

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360ccc-2(c)), this approval qualifies for 7 years of exclusive marketing rights beginning on the date of approval, because the new animal drug has been declared a designated drug by FDA under section 573(a) of the Act.

The agency has determined under 21 CFR 25.33(d)(4) 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

21 CFR Part 520

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 520 and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Revise § 520.45a to read as follows:

§ 520.45a Albendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 45.5 milligrams (mg) (4.55 percent) or 113.6 mg (11.36 percent) albendazole.

(b) *Sponsor.* See No. 000069 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use—(1) Cattle.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/pound (lb) body weight (10 mg/kilogram (kg)) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni* and *M. expansa*); adult and 4th stage larvae

of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls.

(2) *Sheep.* Administer 4.45 or 11.36 percent suspension:

(i) *Amount.* 3.4 mg/lb body weight (7.5 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica* and *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcincta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams.

(3) *Goats.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/lb body weight (10 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For the treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats.

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to does during the first 30 days of pregnancy or for 30 days after removal of bucks.

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

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

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

■ 4. In § 556.34, revise paragraph (b) and add paragraph (c) to read as follows:

§ 556.34 Albendazole.

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(b) *Tolerances.* The tolerances for albendazole 2-aminosulfone (marker residue) are:

(1) *Cattle—(i) Liver (target tissue):* 0.2 parts per million (ppm).

(ii) *Muscle:* 0.05 ppm.

(2) *Sheep—(i) Liver (target tissue):* 0.25 ppm.

(ii) *Muscle:* 0.05 ppm.

(3) *Goat—(i) Liver (target tissue):* 0.25 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See § 520.45 of this chapter.

Dated: February 19, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF STATE

22 CFR Part 42

[Public Notice: 6114]

Visas: Documentation of immigrants Under the Immigration and Nationality Act, as Amended

AGENCY: Department of State.

ACTION: Final Rule.

SUMMARY: This rule revises the procedure for notifying the beneficiary of an immigrant visa petition of the termination of the immigrant visa registration because of the failure of the beneficiary to pursue the application within a specified time, by providing that such notification will be made by National Visa Center directly to the beneficiary.

DATES: This rule is effective February 29, 2008.

FOR FURTHER INFORMATION CONTACT: Charles Robertson, Legislation and Regulations Division, Visa Services, Department of State, 2401 E Street, NW., Room L-603D, Washington, DC 20520-0106, (202) 663-1202, e-mail (robertsonce@state.gov).

SUPPLEMENTARY INFORMATION:

Why is the Department promulgating this rule?

In the past, the consular officer at the post where an alien was registered as a beneficiary of an immigrant visa petition was responsible for notifying the alien of the termination of the immigrant visa registration if the alien failed to pursue the application within one year after being notified that a visa was available. The consular officer based this notification on information received from the National Visa Center (NVC). Now, the NVC will make this notification directly to the alien.

How does this change affect the alien?

There is no change from the point of view of the alien. The alien still has the ability to apply for reinstatement of the immigrant visa registration. Such application should be sent to the National Visa Center and it will be forwarded to the consular officer at the post where the alien was registered, under the same conditions as before.

Regulatory Findings

Administrative Procedure Act

This regulation involves a foreign affairs function of the United States and, therefore, in accordance with 5 U.S.C. 553(a)(1), is not subject to the rule making procedures set forth at 5 U.S.C. 553.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth at sections 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 603 and 604). Nonetheless, consistent with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. This regulates individual aliens who seek consideration for immigrant visas and does not affect any small entities, as defined in 5 U.S.C. 601(6).

The Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UFMA), Public Law 104-4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will

it significantly or uniquely affect small governments.

The Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121. 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 adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

Executive Order 12866

The Department of State has reviewed this final rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of the final regulation justify its costs. The Department does not consider the final rule to be an economically significant action within the scope of section 3(f)(1) of the Executive Order since it is not likely to have an annual effect on the economy of \$100 million or more or to adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders No. 12372 and No. 13132.

Paperwork Reduction Act

This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

List of Subjects in 22 CFR Part 42

Aliens, Foreign officials, Immigration, Passports and Visas.

■ Accordingly, for the reasons stated in the preamble, Title 22 Part 42 is amended as follows:

PART 42—[AMENDED]

1. The authority citation for part 42 continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105-277, 112 Stat. 2681-795 through 2681-801. Additional authority is derived from Section 104 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA) Pub. L. 104-208, 110 Stat. 3546.

■ 2. Revise § 42.83(c) to read as follows:

§ 42.83 Termination of registration.

* * * * *

(c) *Notice of termination.* Upon the termination of registration under paragraph (a) of this section, the National Visa Center (NVC) shall notify the alien of the termination. The NVC shall also inform the alien of the right to have the registration reinstated if the alien, before the end of the second year after the missed appointment date if paragraph (a) applies, establishes to the satisfaction of the consular officer at the post where the alien is registered that the failure to apply for an immigrant visa was due to circumstances beyond the alien's control. If paragraph (b) applies, the consular officer at the post where the alien is registered shall, upon the termination of registration, notify the alien of the termination and the right to have the registration reinstated if the alien, before the end of the second year after the INA 221(g) refusal, establishes to the satisfaction of the consular officer at such post that the failure to present evidence purporting to overcome the ineligibility under INA 221(g) was due to circumstances beyond the alien's control.

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Dated: February 20, 2008.

Maura Harty,

*Assistant Secretary for Consular Affairs,
Department of State.*

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 171

RIN 1076-AD44

Irrigation Operation and Maintenance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior, Bureau of Indian Affairs (BIA) is revising the regulation governing irrigation projects under its jurisdiction.