Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding FDA's Determination that Zika Virus is no Longer a Relevant Communicable Disease Agent or Disease

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"

May 20, 2024

FDA regulations require human cells, tissues, and cellular and tissue-based product (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)).

FDA has determined ZIKV is no longer an RCDAD under FDA's regulations because, as discussed below, 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 (U.S.) 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.

Guidance History

In 2016, FDA determined that 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. FDA determined that screening of HCT/P donors for clinical evidence of, and risk factors for, ZIKV was needed to reduce the risk of transmission of ZIKV by HCT/Ps. Appropriate testing measures were not available for testing HCT/P donors for ZIKV infection. Accordingly, FDA issued guidance recommending appropriate screening measures for both living and cadaveric donors of HCT/Ps.

In May 2018, FDA issued an updated guidance with information that supported the continuation of screening, as well as updated findings from epidemiological studies, including the impact of ZIKV on public health, updated information regarding the potential for transmission of ZIKV, updates to sexual contact risk factors and updates related to determining whether geographic areas were considered to have "an increased risk for ZIKV transmission."

- *ZIKV Epidemiology Since the 2016 Outbreaks in the U.S. and Worldwide*

The number of ZIKV cases decreased substantially not only in the U.S. but also worldwide. As of this writing (May 20, 2024), 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[1].

Worldwide, the CDC does not identify any countries or territories with current ZIKV outbreaks on their world map travel advisory, at the time of this writing.

FDA has determined that ZIKV no longer meets the definition of a "relevant communicable disease agent or disease" under 21 CFR 1271.3(r)(2), and HCT/P establishments may discontinue screening donors for ZIKV. As noted above, FDA will continue to monitor ZIKV epidemiology in the U.S. and worldwide.

[1] **Zika Cases in the United States | Zika Virus | CDC**