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 a new airworthiness directive to read as follows:

97–26–03 Eurocopter Deutschland: Amendment 39–10246. Docket No. 97–SW–45–AD.

Applicability: Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To detects cracks in the main rotor mast flange (flange), which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight, and thereafter at intervals not to exceed 100 hours time-in-service, visually inspect the flange in the ribbed area for cracks using a 5-power or higher magnifying glass in accordance with paragraphs 2.A.1. and 2.A.2. of the Accomplishment Instructions in Eurocopter Deutschland GmbH Alert Service Bulletin MBB–BK 117 No. ASB–MBB–BK 117–10–114, dated August 27, 1997.

(b) If a crack is found as a result of the inspections specified in paragraph (a) of this AD, remove the cracked main rotor mast and replace it with an airworthy main rotor mast.

(c) 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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

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

(d) Special flight permits will not be issued.

(e) The inspection shall be done in accordance with Eurocopter Deutschland GmbH Alert Service Bulletin MBB–BK 117 No. ASB–MBB–BK 117–10–114, dated August 27, 1997. 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 American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 31, 1997.

Note 3: The subject of this AD is addressed in Luftahrt-Bundesamt (Germany) AD 97–276, effective September 25, 1997.

Issued in Fort Worth, Texas, on December 5, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–32721 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Doramectin

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 Pfizer, Inc. The NADA provides for topical use of doramectin for treatment and control of certain worm, grub, lice, and mite infections of cattle.

EFFECTIVE DATE: December 16, 1997.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is sponsor of NADA 141–095 that provides for the use of Dectomax® (doramectin) 0.5 percent pour-on solution for beef cattle and female dairy cattle less than 20 months of age for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, to control infections and protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days after treatment. The NADA is approved as of September 16, 1997, and the regulations are amended by adding new § 524.770 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 food-producing animals qualifies for 3 years of marketing exclusivity beginning September 16, 1997, because the NADA contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 OR 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 524.770 is added to read as follows:

§ 524.770 Doramectin.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams of doramectin.

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use—Cattle*—(1) *Amount.* 5 milligrams per 10 kilograms (5 milligrams per 22 pounds).

(2) *Indications for use.* For treatment and control of infections of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days after treatment.

(3) *Limitations.* Administer as a single dose. Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–32807 Filed 12–15–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AC06

Amendments to Transportation Allowance Regulations for Federal and Indian Leases to Specify Allowable Costs and Related Amendments To Gas Valuation Regulations

AGENCY: Minerals Management Service, Interior.

ACTION: Final rulemaking.

SUMMARY: The Minerals Management Service (MMS) is amending its regulations governing valuation for royalty purposes of gas produced from Federal and Indian leases. The rule primarily addresses allowances for transportation of gas. The amendments clarify the methods by which gas royalties and deductions for gas transportation are calculated.

DATE: Effective February 1, 1998.

ADDRESSES: David S. Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165; courier delivery to Building 85, Denver Federal Center, Denver, Colorado 80225, telephone (303) 231–3432, FAX (303) 231–3385, e-Mail David__Guzy@mms.gov.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, phone (303) 231–3432, FAX (303) 231–3385, e-Mail David__Guzy@mms.gov.

SUPPLEMENTARY INFORMATION: The principal authors of this rule are Theresa Walsh Bayani and Susan Lupinski, from Royalty Valuation Division, MMS, Lakewood, Colorado.

I. Background

MMS published a set of rules in 30 CFR part 206 governing gas valuation and gas transportation calculation methods to clarify and codify the departmental policy of granting deductions for the reasonable actual costs of transporting gas from a Federal or Indian lease when the gas is sold at a market away from the lease (53 FR 1272, January 15, 1988).

Since the 1988 rulemaking, Federal Energy Regulatory Commission (FERC) regulatory actions have significantly affected the gas transportation industry. Before these changes, gas pipeline companies served as the primary merchants in the natural gas industry. During that environment, pipelines:

- Bought gas at the wellhead,
- Transported the gas, and
- Sold the gas at the city gate to local distribution companies (LDC).

In the mid-1980's, FERC began establishing a competitive gas market, allowing shippers access to the pipeline transportation grid. These actions ensured that willing buyers and sellers could negotiate their own sales transactions.

Specifically, starting with the implementation of FERC Order 436, FERC began regulating pipelines as open access transporters and requiring nondiscriminatory transportation. This permitted downstream gas users (such as LDCs and industrial users) to buy gas directly from gas merchants in the production area and to ship that gas through interstate pipelines.

FERC Order 436 and amendments, plus the elimination of price controls, created a vigorous spot market. Producers and marketers, in competition for the sale of gas to end users, are now transporting substantial volumes of gas that they own through interstate pipelines.

In the early 1990's, FERC recognized that pipelines still held an advantage over competing sellers of gas. Pipelines held substantial market power and sold gas bundled with a transportation service. FERC remedied the inequities in the gas market by issuing FERC Order 636, effective May 18, 1992. Under the provisions of this order, FERC:

- Required the separation (unbundling) of sales and gas transportation services;
- Enabled the implementation of a capacity release program; and
- Allowed pipelines to assess shippers surcharges for services such as transition costs and FERC's annual charges (57 FR 13267, April 16, 1992).

The unbundled costs—previously embedded in a lump-sum charge—include:

- Transmission;
- Storage;
- Production; and
- Gathering costs.

Necessity for This Rulemaking

We reviewed our current gas transportation regulations (30 CFR 206.156 and 206.157 (for Federal leases), and 206.176 and 206.177 (for Indian leases) (1996)) and determined that they provide general authority to calculate transportation deductions for cost components resulting from implementing FERC Order 636 and previous FERC orders. However, we have determined that lessees and royalty payors need specific guidance and certainty on which components are deductible as transportation costs from royalty. This guidance is necessary because components previously aggregated and unidentifiable may now be separately identified in transportation contracts, and new costs unique to the FERC Order 636 environment are emerging.

Further, some of the components reflect non-deductible costs of marketing rather than transportation. We believe that without the clarification provided in this rule, lessees and payors