DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2015-0044; Airspace Docket No. 15-ASO-3]

Proposed Amendment of Class E Airspace; Greenville, SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking

(NPRM).

SUMMARY: This action proposes to amend Class E Airspace at Greenville, SC as new Standard Instrument Approach Procedures have been developed at Greenville Downtown Airport. This action would enhance the safety and management of Instrument Flight Rules (IFR) operations at the airport. This action also would update the geographic coordinates of the airport.

DATES: Comments must be received on or before June 8, 2015. **ADDRESSES:** Send comments on this rule

to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Bldg Ground Floor Rm W12-140, Washington, DC 20590-0001; Telephone: 1-800-647-5527; Fax: 202-493–2251. You must identify the Docket Number FAA-2015-0044; Airspace Docket No. 15-ASO-3, at the beginning of your comments. You may also submit and review received comments through the Internet at http:// www.regulations.gov. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this proposed incorporation by reference material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783.

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:

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2015–0044; Airspace Docket No. 15–ASO–3) and be submitted in triplicate to the Docket Management System (see ADDRESSES section for address and phone number). You may also submit comments through the Internet at http://www.regulations.gov.

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2015-0044; Airspace Docket No. 15-ASO-3." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through http://www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory circular No. 11-2A, Notice of Proposed Rulemaking distribution System, which describes the application procedure.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the ADDRESSES section of this proposed rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet above the surface at Greenville Downtown Airport, Greenville, SC. Airspace reconfiguration to within a 9.3mile radius of the airport is necessary to support new Standard Instrument Approach Procedures developed at Greenville Downtown Airport, and for continued safety and management of IFR operations at the airport. The geographic coordinates of the airport would be adjusted to coincide with the FAAs aeronautical database.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9Y, dated August 6, 2014, and effective September 15, 2014, 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 proposed 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 will only affect air traffic procedures and air navigation, it is certified that this proposed 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 proposed 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 proposed regulation is within the scope of that authority as it would amend Class E airspace at Greenville Downtown Airport, Greenville, SC.

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, effective September 15, 2014, is amended as follows:

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

* * * * *

ASO SC E5 Greenville, SC [Amended]

Greenville Downtown Airport, SC (Lat. 34°50′53″ N.,long.82°21′00 W.) Greenville-Spartanburg International Airport, SC

(Lat. 34°53′44″ N., long. 82°13′08″ W.) Donaldson Center Airport

(Lat. 34°45′30″ N., long. 82°22′35″ W.) DYANA NDB

(Lat. 34°41'28" N., long. 82°26'37" W.)

That airspace extending upward from 700 feet above the surface within a 9.3-mile radius of Greenville Downtown Airport, and within a 10-mile radius of Greenville-Spartanburg International Airport, and within a 6.7-mile radius of Donaldson Center Airport, and within 4 miles northwest and 8 miles southeast of of the 224° bearing from the DYANA NDB extending from the 6.7-mile radius to 16 miles southwest of Donaldson Center Airport.

Issued in College Park, Georgia, on March 30, 2015.

Gerald E. Lynch,

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

[FR Doc. 2015–09398 Filed 4–23–15; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. FDA-2011-N-0830]

RIN 0910-AF97

Abbreviated New Drug Applications and 505(b)(2) Applications; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the Federal Register of February 6, 2015. In the proposed rule, FDA requested comments on its proposal to implement portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that govern the approval of 505(b)(2)

applications and abbreviated new drug applications (ANDAs). FDA also requested comment on its proposal to amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published February 6, 2015 (80 FR 6802). Submit either electronic or written comments on the proposed rule by June 8, 2015.

ADDRESSES: You may submit comments by any of the following methods:

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:

• Mail/Hand delivery/Courier (for paper 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 Docket No. FDA—2011—N—0830 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:

Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6268, Silver Spring, MD 20993–0002, 301– 796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 6, 2015, FDA published a proposed rule with a 90-day comment period to