

Management (see **DATES** and **ADDRESSES**) for public review and comment for 30 days. Oxitec Ltd. prepared the draft EA. The preliminary FONSI is based upon Oxitec Ltd.'s draft EA. FDA is considering the draft EA and tentatively agrees with its conclusion that conduct of this trial will result in no significant impacts on the environment. If nothing changes FDA's tentative determination, FDA will prepare and release its own revised, final EA and final FONSI. The Agency intends to take comments received under advisement in determining whether to prepare a revised, final EA and FONSI. If FDA does not agree with the preliminary conclusion that conduct of this trial will result in no significant impacts on the environment, it will prepare an environmental impact statement.

Dated: March 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-05622 Filed 3-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0820]

#### Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committees:* Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee.

*General Function of the Committees:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on May 3, 2016, from 8 a.m. to 5 p.m. and May 4, 2016, from 8 a.m. to 5 p.m.

**ADDRESSES:** FDA is opening a docket for public comment on this meeting. The docket number is FDA-2016-N-0820. The docket will open for public comment on March 14, 2016. The docket will close on June 4, 2016. Interested persons may submit either

electronic or written comments regarding this meeting. Submit electronic comments 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. All comments received will be posted without change, including any personal information provided. 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. Comments received on or before April 19, 2016, will be provided to the committees before the meeting.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

*Contact Person:* Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [AADPAC@fda.hhs.gov](mailto:AADPAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) requires FDA to bring, at least annually, one or more drugs with Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) before its Drug Safety and Risk Management Advisory Committee (DSaRM). On May 3 and 4, 2016, the committees will discuss results from

assessments of the extended-release and long-acting (ER/LA) Opioid Analgesics REMS. The Agency will seek the committees' comments as to whether this REMS with ETASU assures safe use, is not unduly burdensome to patient access to the drugs, and to the extent practicable, minimizes the burden to the healthcare delivery system.

The ER/LA Opioid Analgesics REMS requires that prescriber training will be made available to healthcare providers who prescribe ER/LA opioid analgesics. Training is considered "REMS-compliant" if: (1) It, for training provided by continuing education providers, is offered by an accredited provider to licensed prescribers, (2) it includes all elements of the FDA Blueprint for Prescriber Education for ER/LA Opioid Analgesics (Blueprint), (3) it includes a knowledge assessment of all the sections of the Blueprint, and (4) it is subject to independent audit to confirm that conditions of the REMS training have been met. The Agency will seek the committees' input on possible modifications to the ER/LA Opioid Analgesics REMS, including expansion of the scope and content of prescriber training and expansion of the REMS program to include immediate-release opioids.

Comments from the public can be submitted to the docket (see the **ADDRESSES** section) on a broad evaluation of the ER/LA Opioid Analgesics REMS program and whether the ER/LA opioid analgesics REMS should be modified as well as any proposed modifications. Comments may include but are not limited to: (1) Alternative methodologies for evaluating the overall impact of the program on knowledge and behavior by prescribers and patients, (2) the overall impact of the REMS on the adverse events it is intended to mitigate; (3) whether the FDA Blueprint or other tools (e.g., Medication Guide or Patient Counseling Document) should be revised and/or expanded; (4) the use of the continuing education as a component of the REMS as a mechanism for providing prescriber training; (5) whether to expand the REMS program to include immediate-release opioids; and (6) how additional REMS tools or ETASU (e.g., required prescriber or pharmacist training, required patient agreements), if recommended, may impact the healthcare delivery system and patient access to ER/LA opioid analgesics.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before April 19, 2016, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. on May 4, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 11, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 12, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 8, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-05573 Filed 3-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-4750]

#### Implementation of the "Deemed To Be a License" Provision of the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability and Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009." This draft guidance describes FDA's approach to implementation of the statutory provision under which an application for a biological product approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) on or before March 23, 2020, will be deemed to be a license for the biological product under the Public Health Service Act (PHS Act) on March 23, 2020. Specifically, this draft guidance describes FDA's interpretation of the "deemed to be a license" provision of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) for biological products that have been or will be approved under the FD&C Act on or before March 23, 2020. This draft guidance also provides recommendations to sponsors of proposed protein products intended for submission in an application that may not receive final approval under the FD&C Act on or before March 23, 2020, to facilitate alignment of product development plans with FDA's interpretation the transition provisions of the BPCI Act.

**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 May 13, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2015-D-4750 for "Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability and Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be