to the Office of the Executive Director, Bureau of Consular Affairs, Department of State, Suite H1004, 2401 E Street NW., Washington, DC 20520. Comments may also be forwarded via e-mail to *fees@state.gov*. In addition, this document may be viewed and comments submitted by going to the ''Regulations.gov'' Web site at *http://www.regulations.gov/index.cfm*.

FOR FURTHER INFORMATION CONTACT: Phillip Min, Office of the Executive Director, Bureau of Consular Affairs, telefax: 202–663–2499; e-mail: *fees@state.gov*.

SUPPLEMENTARY INFORMATION:

Background

This rule amends the Schedule of Fees for Consular Services, 22 CFR 22.1, effective immediately. In addition, the amendment made by this rule will be incorporated into the proposed Schedule of Fees published as a proposed rule for comment in the **Federal Register** (Public Notice 4765) on July 19, 2004. See 69 FR 42913–42919.

Consular officers are required by law to charge fees as established in the Schedule of Fees for Consular Services, and they may not grant exemptions from fees set forth in the Schedule except as specifically authorized in the Schedule. The Schedule includes nonimmigrant visa reciprocity fees established pursuant to Section 281 of the Immigration and Nationality Act (8 U.S.C. 1351), and a nonimmigrant visa application processing fee, commonly known as the ''machine readable visa'' or ''MRV'' fee, which generally recovers from the visa applicant the full cost of processing the visa application on the assumption that in most cases nonimmigrant visa services are provided primarily for the benefit of the individual applicant. Current exemptions from the MRV fee exist only for applicants for A, G, C–3, NATO, and diplomatic visas; applicants for J visas participating in U.S. Government-sponsored exchanges; persons who need replacement visas when the original visa was not properly affixed or needs to be reissued through no fault of the applicant; applicants traveling to provide charitable services as determined by the Department of State; and U.S. Government employees traveling on official business.