DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0578; Airspace Docket No. 11–ASO–24]

Establishment of Class D and E Airspace and Amendment of Class E; Brooksville, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class D and E airspace and amends existing Class E airspace at Brooksville, FL, to accommodate a new air traffic control tower at Hernando County Airport This action enhances the safety and management of Instrument Flight Rules (IFR) operations for standard instrument approach procedures at the airport. This action also makes a minor adjustment to the geographic coordinates of the airport.

DATES: Effective 0901 UTC, February 9, 2012. The Director of the **Federal Register** approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

History

On September 7, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class D and E airspace and amend existing Class E airspace at Brooksville, FL, to accommodate a new air traffic control tower at Hernando County Airport (76 FR 55298). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and E airspace designations are published in Paragraphs 5000, 6002, and 6005, respectively, of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class D airspace extending upward from the surface to and including 1,500 feet MSL within a 5.1-mile radius of Hernando County Airport, Brooksville, FL, and Class E surface area airspace within a 5.1-mile radius of the airport. This action also amends Class E airspace extending upward from 700 feet above the surface within a 7.6-mile radius of the airport. Additional controlled airspace is necessary to support the new air traffic control tower and new standard instrument approach procedures developed for continued safety and management of IFR operations at Hernando County Airport. Also, the geographic coordinates of the airport are adjusted to be in concert with the FAAs aeronautical database.

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, is non-controversial and unlikely to result in adverse or negative comments. 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 United States Code. Subtitle I, 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 establishes and amends controlled airspace at Hernando County Airport, Brooksville, FL.

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—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 Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 5000 Class D Airspace

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ASO FL D Brooksville, FL [NEW]

Hernando County Airport, FL
(Lat. 28°28′42″ N., long. 82°27′33″ W.)

That airspace extending upward from the surface up to and including 1,500 feet MSL within a 5.1-mile radius of the Hernando County Airport. This Class D airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E Airspace Designated as Surface Areas

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ASO FL E2 Brooksville, FL [NEW]

Hernando County Airport, FL
(Lat. 28°28′42″ N., long. 82°27′33″ W.)

That airspace extending from the surface within a 5.1-mile radius of Hernando County Airport. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 feet or More Above the Surface of the Earth.

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ASO FL E5 Brooksville, FL [AMENDED]

Hernando County Airport, FL
(Lat. 28°28′42″ N., long. 82°27′33″ W.)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of Hernando County Airport.

Issued in College Park, Georgia, on December 5, 2011.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2011–32037 Filed 12–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2011–N–0898]

Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an interim final rule amending its postmarketing reporting regulations implementing certain provisions of the Federal Food, Drug and Cosmetic Act. The provisions of the Federal Food, Drug and Cosmetic Act require manufacturers who are the sole manufacturers of certain drug products to notify FDA at least 6 months before discontinuance of manufacture of the products. This interim final rule modifies the term ''discontinuance'' and clarifies the term ''sole manufacturer'' with respect to notification of discontinuance requirements. The broader reporting resulting from these changes will enable FDA to improve its collection and distribution of drug shortage information to physician and patient organizations and to work with manufacturers and other stakeholders to respond to potential drug shortages.

DATES: This interim final rule is effective January 18, 2012. Submit either electronic or written comments on the provisions of this interim final rule by February 17, 2012. Submit comments on the information collection requirements under the Paperwork Reduction Act of 1995 by January 3, 2012 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0898 by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

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

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.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0898 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, 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.regulations.gov* and insert the docket number, 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: Kalah Auchincloss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, (301) 796–0659, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, (301) 827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 18, 2007 (72 FR 58993), we (FDA) issued a final rule to revise our postmarketing reporting requirements to implement section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c). Section 506C of the Federal Food, Drug, and Cosmetic Act (section 506C) requires manufacturers who are the sole manufacturers of certain drug products to notify us at least 6 months before discontinuance of manufacture of the products. Section 506C applies to sole manufacturers of products that meet the following three criteria:

1. The products are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition;

2. The products are approved under section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) or (j)); and

3. The products are not originally derived from human tissue and replaced by a recombinant product.

These three criteria are statutory requirements. FDA assesses whether a drug is ''life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition'' on a case-by-case basis, but intends to provide further guidance on this issue in the near future.

Section 506C also requires us to distribute certain information about covered discontinuances to appropriate physician and patient organizations. Under section 506C, FDA may reduce the 6-month notification period if we find good cause exists for the reduction.

Recent experience with drug shortages in the United States has shown the serious and immediate impacts they can have on patients and healthcare providers, particularly those shortages involving drugs that are manufactured by a small number of firms and for which there are no good therapeutic substitutes available. The number of drug shortages annually has tripled from 61 in 2005 to 178 in 2010. Some shortages delay or deny needed care for patients, because they involve critical drugs used to treat cancer, to provide required parenteral nutrition, or to address other serious medical conditions. Other shortages can result in providers prescribing second-line alternatives, which may be less effective and higher risk than first-line therapies. A survey of 1,800 health practitioners conducted by the Institute for Safe Medication Practices (ISMP) concluded that drug shortages could lead to medication errors and poor patient outcomes because shortages can result in the use of secondary alternative therapies (Ref. 1).

In light of increasing concerns about the impact of drug shortages on health care in the United States, on October 31, 2011, the President issued Executive Order 13588 directing the FDA to ''take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines'' and noting that ''one important step is ensuring that the FDA and the public