established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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Issued in Seattle, Washington, on January 11, 2002.

Charles E. Davis,

Acting Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 02–4199 Filed 2–20–02; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 01–ANM–18]

Proposed Modification of Class E Airspace, Hailey, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This action proposes to modify existing Class E airspace at Hailey, ID. Newly developed Area Navigation (RNAV) Special Standard Instrument Approach Procedure (SIAP) at the Friedman Memorial Airport has made this proposal necessary. Additional Class E 700-feet and 1,200-feet controlled airspace, above the surface of the earth is required to contain aircraft executing the RNAV Z RWY 31 Global Positioning System (GPS) 31R Special SIAP at Friedman Memorial Airport. The intended effect of this action is to provide adequate Class E controlled airspace between the terminal and the en route phase of flight for aircraft executing Instrument Flight Rules (IFR) operations at Friedman Memorial Airport, Hailey, ID.

DATES: Comments must be received on or before April 8, 2002.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, ANM–520, Federal Aviation Administration, Docket No. 01–ANM–18, 1601 Lind Avenue SW., Renton, Washington 98055–4056.

An informal docket may also be examined during normal business hours in the office of the Manager, Air Traffic Division, Airspace Branch, at the address listed above.

FOR FURTHER INFORMATION CONTACT: Brian Durham, ANM–520.7, Federal Aviation Administration, Docket No. 01–ANM–18, 1601 Lind Avenue SW., Renton, Washington 98055–4056: telephone number: (425) 227–2527.

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 the airspace docket number and be submitted in triplicate to the address listed above. 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 Airspace Docket No. 01–ANM–18.'' The 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 the light of comments received. All comments submitted will be available for examination at the address listed above 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 NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Airspace Branch, ANM–520, 1601 Lind Avenue SW., Renton, Washington 98055–4059. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by modifying existing Class E airspace at Hailey, ID. Newly developed RNAV Z RWY31 Special SIAP at the Friedman Memorial Airport has made this proposal necessary. Additional Class E 700-feet and E 1,200-feet controlled airspace, above the surface of the earth is required to contain aircraft executing the Instrument Flight Rules (IFR) operations, at Friedman Memorial Airport. The FAA establishes class E airspace where necessary to contain aircraft transitioning between the terminal and en route environments. The intended effect of this proposal is designed to provide for the safe and efficient use of the navigable airspace. This proposal would promote safety flight operations under IFR at the Friedman Memorial Airport and between the terminal and en route transition stages.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from 700-feet or more above the surface of the earth, are published in Paragraph 6005, of FAA Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

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. It, therefore, (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 11013; 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).

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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; 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 71.1 of the Federal Aviation Administration Order 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700-feet or more above the surface of the earth.

* * * * *

ANM ID E5 Hailey, ID [Revised]

Friedman Memorial Airport, ID
(Lat. 43°40′34″N., long. 114°17′45″W.)

That airspace extending upward from 700-feet above the surface within a 5.5 mile radius of Friedman Memorial Airport, and within 2 miles each side of the 328° bearing from the airport extending from the 5.5 mile radius to 7.4 miles northwest of the airport, and within 2 miles each side of the 159° bearing from the airport extending from the 5.5 mile radius to 7.6 miles southeast of the airport; and that airspace extending upward from 1,200-feet above the surface, bounded by a line beginning at lat. 43°50′00″N., long. 114°38′27″W.; to lat. 43°50′00″N., long. 114°00′00″W.; to lat. 43°12′55″N., long. 114°00′00″W.; to lat. 43°12′55″N., long. 114°38′27″W.; thence to point of origin; excluding that airspace within Federal Airways and the Burley, ID, Class E airspace area.

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Issued in Seattle, Washington, on January 11, 2002.

Charles E. Davis,

Acting Assistant Manager, Air Traffic Division, Northwest Mountain Region.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket Nos. 01P–0119 and 01P–0235]

Clinical Chemistry and Clinical Toxicology Devices; Reclassification of Cyclosporine and Tacrolimus Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify cyclosporine and tacrolimus assays from class III (premarket approval) to class II (special controls). Cyclosporine and tacrolimus assays are intended for the quantitative determination of cyclosporine and tacrolimus concentrations and are used as an aid in the management of transplant patients receiving these drugs. FDA is proposing this action after reviewing reclassification petitions submitted by Dade Behring, Inc., and Microgenics, Inc. The agency is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the Federal Register, FDA is announcing the availability of a class II special controls draft guidance entitled ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA.''

DATES: Submit written or electronic comments by April 22, 2002. See section XI of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act, as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the act. This section allows FDA to initiate reclassification of a postamendments class III device under section 513(f)(1) of the act, or the manufacturer or importer of a device to petition the Secretary of the Department of Health and Human Services for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. To change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

II. Regulatory History of the Device

Cyclosporine assays are used for the quantitative determination of cyclosporine concentrations as an aid in the management of transplant patients receiving cyclosporine. Tacrolimus