REGULATORY ALERT:

FDA's Determination that Zika Virus is No Longer an RCDAD

May 21, 2024

Withdrawal of Guidance titled "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products"

FDA regulations require HCT/P establishments to make a donor eligibility determination for donors of HCT/Ps based on donor screening and testing. When, in the agency's view, a new relevant communicable disease agent or disease exists for which there may be a risk of transmission by an HCT/P, and the disease or disease agent "has sufficient incidence and/or prevalence to affect the potential donor population" (21 CFR 1271.3(r)(2)) and meets certain other factors described in FDA's regulations, then FDA may determine the disease or disease agent is a "relevant communicable disease agent or disease" (RCDAD).

In 2016, FDA determined that Zika virus (ZIKV) was an RCDAD under its regulations in 21 CFR 1271.3(r)(2). This determination was based on the risk of transmission by HCT/Ps, severity of effect, the availability of appropriate screening measures, and the available evidence that demonstrated, at the time, that ZIKV had significant incidence and prevalence to affect the potential HCT/P donor population (21 CFR 1271.3(r)(2)).

The number of ZIKV cases decreased substantially not only in the U.S. but also worldwide. There are no areas of local, mosquito-borne ZIKV transmission in U.S. states and no local, mosquito-borne transmission has occurred since 2017. The number of travel-associated ZIKV cases in the U.S. has substantially declined. In U.S. territories, there have been no confirmed ZIKV disease cases reported since 2019.

FDA has determined that ZIKV no longer meets the definition of an RCDAD under FDA's regulations because the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential HCT/P donor population. Accordingly, FDA is withdrawing the guidance titled, "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products," dated May 2018. Because ZIKV is no longer an RCDAD, HCT/P establishments may discontinue screening donors for ZIKV and revise their relevant procedures to reflect this change.

FDA will continue to monitor ZIKV epidemiology in the United States and worldwide. If there is a change in epidemiology that leads FDA to conclude that ZIKV again may have "sufficient incidence and/or prevalence to affect the potential HCT/P donor population," then FDA may again determine that ZIKV is an RCDAD and issue guidance with recommendations to reduce the risk of transmission of ZIKV by HCT/Ps.

Zika Cases in the United States | Zika Virus | CDC

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/information-human-cell-tissue-and-cellular-and-tissue-based-product-hctp-establishments-regarding