**FDA issues recommendations to reduce the risk for Zika virus blood transmission in the United States**

**For Immediate Release**

February 16, 2016

**Release**

As a safety measure against the emerging Zika virus outbreak, today the U.S. Food and Drug Administration issued a new guidance recommending the deferral of individuals from donating blood if they have been to areas with active Zika virus transmission, potentially have been exposed to the virus, or have had a confirmed Zika virus infection.

“The FDA has critical responsibilities in outbreak situations and has been working rapidly to take important steps to respond to the emerging Zika virus outbreak,” said Luciana Borio, M.D., the FDA’s acting chief scientist. “We are issuing this guidance for immediate implementation in order to better protect the U.S. blood supply.”

While there have been no reports to date of Zika virus entering the U.S. blood supply, the risk of blood transmission is considered likely based on the most current scientific evidence of how Zika virus and similar viruses (flaviviruses) are spread and recent reports of transfusion-associated infection outside of the U.S. Furthermore, about 4 out of 5 of those infected with Zika virus do not become symptomatic. For these reasons, the FDA is recommending that blood establishments defer blood donations from individuals in accordance with the new guidance.

*In areas without active Zika virus transmission*, the FDA recommends that donors at risk for Zika virus infection be deferred for four weeks. Individuals considered to be at risk include: those who have had [symptoms suggestive of Zika virus infection](http://www.cdc.gov/zika/symptoms/index.html)during the past four weeks, those who have had sexual contact with a person who has traveled to, or resided in, an area with active Zika virus transmission during the prior three months, and those who have traveled to areas with active transmission of Zika virus during the past four weeks.

*In*[*areas with active Zika virus transmission*](http://www.cdc.gov/zika/geo/index.html), the FDA recommends that Whole Blood and blood components for transfusion be obtained from areas of the U.S. without active transmission. Blood establishments may continue collecting and preparing platelets and plasma if an FDA-approved, pathogen-reduction device is used. The guidance also recommends blood establishments update donor education materials with information about Zika virus signs and symptoms and ask potentially affected donors to refrain from giving blood.

“Based on the best available evidence, we believe the new recommendations will help reduce the risk of collecting blood and blood components from donors who may be infected with the Zika virus,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research.  
  
Following the issuance of these recommendations, the FDA also intends to issue a guidance that will address appropriate donor deferral measures for human cells, tissues, and cellular and tissue-based products (HCT/Ps), given recent reports of sexual transmission of the virus.

In addition to protecting the nation’s blood supply, the FDA is also prioritizing the development of blood screening and diagnostic tests that may be useful for identifying the presence of the virus, preparing to evaluate the safety and efficacy of investigational vaccines and therapeutics that might be developed, and reviewing technology that may help suppress populations of the mosquitoes that can spread the virus.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

**Related Information**

* [FDA: Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus](http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM486360.pdf)
* [FDA: Zika Virus Response Updates from FDA](http://www.fda.gov/%20EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm)
* [FDA: Keeping Blood Transfusions Safe](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/BloodSafety/ucm095522.htm)
* [CDC: Zika Virus](http://www.cdc.gov/zika/index.html)
* [CDC: Areas with Zika](http://www.cdc.gov/zika/geo/index.html)
* [CDC: Symptoms, Diagnosis, & Treatment](http://www.cdc.gov/zika/symptoms/index.html)