

ZIKA VIRUS and Emergency Legal Preparedness: FDA Zika Response Efforts

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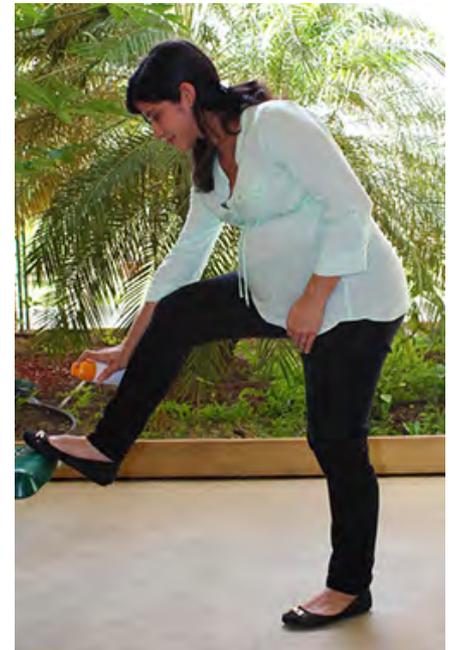
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FDA and Medical Countermeasures

- FDA's overarching medical countermeasures (MCM) objective is to facilitate the **development** of and **access** to safe and effective MCMs (i.e., drugs, biologics, and devices including diagnostics and personal protective equipment) to counter high-priority chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats (e.g., Zika, Ebola, pandemic influenza).

ZIKA RESPONSE

- FDA is fully engaged with the US government, private sector, international community, and other partners in responding to the Zika virus outbreak, helping to help minimize the impact of the Zika outbreak
- Currently, no FDA-approved, licensed, or cleared medical products available to prevent, treat, or diagnose Zika virus
- **5 primary areas of activity include:**
 - (1) Blood safety
 - (2) Clinical diagnostic tests
 - (3) Vector control
 - (4) Vaccine development, and
 - (5) Monitoring for fraudulent products



(1) Blood Safety

Helping to protect the safety of the nation's blood supply and tissues/organs

- Guidance documents:
 - (Aug. 2016) *Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components*
<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf>
 - FDA now recommends **universal** testing of donated whole blood and blood components for Zika virus in the U.S. and its territories
 - Replaces 2 previously issued guidance documents (Feb. and Mar. 2016)
- 2 Investigational tests to screen blood donations:
 - March 2016 (in use in Puerto Rico since early April)
 - June 2016
 - Together, these tests have enabled blood donor screening to be put in place in areas of the U.S. where local virus transmission is detected, or is anticipated but not yet detected

(2) Clinical Diagnostic Tests



- There are no FDA-approved/cleared commercially available diagnostic tests for Zika virus
- There are 2 types of clinical tests needed:
 - tests to diagnose acute infection (PCR tests)
 - Tests to assess whether an individual who was potentially exposed was actually infected (serological tests)
- To date, FDA has issued 10 Emergency Use Authorizations (EUAs) to allow use of CDC and commercially developed Zika diagnostic tests
 - 2 serological tests and 8 PCR tests
- FDA is working interactively with developers, encouraging EUA submissions:
 - Created a draft review template delineating data requirements
 - Created FDA Zika Virus Reference Materials for NAT-based IVDs available to diagnostic developers

(3) Vector Control

Reviewing proposals for innovative vector control strategies

- FDA reviewed an Investigational New Animal Drug (INAD) file from Oxitec, Ltd., for its GE line of *Aedes aegypti* mosquito with the intent of suppressing the population of mosquitoes at the release site(s) (i.e., not Zika reduction claims)
- Oxitec mosquitoes contain a “new animal drug” by virtue of insertion of a heritable rDNA construct to the insect that is intended to alter the structure or function of an animal, and is thus regulated under the Federal Food, Drug, & Cosmetic Act (FD&C Act)
- To comply with the National Environmental Policy Act (NEPA), FDA:
 - Conducted a draft Environmental Assessment (EA) (March 2016), and a preliminary Finding of No Significant Impact (FONSI) for a field trial in Key Haven, FL
 - Reviewed thousands of public comments
 - Released a final EA and FONSI (August 2016), agreeing with draft EA’s conclusion the proposed field trial will not have significant impacts on the environment
- Oxitec is awaiting approval from local communities to proceed with the proposed field trial
- FDA reviews for commercial approval after all the components of the INAD file are complete

(4) Vaccine and Therapeutics

There are no FDA-licensed or approved vaccines or therapeutics for Zika virus

- FDA is actively working with our federal colleagues at the NIH, CDC, and the Biomedical Advanced Research and Development Authority (BARDA), as well as manufacturers, to accelerate development of candidate products that demonstrate most promise
 - Several investigational vaccines are under development; NIH recently initiated the first early-stage human clinical trials
 - FDA is unaware of treatments for Zika virus infection in advanced development at this time

(5) Fraudulent Products



- Unfortunately, during outbreaks situations, fraudulent products claiming to prevent, treat, or cure a disease almost always appear
- FDA monitors for fraudulent products and false product claims related to the Zika virus and takes appropriate action to protect consumers
- Consumers who have seen fraudulent products or false claims are encouraged to report them to FDA:
 - <http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm>

Additional Resources



- **FDA Zika Response Updates Website**

- <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm>
- Available in Spanish and Portuguese:
 - <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm497802.htm>
 - <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm499738.htm>

- **FDA Medical Countermeasures Initiative (MCMi)**

- www.fda.gov/medicalcountermeasures

- **FDA EUA Website** (*official updates, current & terminated EUAs, guidance*)

- www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm

- **FDA Draft Guidance on EUAs and other MCM Emergency Use Authorities**

- <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm> (April 2016)

- **FDA MCM Emergency Use Authorities Website** (*official updates*)

- <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411432.htm>

