

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

*DMB*

Display Date	<u>1-23-01</u>
Publication Date	<u>1-24-01</u>
Certifier	<u>TAB</u>

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**Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Suspension**

**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 new animal drug application (NADA) filed by Blue Ridge Pharmaceuticals, Inc. The NADA provides for veterinary prescription use of ivermectin otic suspension for the treatment of adult ear mite infestations in cats and kittens.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

**SUPPLEMENTARY INFORMATION:** Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed NADA 141-174 that provides for veterinary prescription use of ACAREXX® (0.01% ivermectin) Otic Suspension for the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven. The NADA provides for use of one 0.5-milliliter tube per ear. The NADA is approved as of December 5, 2000, and the regulations are amended by adding 21 CFR 524.1195 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, Blue Ridge Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning December 5, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

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

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 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

#### *21 CFR Part 524*

Animal drugs.

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 510 and 524 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “Blue Ridge Pharmaceuticals, Inc.” and in the table in paragraph (c)(2) by numerically adding an entry for “065274” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * * * * Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410 * * * * *	* * * * * 065274 * * * * *

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * * 065274 * * * * *	* * * * * Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410 * * * * *

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

2. Section 524.1195 is added to read as follows:

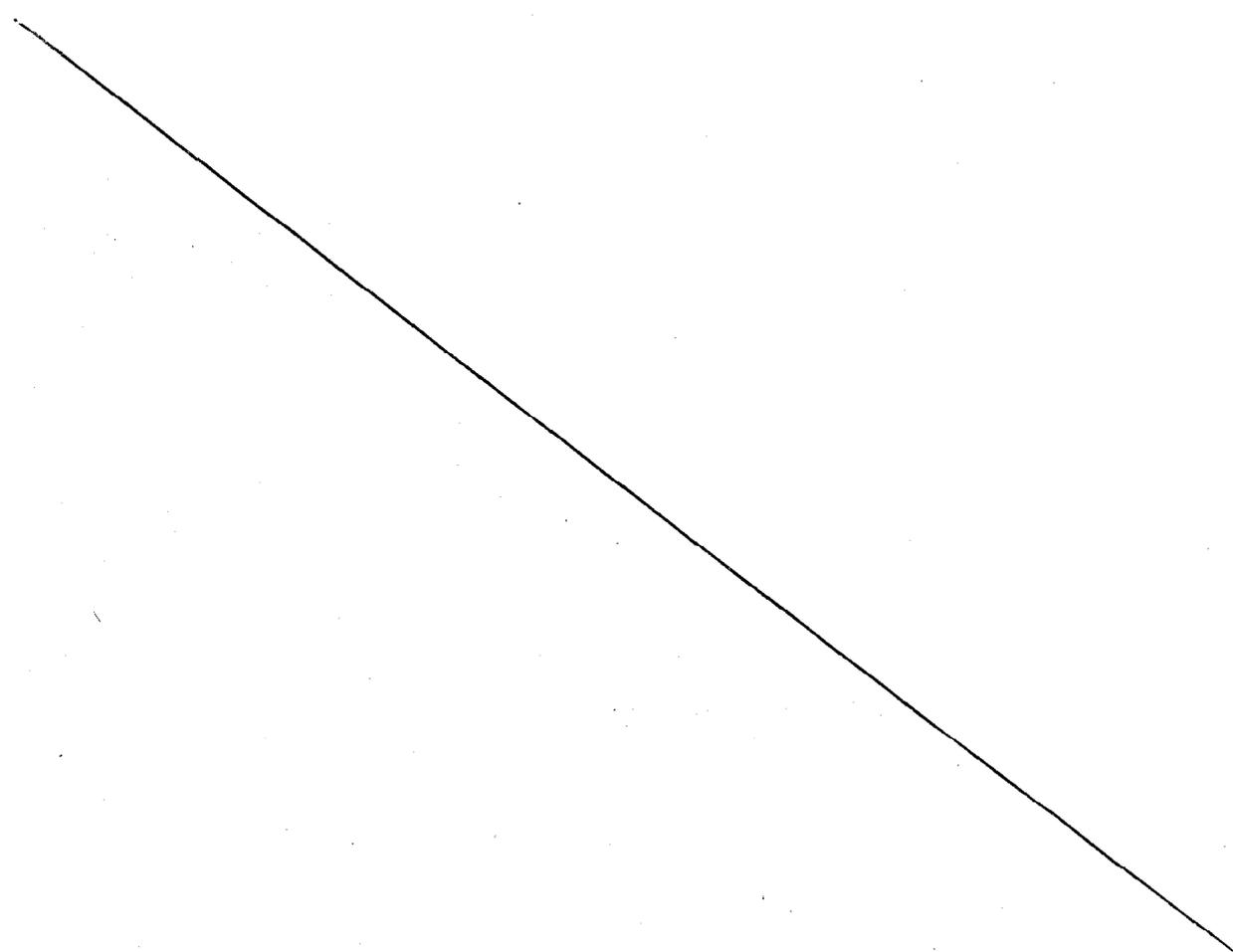
**§ 524.1195 Ivermectin otic suspension.**

(a) *Specifications.* Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

(b) *Sponsor.* See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) *Indications for use.* For the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven.



(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 1/8/01  
January 8, 2001

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



Stephen F. Sundlof  
Director  
Center for Veterinary Medicine



[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

**BILLING CODE 4160-01-F**