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"

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.

FDA has determined ZIKV is no longer 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 Accordingly, FDA has withdrawn the guidance titled, "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products," dated May 2018 (which updated and superseded the guidance of the same title dated March 2016). 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.