have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–02–01 Boeing: Amendment 39–12085. Docket 99–NM–380–AD.

Applicability: Model 737–300, –400, and –500 series airplanes, certificated in any category; as listed in Boeing Alert Service Bulletin 737–53A1208, dated May 6, 1999.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect fatigue cracking of the forward pressure bulkhead, which could result in rapid decompression of the airplane fuselage, accomplish the following:

Initial and Repetitive Inspections

(a) Before the accumulation of 20,000 total flight cycles, or within 3,000 flight cycles after the effective date of this AD, whichever occurs later: Perform the applicable inspections of the vertical and side chord areas of the forward pressure bulkhead to detect cracking, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1208, dated May 6, 1999. Thereafter, repeat the inspections at intervals not to exceed 6,000 flight cycles until the preventive modifications required by paragraph (c) of this AD have been accomplished.

Repair

(b) If any cracking is detected during any inspection required by paragraph (a) of this AD, before further flight, repair the area in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1208, dated May 6, 1999.

Terminating Action

(c) Before the accumulation of 75,000 total flight cycles, or within 12,000 flight cycles after the effective date of this AD, whichever occurs later: Accomplish preventive modifications of the vertical and side chord areas of the forward pressure bulkhead, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1208, dated May 6, 1999. Accomplishment of these modifications constitutes terminating action for the repetitive inspections required by paragraph (a) of this AD.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(f) The actions shall be done in accordance with Boeing Alert Service Bulletin 737–53A1208, dated May 6, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(g) This amendment becomes effective on February 28, 2001.

Issued in Renton, Washington, on January 12, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1660 Filed 1–23–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin 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 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 January 24, 2001.

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: January 8, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–1869 Filed 1–23–01; 8:45 am]

BILLING CODE 4160–01–F