

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 proposed 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).

T-210 BRADO, FL to Taylor, FL [New]

| | | |
|------------------------|--------------|---|
| BRADO, FL | WP | (Lat. 29°55'22" N., long. 81°28'08" W.) |
| OHLEE, FL | WP | (Lat. 30°16'00" N., long. 82°06'34" W.) |
| Taylor, FL (TAY) | VORTAC | (Lat. 30°30'17" N., long. 82°33'10" W.) |

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Issued in Washington, DC, on December 30, 2005.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E6-68 Filed 1-6-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2005-23424; Airspace Docket No. 05-AEA-23]

RIN 2120-AA66

Proposed Establishment of VOR Federal Airway V-623; NJ and NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Very High Frequency Omnidirectional Range (VOR) Federal Airway V-623 between the Sparta, NJ, Very High Frequency Omnidirectional Range Tactical Air Navigation (VORTAC) and the Carmel, NY, Very High Frequency Omnidirectional Range/Distance Measuring Equipment (VOR/DME). The purpose of the proposed airway is to enhance the management of air traffic transiting from the New England area to airports in the Newark, NJ, area.

DATES: Comments must be received on or before February 23, 2006.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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.

| | |
|--------------|---|
| WP | (Lat. 29°55'22" N., long. 81°28'08" W.) |
| WP | (Lat. 30°16'00" N., long. 82°06'34" W.) |
| VORTAC | (Lat. 30°30'17" N., long. 82°33'10" W.) |

20590-0001. You must identify FAA Docket No. FAA-2005-23424 and Airspace Docket No. 05-AEA-23, at the beginning of your comments. You may also submit comments through the Internet at http://dms.dot.gov.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2005-23424 and Airspace Docket No. 05-AEA-23) and be submitted in triplicate to the Docket Management System (see ADDRESSES section for address and phone number). You may also submit comments through the Internet at http://dms.dot.gov.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2005-23424 and Airspace Docket No. 05-AEA-23." The

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

Paragraph 6011—Area Navigation Routes

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postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at http://dms.dot.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at http://www.faa.gov, or the Federal Register's Web page at http://www.gpoaccess.gov/fr/index.html.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see ADDRESSES section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, 159-30 Rockaway Boulevard, Jamaica, NY 11434-4848.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed

Rulemaking Distribution System, which describes the application procedure.

Background

On February 7, 2005, the FAA published in the **Federal Register** a final rule establishing V-623 (70 FR 6336). However, navigation aid signal coverage problems were identified, which could not be resolved, so the FAA revoked the airway on June 3, 2005 (70 FR 32484). Subsequently, a segment of the airway was redesigned along a satisfactory navigation aid radial. Therefore, the FAA is again proposing to establish V-623.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to establish V-623 between the Sparta, NJ, VORTAC and the Carmel, NY, VOR/DME. The proposed airway is needed to enhance the management of air traffic transiting from the New England area to airports in the Newark, NJ, area.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed 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 proposed 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

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The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

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V-623 [New]

From Sparta, NJ; INT Sparta, NJ 060°(M) 047°(T) and Carmel 275°(M) 263°(T) radials; Carmel.

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Issued in Washington, DC, on December 30, 2005.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E6-69 Filed 1-6-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005N-0471]

Immunology and Microbiology Devices; Reclassification of Herpes Simplex Virus (Types 1 and/or 2) Serological Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify herpes simplex virus (HSV) (types 1 and/or 2) serological assays from class III (premarket approval) to class II (special controls). HSV serological assays (types 1 and/or 2) are intended for testing specimens from individuals who have signs and symptoms of infection consistent with HSV 1 and/or 2 or for determining if an individual has been previously infected with HSV 1 and/or 2, as well as for providing epidemiological information about these infections. The detection of HSV antibodies, in conjunction with other clinical laboratory findings, aids in the clinical laboratory diagnosis of an infection by HSV 1 and/or 2. FDA is proposing this reclassification on its own initiative based on new information. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft

guidance document that would serve as the special control, if FDA reclassifies this device.

DATES: Submit written or electronic comments by April 10, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N-0471, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

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

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

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 or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number 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.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, 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.fda.gov/ohrms/dockets/default.htm> 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: Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither