

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°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

Reduction Act of 1995 for 60 days, until February 11, 2014. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

## II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-30881 Filed 12-26-13; 8:45 am]

BILLING CODE 4160-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R08-OAR-2011-0834; FRL-9904-90-Region 8]

### Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Second Ten-Year PM<sub>10</sub> Maintenance Plan for Pagosa Springs

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to partially approve and partially disapprove State Implementation Plan (SIP) revisions submitted by the State of Colorado. On March 31, 2010, the Governor of Colorado's designee submitted to EPA a revised maintenance plan for the Pagosa Springs area for the National Ambient Air Quality Standards (NAAQS) for particulate matter with an aerodynamic diameter less than or equal to 10 microns (PM<sub>10</sub>). The State adopted the revised maintenance plan on November 19, 2009. As required by Clean Air Act (CAA) section 175A(b), this revised maintenance plan addresses maintenance of the PM<sub>10</sub> standard for a second 10-year period beyond the area's original redesignation to attainment for the PM<sub>10</sub> NAAQS. EPA is proposing to approve the revised maintenance plan

with the exception of one aspect of the plan's contingency measures. EPA's proposed approval includes the revised maintenance plan's 2021 transportation conformity motor vehicle emissions budget for PM<sub>10</sub>. In proposing to approve the revised maintenance plan, we are proposing to exclude from use in determining that Pagosa Springs continues to attain the PM<sub>10</sub> NAAQS, exceedances of the PM<sub>10</sub> NAAQS that were recorded at the Pagosa Springs PM<sub>10</sub> monitor on March 22, 2009, April 3, 2009, April 5, 2010, April 28, 2010, April 29, 2010, May 11, 2010, and May 22, 2010 because the exceedances meet the criteria for exceptional events caused by high wind natural events. This action is being taken under sections 110 and 175A of the CAA.

**DATES:** Written comments must be received on or before January 27, 2014.

**ADDRESSES:** Submit your comments, identified by Docket number EPA-R08-OAR-2011-0834, by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- Email: [olson.kyle@epa.gov](mailto:olson.kyle@epa.gov).
- Fax: (303) 312-6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** section if you are faxing comments).
- Mail: Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129.
- Hand Delivery: Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. EPA-R08-OAR-2011-0834. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity

or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding Federal holidays. **FOR FURTHER INFORMATION CONTACT:** Kyle Olson, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129, (303) 312-6002, [olson.kyle@epa.gov](mailto:olson.kyle@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **Definitions**

For the purpose of this document, we are giving meaning to certain words or initials as follows:

- i. The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.
- ii. The initials *APCD* mean or refer to the Colorado Air Pollution Control Division.
- iii. The initials *AQCC* mean or refer to the Colorado Air Quality Control Commission.