FDA APPROVES INVESTIGATIONAL BLOOD TESTING FOR ZIKA IN PUERTO RICO

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(WASHINGTON) — The U.S. Food and Drug Administration (FDA) announced Wednesday it is making available an investigational test to screen blood donations for Zika virus in Puerto Rico.

The FDA said the screening test could be used under a new investigational drug application (IND) for screening blood donated in areas where the mosquito-borne transmission of the Zika virus is active.

“The availability of an investigational test to screen donated blood for Zika virus is an important step forward in maintaining the safety of the nation’s blood supply, especially for those U.S. territories already experiencing active transmission,” Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research, said in a statement. “In the future, should Zika virus transmission occur in other areas, blood collection establishments will be able to continue to collect blood and use the investigational screening test, minimizing disruption to the blood supply.”

The FDA issued a guidance on Feb. 16 to blood establishments in order to reduce the risk of Zika transmission. The FDA recommends in the guidance that areas with active Zika virus transmission should obtain Whole Blood and blood components from regions without active transmission of Zika.

The FDA guidance also states establishments in areas that have active Zika transmission can only collect blood locally if a licensed test for screening donated blood is available.

The agency's recommendations for Zika blood donor deferrals stay in place.

The FDA, with the help of the Office of the Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority, and the Centers for Disease Control and Prevention are working to help manufacturers build donation screening tests to protect the supply of Puerto Rico's blood and blood components throughout the Zika outbreak.