4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0545]

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance document provides blood establishments that collect Whole Blood and blood components with revised recommendations to reduce the risk of transmission of Zika virus (ZIKV) by blood and blood components. The guidance does not apply to the collection of Source Plasma. The guidance announced in this notice supersedes the document of the same title dated August 2016 (August 2016 Guidance).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-0545 for "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and

Blood Components; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance provides blood establishments that collect Whole Blood and blood components with revised recommendations to reduce the risk of transmission of ZIKV by blood and blood components. The guidance does not apply to the collection of Source Plasma. This guidance supersedes the August 2016 Guidance.

In the August 2016 Guidance, FDA recognized ZIKV as a relevant transfusion-transmitted infection under 21 CFR 630.3(h) and recommended universal individual donation nucleic acid testing (ID NAT) for ZIKV or the use of an FDA-approved pathogen reduction device. Since 2016, the number of ZIKV disease cases in the U.S. States and territories has decreased considerably. In addition, FDA has licensed a nucleic acid screening test(s) for the detection of ZIKV in individual or pooled samples. Considering the changing epidemiology of ZIKV in the United States and the availability of licensed screening tests, FDA is revising the recommendations contained in the August 2016 Guidance. In this guidance FDA explains that, in order to comply with the testing requirements in 21 CFR 610.40(a)(3), blood establishments must test all donations collected in the United States and its territories with a licensed nucleic acid test for ZIKV, using either ID NAT or minipool (MP) NAT. The guidance explains the basis for FDA's determination that universal MP NAT screening, with certain conditions identified to trigger ID NAT when local mosquito-borne ZIKV transmission is presumed in a collection area, provides an adequate and appropriate safeguard against the current and future risk of ZIKV transmission through blood transfusion. Alternatively, blood establishments can use an FDA-approved pathogen reduction device. The revised recommendations are less burdensome for blood establishments because fewer tests will be performed when donations are tested by MP NAT compared to ID NAT. However, the recommendations are consistent with public health considering the changing course of the ZIKV epidemic in the United States and the sensitivity of the licensed test(s) to detect ZIKV in blood donation.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the Agency has

determined that prior public participation is not feasible or appropriate. Specifically, we are not seeking comments because the guidance presents a less burdensome policy for reducing the risk of transfusion-transmitted ZIKV that is consistent with public health. The guidance represents the current thinking of FDA on recommendations for reducing the risk of Zika virus transmission by blood and blood components. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 601 and 640, and Form FDA 356h have been approved under OMB control number 0910-0338; and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910-0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: June 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14537 Filed: 7/6/2018 8:45 am; Publication Date: 7/9/2018]