4164-01-P

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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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