professionals and discusses one of the exceptions for establishments from certain regulatory requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 22, 2014

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception'' dated October 2014. The draft guidance document is intended for use by tissue establishments and healthcare professionals. When finalized, the guidance document will provide our current thinking with respect to the exception set forth in Title 21 of the Code of Federal Regulations 1271.15(b) (21 CFR 1271.15(b)). The draft guidance is presented in question and answer format and includes examples based on inquiries received by the Agency since the final rule, ''Human Cells, Tissues, and Cellular and Tissue Based Products; Establishment Registration and Listing'' published in the **Federal Register** of January 19, 2001 (66 FR 5447).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: *October 17, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25217 Filed 10–22–14; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0542; FRL–9917–76–Region 9]

Revisions to the California State Implementation Plan; Imperial County; Ozone Precursor Emissions Inventories

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Imperial County portion of the California State Implementation Plan (SIP). This revision concerns Clean Air Act (CAA) requirements for volatile organic compounds and oxides of nitrogen emissions inventories in areas designated nonattainment for the 1997 8-hour ozone National Ambient Air Quality Standard (NAAQS). We are proposing to approve the 2002 volatile organic compound and oxides of nitrogen emissions inventories as submitted by Imperial County and California.

DATES: Any comments on this proposal must arrive by November 24, 2014.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2012–0542, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: wamsley.jerry@epa.gov.*

3. *Mail or deliver:* Jerry Wamsley (Air-2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. 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.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jerry Wamsley, EPA Region IX, (415) 947–4111, *wamsley.jerry@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal concerns the volatile organic compound (VOC) and oxides of nitrogen (NO_X) 2002 emissions inventories submitted by California on December 21, 2010 in the document ''Final 2009 1997 8-hour Ozone Modified Air Quality Management Plan'' for Imperial County. California submitted these emissions inventories to meet CAA requirements under the 1997 8-hour ozone NAAQS. In the Rules and Regulations section of this **Federal Register**, we are approving these VOC and NO_X emissions inventories provided by California in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on a portion of the state's submittal and if that provision may be severed from the remainder of the submittal, we may adopt as final those provisions of the submittal that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: September 24, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2014–24752 Filed 10–22–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0547; FRL–9918–39–Region 9]

Partial Approval and Partial Disapproval of Air Quality State Implementation Plans; California; Infrastructure Requirements for Ozone, Fine Particulate Matter ($PM_{2.5}$), Lead (Pb), Nitrogen Dioxide (NO_2), and Sulfur Dioxide (SO_2)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to partially approve and partially disapprove several State Implementation Plan (SIP) revisions submitted by the State of California pursuant to the requirements of the Clean Air Act (CAA or the Act) for the implementation, maintenance, and enforcement of national ambient air quality standards (NAAQS) for ozone, fine particulate patter ($PM_{2.5}$), lead (Pb), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2). We refer to such SIP revisions as ''infrastructure'' SIPs because they are intended to address basic structural SIP requirements for new or revised NAAQS including, but not limited to, legal authority, regulatory structure, resources, permit programs, and monitoring necessary to assure attainment and maintenance of the standards. In addition, we are proposing to reclassify certain regions of the state for emergency episode planning purposes with respect to ozone, NO_2, SO_2, and particulate matter (PM). Finally, we are proposing to approve into the SIP several state provisions addressing CAA conflict of interest requirements into the California SIP and an emergency episode planning rule for Great Basin Unified Air Pollution Control District (APCD) for PM. We are taking comments on this proposal and, after considering any comments submitted, plan to take final action.

DATES: Written comments must be received on or before November 24, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2014–0547, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email: mays.rory@epa.gov.*

3. *Mail or deliver:* Rory Mays (AIR–2), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. 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.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Rory Mays, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3227, *mays.rory@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to EPA.

Table of Contents