airspace. This regulation is within the scope of that authority as it amends Class E airspace extending upward from 700 feet above the surface at Marion County Regional Airport, Flippin, AR, and Baxter County Airport, Mountain Home, AR, to support instrument flight rule operations at these airports.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 60789; November 27, 2018) for Docket No. FAA–2018–0952 to amend Class E airspace extending upward from 700 feet above the surface at Marion County Regional Airport, Flippin, AR, and Baxter County Airport, Mountain Home, AR. 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 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations 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 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C 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 by: Modifying the Class E airspace extending upward from 700 feet above the surface at Marion County Regional Airport, Flippin, AR, to within a 6.5-mile radius (increased from a 6.4-mile radius); removing the Flippin VOR/DME from the airspace legal description; removing the extension east of the airport; removing the city associated with the airport from the airspace legal description to comply with FAA Order 7400.2L, Procedures for Handling Airspace Matters; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

And modifying the Class E airspace extending upward from 700 feet above the surface at Baxter County Airport (previously Baxter County Regional Airport), Mountain Home, AR, by removing the extension south of the airport associated with the Flippin VOR/DME; removing the city associated with the airport from the airspace legal description to comply with FAA Order 7400.2L; and updating the name of the airport to coincide with the FAA's aeronautical database. This action is the result of an airspace review caused by the decommissioning of the Flippin VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

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, 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 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 5–6.5.a. 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 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

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

* * * * *

ASW AR E5 Flippin, AR [Amended]

Marion County Regional Airport, AR
(Lat. 36°17′27″ N, long. 92°35′25″ W)
Baxter County Airport, AR
(Lat. 36°22′08″ N, long. 92°28′14″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Marion County Regional Airport and within a 6.5-mile radius of Baxter County Airport.

Issued in Fort Worth, Texas, on February 20, 2019.

John A. Witucki,

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

[FR Doc. 2019–03284 Filed 2–27–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. FDA–2019–N–0646]

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its regulations to reflect a change of address for the Center for Drug Evaluation and Research's (CDER's) Office of Generic Drugs (OGD) Document Room from Rockville, MD, to Beltsville, MD. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective April 1, 2019.

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–7997.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 312 and 314 (21 CFR parts 312 and 314) to reflect a change of address for CDER's OGD Document Room from Rockville, MD, to Beltsville, MD. The new address is as follows: Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update a mailing address for those submissions not required to be submitted through FDA's Electronic Submission Gateway. Unless granted a waiver or exemption from the requirements of section 745A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1), submissions under section 505(j) of the FD&C Act (21 U.S.C. 355(j)) are required to be submitted in electronic format.[1]

The amendments are as follows:

- In § 312.140(a)(1), the address for applicants to submit investigational new drug applications (INDs) for in vivo bioavailability and bioequivalence studies to support abbreviated new drug applications (ANDAs) is updated to the Beltsville Central Document Room location.
- In § 314.52(a)(2), for 505(b)(2) applicants submitting a patent certification, the address to send written or electronic communication to obtain the address of a new drug application (NDA) holder or its attorney, agent, or authorized official is updated to the Beltsville Central Document Room location.
- In § 314.53(f)(1), the address for persons other than the NDA holder to send patent listing dispute communication is updated to the Beltsville Central Document Room location.
- In § 314.95(a)(2), for ANDA applicants submitting a patent certification, the address to send written or electronic communication to obtain the address of an NDA holder or its attorney, agent, or authorized official is updated to the Beltsville Central Document Room location.
- In § 314.440(a)(2), the address for applicants to submit ANDAs, amendments, supplements, resubmissions, and correspondence not associated with an ANDA is updated to the Beltsville Central Document Room location.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312 and 314 are amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 1. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

■ 2. In § 312.140, revise paragraph (a)(1) to read as follows:

§ 312.140 Address for correspondence.

(a) * * *

(1) *For drug products regulated by CDER.* Send the IND submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 3. The authority citation for part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 371, 374, 379e, 379k–1.

§ 314.52 [Amended]

■ 4. In § 314.52(a)(2), remove the text ''Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855'' and add in its place the text ''Central Document Room, Attn: Orange Book Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

§ 314.53 [Amended]

■ 5. In § 314.53(f)(1), remove the text ''Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, 7620 Standish Pl., Rockville, MD 20855'' and add in its place the text ''Central Document Room, Attn: Orange Book Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

§ 314.95 [Amended]

■ 6. In § 314.95(a)(2), remove the text ''Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855'' and add in its place the text ''Central Document Room, Attn: Orange Book Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

■ 7. In § 314.440, revise paragraph (a)(2) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) * * *

(2) Except as provided in paragraph (a)(4) of this section, an abbreviated application under § 314.94, and amendments, supplements, and resubmissions should be directed to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. This includes items sent by parcel post or overnight courier service. Correspondence not associated with an abbreviated application also should be addressed to 5901–B Ammendale Rd., Beltsville, MD 20705–1266.

* * * * *

Dated: February 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03542 Filed 2–27–19; 8:45 am]

BILLING CODE 4164–01–P

[1] See FDA guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (January 2019, Revision 6). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.*