§ 35.43 Generally.

(a) For purposes of this subpart:

(1) *Affiliate* of a specified company means:

(i) For any person other than an exempt wholesale generator:

(A) Any person that directly or indirectly owns, controls, or holds with power to vote, 10 percent or more of the outstanding voting securities of the specified company;

(B) Any company 10 percent or more of whose outstanding voting securities are owned, controlled, or held with power to vote, directly or indirectly, by the specified company;

(C) Any person or class of persons that the Commission determines, after appropriate notice and opportunity for hearing, to stand in such relation to the specified company that there is liable to be an absence of arm's-length bargaining in transactions between them as to make it necessary or appropriate in the public interest or for the protection of investors or consumers that the person be treated as an affiliate; and

(D) Any person that is under common control with the specified company.

(E) For purposes of paragraph (a)(1)(i) of this section, owning, controlling or holding with power to vote, less than 10 percent of the outstanding voting securities of a specified company creates a rebuttable presumption of lack of control.

(ii) For any exempt wholesale generator (as defined under § 366.1 of this chapter), consistent with section 214 of the Federal Power Act (16 U.S.C. 824m), which provides that ''affiliate'' will have the same meaning as provided in section 2(a) of the Public Utility Holding Company Act of 1935 (15 U.S.C. 79b(a)(11)):

(A) Any person that directly or indirectly owns, controls, or holds with power to vote, 5 percent or more of the outstanding voting securities of the specified company;

(B) Any company 5 percent or more of whose outstanding voting securities are owned, controlled, or held with power to vote, directly or indirectly, by the specified company;

(C) Any individual who is an officer or director of the specified company, or of any company which is an affiliate thereof under paragraph (a)(1)(ii)(A) of this section; and

(D) Any person or class of persons that the Commission determines, after appropriate notice and opportunity for hearing, to stand in such relation to the specified company that there is liable to be an absence of arm's-length bargaining in transactions between them as to make it necessary or appropriate in the public interest or for the protection of investors or consumers that the person be treated as an affiliate.

(2) *Captive customers* means any wholesale or retail electric energy customers served by a franchised public utility under cost-based regulation.

(3) *Franchised public utility* means a public utility with a franchised service obligation under state law.

(4) *Market-regulated power sales affiliate* means any power seller affiliate other than a franchised public utility, including a power marketer, exempt wholesale generator, qualifying facility or other power seller affiliate, whose power sales are regulated in whole or in part on a market-rate basis.

(5) *Non-utility affiliate* means any affiliate that is not in the power sales or transmission business, other than a local gas distribution company or an interstate natural gas pipeline.

(b) The provisions of this subpart apply to all franchised public utilities that have captive customers or that own or provide transmission service over jurisdictional transmission facilities.

§ 35.44 Protections against affiliate cross-subsidization.

(a) *Restriction on affiliate sales of electric energy.* No wholesale sale of electric energy may be made between a franchised public utility with captive customers and a market-regulated power sales affiliate without first receiving Commission authorization for the transaction under section 205 of the Federal Power Act.

(b) *Non-power goods or services.*

(1) Unless otherwise permitted by Commission rule or order, sales of any non-power goods or services by a franchised public utility that has captive customers or that owns or provides transmission service over jurisdictional transmission facilities, including sales made to or through its affiliated exempt wholesale generators or qualifying facilities, to a market-regulated power sales affiliate or non-utility affiliate must be at the higher of cost or market price.

(2) Unless otherwise permitted by Commission rule or order, and except as permitted by paragraph (b)(3) of this section, a franchised public utility that has captive customers or that owns or provides transmission service over jurisdictional transmission facilities, may not purchase or receive non-power goods and services from a market-regulated power sales affiliate or a non-utility affiliate at a price above market.

(3) A franchised public utility that has captive customers or that owns or provides transmission service over jurisdictional transmission facilities, may only purchase or receive non-power goods and services from a centralized service company at cost.

[FR Doc. E8–3820 Filed 2–28–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

New Animal Drugs; Albendazole

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 Pfizer, Inc. The supplemental NADA provides for use of albendazole oral suspension in nonlactating goats for the treatment of liver flukes.

DATES: This rule is effective February 29, 2008.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8342, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 110–048 that provides for the use of VALBAZEN (albendazole) Oral Suspension for the treatment of liver flukes in nonlactating goats. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5582, which were compiled under National Research Support Project-7 (NRSP–7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. The supplemental NADA is approved as of January 24, 2008, and the regulations are amended in 21 CFR 520.45a and 556.34 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of the 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.

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 circumcinta* 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.

* * * * *

(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.

[FR Doc. E8–3877 Filed 2–28–08; 8:45 am]

BILLING CODE 4160–01–S

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: