Rules and Regulations

Federal Register
Vol. 73, No. 129
Thursday, July 3, 2008

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0038; Airspace Docket No. 07–ANM–16]

Establishment of Low Altitude Area Navigation Route (T-Route); Southwest Oregon

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a low altitude Area Navigation (RNAV) route, designated T–274 in the State of Oregon. T-routes are low altitude Air Traffic Service (ATS) routes, based on RNAV, for use by aircraft having instrument flight rules (IFR)-approved Global Positioning System (GPS)/Global Navigation Satellite System (GNSS) equipment. The FAA is taking this action to enhance safety and improve the efficient use of the navigable airspace in Oregon.

DATES: *Effective Date:* 0901UTC, September 25, 2008. 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: Ken McElroy, Airspace and Rules Group, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

On February 14, 2008, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish a low altitude T-route in southwest Oregon (73 FR 8628). Interested parties were invited to participate in this rulemaking effort by submitting written comments on this proposal to the FAA. Four comments were received in response to the NPRM, each supporting the establishment of the route and recommending lower minimum en route altitudes (MEA). The Aircraft Owners and Pilots Association recommended the FAA modify its proposal to ensure that T–274 has a lower MEA than current Very High Frequency Omnidirectional Range (VOR) Federal airways. Regarding route altitudes, the charted depiction will include MEA requirements which are established in accordance with 14 CFR part 95. The establishment of MEAs is outside the scope of this rule.

Low altitude RNAV routes are published in paragraph 6011 of FAA Order 7400.9R signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The low altitude RNAV routes listed in this document will be published subsequently in the Order.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 establishes a low altitude RNAV route in southwest Oregon. The route is designated T–274, and will be depicted on the appropriate IFR En Route Low Altitude charts. T-routes are low altitude RNAV ATS routes, similar to VOR Federal airways, but based on GNSS navigation. RNAV-equipped aircraft capable of filing flight plan equipment suffix ''G'' may file for these routes.

The T-route described in this rule will enhance safety, and facilitate more flexible and efficient use of the navigable airspace for en route IFR operations transitioning through mountainous terrain of southwest Oregon.

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 establishes an RNAV T-route in southwest Oregon.

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, 311b, and 311k. 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 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 6011 Contiguous United States Area Navigation Routes

* * * * *

T–274 CRAAF to Newport, OR (ONP) [New]

CRAAF
Fix (lat. 44°45′37″ N., long. 123°21′06″ W.)
Newport, OR (ONP)
VORTAC (lat. 44°34′31″ N., long. 124°03′38″ W.)

* * * * *

Issued in Washington, DC, on June 23, 2008.

Ellen Crum,

Acting Manager, Airspace and Rules Group.

[FR Doc. E8–15020 Filed 7–2–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 530

[Docket No. FDA–2008–N–0326]

New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals. We are issuing this order based on evidence that extralabel use of these drugs in food-producing animals will likely cause an adverse event in humans and, as such, presents a risk to the public health.

DATES: This rule becomes effective October 1, 2008. Submit written or electronic comments on this document by September 2, 2008.

ADDRESSES: You may submit comments, identified by [Docket No. FDA–2008–N–0326], by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD, 20855, 240–276–9200, e-mail: *neal.bataller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. AMDUCA

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) (Public Law 103–396) was signed into law on October 22, 1994. It amended the Federal Food, Drug, and Cosmetic Act (the act) to permit licensed veterinarians to prescribe extralabel uses of approved animal and human drugs in animals. In the **Federal Register** of November 7, 1996 (61 FR 57732), we published the implementing regulations (codified at part 530 (21 CFR part 530)) for AMDUCA. The sections regarding prohibition of extralabel use of drugs in animals are § § 530.21, 530.25, and 530.30. These sections describe the basis for issuing an order prohibiting an extralabel drug use in animals and the procedure to be followed in issuing an order of prohibition.

We may issue a prohibition order if we find that extralabel use of a drug in animals presents a risk to the public health. Under § 530.3(e), this means that we have evidence demonstrating that the use of the drug has caused, or likely will cause an adverse event.

Section 530.25 provides for a public comment period of not less than 60 days. It also provides that the order of prohibition become effective 90 days after the date of publication, unless we revoke or modify the order, or extend the period of public comment. The list of drugs prohibited from extralabel use is found in § 530.41.

B. Cephalosporins

Cephalosporins are members of the β-lactam class of antimicrobials. These antimicrobials work by targeting synthesis of the bacterial cell wall, resulting in increased permeability and eventual hydrolysis of the cell. Members of the cephalosporin class have a β-lactam ring fused to a sulfur-containing ring-expanded system (Ref. 1).

Certain cephalosporins are currently approved for use in a number of animal species. These approved uses include the treatment of respiratory disease in cattle, swine, sheep, and goats, as well as acute bovine interdigital necrobacillosis, acute metritis, and clinical and sub-clinical mastitis in cattle. They are also approved for the control of bovine respiratory disease, and the control of early mortality associated with *Escherichia coli* infections in day-old chicks and poults. Furthermore, approved animal uses of cephalosporins include the treatment of skin and soft tissue infections in dogs and cats, genitourinary tract infections (cystitis) in dogs, and respiratory tract infections in horses.

Cephalosporins are also some of the most widely used antimicrobial agents in human medicine. Older agents are widely used as therapy for skin and soft tissue infections caused by *Staphylococcus aureus* and *Streptococcus pyogenes*, as well as treatment of upper respiratory tract infections, intra-abdominal infections, pelvic inflammatory disease, and diabetic foot infections. Newer cephalosporins, with or without aminoglycosides, have been considered drugs of choice for serious infections caused by *Klebsiella*, *Enterobacter*, *Proteus*, *Providencia*, *Serratia*, and *Haemophilus* spp. These cephalosporins are also used to treat systemic salmonellosis, although not specifically approved for this purpose. Fourth