Robert Parker Hospital Heliport. The affected Class E–5 airspace for the airports included in these descriptions will be consolidated into the amended Binghamton, NY airspace description contained in Docket No. FAA–2005–22100, Airspace Docket No. 05–AEA–16, effective February 16, 2006.

DATES: Effective date: February 16, 2006.

Comment Date: Comments must be received on or before November 25, 2005.

ADDRESSES: Send comments on the rule to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2005–22494; Airspace Docket No. 05–AEA–22 at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov.* You may review the public docket containing the rule, any comments received, and any final disposition in person in the Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Area Director, Eastern Terminal Operations, Federal Aviation Administration, 1 Aviation Plaza, Jamaica, NY 11434–4890.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace and Operations, ETSU, Federal Aviation Administration, 1 Aviation Plaza, Jamaica, NY 11434–4809, telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Although this action is a final rule, which involves the amendment of Class E airspace surrounding Binghamton, NY, by consolidating that airspace into one description, and was not preceded by notice and public procedure, comments are invited on the rule. This rule will become effective on the date specified in the **DATES** section. However, after the review of any comments, if the FAA finds that further changes are appropriate, it will initiate rulemaking proceedings to extend the effective date or to amend the regulation.

Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule, and in determining whether additional rulemaking is required. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the rule which might suggest the need to modify the rule.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) amends the description of Class E airspace in the Binghamton, NY area by removing the airspace designations for Cortland, NY, Cortland County-Chase Field Airport (N03); Ithaca, NY, Tompkins County Airport (ITH); Elmira, NY, Elmira/Corning Regional Airport (ELM); Endicott, NY, Tri-Cities Airport (CZG); and Sayre, PA, Robert Parker Hospital Heliport. It consolidates those airspace areas into the amended Binghamton, NY description. The proliferation of airports with Instrument Flight Rule (IFR) operations within the Binghamton, NY geographic area has resulted in the overlap of numerous Class E airspace areas that complicate the chart depictions.

This action clarifies the airspace and diminishes the scope and complexity of charting. The IFR airports within those areas will be incorporated into the Binghamton, NY Class E airspace area. Accordingly, since this action merely consolidates these airspace areas into one airspace designation and has inconsequential impact on aircraft operations in the area, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Class E airspace designations for airspace extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9N, dated September 1, 2005, and effective September 16, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order. 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 will not have 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, Incorporated 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—[AMENDED]

■ 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 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005 and effective September 16, 2005, is amended as follows:

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

* * * * *

AEA NY E5 Cortland, NY [Removed]

AEA NY E5 Ithaca, NY [Removed]

AEA NY E5 Elmira, NY [Removed]

AEA NY E5 Endicott, NY [Removed]

AEA PA E5 Sayre, PA [Removed]

* * * * *

Issued in Jamaica, New York on October 11, 2005.

John G. McCartney,

Acting Area Director, Eastern Terminal Operations.

[FR Doc. 05–21321 Filed 10–25–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005P–0397]

Medical Devices; Immunology and Microbiology Devices; Classification of Cystic Fibrosis Transmembrane Conductance Regulator Gene Mutation Detection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the cystic fibrosis transmembrane conductance regulator (CFTR) gene

mutation detection systems into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for the device.

DATES: This final rule is effective November 25, 2005. The classification was effective May 9, 2005.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0597.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with 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 marketed 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) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request that FDA classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on April 1, 2005, classifying the Tm Bioscience Corp., Tag-It™ Cystic Fibrosis Kit into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On April 5, 2005, Tm Bioscience Corp., submitted a petition requesting classification of the Tag-It™ Cystic Fibrosis Kit under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Tm Bioscience Corp., Tag-It™ Cystic Fibrosis Kit can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system'' and it is identified as a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for stand-alone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening. CFTR gene mutation detection systems may consist of different reagents and instruments, including polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, sequencers, signal detection instruments, and software packages.

FDA has identified the risks to health associated specifically with this type of device as improper clinical recommendations and improper medical patient management due to failure of the test to perform as indicated or errors in interpretation of results. Specifically, in the context of carrier-screening in adults, a false-negative or false-positive result or interpretation could lead to inaccurate estimates of a couple's risk of having a child with cystic fibrosis. In the context of assisting in the diagnosis of CF in newborns and children, a false-negative could lead to a delay in the definitive diagnosis and treatment; a false-positive could lead to unnecessary or inappropriate treatment.

FDA believes that the class II special controls guidance document aids in mitigating the potential risks to health by providing recommendations for validation of performance characteristics, as well as for labeling. The guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that the special controls guidance document, in addition to general controls, addresses the risks to health identified previously and provides reasonable assurance of the safety and effectiveness of the device. Therefore, on May 9, 2005, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this device by adding § 866.5900.

Following the effective date of this final rule, any firm submitting a 510(k) premarket notification for a CFTR gene mutation detection system will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the CFTR gene

mutation detection system they intend to market.

II. What Is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. What Is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order and so it not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply with the Paperwork Reduction Act of 1995?

FDA concludes that this rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also concludes that the special controls guidance document identified by this rule contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems.''

VI. What References are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Tm Bioscience Corp., dated April 4, 2005.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 866.5900 to subpart F to read as follows:

§ 866.5900 Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.

(a) *Identification.* The CFTR gene mutation detection system is a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for stand-alone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection System.'' See § 866.1(e) for the availability of this guidance document.

Dated: October 17, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–21348 Filed 10–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–05–124]

RIN 1625–AA–09

Drawbridge Operation Regulations; Knapps Narrows, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Route 33/Knapps Narrows Bridge, at mile 0.4, across Knapps Narrows, at Tilghman, Maryland. This deviation allows the drawbridge to remain closed-to-navigation each day from 9 p.m. to 5 a.m., beginning on Monday, October 24 until Friday, October 28, 2005, to facilitate mechanical repairs.

DATES: The deviation is effective from 9 p.m. to 5 a.m. from October 24 until October 28, 2005.