DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0545]

Recommendations for Donor Screening, Deferral, and Product Management To Reduce the Risk of Transfusion-Transmission of Zika Virus; 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 document entitled ''Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry.'' The guidance document provides blood establishments that collect blood and blood components with recommendations for donor screening, donor deferral, and product management to reduce the risk of transfusion-transmitted Zika virus (ZIKV). The guidance applies to the collection of Whole Blood and blood components intended for transfusion. The guidance does not apply to the collection of Source Plasma.

DATES: The Agency is soliciting public comment, but is implementing this guidance immediately because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 ''Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Valerie Butler, 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 guidance document entitled ''Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus; Guidance for Industry.'' The guidance document provides blood establishments that collect blood and blood components with recommendations for donor screening, donor deferral, and product management to reduce the risk of transfusion-transmitted ZIKV. The guidance applies to the collection of Whole Blood and blood components intended for transfusion. The guidance does not apply to the collection of Source Plasma, which is used for further manufacture of plasma-derived products. Viral inactivation and removal methods are currently used to clear

viruses in the manufacturing process for such plasma-derived products.

ZIKV is an arbovirus from the Flaviviridae family, genus *Flavivirus.* It is transmitted to humans primarily by the *Aedes aegypti* mosquito, but it may also be transmitted by the *Aedes albopictus* mosquito. In addition, intrauterine, perinatal, and sexual transmission of ZIKV has been reported. Two instances of possible transfusion-transmission of ZIKV in Brazil have been described in media announcements.

The most common ZIKV disease symptoms include fever, arthralgia, maculopapular rash, and conjunctivitis. Neurological manifestations and congenital anomalies have been associated with ZIKV disease outbreaks. Association of ZIKV infection with Guillain-Barré syndrome cases has been reported during outbreaks in Polynesia and in Brazil. In Brazil there has also been a marked increase in the incidence of microcephaly in regions most affected by the ZIKV epidemic.

ZIKV reached the Americas in early 2015 with local transmission first reported in Brazil and as of February 10, 2016, there are 30 countries and territories worldwide with active local transmission of the virus. As of February 10, 2016, local mosquito-borne transmission of ZIKV has not been reported in the continental United States, but cases have been reported in travelers returning to the United States from areas with local transmission.

Consistent with existing regulations and applicable guidance, donors must be in good health at the time of donation § 640.3(b) (21 CFR 640.3(b)) as indicated by, among other things, freedom from any disease transmissible by blood transfusion, as can be determined by history and examination (§ 640.3(b)(6)). Standard operating procedures that are already in place should result in the deferral of individuals who have symptoms consistent with ZIKV infection at the time of donation. The recommendations in the guidance are intended to reduce the risk of collecting blood and blood components from at-risk donors who could be potentially infected with ZIKV and do not display clinical symptoms during the incubation period or have an asymptomatic infection.

The guidance recommends that blood collection establishments in areas without active transmission of ZIKV defer donors at risk for ZIKV infection as follows: Defer for 4 weeks after the resolution of symptoms a donor with a history of ZIKV infection or a donor who reports symptoms suggestive of ZIKV within 2 weeks of departure from an area with active transmission of ZIKV; defer for 4 weeks after the last sexual contact a donor who has had sexual contact with a man who has been diagnosed with ZIKV or who traveled to or resided in an area with active transmission of ZIKV in the 3 months prior to that instance of sexual contact; and defer for 4 weeks from the date of his or her departure, a donor who has been a resident of or has travelled to an area with active transmission of ZIKV.

For areas with active transmission of ZIKV, the guidance recommends that blood collection establishments obtain blood and blood components from areas of the United States without active transmission of ZIKV to fulfill orders. However, a blood establishment may collect platelets and plasma locally if the blood establishment implements FDA-approved pathogen reduction technology for platelets and plasma. Further, blood establishments in areas of active transmission may collect blood components locally provided the establishment tests blood donations with an FDA-licensed blood donor screening test for ZIKV, when such a test becomes available.

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. The guidance represents the current thinking of FDA on ''Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus.'' 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.

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 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 606.100(b), 606.160(b)(1), and 640.3(a) have been approved under OMB control number 0910–0116.

III. Electronic Access

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

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03393 Filed 2–18–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on submission of rotational plans for health warning label statements for smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by April 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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