promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS.

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR part 71.1 of the Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

Paragraph 6002 Class E Airspace area extending upward from the surface of the earth.

* * * * *

ANM OR E2 Aspen, CO [Added]

Aspen-Pitkin County/Sardy Field
(Lat. 39°13′23″ N., long. 106°52′08″ W.)

Within a 4.3-mile radius of Aspen-Pitkin County/Sardy Field. This Class E airspace is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington on June 10, 2005.

Raul C. Treviño,

Area Director, Western En Route and Oceanic Operations.

[FR Doc. 05–13644 Filed 7–11–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA 2003–16676; Airspace Docket No. 03–ASO–16]

RIN 2120–AA66

Revision of VOR Federal Airway V–537

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revises Very High Frequency Omnidirectional Range (VOR) Federal Airway V–537 by changing the origination point of the airway from the Vero Beach, FL, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) to the Palm Beach, FL, VORTAC. The FAA is taking this action to enhance the management of aircraft in the Palm Beach, FL, area.

EFFECTIVE DATE: 0901 UTC, October 27, 2005.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace and Rules, Office of System Operations and Safety, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

On February 3, 2004, the FAA proposed to modify V–537 by changing the origination point of the airway from the Vero Beach VORTAC to the Palm Beach VORTAC (69 FR 5098). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received. With the exception of editorial changes, this amendment is the same as that proposed in the notice.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by revising the legal description of V–537 in the vicinity of Palm Beach, FL. The revision incorporates into the airway routing that is used by air traffic control when directing aircraft to Palm Beach, FL. Currently, Miami Air Route Traffic Control Center issues a clearance to aircraft destined for the Palm Beach terminal area by directing aircraft to proceed via the Vero Beach VORTAC, then along V–295 to STOOP intersection, then via V–492 to the Palm Beach VORTAC. This modification incorporates this routing as an extension to V–537. The modification to V–537 will reduce pilot-controller communications, alleviate radio frequency congestion, reduce the potential for pilot readback errors, and enhance the management of aircraft operations in the Vero Beach-Palm Beach area.

Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.9M, dated August 30, 2004, and effective September 16, 2004, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document will be published subsequently in the order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways.

* * * * *

V–537 [Revised]

From Palm Beach, FL; INT Palm Beach 356° and Vero Beach, FL, 143° radials; Vero Beach; INT Vero Beach 318° and Orlando. FL, 140° radials; INT Orlando 140° and Melbourne, FL 298° radials; INT Melbourne 298° and Ocala, FL 145° radials; Ocala; Gators, FL; Greenville, FL; Moultrie, GA; to Macon, GA.

* * * * *

Issued in Washington, DC, on July 6, 2005.

Edith V. Parish,

Acting Manager, Airspace and Rules.

[FR Doc. 05–13682 Filed 7–11–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

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 the veterinary prescription use of tulathromycin solution in cattle and in swine, by injection, for the management of respiratory disease. FDA is also amending the regulations to add the acceptable daily intake for total residues of tulathromycin and tolerances for residues of tulathromycin in edible tissues of cattle and swine.

DATES: This rule is effective July 12, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–244 for DRAXXIN (tulathromycin) Injectable Solution. The NADA provides for the veterinary prescription use of tulathromycin solution in cattle, by subcutaneous injection, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*; and in swine, by intramuscular injection, for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, and *H. parasuis*. The application is approved as of May 24, 2005, and the regulations are amended in part 522 (21 CFR part 522) by adding § 522.2630 and in part 556 (21 CFR part 556) by adding § 556.745 to reflect the approval. The basis of approval is discussed in the freedom of information (FOI) summary.

In accordance with the FOI 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 24, 2005.

The agency has determined under 21 CFR 25.33(d)(5) that these actions are of a type that do 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 522

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 redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.2630 is added to read as follows:

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use*—(1) *Beef and nonlactating dairy cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni.*

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobaccillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, and *H. parasuis*.

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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 556.745 is added to read as follows:

§ 556.745 Tulathromycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tulathromycin is 15 micrograms per kilogram of body weight per day.