

described in § 558.600(c)(4) (21 CFR 558.600(c)(4)). The supplemental NADA is approved as of August 6, 1998, and the regulations are amended in § 558.600(c)(4)(ii) to reflect the approval.

Approval of this supplemental NADA does not require additional safety or effectiveness data. A freedom of information summary as provided under 21 CFR part 20 and 514.11(e)(2)(ii) is not required.

The agency has determined under 21 CFR 25.33(a)(3) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.600 [Amended]

2. Section 558.600 *Tiamulin* is amended in paragraph (c)(4)(ii) by removing “046573 and 063238” and adding in its place “046573, 053389, and 063238”.

Dated: September 20, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-26426 Filed 10-1-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Monensin and Bacitracin Methyle Disalicylate

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 new animal

drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for using approved single ingredient monensin and bacitracin methylene disalicylate (BMD) Type A medicated articles to make an additional approved combination for a monensin/BMD Type C medicated turkey feed.

EFFECTIVE DATE: October 2, 1998.

FOR FURTHER INFORMATION CONTACT:

Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 140-937 that provides for combining approved Coban® (45 and 60 grams per pound (g/lb) monensin) and BMD® (25, 30, 40, 50, 60, or 75 g/lb BMD) Type A medicated articles to make Type C medicated turkey feeds containing 54 to 90 g/ton (t) monensin and 200 g/t BMD. The monensin/BMD Type C turkey feeds are used for the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to BMD. The supplemental NADA is approved as of August 13, 1998, and 21 CFR 558.355(f)(2)(iii) is added to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 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)(2) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

2. Section 558.355 is amended by adding paragraph (f)(2)(iii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(iii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 200 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

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Dated: September 20, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-26425 Filed 10-1-98; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2894]

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

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule finalizes, with one amendment, the interim rule published May 1, 1998, (63 FR 24107) relating to the waiver of visa fees for a

nonimmigrant alien who will be engaged in charitable activities in the United States. It also discusses the comments received in response to that rule.

DATES: This rule is effective October 2, 1998.

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: Only one set of comments was received in response to the interim rule. The responder approved of the formulation of the requirement relating to the fees being a financial burden but had reservations about the other portions of the regulations added as a new paragraph (2) to 22 CFR 41.107(c).

Charitable Organizations

Specifically, the commenter was concerned by the language relating to a foreign charitable organization as needing to be recognized by its government "under criteria substantially similar to those of section 501(c)(3)" (the benchmark for charitable institutions in the United States), to wit, "To interpret 'substantially similar' to mean 'almost the same', is problematic". The commenter thus proposes that we apply the 501(c)(3) analogy only to institutions in countries which do not have any laws recognizing public charities.

The interim rule analogized to section 501(c)(3) of the Internal Revenue Code because it relates specifically to organizations engaged in charitable activities, as distinct from other non-profit organizations which are also tax-exempt under 501(c). We believe this to be a necessary distinction in connection with a provision of law designed explicitly to benefit those "coming to the United States primarily for * * * a charitable purpose". We are willing to accept the legal classification by other governments of charitable institutions, however, and modify that subparagraph accordingly.

Who Can Benefit?

The commenter was also concerned that section 41.107(c)(2)(ii) "could be interpreted as limiting the charitable activities for services 'only to the poor and needy'" (emphasis supplied by the commenter). "The statutory language does not limit the range of charitable services to the poor and needy." Fear was then expressed that this could disqualify providers of nursing services in hospitals that treat both those who

are poor and needy and those who are not. The Department believes that the intent of the provision, informally dubbed by its sponsor as "the Mother Theresa amendment", did indeed relate specifically to assistance to the poor and needy. This belief stems directly from the express language of the statute: "* * * the Secretary shall waive or reduce the fee * * * for any alien coming to the United States primarily for, * * * direct service or assistance to poor or otherwise needy individuals in the United States." (emphasis supplied) The Department also believes, however, that laws must be implemented reasonably, and therefore would not disqualify health-care providers who would be working at not-for-profit hospitals that were established primarily for the care of the poor and needy but may also take in some (not more than 25%) paying patients. Therefore, although the regulation will not be amended, the Department will issue further guidance to consular officers in this regard.

Location and Duration

Not least, the commenting organization was concerned by paragraph (c)(2)(iii) which requires that the letter requesting the fee waiver specify the location in which the alien(s) will be providing charitable services. Many religious organizations have widespread service locations and the commenter suggested that the sponsoring agency should determine when or where the alien(s) would be performing the charitable acts. The regulation merely requires that determination to have been made and stated in the application.

The Department must interpret the law, with respect to the issuance or refusal of visas, with due respect not only to the letter and intent of the provision but also to the practicalities involved. These practicalities include both placing the least burdensome impact possible on the beneficiary and providing the most effective, least bureaucratic methods to ensure that the law not be abused.

The Department does not believe that this particular commenting organization would take advantage of any loosening of the regulatory language. Nonetheless, experience dictates that attempted fraud and misrepresentation are and always have been rampant with respect to entry into the United States. The statute in this case is clear: "Subject to such criteria as the Secretary of State may prescribe, * * * for any alien coming to the United States primarily for, or in activities related to, a charitable purpose

involving health or nursing care, the provision of food or housing, job training, or any other similar direct service or assistance to poor or otherwise needy individuals * * *" (emphasis supplied). The regulation set forth on May 1 requires only the assertion of verifiable data regarding the specific charitable purpose for which the alien intends to enter the United States as a nonimmigrant. In the absence of both a location and a proposed duration of stay which are clearly related to the charitable purpose for which the alien seeks to enter, compliance with the statutory requirement could not be verified at the time of application.

Therefore, the interim regulation becomes a final rule with one amendment as noted above.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports and visas.

In view of the foregoing, the interim rule amending 22 CFR part 41 which was published at 63 FR 24107 on May 1, 1998, is adopted as a final rule with the following change:

PART 41—[AMENDED]

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

Authority: 8 U.S.C. 1104.

2. Section 41.107(c)(2)(i) is amended to read as follows:

§ 41.107 Visa fees

* * * * *

(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 in a country having laws according recognition to charitable institutions, that it establishes that it is recognized as a charitable institution by that government; and if a foreign organization based in a country without such laws, that it is engaged in activities substantially similar to those underlying section 501(c)(3), and

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Dated: September 8, 1998.

Mary A. Ryan,

Assistant Secretary for Consular Affairs.

[FR Doc. 98-26383 Filed 10-1-98; 8:45 am]

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