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Ms. Leslie Kux
Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-0768; Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comment to the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) on *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products, Guidance for Industry*. APIC is a non-profit, multidisciplinary organization representing over 15,000 infection preventionists, whose mission is to create a safer world through prevention of infection.

APIC applauds the FDA for releasing this important guidance, as it is becoming more evident that Zika virus transmission is occurring outside of the usual vector-borne pathway common to flaviviruses. Among those who become infected with Zika virus, 80% are asymptomatic, which increases the theoretical risk of cross-transmission via donor-derived products. While APIC supports this abundance of caution approach, we encourage the FDA to revisit and revise this document as more evidence and information becomes available about non-vector transmission of Zika virus, with particular regard to viral concentrations and persistence in tissues.

APIC also supports the FDA's omission of donor serological testing as an eligibility screening tool. APIC recommends that FDA incorporate reliable donor serological testing into future iterations of this guidance document as such testing becomes more widely available.

Regarding donor eligibility requirements, APIC supports the use of medical and travel history to determine donor eligibility since current laboratory-based donor screening methods are insufficient. APIC encourages the FDA to quantify the risk and impact on the donor pool by using these methods for determining eligibility.



Thank you for the opportunity to review this immediate implementation guidance and provide input on behalf of our members. We look forward to working with the FDA to continue to promote patient safety.

Sincerely,

Susan Dolan

Susan Dolan, RN, MS, CIC
2016 APIC President