Grumman Model G–73 Mallard airplanes.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the GPWS equipment to provide certain aural warnings, which could inhibit the ability of the flight crew to prevent the airplane from impacting the ground, accomplish the following:

(a) Within 60 days after the effective date of this AD, remove and replace Centaurus Model C3–100 GPWS equipment with a similar type of equipment that meets minimum performance standards specified in Technical Standard Order (TSO) C–92b, dated August 19, 1976. Accomplish the actions in accordance with a method approved by the Manager, Flight Test and Systems Branch, ANM–111, FAA, Transport Airplane Directorate.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager,

Flight Test and Systems Branch, ANM–111. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Flight Test and Systems Branch, ANM–111.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Flight Test and Systems Branch, ANM–111.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on February 25, 1997.

Issued in Renton, Washington, on January 3, 1997.

S. R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–1351 Filed 1–17–97; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 71

[Airspace Docket No. 96–AEA–09]

Establishment of Class E Airspace; Montauk, NY; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects the airspace description of the Montauk, NY, Class E airspace area published in a final rule on November 27, 1996 (61 FR 60187), Airspace Docket Number 96–AEA–09.

EFFECTIVE DATE: January 21, 1997.

FOR FURTHER INFORMATION CONTACT: Michael J. Sammartino, Air Traffic Division, Operations Branch, AEA–530, Federal Aviation Administration, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430; telephone: (718) 553–4530.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 96–30207, Airspace Docket 96–AEA–09, published on November 27, 1996 (61 FR 60187) established the Class E airspace at Montauk, NY. An error was discovered in the legal description. This action adds the Hampton VORTAC to the legal description.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the airspace legal description, as published on November 27, 1996 (61 FR 60187), Federal Register Document 96–30207; page 60187, column 3 is corrected in the legal description to the incorporation by reference in 14 CFR 71.1 as follows:

§ 71.1 [Corrected]

* * * * *

AEA NY E5 Montauk, NY [Corrected]

Montauk Airport, NY
(lat. 41°04′35″ N, long. 71°55′15″ W)
Hampton VORTAC
(lat. 40°55′08″ N, long. 72°19′00″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Montauk Airport and within 4 miles each side of the 062° bearing from the Hampton VORTAC extending from the 6.5-mile radius to 10 miles northeast of the VORTAC and excluding that portion within the Block Island, RI 700 foot Class E Airspace Area and that portion within the East Hampton, NY Class E Airspace Area.

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Issued in Jamaica, New York, on January 8, 1997.

James K. Buckles,

Acting Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–1399 Filed 1–17–97; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 96–AEA–13]

Amendment to Class E Airspace; Galax, VA

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Final rule.

SUMMARY: This amendment modifies the Class E airspace at Galax, VA, to accommodate a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 36 at Twin County Airport. This amendment also corrects the geographic position of Twin County Airport published as a Notice of Proposed Rulemaking in the Federal Register November 27, 1996 (61 FR 60237). The intended effect of this action is to provide adequate controlled airspace for instrument flight rules (IFR) operations at the airport.

EFFECTIVE DATE: 0901 UTC, March 27, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Frances Jordan, Airspace Specialist, Operations Branch, AEA–530, Air Traffic Division, Eastern Region, Federal Aviation Administration, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430, telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

History

On November 27, 1996, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by modifying Class E airspace at Galax, VA, (61 FR 60237). This action would provide adequate Class E airspace for IFR operations at Twin County Airport.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

Class E airspace areas designations are published in paragraph 6005 of FAA Order 7400.9D, dated September 4, 1996, and effective September 16, 1996, 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 Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) modifies Class E airspace area at Galax, VA, to accommodate a GPS RWY 36 SIAP and for IFR operations at Twin County Airport.

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 10034; 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, 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—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

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

* * * * *

AEA VA E5 Galax, VA [Revised]

Twin County Airport, VA
(lat. 36°45′58″ N, long. 80°49′25″ W)
Pulaski VORTAC
(lat. 37°05′16″ N, long. 80°42′46″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Twin County Airport and within 4 miles each side of the Pulaski VORTAC 194° radial extending from the 6.3-mile radius to 7 miles south of the VORTAC and within 4 miles each side of the 179° bearing from the airport extending from the 6.3-mile radius to 12 miles south of the airport.

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Issued in Jamaica, New York on January 8, 1997.

James K. Buckles,

Acting Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–1400 Filed 1–17–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 95N–0033]

Dental Devices; Endodontic Dry Heat Sterilizer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the endodontic dry heat sterilizer, a medical device. Commercial distribution of this device must cease, unless a manufacturer or importer has filed with FDA a PMA or a notice of completion of a PDP for its version of the endodontic dry heat sterilizer within 90 days of the effective date of this regulation. This regulation reflects FDA's exercise of its discretion to require a PMA or notice of completion of a PDP for the preamendments device.

EFFECTIVE DATE: January 21, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 12, 1987 (52 FR 30082), FDA issued a final rule classifying the endodontic dry heat sterilizer (§ 872.6730 (21 CFR 872.6730)) into class III (premarket approval). Section 872.6730 applies to: (1) Any endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976, the date of enactment of the Medical Devices Amendments of 1976 (Pub L. 94–295), and (2) any device that FDA has found to be substantially equivalent to the endodontic heat sterilizer and that has been marketed on or after May 28, 1976.

In the Federal Register of December 30, 1980 (45 FR 86155), FDA published the recommendation of the Dental Device Classification Panel (the panel), of the Medical Devices Advisory Committee, an FDA advisory committee, regarding the classification of the device.

The panel recommended that the device be in class III (premarket approval) because the device presented an unreasonable risk of illness or injury. According to the panel, the devices failed to sterilize adequately various endodontic and dental instruments. The panel felt that the failures could be the result of: (1) The device not reaching and maintaining an adequate temperature because of a faulty thermostat or (2) the result of unequal heat distribution by the glass beads throughout the well despite sufficient heat. The panel believed that it was not possible to establish an adequate performance standard for the device because satisfactory performance had never been demonstrated. The panel recommended the device to be subject to premarket approval to ensure that manufacturers of the device demonstrate satisfactory performance and that further study was necessary to determine the causes of the device's ineffectiveness.

FDA agreed with the panel's recommendation that endodontic dry heat sterilizers be classified into class III. FDA believed that there was an unreasonable risk of illness or injury because of the potential failure of the device to sterilize dental instruments adequately. FDA believed that there was inadequate information to determine if general controls or a performance standard would provide reasonable assurance of safety and effectiveness.

In the Federal Register of June 7, 1995 (60 FR 30032), FDA published a proposed rule to require the filing under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)) of a PMA or a notice of completion of a PDP for the endodontic dry heat sterilizer. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and the benefits to the public from use of the device (60 FR 30032 at 30037). The June 7, 1995, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in classification of the endodontic heat sterilizer was required to be submitted by September 5, 1995. The comment period closed August 7, 1995.