OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it 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,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–05641 Filed 3–11–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Strengthening Relationship Education and Marriage Services (STREAMS) Evaluation.

OMB No.: New Collection.

Description: The Office of Family Assistance (OFA) within the Administration for Children and Familes (ACF) at the U.S. Department of Health and Human Services has issued grants to 46 organizations to provide healthy marriage and relationship education (HMRE) services. The Office of Planning, Research, and Evaluation (OPRE) within ACF proposes data collection activity in six HMRE grantees as part of the Strengthening Relationship Education and Marriage Services (STREAMS) evaluation. The purpose of STREAMS is to measure the effectiveness and quality of HMRE programs designed to strengthen intimate relationships. In particular, the evaluation will examine HMRE programs for youth in high school, at-risk youth, and adults. The study will fill knowledge gaps about the effectiveness of HMRE programming for youth and adults and strategies for improving program delivery and participant engagement in services. The STREAMS evaluation will include two components, an impact study and a process study.

1. Impact Study. The goal of the impact study is to provide rigorous estimates of the effectiveness of program services and interventions to improve program implementation. The impact study will use an experimental design. Eligible program applicants will be randomly assigned to either a program group that is offered program services or a control group that is not. Grantee staff will use an add-on to an existing program MIS (the nFORM system, OMB no. 0970–0460) to conduct random assignment in sites enrolling at-risk youth and adults. STREAMS will use classroom-level or school-level random assignment for programs serving youth in high school. STREAMS will collect baseline information from eligible program applicants prior to random assignment and administer a follow-up survey to all study participants 12 months after random assignment.

2. Process study. The goal of the process study is to support the interpretation of impact findings and document program operations to support future replication. STREAMS will conduct semi-structured interviews with program staff and selected community stakeholders, conduct focus groups with program participants, administer a paper-and-pencil survey to program staff, and collect data on adherence to program curricula through an add on to an existing program MIS (nFORM, OMB no. 0970–0460).

This 30-Day Notice includes the following data collection activities: (1) A topic guide for semi-structured interviews with program staff and community stakeholders, (2) focus group guides for adult program participants, (3) focus group guides for youth in schools, (4) a staff survey, (5) the MIS functions for collecting data on adherence to program curricula (6) introductory script that program staff will use to introduce the study to participants, (7) the MIS functions for conducting random assignment, (8) a baseline survey for youth, (9) a follow-up survey for youth, (10) a baseline survey for adults, and (11) a follow-up survey for adults.

Respondents: Program applicants, study participants, grantee staff, and local stakeholders (such as staff at referral agencies).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
1. Topic guide for staff and stakeholder interviews	150	50	1	1	50
2. Focus group guide for adults	120	40	1	1.5	60
3. Focus group guide for youth in schools	60	20	1	1.5	30
4. Staff survey	120	40	1	.5	20
5. Study MIS session adherence form	48	48	104	.08	399
6a. Introductory script, grantee staff	8	[1]8	219	.08	140
6b. Introductory script, program applicants	5,250	1,750	1	.08	140
7. Study MIS to conduct random assignment	8	[1]8	208	.08	133
8. Baseline survey for youth	3,600	1,200	1	.5	600
9. Follow-up survey for youth	3,240	1,080	1	.5	540
10. Baseline survey for adults	4,000	1,333	1	.5	667
11. Follow-up survey for adults	3,200	1,067	1	.75	800

Estimated Total Annual Burden Hours: 3,579.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it

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,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2016–05605 Filed 3–11–16; 8:45 am]

BILLING CODE 4184–73–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 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.*

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