Emergency Legal Preparedness and FDA Response to Zika Virus

ABA Washington Health Summit

December 12, 2016

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
Counterterrorism and Emerging Threats

- Protecting the U.S. from threats
  - Chemical, biological, radiological, nuclear (CBRN)
  - Emerging infectious diseases

- Ensuring that medical countermeasures (MCMs) to counter these threats are safe, effective, and secure
  - Drugs, vaccines, devices (e.g., diagnostic tests, personal protective equipment (PPE))

- Office of Counterterrorism and Emerging Threats
  - Facilitate the development and availability of safe, effective MCMs
  - Serve as point of entry on policy and planning for global health security, counterterrorism, emerging threats
  - Identify and resolve complex scientific and regulatory challenges for MCMs within FDA and with USG partners
Overview of Public Health Legal Preparedness
Public Health Legal Preparedness

• Term first appeared in late 1990s; subset of public health preparedness

• Recognizes essential role law plays in protecting the public from catastrophic health events
  ▪ Core foundation to ensure U.S. is prepared to prevent, respond to, and reduce adverse effects of public health emergencies

• May impact a range of players during disasters
  ▪ e.g.) health officials, hospitals, health care practitioners, businesses, MCM manufacturers, public, etc.

Levels (and Layers) of Authority

- **Global**
  - WHO (Director-General) (e.g., IHR, PHEIC declaration)
  - Individual countries (substantial variation in laws, capabilities, declarations)

- **Federal (e.g., President, Cabinet Secretaries)**
  - e.g.) emergency laws, declarations

- **State (e.g., Governor, Secretary of Health)**
  - e.g.) traditional public health powers (police powers), emergency laws and declarations (much variation)

- **Local (e.g., Mayor, County Executive, Health Officer)**
Examples of Tools

• Declarations
• Executive orders
• Isolation and quarantine authorities (federal and state)
• Volunteer and other liability protections
• Emergency use authorities for MCMs
• 1135 waivers
• Mutual aid agreements—Emergency Management Assistance Compact (EMAC)
Examples of Federal Legal Preparedness Authorities

- Pandemic and All-Hazards Preparedness Reauthorization Act (2013) (PL 113-5)
- 21st Century Cures Act (2016)
Why are legal/regulatory mechanisms for emergency use of MCMs needed?

Without these mechanisms, certain preparedness and response activities at the local, state, and/or federal levels could otherwise violate provisions of the FD&C Act:

• Some MCMs needed for a response might not be approved, licensed, or cleared by FDA (e.g., Ebola, Zika)

• Some MCMs needed for a response might be approved by FDA, but not for the emergency use (e.g., for a new indication)

• Some might be approved for the emergency use, but:
  – Need to be dispensed (e.g., at PODs) without individual prescriptions and/or by someone who is not a licensed health care professional, and with emergency use instructions (e.g., fact sheets)
  – MCMs might be used beyond their manufacturer-labeled expiration date

• Also, to ensure that available Public Readiness and Emergency Preparedness (PREP) Act protections apply
FDA Authorities to Facilitate Access to MCMs

• Emergency Use Authorization (EUA)
  – FD&C Act § 564
  – Allows FDA to authorize for use in CBRN emergencies the use of unapproved MCMs or the unapproved use of approved MCMs
  – Established by Project BioShield Act (2004); amended by PAHPRA (2013)

• Other emergency use authorities
  – FD&C Act §§ 564A, 505-1, and 564B
  – Allows FDA to authorize emergency dispensing, expiry dating extensions, and waivers of CGMP and REMS requirements, and CDC to issue emergency use instructions, for approved MCMs without rendering a product unapproved, adulterated, or misbranded
  – Established by PAHPRA (2013)

• Expanded access to investigational drugs and devices
  – Investigational New Drug Application (IND) (21 CFR Parts 312.300-320)
  – Investigational Device Exemption (IDE) (21 CFR Part 812)
EUA Authority (FD&C Act § 564)

• With an EUA, FDA can authorize for use in CBRN emergencies:
  – The use of unapproved MCMs or
  – The unapproved use of approved MCMs (e.g., for a new indication)

• When scientific evidence is available to support MCM use in a CBRN emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act; also helps to ensure applicable PREP Act coverage

• Overview of requirements for EUA issuance:
  1. DHS, DoD, or HHS Secretary makes a specific type of determination
  2. HHS Secretary issues a declaration that circumstances exist to justify EUA issuance based on 1 of the 4 types of determinations (this is not a PHS Act § 319 Public Health Emergency declaration)
  3. FDA ensures EUA criteria for issuance are met and issues the EUA when appropriate
Public Health Law in Action: Zika Virus Response
Global Zika Virus Response

• Global
  – WHO: Declared a Public Health Emergency of International Concern (PHEIC) because of clusters of microcephaly and other neurological disorders in some areas affected by Zika virus (2/1/16; ended 11/16)
  – Various countries (e.g., Brazil, Mexico, Peru)

• Federal
  – HHS declarations
    • “a public health emergency of national significance exists within the Commonwealth of Puerto Rico relating to pregnant women and children born to pregnant women with Zika” (PHS Act § 319) (8/12/16)
    • EUA determination/declaration (FD&C Act § 564) (2/26/16); EUAs issued
  – CMS (e.g., Guidance for the Deployment of the Emergency Use Approval [sic] (EUA) Zika Virus Tests)
  – Zika Response and Preparedness Act (PL 114-223)

• State/Local (e.g., Florida, Puerto Rico, Hawai‘i)
FDA Roles & Responsibilities

Inter-Agency Coordination/Policy Development

International Coordination

Facilitating Product Development and Availability

Monitoring Fraudulent Product Claims
FDA Zika Virus Response

• FDA is fully engaged with USG and other partners in responding to the Zika virus outbreak

• Currently, no FDA-approved, licensed, or cleared medical products available to prevent, treat, or diagnose Zika virus

• Prepared to leverage our authorities to help accelerate the development and availability of safe and effective medical products for Zika virus

• Primary areas of activity include:
  
  (1) Blood safety
  (2) Clinical diagnostic tests
  (3) Vaccine and therapeutic development
  (4) Vector control
  (5) Fraudulent product monitoring
FDA advises testing for Zika virus in all donated blood in the U.S.

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components

Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the agency has determined that prior public participation is not feasible or appropriate.
Blood Safety

- Protecting the safety of the blood supply and human cells and tissues used for medical, surgical, or reproductive procedures
  - Guidance
    - (Feb. 2016) *Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus (and March 2016 Questions and Answers)*
    - (March 2016) *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products*
    - (Aug. 2016) *Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components*
      - As a further safety measure, FDA now recommends universal testing of donated whole blood and blood components for Zika virus in the U.S. and its territories
      - Replaces donor screening guidance issued in Feb. and March 2016
  - Investigational tests to screen blood donations (March & June 2016)
    - Together, these tests have enabled blood donor screening to be put in place to help maintain the safety of the U.S. blood supply
CDC's Response to Zika

Only Some People Need Zika Testing

Zika virus testing is recommended only for certain situations. If you have questions or think you should be tested, talk to your healthcare provider.

If you have symptoms of Zika or are a pregnant woman:

- You have traveled to an area with active Zika virus transmission.
- You have had unprotected sex with a partner who lives in or has traveled to an area with Zika.
- Your pregnant patient answered "YES" to any question, assess for signs and symptoms of Zika virus disease.

Zika Screening Tool for Pregnant Women

Assess for Possible Exposure to Zika Virus Infection

[Diagram showing assessment process]

CDC's Response to Zika

When to Test for Zika Virus

As a healthcare provider, you decide if a patient should be tested for Zika virus infection. The algorithm below will help you determine whether or not to test your patient for Zika virus infection. For information on which tests to use, see CDC's interim guidance.

1. Does the patient live in or has the patient recently traveled to an area with Zika?
   - YES: Test for Zika
   - NO: Proceed to the next question.

2. If the patient had unprotected sex with a partner who has lived in or traveled to an area with Zika?
   - YES: Test for Zika
   - NO: Proceed to the next question.

3. If your pregnant patient answered "YES" to any question, assess for signs and symptoms of Zika virus disease.
   - YES: Test in accordance with CDC guidance for symptomatic pregnant person.
   - NO: Test in accordance with CDC guidance for asymptomatic pregnant person.

Recommend Zika virus testing for asymptomatic pregnant women.
Clinical Diagnostic Tests

• Facilitating the development and availability of medical diagnostic tests
  – No FDA-cleared diagnostic tests for Zika virus are currently available
  – To date, FDA has issued 14 EUAs to allow use of CDC and commercially developed Zika diagnostic tests:
    • 2 serologic tests (to assess whether individuals who may have recently been exposed to Zika virus were actually infected)
    • 12 PCR tests (to diagnose acute/active Zika infection)
  – Issuance of these EUAs was based on:
    • **HHS Secretary’s § 564 determination** that “there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus”
    • **HHS Secretary’s § 564 declaration** that “circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection”
Clinical Diagnostic Tests

- FDA encourages commercial diagnostic developers and researchers developing laboratory developed tests for Zika virus to submit an EUA request—FDA will work interactively with developers to support such requests.

- For additional Zika EUA information:
  - EUAs (various dates of issuance): http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm
**LETTER**

**Vaccine protection against Zika virus**

Rafael A. Laroocca, Peter Abbing, Jean Pierre P. Perou, Paolo M. de A. Zanello, Michael Boyd, David Ng'Ang'a, Marina Kirilova, Ramya Nityanandam, Christine A. Bric multi, Erica N. Borduchci, Patricia R. Gdzie, David Lett

**Rapid development of a DNA vaccine for Zika virus**


Zika virus (ZIKV) was identified as a cause of disease in the Americas and Caribbean that began in 2015 with disease and travel-related exposures. A vaccine against this virus is imperative. We report here the purification of preeminent of T-cell epitopes from ZIKV antigens in primates, and protection against viremia and disease in non-human primates.

**Considerations for Developing a Zika Virus Vaccine**

Hilary D. Marston, M.D., M.P.H., Nicole Lurie, M.D., M.S.P.H, Luciana L. Borio, M.D., and Anthony S. Fauci, M.D.

The rapid spread of Zika virus through the Americas and its devastating consequences for pregnant women and infants have precipitated an international, multisectoral response. Nation avert congenital anomalies will most likely require postlicensure studies. Prevention of congenital anomalies through vaccination of women in these at-risk populations will be critical. This Perspective discusses the challenges and considerations for developing an effective and safe Zika virus vaccine.

**Protective efficacy of multiple vaccine platforms against Zika virus challenge in rhesus monkeys**

Vaccine and Therapeutic Development

• Advancing the development of investigational vaccines and therapeutics
  – There are no FDA-licensed or approved vaccines or treatments for Zika virus
    • Several investigational vaccines are under development, including early human clinical trials
  – FDA is actively working with our Federal colleagues at CDC, NIH, and the Biomedical Advanced Research and Development Authority (BARDA) and with the private sector on advancing development and availability
  – We are prepared to evaluate the safety and efficacy of any investigational vaccines and therapeutics that might be developed to help mitigate this outbreak
FDA Releases Final Environmental Assessment for Genetically Engineered Mosquito

Update
August 5, 2016

The FDA has completed the environmental review for a proposed field trial to determine whether the release of Oxitec Ltd.’s genetically engineered (GE) mosquitoes (OX513A) will suppress the local *Aedes aegypti* mosquito population in the release area at Key Haven, Florida. After considering thousands of public comments, the FDA has published a final environmental assessment (EA) and finding of no significant impact (FONSI) that agrees with the EA’s conclusion that the proposed field trial will not have significant impacts on the environment.
Vector Control

• Reviewing proposals for innovative strategies to help limit the ability of mosquitoes to spread disease
  – Investigational New Animal Drug (INAD) file from Oxitec, Ltd., for its genetically engineered (GE) line of *Aedes aegypti* mosquito (OX513A) with the intent of suppressing the population of mosquitoes at the release site(s)

  • **March 2016:** FDA released a draft Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) for a field trial of the GE mosquito in Key Haven, FL; FDA reviewed thousands of public comments

  • **August 2016:** FDA released final EA and FONSI agreeing with draft EA’s conclusion the field trial will not have significant impacts on environment

    – **FDA’s finalization of the EA and FONSI does not mean that Oxitec’s GE mosquitoes are approved for commercial use.** Oxitec is responsible for ensuring all other local, state, and federal requirements are met before conducting the proposed field trial, and the community has decided to vote on whether to proceed with the trial

Fraudulent Product Monitoring

• Protecting the public from fraudulent products
  – Unfortunately, during outbreak 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
Looking Ahead...
Additional Resources

- FDA Zika Response Updates Website
  - [http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm)

- FDA Medical Countermeasures Initiative (MCMi)
  - [www.fda.gov/medicalcountermeasures](http://www.fda.gov/medicalcountermeasures)

- FDA EUA Website *(official updates, current & terminated EUAs, guidance)*
  - [www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm)

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

- FDA MCM Emergency Use Authorities Website

- PREP Act (HHS)
  - [http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx](http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx)
### EUAs Issued by FDA (cont. on next slides)

<table>
<thead>
<tr>
<th>Year</th>
<th>MCM</th>
<th>Requester</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anthrax (Bacillus anthracis)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>Anthrax Vaccine Adsorbed (AVA)</td>
<td>DoD</td>
<td>Terminated</td>
</tr>
<tr>
<td>2011</td>
<td>Doxycycline (oral forms) for mass dispensing</td>
<td>HHS (CDC)</td>
<td>Current*</td>
</tr>
<tr>
<td><strong>2009 H1N1 Influenza Pandemic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009-2010</td>
<td>Antivirals (3)</td>
<td>HHS (CDC)</td>
<td>Terminated (all H1N1 EUAs)</td>
</tr>
<tr>
<td></td>
<td>IVDs (18)</td>
<td>Various</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disposable N95 respirators</td>
<td>HHS (CDC)</td>
<td></td>
</tr>
<tr>
<td><strong>Novel Influenza A (H7N9) Virus</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td>2014</td>
<td>Lyra Influenza A Subtype H7N9 Assay</td>
<td>Quidel Corp.</td>
<td>Current</td>
</tr>
<tr>
<td>2014</td>
<td>A/H7N9 Influenza Rapid Test</td>
<td>Arbor Vita Corp.</td>
<td>Current</td>
</tr>
</tbody>
</table>

* To be terminated due to April 2016 issuance of doxycycline emergency dispensing order, CGMP waiver, and CDC EUI (under sec. 564A of the FD&C Act).

For the most current FDA EUA information, see: [www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm).
<table>
<thead>
<tr>
<th>Year</th>
<th>MCM</th>
<th>Requester</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Middle East Respiratory Syndrome Coronavirus (MERS-CoV)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013 (reissued 2014)</td>
<td>CDC Novel Coronavirus 2012 Real-time RT-PCR Assay</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td><strong>Enterovirus D68 (EV-D68)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>CDC EV-D68 2014 rRT-PCR Assay</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td><strong>Zika Virus</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016 (amended 2016)</td>
<td>CDC Zika MAC-ELISA (IgM)</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td>2016 (amended 2016)</td>
<td>CDC Zika Triplex rRT-PCR Assay</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td>2016 (amended 2016)</td>
<td>Zika Virus RNA Qualitative Real-Time RT-PCR</td>
<td>Focus Diag., Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2016 (amended 2016)</td>
<td>Aptima Zika Virus assay</td>
<td>Hologic, Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>Viracor-IBT Laboratories, Inc.’s Zika Virus Real-time RT-PCR Test</td>
<td>Viracor-IBT</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>VERSANT® Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics</td>
<td>Siemens Healthcare Diagnostics Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>xMAP® MultiFLEX™ Zika RNA Assay</td>
<td>Luminex Corporation</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>ZIKV Detect™ IgM Capture ELISA</td>
<td>InBios International, Inc.</td>
<td>Current</td>
</tr>
</tbody>
</table>

For the most current FDA EUA information, see: [www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm).
### EUAs Issued by FDA (cont.)

<table>
<thead>
<tr>
<th>Year</th>
<th>MCM</th>
<th>Requester</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Zika Virus (cont.)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016 (amended 2016)</td>
<td>LightMix® Zika rRT-PCR Test</td>
<td>Roche Molecular Systems, Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>Sentosa® SA ZIKV RT-PCR Test</td>
<td>Vela Diagnostics USA, Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>Zika Virus Detection by RT - PCR Test</td>
<td>ARUP Laboratories</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>Abbott RealTime ZIKA</td>
<td>Abbott Molecular Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2016</td>
<td>Zika ELITe MGB® Kit U.S.</td>
<td>ELITechGroup Inc. Molecular Diagnostics</td>
<td>Current</td>
</tr>
</tbody>
</table>

For the most current FDA EUA information, see: [www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm).
<table>
<thead>
<tr>
<th>Year</th>
<th>MCM</th>
<th>Requester</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>DoD EZ1 Real-time RT-PCR Assay</td>
<td>DoD</td>
<td>Current</td>
</tr>
<tr>
<td>(reissued 2014)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>CDC Ebola VP40 rRT-PCR Assay</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td>(reissued 2015)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>CDC Ebola NP rRT-PCR Assay</td>
<td>HHS (CDC)</td>
<td>Current</td>
</tr>
<tr>
<td>(reissued 2015)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>FilmArray NGDS BT-E Assay</td>
<td>BioFire Defense, LLC</td>
<td>Current</td>
</tr>
<tr>
<td>(reissued 2015)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>FilmArray Biothreat-E test</td>
<td>BioFire Defense, LLC</td>
<td>Current</td>
</tr>
<tr>
<td>2014</td>
<td>RealStar Ebolavirus RT-PCR Kit 1.0</td>
<td>altona Diag. GmbH</td>
<td>Current</td>
</tr>
<tr>
<td>(reissued 2014)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>LightMix Ebola Zaire rRT-PCR Test</td>
<td>Roche Molecular Systems, Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>2015</td>
<td>ReEBOV Antigen Rapid Test</td>
<td>Zalgen Labs, LLC</td>
<td>Current</td>
</tr>
<tr>
<td>(reissued 2016)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>Xpert Ebola Assay</td>
<td>Cepheid</td>
<td>Current</td>
</tr>
<tr>
<td>2015</td>
<td>OraQuick Ebola Rapid Antigen Test</td>
<td>OraSure Technologies, Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>(use with whole blood)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>OraQuick Ebola Rapid Antigen Test</td>
<td>OraSure Technologies, Inc.</td>
<td>Current</td>
</tr>
<tr>
<td>(use with cadaveric oral fluid)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>Idylla Ebola Virus Triage Test</td>
<td>Biocartis NV</td>
<td>Current</td>
</tr>
</tbody>
</table>

For the most current FDA EUA information, see: [www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm).
Thank you!

Website:  www.fda.gov/MedicalCountermeasures
Twitter:   @FDA_MCMi
Contact:  brooke.courtney@fda.hhs.gov
          AskMCMi@fda.hhs.gov