**(m) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing 737–100/200/200C/300/400/500 Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D6–38278–CMR, dated March 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on November 20, 2019.

**Dorr Anderson,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019–26963 Filed 12–13–19; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2019–0563; Airspace Docket No. 19–ANE–4]**

**RIN 2120–AA66**

## Amendment of Class E Airspace; Pittsfield, MA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends Class E airspace extending upward from 700 feet above the surface at Pittsfield Municipal Airport, Pittsfield, MA, to accommodate airspace reconfiguration due to the redesign of the Localizer (LOC)/Distance Measuring Equipment (DME) Runway (RWY) 26 approach. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this airport. This action also updates the geographic coordinates of this airport.

**DATES:** Effective 0901 UTC, January 30, 2020. 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 7400.11 and publication of conforming amendments.

**ADDRESSES:** FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave, College Park, GA 30337; telephone (404) 305–6364.

**SUPPLEMENTARY INFORMATION:**

### Authority for This Rulemaking

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 amends Class E airspace extending upward from 700 feet above the surface for Pittsfield Municipal Airport, Pittsfield, MA, due to the redesign of the LOC/DME RWY 26 approach.

### History

The FAA published a notice of proposed rulemaking in the **Federal Register** (84 FR 41938, August 16, 2019) for Docket No. FAA–2019–0563 to amend Class E airspace extending upward from 700 feet above the surface for Pittsfield Municipal Airport, Pittsfield, MA, due to the redesign of the LOC/DME RWY 26 approach.

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 E airspace designations are published in Paragraph 6005 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

### Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

### The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 amends Class E airspace extending upward from 700 feet above the surface at Pittsfield Municipal Airport, Pittsfield, MA, by increasing the airport radius to 9.6 miles (from 4 miles), enlarging the northeast extension of the airport to 6-miles each side of a 064° bearing of the airport, extending from the 9.6-mile radius to 18-miles northeast of the airport, and eliminating the southwest extension of the airport to accommodate airspace reconfiguration due to the redesign of the LOC/DME RWY 26 approach into the airport. Also, the geographic coordinates of the airport are adjusted to coincide with the FAA's aeronautical database. These changes are necessary for continued safety and management of IFR operations at this airport.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

### Regulatory Notices and Analyses

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. 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 only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**Lists 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(f), 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

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

* * * * *

**ANE MA E5 Pittsfield, MA [Amended]**

Pittsfield Municipal Airport, MA
(Lat. 42°25′39″ N, long. 73°17′27″ W)

That airspace extending upward from 700 feet above the surface within a 9.6-mile radius of the Pittsfield Municipal Airport, and within 6-miles each side of the 064° bearing of the airport, extending from the 9.6-mile radius to 18-miles northeast of the airport.

Issued in College Park, Georgia, on December 4, 2019.

**Ryan Almasy,**

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

[FR Doc. 2019–26857 Filed 12–13–19; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 310

**[Docket No. FDA–2017–N–6924]**

**RIN 0910–AH47**

## Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule repealing a regulation that requires an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for any drug product that is sterilized by irradiation (the irradiation regulation). Repealing the irradiation regulation will mean that over-the-counter (OTC) drug products that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements can be marketed legally without an NDA or ANDA, even if they are sterilized by irradiation. FDA is taking this action because the irradiation regulation is out of date and unnecessary.

**DATES:** This rule is effective January 15, 2020.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Sudha Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5234, Silver Spring, MD 20993–0002, 301–796–3345.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**



**I. Executive Summary**

In this final rule, FDA repeals the irradiation regulation, which provided that any drug sterilized by irradiation was a new drug. OTC drugs marketed pursuant to the OTC Drug Review that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements now can be marketed legally without an FDA-approved NDA or ANDA, even if the drugs are sterilized by irradiation. As the Agency explained in the proposed rule published in the **Federal Register** of September 12, 2018 (83 FR 46121), FDA is taking this action because the Agency no longer concludes that drugs sterilized by irradiation are necessarily new drugs. The technology of controlled nuclear radiation for sterilization of drugs is now well understood. In addition, drugs that are marketed pursuant to the OTC Drug Review must be manufactured in compliance with current good manufacturing practices (CGMPs). Appropriate and effective sterilization of drugs, including by irradiation, is adequately addressed by the CGMP requirements. Repealing the irradiation regulation eliminates a requirement that is no longer necessary and will not diminish public health protections.

The estimated one-time costs of this rule range from $25 to $32. Avoiding the unnecessary preparation and review of a premarket drug application will generate an estimated one-time cost savings that range from about $0.40 million to $2.16 million. Over 10 years with a 7 percent discount rate, the annualized net cost savings range from $0.05 million to $0.29 million, with a primary estimate of $0.06 million; with a 3 percent discount rate, the annualized net cost savings range from $0.05 million to $0.25 million, with a primary estimate of $0.05 million. Over an infinite horizon, we assume that one sponsor will benefit from this deregulatory action every 10 years; the present value of the net cost savings over the infinite horizon range from $0.76 million to $4.11 million with a 7