a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the specified closing date for comments will be considered, and this rule may be amended or withdrawn in light of comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 98–ASW–40.'' The postcard will be date stamped and returned to the commenter.

The Rule

This amendment to 14 CFR part 71 realigns V–369 located in the Dallas/Fort Worth area. Due to the decommissioning of the Dallas/Fort Worth VORTAC, V–369 is being realigned to the newly commissioned Maverick VOR/DME, which is located .66 nautical miles west of the former Dallas/Fort Worth VORTAC. Realigning V–369 will ensure that air traffic operations are not interrupted by virtue of the decommissioning of the Dallas/Fort Worth VORTAC and the commissioning of the Maverick VOR/DME. The effective date of this direct final rule will coincide with the effective date of the commissioning of the Maverick VOR/DME. The FAA is taking this action to improve the management of air traffic operations in the vicinity of Dallas/Fort Worth area.

Domestic VOR Federal Airways are published in paragraph 6010(a) of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The airways listed in this document will be published subsequently in the Order.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is not controversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under 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, positive or negative, 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).

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; AIRWAYS; 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 the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V–369 [Revised]

From Navasota, TX; Groesbeck, TX; to Maverick, TX.

* * * * *

Issued in Washington, DC, on July 23, 1998.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 98–20346 Filed 7–29–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–ANM–15]

RIN 2120–AA66

Modification of VOR Federal Airway V–465

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Very High Frequency Omnidirectional Range (VOR) Federal Airway V–465 (V–465) by lowering the floor of a portion of the airway from 12,400 mean sea level (MSL) to 1,200 feet above the surface. This action also establishes a new segment of V–465 between Billings, Montana (MT), and Miles City, MT. The FAA is taking this action to support an instrument approach procedure into the Jackson Hole Airport, Wyoming (WY), and enhance the management of air traffic operations in the Jackson Hole, WY, area.

EFFECTIVE DATE: 0901 UTC October 8, 1998.

FOR FURTHER INFORMATION CONTACT: Joseph White, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

On December 15, 1997, the FAA proposed to amend 14 CFR part 71 (part 71) to modify a portion of V–465 (62 FR 65631). Interested parties were invited

to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Except for editorial changes this amendment is the same as that proposed in the notice.

The Rule

This action amends part 71 by lowering the floor of a portion of V–465 from 12,400 MSL to 1,200 feet above the surface. This action supports the instrument approach procedure requirements into the Jackson Hole Airport, Jackson, WY.

This action also establishes a new segment of V–465 between Billings, MT, and Miles City, MT. When V–465 was established, the FAA intended that the airway include a segment between Billings, MT, and Miles City, MT; however, the airway segment was omitted due to a typographical error. This action properly defines that portion of V–465 between Billings, MT, and Miles City, MT, that was omitted in previous publications. This new segment does not result in any additional controlled airspace because the segment is co-located with a segment of V–2.

The FAA is taking this action to enhance the management of air traffic operations in the Jackson Hole, WY, area.

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 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.

Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The airways listed in this document will be published subsequently in the Order.

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; AIRWAYS; 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 [Revised]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V–465 [Revised]

From Bullion, NV, Wells, NV; 12 miles; 30 miles, 115 MSL, 20 miles, 90 MSL, 36 miles, 115 MSL, 24 miles, 95 MSL, Malad City, ID; Jackson, WY; Dunoir, WY; 14 miles, 45 miles, 137 MSL, Billings, MT; Miles City, MT; Williston, ND.

* * * * *

Issued in Washington, DC, on July 24, 1998.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 98–20341 Filed 7–29–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 341

[Docket No. 76N–052N]

RIN 0910–AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion caused by acute or chronic rhinitis) to add the ingredient levmetamfetamine (formerly l-desoxyephedrine) and to classify this ingredient as generally recognized as safe and effective for OTC use. The agency is also removing l-desoxyephedrine from the list of nonmonograph active ingredients. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: July 30, 1999.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 23, 1994 (59 FR 43386), the agency published a final rule in the form of a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective. The final monograph did not include l-desoxyephedrine as a nasal decongestant active ingredient because it was not currently standardized and characterized for quality and purity in an official compendium, i.e., the United States Pharmacopeia (USP)/National Formulary (59 FR 43386 at 43408). Instead, the final rule listed l-desoxyephedrine in § 310.545(a)(6)(ii)(B) (21 CFR 310.545(a)(6)(ii)(B)) as not generally recognized as safe and effective. The agency stated in the final rule that OTC drug products containing l-desoxyephedrine as a topical nasal decongestant active ingredient were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)). The effective date of the final rule was August 23, 1995.

In the **Federal Register** of March 8, 1996 (61 FR 9570), the agency stayed the entry for ''l-desoxyephedrine (topical)'' in § 310.545(a)(6)(ii)(B) until further notice. The agency explained that a citizen petition submitted in response to the OTC nasal decongestant final rule requested that the agency defer the effective date of § 310.545(a)(6)(ii)(B) as it applies to l-desoxyephedrine (topical) until December 31, 1996. The petitioner stated that it had forwarded a draft compendial monograph for l-desoxyephedrine to the USP in late July 1995. The agency added that when l-desoxyephedrine becomes official in the