MIAMIBEACH

OFFICE OF THE CITY MANAGER

NO. LTC # **463-2016**

LETTER TO COMMISSION

TO: Mayor Philip Levine and Members of the City Commission

FROM: Jimmy L. Morales, City Manager

DATE: October 28, 2016

SUBJECT: Genetically Engineered Mosquitos

The purpose of this letter to Commission is to share the Department of Health & Human Services, Food & Drug Administration (FDA) response to the City's request to issue an *emergency use authorization* (EUA) to release Oxitec Ltd.'s genetically engineered mosquito in Miami Beach. In summary, the FDA is advising us that an EUA is not required at this point in the process. Since the FDA's environmental assessment states that the proposed field trial in the Florida Keys Mosquito Control District will have no significant effect on the environment it is now in the hands of the District and of the company on how and when to proceed. As you may know, Monroe County is conducting a referendum on November 8, 2016 to gauge local support for a trial.

I have been advised that Miami-Dade Mosquito Control is scheduling a meeting with representatives from Oxitec after the election, and we will be invited to attend and participate in those discussions.

I will keep the Commission apprised of any further developments.

Attachment: Letter

CC: Alina T. Hudak, Miami Dade County Deputy Mayor

JLM/SMT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

October 19, 2016

The Honorable Jimmy L. Morales
City Manager
City of Miami Beach
1700 Convention Center Drive
Miami Beach, FL 33139

Dear Mr. Morales:

Thank you for your letter, on behalf of the Mayor and City Commission of Miami Beach, to Secretary Sylvia Mathews Burwell, requesting the issuance of an Emergency Use Authorization (EUA) to enable the use of Oxitec Ltd.'s (Oxitec) genetically engineered (GE) mosquitoes in Florida. Your letter was forwarded to me for response.

Since the early reports of the potential link between Zika virus infection and microcephaly and other severe fetal brain defects, the Administration and the Department of Health and Human Services (HHS or the Department) have worked quickly to take actions to protect the American people, including: supporting the development and availability of clinical diagnostics to identify the presence of exposure to Zika virus in individuals; developing new Zika-specific vaccines; supporting the development and availability of screening tests to protect the blood supply; delivering the latest guidance across the health care system through the Hospital Preparedness Program; and providing assistance to state and local governments. The Department is also providing financial and technical resources to states, local jurisdictions, and territories through our Epidemiology and Laboratory Capacity (ELC) and Public Health Emergency Preparedness (PHEP) cooperative agreements. These resources strengthen the state and local capacity to prepare for, and respond to, emerging threats like Zika virus. This preparation and response capacity includes vector control.

Historically, vector control has been a state and local responsibility achieved through a multi-modal approach, including surveillance of mosquito activity, reduction in breeding sites, use of chemical insecticides with resistance testing, and other biological control methods as appropriate. As you know, there has been public discussion of a new method to potentially help control mosquito populations through the use of a GE line of the mosquito *Aedes aegypti* (OX513A) developed by Oxitec. The release of non-biting male Oxitec GE mosquitoes is intended to suppress the wild mosquito population in the release area over time; the offspring from male GE mosquitoes and wild-type female mosquitos will die before adulthood.

Novel vector control strategies, such as GE mosquitoes, may play a role in protecting public health, and the U.S. Food and Drug Administration (FDA or the Agency) is engaged in reviewing the use of these innovative strategies to help suppress the population of virus-carrying mosquitoes in a safe and effective manner. Oxitec's mosquitoes are one possible approach that

could be incorporated into an integrated mosquito control program; however, it is too early to say with any certainty whether such an approach would be successful. An integrated mosquito control program uses multiple approaches, including chemical adulticides and larvicides as well as source reduction. It is also critical that people take steps to protect themselves from mosquito bites with methods such as window screens, repellents, and protective clothing.

Oxitec opened an investigational new animal drug (INAD) file concerning its GE mosquito and submitted data and information to that file related to a proposed field trial in Key Haven, Florida. The goal of the trial is to determine whether the release of the company's GE mosquitoes will suppress the local *Aedes aegypti* mosquito population in the release site. On August 5, after considering thousands of public comments, FDA released a final environmental assessment (EA) for the proposed field trial. FDA also published a finding of no significant impact (FONSI) agreeing with the EA's conclusion that the proposed field trial will not have significant impacts on the environment. These documents are available on FDA's website at: http://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm446529.htm. It is now Oxitec's decision, together with its local partner, the Florida Keys Mosquito Control District (FKMCD), to determine whether and when to begin the proposed field trial in Key Haven. Before going forward, the FKMCD is conducting a referendum throughout Monroe County (the Keys) on Election Day in November to determine whether the local community supports going forward with the trial.

In the case of the proposed Key Haven trial, the FKMCD contacted Oxitec about the possibility of releasing its GE mosquitoes in the Florida Keys. As the developer of the GE mosquitoes, Oxitec, working with the FKMCD, then submitted data and information to FDA concerning the proposed investigational release. If other localities within Florida are also interested in pursuing an investigational release of Oxitec's GE mosquitoes within their respective jurisdictions, they should contact the company directly. Oxitec could then submit the required information to FDA regarding the proposed release, in addition to working with any other federal, state, or local authorities that might have applicable authority.

HHS and FDA stand ready to use our authorities to the fullest extent to help facilitate the development and availability of products that may help mitigate emerging infectious disease threats, such as Zika. As always, we will approach our decision-making in the best interest of public health. Your letter requests specifically that FDA authorize the use of Oxitec GE mosquitoes under the Agency's emergency use authority (EUA), under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in any Florida area where Zika is being transmitted or is likely to be transmitted. However, our interpretation is that section 564 of the FD&C Act does not apply to animal drugs.[1] Therefore, as noted above, we suggest you contact

[1] The Oxitec mosquito contains a new animal drug subject to FDA regulation because the inserted rDNA construct is intended to alter the structure or any function of the animal. Therefore, it meets the definition of a "drug" under the FD&C Act. FDA is regulating the Oxitec mosquito in consultation with the Centers for Disease Control and Prevention and the U.S. Environmental Protection Agency, consistent with the Coordinated Framework for the Regulation of Biotechnology.

Oxitec directly should you be interested in pursuing an investigational release of the company's GE mosquitoes.

Thank you again for contacting us regarding this important matter.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs