



May 12, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted via Regulations.gov

Re: Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning Investigational Use of Oxitec OX513A Mosquitoes; Availability. Docket No. FDA-2014-N-2235; Fed. Reg. 81:49, 13371 (March 14, 2016).

Dear Sir or Madam:

CropLife America (CLA) appreciates the opportunity to provide comment on the recent Notice (Docket ID No. FDA-2014-N-2235) by the U.S. Department of Health and Human Services, Food and Drug Administration (FDA or the Agency) on the draft environmental assessment (EA) submitted by Oxitec, Ltd. and the Agency's preliminary finding of no significant impact (FONSI) in support of the conduct of the investigational release of genetically engineered (GE) mosquitoes under an investigational new animal drug exemption.

Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all of the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners. Our members support development of new and innovative technologies to protect crops and human health and welcome the development of GE mosquitoes for control of the *Aedes aegypti* to protect against mosquito-borne diseases such Zika, Dengue, and Chikungunya.

CLA supports the risk-based scientific approach taken by FDA to establish the safety of the GE mosquitos through its preliminary FONSI. Such technological advances with the potential to help protect the health of Americans, as well as populations around the globe, must be advanced. Moreover, the proposed field trial of these GE mosquitoes as part of an existing mosquito control program in Key Haven, FL, helps ensure the safe management of this technology, including demonstration of any environmental impacts for future development.

We reiterate the comments of other stakeholders in agriculture (See docket submissions by Iowa State University, National Association of State Departments of Agriculture, South Dakota State University, and American Farm Bureau Federation) in support of FDA agreement to the conduct of the proposed investigational release (field trial).

Representing the Crop Protection Industry

1156 15th St. N.W., Suite 400 Washington, D.C. 20005 • 202.296.1585 phone 202.463.0474 fax www.croplifeamerica.org

We look forward to working with FDA and other stakeholders in the agriculture and public health communities to review the outcomes of this important study. Should you have any questions or wish to discuss any of the statements specifically, please contact Dr. Janet E Collins, Senior Vice President Science and Regulatory Affairs at collins@croplifeamerica.org or (202) 833-4474.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Jay Vroom". The signature is written in a cursive, flowing style.

Jay J. Vroom
President and CEO