TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS

	Date	Electronic address	Address	Other information
Public meeting	November 13, 2014	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	Wiley Building, 5100 Paint Branch Pkwy., College Park, MD 20740.	Onsite registration from 8 a.m.–8:30 a.m.
Advance registration	By November 7, 2014	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make an oral presentation.	By October 27, 2014	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*[2].		Requests made on the day of the meeting to make an oral presentation will be granted only if time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov*, including any personal information provided.
Request special accommodations due to a disability.	By October 27, 2014	Juanita Yates, email: *Juanita.yates@fda.hhs.gov.*	See **FOR FURTHER INFORMATION CONTACT**.	
Submit electronic or written comments.	By December 15, 2014	Docket Nos. FDA–2011–N–0920, FDA–2011–N–0921, FDA–2011–N–0922, and FDA–2011–N–0143; *http://www.regulations.gov.*	Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	

[1] You may also register via email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott St., Suite 111, Allen, TX 75013, 704–258–4983, FAX: 469–854–6992, email: *ctreece@planningprofessionals.com.* Onsite registration will also be available.

[2] You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1731, email: *Juanita.yates@fda.hhs.gov.*

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the relevant rulemaking and will be accessible to the public at *http://www.regulations.gov.* The transcript of the proceedings from the public meeting will become part of the administrative record for each of the rulemakings. Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and at FDA's FSMA Web site at: *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be live Webcasting the event. When available, the Webcast video recording of the public meeting will be accessible at FDA's FSMA Web site at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm.*

Dated: October 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25261 Filed 10–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2014–D–1584]

Same Surgical Procedure Exception Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comment on draft guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Same Surgical Procedure Exception Questions and Answers Regarding the Scope of the Exception'' dated October 2014. The draft guidance document is intended for tissue establishments and healthcare

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]

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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