related issue. The review is conducted at the discretion of OASCR or if there has been a formal finding of non-compliance.

(g) *Conducted programs and activities* means the program services, benefits, or resources delivered directly to the public by USDA.

(h) *Days* mean calendar days, not business days.

(i) *Department (used interchangeably with USDA)* means the Department of Agriculture and includes each of its operating agencies and other organizational units.

(j) *Discrimination* means unlawful treatment or denial of benefits, services, rights, or privileges to a person or persons based on race, color, national origin, religion, sex (including gender identity), sexual orientation, disability, age, marital status, sexual orientation, familial status, parental status, income derived from a public assistance program, political beliefs, or gender identity.

(k) *Secretary* means the Secretary of Agriculture or any officer or employee of the Department whom the Secretary has heretofore delegated, or whom the Secretary may hereafter delegate, the authority to act in his or her stead under the regulations in this part.

§ 15d.3 Discrimination prohibited.

(a) No agency, officer, or employee of USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by USDA.

(b) No person shall be subjected to reprisal for opposing any practice(s) prohibited by this part, for filing a complaint, or for participating in any other manner in a proceeding under this part.

§ 15d.4 Compliance.

(a) *Compliance program.* OASCR shall evaluate each agency's efforts to comply with this part and shall make recommendations for improving such efforts.

(1) OASCR shall oversee the compliance reviews and evaluations, and issue compliance reports that monitor compliance efforts to ensure that there is equitable and fair treatment in conducted programs.

(2) OASCR shall monitor all settlement agreements pertaining to program complaints for compliance to ensure full implementation and enforcement.

(3) OASCR shall oversee Agency Head Assessments to ensure that Agency Heads are in compliance with civil rights laws and regulations.

(4) OASCR shall monitor all findings of non-compliance to ensure that compliance is achieved.

(5) OASCR shall require agencies to collect the race, ethnicity, and gender of applicants and program participants, who choose to provide such information on a voluntary basis, in USDA-conducted programs, for purposes of civil rights compliance, oversight, and evaluation.

(b) *Agency data collection and compliance reports.* (1) Each Agency shall, for civil rights compliance, collect, maintain, and annually compile data on all program applicants and participants in conducted programs by county and State, including but not limited to, application and participation rate data regarding socially disadvantaged and limited resources applicants and participants. At a minimum, the data should include:

(i) Numbers of applicants and participants by race, ethnicity, and gender, subject to appropriate privacy protections, as determined by the Secretary and in accordance with law; and

(ii) The application and participation rate, by race, ethnicity, and gender, as a percentage of the total participation rate.

(2) Each Agency shall submit to OASCR timely, complete, and accurate program application and participation reports containing the information described in paragraph (b)(1) of this section, on an annual basis, and upon the request of OASCR independently of the annual requirement.

(c) *Complaint reporting compliance.* OASCR shall ensure compliance with mandated complaint reporting requirements, such as those required by section 14006 of the Food, Conservation, and Energy Act of 2008 (PL 110–246).

§ 15d.5 Complaints.

(a) Any person who believes that he or she (or any specific class of individuals) has been, or is being, subjected to practices prohibited by this part may file (or file through an authorized representative) a written complaint alleging such discrimination. The written complaint must be filed within 180 calendar days from the date the person knew or reasonably should have known of the alleged discrimination, unless the time is extended for good cause by ASCR or the designee. Any person who complains of discrimination under this part in any fashion shall be advised of the right to file a complaint as herein provided.

(b) All complaints under this part should be filed with the Office of the Assistant Secretary for Civil Rights (ASCR), 1400 Independence Ave SW., U.S. Department of Agriculture, Washington, DC 20250, who will investigate the complaints. The ASCR will make final determinations as to the merits of complaints under this part and as to the corrective actions required to resolve program complaints. The complainant will be notified of the final determination on the complaint.

(c) Any complaint filed under this part alleging discrimination on the basis of disability will be processed under 7 CFR part 15e.

(d) For complaints OASCR deems appropriate for ADR, OASCR shall offer ADR services to complainants.

Dated: December 19, 2013.

Krysta Harden,

Deputy Secretary.

[FR Doc. 2013–30812 Filed 12–26–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2013–0957; Airspace Docket No. 13–AWP–18]

Proposed Establishment of Class E Airspace; Flagstaff, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at the Flagstaff VHF Omni-Directional Radio Range/Distance Measuring Equipment (VOR/DME) navigation aid, Flagstaff, AZ, to facilitate vectoring of Instrument Flight Rules (IFR) aircraft under control of Albuquerque Air Route Traffic Control Center (ARTCC). The FAA is proposing this action to enhance the safety and management of aircraft operations within the National Airspace System.

DATES: Comments must be received on or before February 10, 2014.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA

Docket No. FAA–2013–0957; Airspace Docket No. 13–AWP–18, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking 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 2013–0957 and Airspace Docket No. 13–AWP–18) 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*.

Commenters 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 FAA Docket No. FAA–2013–0957 and Airspace Docket No. 13–AWP–18''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. 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 through the Internet at *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 the 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 during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E en route domestic airspace extending upward from 1,200 feet above the surface at the Flagstaff VOR/DME navigation aid, Flagstaff, AZ. This action would contain aircraft while in IFR conditions under control of Albuquerque ARTCC by vectoring aircraft from en route airspace to terminal areas.

Class E airspace designations are published in paragraph 6006, of FAA Order 7400.9X, dated August 7, 2013, and effective September 15, 2013, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed 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 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 this proposed rule, when promulgated, would 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 U.S. Code. Subtitle 1, Section 106, describes the authority for 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 the 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 would establish controlled airspace at the Flagstaff VOR/DME navigation aid, Flagstaff, AZ.

This proposal will 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.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, 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 14 CFR 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 the Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 7, 2013, and effective September 15, 2013 is amended as follows:

Paragraph 6006 En route domestic airspace areas

* * * * *

AWP AZ E6 Flagstaff, AZ [New]

Flagstaff VOR/DME, AZ
(Lat. 35°08′50″ N., long. 111°40′27″ W.)

That airspace extending upward from 1,200 feet above the surface within an area bounded by lat. 35°51′00″ N., long. 109°19′00″ W.; to lat. 35°41′00″ N., long. 109°38′30″ W.; to lat. 34°47′52″ N., long.

110°18′52″ W.; to lat. 34°30′00″ N., long. 109°35′00″ W.; to lat. 34°00′00″ N., long. 108°53′00″ W.; to lat. 33°52′30″ N., long. 108°45′00″ W.; to lat. 32°29′30″ N., long. 110°45′45″ W.; to lat. 33°33′12″ N., long. 111°51′21″ W.; to lat. 34°01′00″ N., long. 114°00′00″ W.; to lat. 34°40′00″ N., long. 114°00′00″ W.; to lat. 34°52′00″ N., long. 113°42′00″ W.; to lat. 34°55′00″ N., long. 113°37′00″ W.; to lat. 35°15′20″ N., long. 112°55′40″ W.; to lat. 35°23′00″ N., long. 112°40′00″ W.; to lat. 35°23′48″ N., long. 112°09′11″ W.; to lat. 35°24′00″ N., long. 112°00′00″ W.; to lat. 35°46′00″ N., long. 111°50′30″ W.; to lat. 35°42′00″ N., long. 110°14′00″ W., thence to the point of beginning.

Issued in Seattle, Washington, on December 11, 2013.

Christopher Ramirez,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2013–31093 Filed 12–26–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA–2013–N–0500]

RIN 0910–AG94

Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Correction and Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction and extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is correcting, and extending the comment period for, the proposed rule that appeared in the **Federal Register** of November 13, 2013. In the proposed rule, FDA requested comments on the proposal to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. The proposed rule published without a reference or a link to the accompanying Regulatory Impact Analysis. The Agency is taking this action to correct this omission and to extend the comment period in response to requests for an extension to allow interested persons additional time to submit comments on the proposed rule.

DATES: FDA is extending the comment period on the proposed rule published November 13, 2013, at 78 FR 67985, and on information collection issues under the Paperwork Reduction Act of 1995. Submit either electronic or written comments on the proposed rule by March 13, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 11, 2014 (see the ''Paperwork Reduction Act of 1995'' section of the proposed rule).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0500 and/or Regulatory Information Number (RIN) 0910–AG94, 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 Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of the proposed rule.

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 Agency name and Docket No. FDA–2013–N–0500 and RIN 0910–AG94 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 ''Request for 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(s), 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. 6304, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 13, 2013 (78 FR 67985), FDA published a proposed rule with a 60-day comment period to request comments on the proposal to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. Comments on the proposal to permit holders of abbreviated new drug applications to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug upon submission of a ''changes being effected'' supplement will inform FDA's rulemaking.

The proposed rule published without reference or a link to the accompanying Regulatory Impact Analysis. Accordingly, the following corrections are made to FR Doc. 2013–26799, appearing on page 67985, in the **Federal Register** of November 13, 2013:

1. On page 67996, in the first column, at the end of section IV. Analysis of Impacts, the following is added as a third full paragraph: ''The full discussion of economic impacts is available in docket FDA–2013–N–0500 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 3).''

2. On page 67997, in the third column, the following is added as a third reference: ''3. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.''*

The Agency has received requests for a 60-day extension of the comment period for the proposed rule. These requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 60 days, until March 13, 2014. FDA also is extending the comment period for information collection issues under the Paperwork