Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''Marsam Pharmaceuticals, Inc.,'' and in the table in paragraph (c)(2) by numerically adding an entry for ''000209'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * * *
Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.	000209
* * *	* * * * *

(2) * * *

Drug labeler code	Firm name and address
* *	* * * * *
000209	Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.
* *	* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 529.1186 is amended by revising paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 000074, 000209, 010019, 012164, and 059258 in § 510.600(c) of this chapter.

* * * * *

Dated: April 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–11685 Filed 4–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Spectinomycin 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 a new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The NADA provides for veterinary prescription use of spectinomycin solution as a subcutaneous injection in cattle for treatment of bovine respiratory disease.

EFFECTIVE DATE: May 1, 1998.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed NADA 141–077 that provides for veterinary prescription use of Adspec™ (spectinomycin) sterile solution for cattle, by subcutaneous injection in the neck, for treatment of bovine respiratory disease (pneumonia) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. The NADA is approved as of January 28, 1998, and the regulations are amended by adding § 522.2121 (21 CFR 522.2121) to reflect the approval.

A tolerance for residues of spectinomycin in edible tissues of cattle has not been previously established. The regulations are amended in 21 CFR 556.600 to provide a tolerance for spectinomycin residues in cattle kidney (target tissue) and in cattle muscle.

FDA is also amending the regulations to provide for the acceptable daily intake (ADI) for total residues of spectinomycin. The ADI is the amount of total drug residue that can be consumed by humans every day. Previously, FDA had provided for safe concentrations, which represent the ADI corrected for consumption. The safe concentrations were confusing because few individuals understood the relationship between safe concentration, a value representing total residues, and tolerance, the part of the drug residue in a given tissue that is detected by an analytical method. To eliminate this confusion, FDA is codifying the ADI.

Also, the heading of § 522.2120 *Spectinomycin injection* (21 CFR 522.2120) is revised to ''§ 522.2120 *Spectinomycin dihydrochloride injection*'' to clarify the difference between § 522.2120 and § 522.2121 *Spectinomycin sulfate solution*.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning January 28, 1998, because the application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are 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.

§ 522.2120 [Amended]

2. Section 522.2120 *Spectinomycin injection* is amended by revising the heading to read ''*Spectinomycin dihydrochloride injection*.''

3. Section 522.2121 is added to read as follows:

§ 522.2121 Spectinomycin sulfate solution.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams of spectinomycin.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.600 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Dose*. 10 to 15 milligrams per kilogram of body weight, at 24-hour intervals for 3 to 5 consecutive days.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (pneumonia) associated with *Pasteurella haemolytica, P. multocida*, and *Haemophilus somnus*.

(iii) *Limitations*. For subcutaneous injection in the neck. Do not inject more than 50 milliliters at each site. Do not slaughter within 11 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause residues in milk. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

4. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

5. Section 556.600 is revised to read as follows:

§ 556.600 Spectinomycin.

(a) *Acceptible daily intake (ADI)*. The ADI for total residues of spectinomycin is 25 micrograms per kilogram of body weight per day.

(b) *Chickens and turkeys*. A tolerance of 0.1 part per million (ppm) for negligible residues of spectinomycin in uncooked edible tissues of chickens and turkeys is established.

(c) *Cattle*. A tolerance of 4 ppm for parent spectinomycin (marker residue) in kidney (target tissue) is established. A tolerance of 0.4 ppm for parent spectinomycin in cattle muscle is established.

Dated: April 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–11686 Filed 4–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2793]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended—Fees for Application and Issuance of Nonimmigrant Visas

AGENCY: Department of State.

ACTION: Interim rule with request for comments.

SUMMARY: This rule results from a recent amendment to the law. It permits the Secretary of State to waive the visa fees for a nonimmigrant alien who will be engaged in charitable activities in the United States, subject to criteria the Secretary sets up. This provision became effective on the date of enactment. This rule implements that amendment.

DATES: This interim rule is effective May 1, 1998. Written comments are invited and must be received on or before June 30, 1998.

ADDRESSES: Written comments may be submitted, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20520–0106.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20520–0106, (202) 663–1204.

SUPPLEMENTARY INFORMATION: Section 2 of Pub. L. 105–54 of October 7, 1997, amended section 281 of the Immigration and Nationality Act, as amended, (INA), by adding a sentence providing for the waiver or reduction of nonimmigrant visa fees under certain circumstances for aliens coming to the United States to engage in charitable activities.

Current rules relating to nonimmigrant visa fees are contained in 22 CFR 41.107 subsection (c) which describes certain aliens exempted from fees. This rule expands that subsection to include those individuals who are coming primarily for charitable purposes or for purposes related thereto. As Senator Abraham (a co-sponsor) stated in the Senate discussion of the amendment of INA 281, ''It is not in the U.S. interest to impose fees that inhibit or otherwise burden individuals who seek to help our communities.'' It is in this spirit underlying the legislation that this interim rule has been developed.

The statute provides that the waiver or reduction of fees for application and issuance of a nonimmigrant visa is subject to criteria prescribed by the Secretary of State, including the duration of stay and the financial burden upon the charitable organization.In keeping with that injunction, it is deemed appropriate to require prospective beneficiary charitable organizations to request the relief to be provided because of the financial burden and to furnish sufficient information to establish that the alien(s) concerned will be engaged in activities which motivated the