

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

**21 CFR Parts 520 and 556**

**New Animal Drugs; Albendazole**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 [*insert date of publication in the Federal Register*].

**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](mailto: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

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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 Parts 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: Feb 19 2008

February 19, 2008.

Bernadette Dunham *Bernadette Dunham*

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Bernadette Dunham,  
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