2006–20–07 Rolls-Royce Corporation (formerly Allison Engine Company, Allison Gas Turbine Division, and Detroit Diesel Allison): Amendment 39–14776. Docket No. FAA–2005–23392; Directorate Identifier 2005–NE–47–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective November 2, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce Corporation (RRC) models 250–C30, –C30G, –C30G/2, –C30M, –C30P, –C30R, –C30R/1, –C30R/3, –C30R/3M, –C30S, –C30U, –C40B, –C47B, and –C47M turboshaft engines, with a third-stage turbine wheel, part number (P/N) 6898663 or P/N 23065843 installed, or a fourth-stage turbine wheel, P/N 6892764 or P/N 23066744, installed. These engines are installed on, but not limited to, Bell 206L–3, Bell 206L–4, Bell 230, Bell 407, Bell 430, MDHI 369F, MDHI 369FF, MDHI 600N, and Sikorsky S–76A helicopters.

Unsafe Condition

(d) This AD results from analysis by RRC of failures of third-stage turbine wheels. We are issuing this AD to prevent loss of power, possible engine shutdown, or uncontained failure.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

(f) Within 30 days after the effective date of this AD, record each time the third- and fourth-stage turbine wheels enter into the speed range between ''Event Threshold'' and ''Maximum Overspeed Transient''. Use paragraph 2.A. through 2.A.(5) of the Accomplishment Instructions and the applicable Figures 1 through 5 of RRC Alert Commercial Engine Bulletins (CEBs) No. CEB A–72–3272, No. CEB A–72–5048, and No. CEB A–72–6054 (combined in one document), all Revision 2, dated June 27, 2006, to determine the speed range.

(g) Remove and retire any third-stage turbine wheel or fourth-stage turbine wheel after the sixth time the wheel enters into the speed range between ''Event Threshold'' and ''Maximum Overspeed Transient''.

Third- and Fourth-Stage Turbine Wheel Life Limits

(h) The retirement criteria in this AD are in addition to the existing third- and fourth-stage turbine wheel hour and cycle life limits. You must retire the wheels when you exceed any published life limit (transient speed excursions, hours, or cycles).

Alternative Methods of Compliance

(i) The Manager, Chicago Aircraft Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(j) None.

Material Incorporated by Reference

(k) You must use Rolls-Royce Corporation Alert Commercial Engine Bulletins No. CEB A–72–3272, No. CEB A–72–5048, and No. CEB A–72–6054 (combined in one document), all Revision 2, dated June 27, 2006, to perform the actions required by this AD. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Rolls-Royce Corporation, P.O. Box 420, Indianapolis, IN 46206–0420; telephone (317) 230–6400; fax (317) 230–4243 for a copy of this service information. You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on September 20, 2006.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 06–8230 Filed 9–27–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin

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 an abbreviated new animal drug application (ANADA) filed by Sparhawk Laboratories, Inc. The ANADA provides for use of neomycin sulfate soluble powder in livestock for the treatment and control of bacterial enteritis.

DATES: This rule is effective September 28, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, filed ANADA 200–378 for the use of Neomycin Soluble Powder in cattle, swine, sheep, goats, and turkeys for the treatment and control of bacterial enteritis. Sparhawk Laboratories, Inc.'s Neomycin Soluble Powder is approved as a generic copy of NEOMIX 325 (neomycin sulfate) Soluble Powder, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 11–315. The ANADA is approved as of August 31, 2006, and the regulations in 21 CFR 520.1484 and 520.1485 are amended to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In addition, a label statement warning against the use of these products in calves to be processed for veal was not codified at the time supplemental NADAs or ANADAs for oral neomycin products were approved. At this time, FDA is amending the animal drug regulations to reflect required food safety warning statements.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 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.

FDA 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.

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 in 21 CFR Part 520

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 part 520 is 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 § 520.1484 to read as follows:

§ 520.1484 Neomycin.

(a) *Specifications*—(1) Each ounce of powder contains 20.3 grams (g) neomycin sulfate (equivalent to 14.2 g neomycin base).

(2) Each milliliter of solution contains 200 milligrams (mg) neomycin sulfate (equivalent to 140 mg neomycin base).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 000069 and 054925 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) Nos. 000009, 046573, 058005, and 061623 for use of product described in paragraph (a)(1) as in paragraphs (e)(1) and (e)(2) of this section.

(3) Nos. 000009, 054925, and 059130 for use of product described in paragraph (a)(2) as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.430 of this chapter.

(d) *Special labeling considerations.* Labeling shall bear the following warning statements: ''A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.''

(e) *Conditions of use*—(1) *Cattle, swine, sheep, and goats*—(i) *Amount.* 10 mg per pound (/lb) of body weight per day (22 mg per kilogram (/kg)) in divided doses for a maximum of 14 days.

(ii) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

(iii) *Limitations.* Add powder to drinking water or milk; not for use in liquid supplements. Administer solution undiluted or in drinking water. Prepare a fresh solution in drinking water daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: Cattle, 1 day; sheep, 2 days; swine and goats, 3 days.

(2) *Turkeys*—(i) *Amount.* 10 mg/lb of body weight per day (22 mg/kg) for 5 days.

(ii) *Indications for use.* For the control of mortality associated with *E. coli* susceptible to neomycin sulfate in growing turkeys.

(iii) *Limitations.* Add to drinking water; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 5 consecutive days.

§ 520.1485 [Removed]

■ 3. Remove § 520.1485.

Dated: September 12, 2006.

Stephen F. Sundlof

Director, Center for Veterinary Medicine.

[FR Doc. E6–15889 Filed 9–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The supplemental ANADA provides for a new container size, a 40-gram dropper bottle, from which gentamicin sulfate, betamethasone valerate, clotrimazole ointment may be administered for the treatment of acute and chronic canine otitis externa.

DATES: This rule is effective September 28, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–287 for use of TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP ointment) for the treatment of acute and chronic canine otitis externa. The supplemental ANADA provides for a new container size, a 40-gram dropper bottle. The supplemental ANADA is approved as of August 23, 2006, and the regulations are amended in 21 CFR 524.1044g 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 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.

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.

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 in 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 part 524 is amended as follows:

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. In § 524.1044g, revise paragraph (b)(3), paragraph (c)(1) introductory text, and paragraph (c)(1)(ii) to read as follows:

§ 524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

* * * * *

(b) * * *

(3) No. 059130 for use of 10-, 20-, 40-, or 215-g bottles.

(c) * * *

(1) *Amount.* Instill ointment twice daily into the ear canal for 7 consecutive days.

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(ii) From 20-, 40-, or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

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