

For the Nuclear Regulatory Commission.
J.E. Dyer,
Chief Financial Officer.
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2012-0287; Airspace
 Docket No. 11-AWP-21]

RIN 2120-AA66

Amendment of Air Traffic Service Routes; Southwestern United States

AGENCY: Federal Aviation
 Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Jet Route J-2, and VOR Federal airways V-16, V-66 and V-202 in southern Arizona and New Mexico due to the scheduled decommissioning of the Cochise, AZ, VHF Omnidirectional Range Tactical Air Navigation (VORTAC) which currently is used to define segments of the routes.

DATES: Effective date 0901 UTC, July 26, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace, Regulations and ATC Procedures Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

History

On April 23, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish two new RNAV routes in the southwestern United States (78 FR 24156). An NPRM correction published in the **Federal Register** of May 23, 2012 (77 FR 30437) corrected the description of VOR Federal airway V-16.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. One comment was received which expressed support for the proposal.

The Rule

The FAA is amending Title 14, Code of Federal Regulations (14 CFR) part 71

to modify the descriptions of Jet Route J-2, and VOR Federal airways V-16, V-66 and V-202 in southern Arizona and New Mexico. The FAA is taking this action due to the scheduled decommissioning of the Cochise, AZ, VORTAC, which is used in the descriptions of the routes. Specifically, the portion of J-2 that extends from Gila Bend, AZ; to Cochise, AZ; to El Paso, TX is realigned to proceed from Gila Bend to Tucson, AZ, and then to El Paso, TX (with the remainder of the route is unchanged). The portion of V-16 that currently extends from Tucson, AZ; to Cochise, AZ; to Columbus, NM, is realigned to proceed from Tucson, AZ; to San Simon, AZ; then to Columbus, NM (remainder of route unchanged). V-66 is modified by removing language that excludes altitudes above 13,000 feet MSL in one segment of the route no longer required by air traffic control. V-202 currently extends from Tucson, AZ; to Cochise, AZ; to San Simon, AZ; to Silver City, NM; to Truth or Consequences, NM. The western portion of V-202 that extends between Tucson-Cochise-San Simon is deleted. The modified V-202 begins at San Simon, AZ; to Silver City, NM; to Truth or Consequences, NM.

Jet Routes are published in paragraph 2004, and Domestic VOR Federal airways are published in paragraph 6010, of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Jet Routes and VOR Federal airways 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.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator.

Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies Air Traffic Service routes to maintain the continuity of navigation guidance in the southwestern United States.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

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 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 2004 Jet routes.

J-2 [Amended]

From Mission Bay, CA, via Imperial, CA; Bard, AZ; INT of the Bard 089° and Gila Bend, AZ, 261° radials; Gila Bend; Tucson, AZ; El Paso, TX; Fort Stockton, TX; Junction, TX; San Antonio, TX; Humble, TX; Lake Charles, LA; Baton Rouge, LA; Semmes, AL; Crestview, FL; INT of the Crestview 091° and the Seminole, FL, 290° radials; Seminole to Taylor, FL.

Paragraph 6010 Domestic VOR federal airways.

V-16 [Amended]

From Los Angeles, CA; Paradise, CA; Palm Springs, CA; Blythe, CA; Buckeye, AZ; Phoenix, AZ; INT Phoenix 155° and Stanfield, AZ, 105° radials; Tucson, AZ; San Simon, AZ; INT San Simon 119° and Columbus, NM, 277° radials; Columbus, El Paso, TX; Salt Flat, TX; Wink, TX; INT Wink 066° and Big Spring, TX, 260° radials; Big Spring; Abilene, TX; Bowie, TX; Bonham, TX; Paris, TX; Texarkana, AR; Pine Bluff, AR; Marvell, AR; Holly Springs, MS; Jacks Creek, TN; Shelbyville, TN; Hinch Mountain, TN; Volunteer, TN; Holston Mountain, TN; Pulaski, VA; Roanoke, VA; Lynchburg, VA; Flat Rock, VA; Richmond, VA; INT Richmond 039° and Patuxent, MD, 228° radials; Patuxent; Smyrna, DE; Cedar Lake, NJ; Coyle, NJ; INT Coyle 036° and Kennedy, NY, 209° radials; Kennedy; INT Kennedy 040° and Calverton, NY 261° radials; Calverton; Norwich, CT; Boston, MA. The airspace within Mexico and the airspace below 2,000 feet MSL outside the United States is excluded. The airspace within Restricted Areas R-5002A, R-5002C, and R-5002D is excluded during their times of use. The airspace within Restricted Areas R-4005 and R-4006 is excluded.

V-66 [Amended]

From Mission Bay, CA; Imperial, CA; 13 miles, 24 miles, 25 MSL; Bard, AZ; 12 miles, 35 MSL; INT Bard 089° and Gila Bend, AZ, 261° radials; 46 miles, 35 MSL; Gila Bend; Tucson, AZ, 7 miles wide (3 miles south and 4 miles north of centerline); Douglas, AZ; INT Douglas 064° and Columbus, NM, 277° radials; Columbus; El Paso, TX; 6 miles wide; INT El Paso 109° and Hudspeth, TX, 287° radials; 6 miles wide; Hudspeth; Pecos, TX; Midland, TX; INT Midland 083° and Abilene, TX, 252° radials; Abilene; to Millsap, TX. From Crimson, AL, Brookwood, AL; LaGrange, GA; INT LaGrange 120° and Columbus, GA, 068° radials; INT Columbus 068° and Athens, GA, 195° radials; Athens; Greenwood, SC; Sandhills, NC; Raleigh-Durham, NC; Franklin, VA.

V-202 [Amended]

From San Simon, AZ; Silver City, NM; to Truth or Consequences, NM.

Issued in Washington, DC, on June 7, 2012.

Colby Abbott,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2012-14412 Filed 6-14-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA-2012-N-0002]

Conditionally Approved New Animal Drugs for Minor Use and Minor Species; Masitinib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a conditionally approved supplemental application for conditional approval of a new animal drug (CNADA) intended for a minor use filed by AB Science. The supplemental CNADA provides for a revised indication for masitinib mesylate tablets in dogs.

DATES: This rule is effective June 15, 2012.

FOR FURTHER INFORMATION CONTACT: Steven Fleischer, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8234, email: steven.fleischer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: AB Science, 3 Avenue George V, 75008 Paris, France, filed a supplemental CNADA 141-308 for KINAVET-CA1 (masitinib mesylate) Tablets for a revised indication for the treatment of nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids. In accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), this supplemental application is conditionally approved as of January 30, 2012, and the regulations in 21 CFR part 516 are amended to reflect this action.

A summary of safety and effectiveness data and information submitted to support conditional 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.

KINAVET-CA1 (masitinib mesylate) Tablets for the intended uses conditionally approved by FDA under application number 141-308 qualifies for 7 years of exclusive marketing rights beginning on December 15, 2010, the

date of the original conditional approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the FD&C Act (21 U.S.C. 360ccc-2(c)) because it has been declared a designated new animal drug by FDA under section 573(a) of the FD&C Act.

FDA has determined under 21 CFR 25.33 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 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 516 is amended as follows:

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

■ 2. In § 516.1318, revise paragraph (c)(2) to read as follows:

§ 516.1318 Masitinib.

* * * * *

(c) * * *

(2) *Indications for use.* For the treatment of nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids.

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Dated: June 8, 2012.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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