

**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](mailto: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.*  
[FR Doc. 04-19987 Filed 9-1-04; 8:45 am]

**BILLING CODE 4160-01-S**

**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](mailto: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](mailto: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.

The new exemption from the nonimmigrant visa application processing (MRV) fee will provide a waiver of the fee for an applicant who is an immediate family member of a U.S. Government employee killed in the line of duty and who is traveling to attend the employee's funeral and/or burial. The new exemption will also be applicable to a family member visiting a U.S. Government employee who has been critically injured in the line of duty during the period of emergency treatment and convalescence. The exemption will extend to a surviving parent, sibling, spouse, son, or daughter of the deceased or injured U.S. Government employee. This exemption appropriately shifts the cost of visa processing in such cases to the general public because it is in the national interest to assist close non-U.S. citizen relatives of U.S. Government employees killed or critically injured in the line of duty traveling to the United States for funeral and/or burial events or for visitation during emergency treatment and convalescence.

#### Regulatory Findings

##### *Administrative Procedure Act*

The Department is publishing this rule as an interim rule effective upon publication under the good cause authorities of 5 U.S.C. 553(b)(B) and (d)(3) and the exemption provision of 5 U.S.C. 553 (d)(1).

##### *Regulatory Flexibility Act*

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities as defined in 5 U.S.C. 601(6). Adding the exemption will have no economic impact on such entities.

##### *Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

##### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by 5 U.S.C. 801–808, which constitute the Congressional Review portion (Subtitle E) of the Small Business Regulatory Enforcement Act of

1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

##### *Executive Order 12866*

The Department of State does not consider this rule to be a “significant regulatory action” under Executive Order 12866, section 3(f), Regulatory Planning and Review. In addition, the Department is exempt from Executive Order 12866 except to the extent that it is promulgating regulations in conjunction with a domestic agency that are significant regulatory actions. The Department has nevertheless reviewed the regulation to ensure its consistency with the regulatory philosophy and principles set forth in that Executive Order.

##### *Executive Order 12988: Civil Justice Reform*

The Department has reviewed this regulation in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

##### *Executive Order 13132*

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

##### *Paperwork Reduction Act*

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

##### **List of Subjects in 22 CFR Part 22**

Consular services, Fees, Schedule of fees for Consular Services, Passports, Visas.

■ For the reasons set forth in the preamble, part 22 of title 22 of the Code of Federal Regulations is amended as follows:

#### **PART 22—SCHEDULE OF FEES FOR CONSULAR SERVICES— DEPARTMENT OF STATE AND FOREIGN SERVICE**

■ 1. The authority citation for part 22 continues to read as follows:

**Authority:** 8 U.S.C. 1153 note, 1351, 1351 note; 10 U.S.C. 2602(c); 22 U.S.C. 214, 2504(a), 4201, 4206, 4215, 4219; 31 U.S.C. 9701; Pub. L. 105–277, 112 Stat. 2681 *et seq.*; E.O. 10718, 22 FR 4632, 3 CFR, 1954–1958 Comp., p. 382; E.O. 11295, 31 FR 10603, 3 CFR, 1966–1970 Comp., p. 570.

■ 2. Section 22.1 is amended in item 22 of the table by adding paragraph (g) to read as follows:

##### **§ 22.1 Schedule of fees.**

\* \* \* \* \*

##### *Schedule of Fees for Consular Services*

Item No.	Fee
* * *	* * *

\* \* \*

■ 22. \* \* \*  
(g) A parent, sibling, spouse, or child of a U.S. Government employee killed in the line of duty who is traveling to attend the employee's funeral and/or burial; or a parent, sibling, spouse, son, or daughter of a U.S. Government employee critically injured in the line of duty for visitation during emergency treatment and convalescence. [24–MRV EXEMPT] \* \* \* NO FEE

\* \* \*

August 23, 2004.

**Grant Green, Jr.,**

*Under Secretary of State for Management,  
Department of State.*

[FR Doc. 04–20043 Filed 9–1–04; 8:45 am]

**BILLING CODE 4710–06–P**

#### **DEPARTMENT OF THE TREASURY**

##### **Fiscal Service**

##### **31 CFR Part 356**

[Department of the Treasury Circular, Public Debt Series No. 1–93]

#### **Sale and Issue of Marketable Treasury Bills, Notes, and Bonds: Six-Decimal Pricing, Negative-Yield Bidding, Zero-Filling, and Noncompetitive Bidding and Award Limit Increase**

**AGENCY:** Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury (“Treasury,” “We,” or “Us”) is issuing in final form an amendment to its regulations (Uniform Offering Circular for the Sale and Issue of