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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 520 and 556**

:

**Oral Dosage Form New Animal Drugs; Albendazole Suspension**

**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 anthelmintic use of the 11.36 percent albendazole suspension in sheep. Based on FDA's review of the data and information in the NADA, a tolerance for drug residues in muscle and an acceptable daily intake (ADI) are established.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7575.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 110-048 that provides for oral use of Valbazen® (albendazole) 11.36 percent suspension in sheep as an anthelmintic. Currently, the 11.36 percent drug is approved for use in cattle in NADA 110-048, and the 4.55 percent drug is approved for use in sheep in NADA 140-934. Supplemental NADA 110-048 is approved as of December 2, 1998, and the regulations are amended in § 520.45 a(b)(1) (21 CFR 520.45a(b)(1)) to reflect the approval.

In addition, FDA reviewed the data concerning anthelmintic use of albendazole in Pfizer, Inc.'s NADA 110-048 for cattle and NADA 140-934 for sheep to determine a tolerance for residues of albendazole in muscle of cattle and sheep. Based on this review, a tolerance of 50

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parts per billion for albendazole 2-aminosulfone in both cattle and sheep muscle is established. Additionally, the previously established ADI of 5 micrograms per kilogram of body weight per day is codified. Also, the regulations are amended in 21 CFR 556.34 to reflect the ADI and the muscle tolerance.

Furthermore, § 520.45a is amended editorially in paragraph (a)(4) by removing the “(i)” after the “(4)” and adding the “(i)” in place of the “(1)” following the paragraph heading, and by removing paragraph (a)(4)(i)(2).

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)(1) 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**

*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 redelegate 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. Section 520.45a is amended by redesignating the heading of paragraph (a)(4)(i) as the heading of paragraph (a)(4), by redesignating the heading of paragraph (a)(4)(i)(1) as the heading of paragraph (a)(4)(i), by removing paragraph (a)(4)(i)(2), and by revising paragraph (b)(1) to read as follows:

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**§ 520.45a Albendazole suspension.**

(a) \* \* \*

**(4) Conditions of use in cattle—(i) Amount.** \* \* \*

(b)(1) *Specifications.* The product contains 4.55 or 11.36 percent albendazole.

\* \* \* \* \*

**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. Section 556.34 is revised to read as follows:

**§ 556.34 Albendazole.**

(a) *Acceptable daily intake (ADI).* The ADI for total residues of albendazole is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances—( 1) Cattle.* A tolerance is established for albendazole 2-aminosulfone (marker residue) in liver (target tissue) of 0.2 part per million and in muscle of 0.05 part per million.

(2) *Sheep*. A tolerance is established for albendazole 2-aminosulfone (marker residue) in liver (target tissue) of 0.25 part per million and in muscle of 0.05 part per million.

Dated: Dec. 17, 1998

December 17, 1998



Andrew J. Beaulieu  
Acting Director  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**



st [FR Dec. 9-98 Filed 12-17-98; 8:45 am]

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