

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.

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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

enactment of this provision. The request should be furnished in writing, *inter alia* to provide documentation reconciling the number of visas issued with the lesser amount of fees collected.

Thus, the current text of 22 CFR 41.107(c) will become "(c)(1)" and a new (c)(2) will set forth the data required to support the waiver of the fees. These include, in (c)(2)(i), disclosure of whether the organization, if U.S.-based, is tax exempt as a charitable organization under 26 U.S.C. 501(c) or, if foreign, is equivalently recognized as a charitable organization in the country in which based. Section 41.107(c)(2)(ii) requires that the activities in which the alien(s) will engage will be charitable in nature, providing assistance to the poor and needy including, but not limited to, those activities identified in the legislation. Section 41.107(c)(2)(iii) requires such identifying information as the location in which the services will be provided and the number of and identifying data regarding each of the alien(s) concerned. Finally, § 41.107(c)(2)(iv) seeks data on the proposed duration of the temporary stay of the alien(s) in the United States, which should be commensurate with both the classification in which the alien(s) will be applying and the purposes for which the alien(s) will be entering the United States.

Regulatory Analysis and Notices

Interim Rule

The implementation of this rule as an interim rule, with a 60-day provision for post-promulgation public comments, is based on the "good cause" exceptions set forth at 5 U.S.C. 553(b)(3)(B) and 553(d)(3). The provision of law being implemented became effective on enactment on October 7, 1997. It provides a benefit to institutions that it is in the interest of the United States as determined by Congress to benefit. Delay of the benefit for public notice and comment is unnecessary and inconsistent with the intent of the law.

The Regulatory Flexibility Act

Pursuant to § 605 of the Regulatory Flexibility Act, the Department has assessed the potential impact of this rule, and the Assistant Secretary for Consular Affairs hereby certifies, that it is not expected to have a significant economic impact on a substantial number of small entities and will benefit those that are charitable organizations.

E.O. 12988 and E.O. 12866

This rule has been reviewed as required under E.O. 12998 and determined to be in compliance therewith. This rule is exempt from review under E.O. 12866, but has been reviewed internally by the Department to ensure consistency therewith. The rule does not directly affect states or local governments or Federal relationships and does not create unfunded mandates.

5 U.S.C. Chapter 8

As required by 5 U.S.C., chapter 8, the Department has screened this rule and determined that it is not a major rule, as defined in 5 U.S.C. 80412.

Paperwork Reduction Act

While charitable organizations requesting this benefit will have to apply with information matching their situation to legal requirements, that information will be used for agency decisions on individual visas and not used for public dissemination or statistical purposes.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports, Visas.

In view of the foregoing, 22 CFR part 41 is amended as follows:

PART 41—[AMENDED]

1. The authority citation for part 41 continues to read:

Authority: 8 U.S.C. 1104.

2. Section 41.107 is amended by redesignating paragraph (c) as paragraph (c)(1) and adding a new paragraph (c)(2) to read as follows:

§ 41.107 Visa fees.

* * * * *

(c) * * *

(2) The consular officer shall waive the nonimmigrant visa application and issuance fees for an alien who will be engaging in charitable activities for a charitable organization upon the written request of the charitable organization claiming that it will find the fees a financial burden, if the consular officer is satisfied that:

(i) The organization seeking relief from the fees is, if based in the United States, tax-exempt as a charitable organization under the provisions of section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)); if a foreign organization based outside the United States, it establishes that it is recognized as a charitable institution by the government of the country in which it is based under criteria substantially similar to those of section 501(c)(3), and

(ii) The charitable activities in which the alien will engage are specified and will be a part of, or will be related to and in support of, the organization's provision of services, including but not limited to health care, food and housing, job training, and similar direct services and assistance to the poor and needy, and

(iii) The request includes the location of the proposed activities, the number and identifying data of each of the alien(s) who will be applying for visas, and

(iv) The proposed duration of the alien(s)'s temporary stay in the United States is reasonably consistent with the charitable purpose for which the alien(s) seek to enter the United States.

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Dated: April 15, 1998.

Donna J. Hamilton,

Acting Assistant Secretary for Consular Affairs.

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DEPARTMENT OF JUSTICE

28 CFR Part 51

[Order No. 2149-98]

RIN 1190-AA35

Procedures for the Administration of Section 5 of the Voting Rights Act of 1965, as Amended; Revision of Procedures

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice is revising its administrative guidelines regarding preclearance of voting changes under Section 5 of the Voting Rights Act of 1965. The amendment is necessary to conform the Department's guidelines with recent case law.

DATES: Effective May 1, 1998.

FOR FURTHER INFORMATION CONTACT: David H. Hunter, Attorney, Voting Section, Civil Rights Division, 202-307-2898, 1-800-253-3931, or david.h.hunter@usdoj.gov.

SUPPLEMENTARY INFORMATION: Section 5 of the Voting Rights Act of 1965, as amended, 42 U.S.C. 1973c, requires certain jurisdictions (listed in the appendix to the Procedures) to obtain "preclearance" from either the United States District Court for the District of Columbia or from the United States Attorney General before implementing any new standard, practice, or procedure that affects voting.

The Supreme Court held in *Reno v. Bossier Parish School Board*, 117 S.Ct.