

are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2011-0047/Airspace Docket No. 11-AGL-1." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.

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 Central Service Center, 2601 Meacham Blvd., Fort Worth, TX 76137.

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

The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), Part 71 by amending Class E airspace extending upward from 700 feet above the surface for standard instrument approach procedures at Grand Marais/Cook County Airport, Grand Marais, MN. Controlled airspace is needed for the safety and management of IFR operations at the airport.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9U, dated August 18, 2010 and effective September 15, 2010, 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 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 U.S. Code. Subtitle 1, 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 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 would amend controlled airspace at Grand Marais/Cook County Airport, Grand Marais, MN.

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, 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 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010, is amended as follows:

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

* * * * *

AGL MN E5 Grand Marais, MN [Amended]

Grand Marais/Cook County Airport, MN
(Lat. 47°50'18" N., long. 90°22'59" W.)

Cook County NDB
(Lat. 47°50'24" N., long. 90°23'08" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Grand Marais/Cook County Airport, and within 2 miles each side of the 275° bearing from the airport extending from the 6.4-mile radius to 8.3 miles west of the airport, and within 2.2 miles each side of the 104° bearing from the Cook County NDB extending from the 6.4-mile radius to 7 miles east of the airport, excluding that airspace which overlies P-204.

Issued in Fort Worth, TX, on May 11, 2011.

Walter L. Tweedy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2011-D-0102]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Bacillus* Species Detection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Bacillus* spp. Detection." This draft guidance document describes means by which in vitro diagnostic devices for *Bacillus* species (spp.) detection may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify in vitro diagnostic devices for *Bacillus* spp. detection into class II, subject to special controls. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the

final version of the guidance, submit either electronic or written comments on the draft guidance by August 16, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Bacillus* spp. Detection" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Beena Puri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5553, Silver Spring, MD 20993-0002, 301-796-6202.

SUPPLEMENTARY INFORMATION:

I. Background

This draft special controls guidance document was developed to support the proposed classification of in vitro diagnostic devices for *Bacillus* spp. detection, a previously unclassified preamendments device, into class II (special controls). On March 7, 2002, the Microbiology Devices Panel (the Panel) recommended that in vitro diagnostic devices for *Bacillus* spp. detection be classified into class II. The Panel believed that class II with the special controls (guidance document and limitations on the distribution) would provide reasonable assurance of the safety and effectiveness of the device.

After the panel meeting, FDA found three additional in vitro diagnostic devices for *Bacillus* spp. detection to be substantially equivalent to another device within that type. This device has the same intended use as its predicate device but makes use of newer nucleic acid amplification technology (NAAT). While NAAT detection devices exhibit technological differences from the preamendments *Bacillus* spp. detection

devices, FDA has determined that they are as safe and effective as, and do not raise different questions of safety and effectiveness than, their predicates. (See section 513(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(i)).)

This draft guidance document identifies the proposed classification regulation and product code and issues of safety and effectiveness that require special controls. Elsewhere in this **Federal Register**, in its publication of the proposed classification regulation, FDA is including proposed distribution limitations as another special control. FDA believes that the special controls described in the draft guidance and the proposed regulation when combined with general controls will be sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this guidance document, if finalized, in addition to general controls, and the special control in the proposed rule, if finalized, will provide reasonable assurance of the safety and effectiveness of in vitro diagnostic devices for *Bacillus* spp. detection classified under § 866.3045 (21 CFR 866.3045). If classified as a class II device under § 866.3045, an in vitro diagnostic device for *Bacillus* spp. detection will need to comply with the requirement for special controls; manufacturers will need to address the issues requiring special controls as identified in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness as well as comply with any additional controls specified in the classification regulation itself.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Bacillus* spp. Detection," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1667 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, and 21 CFR 809.10 have been approved under OMB control number 0910-0485.

The labeling requirement listed in Section 8A, "Intended Use," is not subject to review under the PRA because it is a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2) and 21 CFR 1040.10(g)).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2011-N-0103]

Microbiology Devices; Classification of In Vitro Diagnostic Device for *Bacillus* Species Detection

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify in vitro diagnostic devices for *Bacillus* species (spp.) detection into