

within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*ACF Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-2235]

#### Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning Investigational Use of Oxitec OX513A Mosquitoes; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency) is announcing the availability for public comment of the draft environmental assessment (EA) submitted by Oxitec Ltd. and a preliminary finding of no significant impact (FONSI) in support of the conduct of an investigational release of genetically engineered (GE) mosquitoes under an investigational new animal drug exemption.

**DATES:** Submit either electronic or written comments on the draft EA by April 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-2014-N-2235 for Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning Investigational Use of Oxitec OX513A Mosquitoes. 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 made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any

information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, 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.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Persons with access to the Internet may obtain the draft EA at either <http://www.fda.gov/animalveterinary/developmentapprovalprocess/environmentalassessments/ucm300656.htm> or <http://www.regulations.gov>.

#### FOR FURTHER INFORMATION CONTACT:

Brinda Dass, Center for Veterinary Medicine (HFV-2), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8247, email: [abig@fda.hhs.gov](mailto:abig@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing that a draft EA and preliminary FONSI, in support of a proposed investigational release (*i.e.*, field trial) of OX513A *Aedes aegypti* GE mosquitoes (OX513A mosquitoes), as part of an existing mosquito control program in Key Haven, FL, are being made available for public comment. The OX513A is a strain of *Ae. aegypti* mosquito whose recombinant DNA (rDNA) construct encodes a conditional lethality trait such that the offspring of the matings of male OX513A mosquitoes and wild type *Ae. aegypti* do not survive to adulthood. The intended result is a decrease in the overall population of *Ae. aegypti* in the environment. Only male OX513A mosquitoes are intended to be released.

To encourage public transparency, and in compliance with 21 CFR 25.51(b)(3), the Agency is placing Oxitec Ltd.'s draft EA and preliminary FONSI that are the subject of this notice on public display at the Division of Dockets

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.*

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**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