

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 this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Submission of Warning Plans for Cigars."

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority ("deeming") (section 901(b) of the FD&C Act (21 U.S.C. 387a)). On May 10, 2016, FDA issued that rule, extending FDA's

tobacco product authority to cigars, among other products (81 FR 28973). Among the requirements that now apply to cigars are health warning statements prescribed under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of public health." The regulation specifies the health warning statements to be displayed and also requires the submission of warning plans that provide for the random, equal display and random distribution of the statements on cigar packaging and advertising.

The draft guidance discusses the regulatory requirements to submit warning plans, who submits a warning plan, the scope of a warning plan, when to submit a warning plan, what information should be submitted in a warning plan, where to submit a warning plan, and what approval of a warning plan means.

#### **II. Significance of Draft Guidance**

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on cigar warning plans. 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.

#### **III. Paperwork Reduction Act of 1995**

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 1143 have been approved under OMB control number 0910-0768.

#### **IV. Electronic Access**

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: August 25, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-20913 Filed 8-30-16; 8:45 am]

**BILLING CODE 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 document entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance document is notifying blood establishments that collect Whole Blood and blood components, that FDA has determined Zika virus (ZIKV) to be a relevant transfusion-transmitted infection (RTTI) and provides FDA's assessment. The guidance also provides recommendations to reduce the risk of transmission of ZIKV by Whole Blood and blood components. The guidance applies to the collection of Whole Blood and blood components. The guidance does not apply to the collection of Source Plasma. The guidance supersedes the February 2016 document entitled, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry" (February 2016 guidance), and the March 2016 document entitled, "Questions and Answers Regarding 'Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry'" no later than 12 weeks after the date of the issuance of this guidance. Implementation of the guidance will be immediate for blood establishments that collect Whole Blood and blood components in States and territories with local transmission of ZIKV by mosquitos, and will be phased in over 4 to 12 weeks in other States and territories using a tiered, risk-based approach. Blood establishments should follow the recommendations in the February 2016 guidance until the recommendations in the guidance document have been fully implemented.

**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 "Revised Recommendations for Reducing the Risk 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 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:** Jonathan McKnight, 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 entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance is notifying blood establishments that collect Whole Blood and blood components that FDA has determined ZIKV to be an RTTI under 21 CFR 630.3(h)(2) and provides FDA's assessment. The guidance provides recommendations to reduce the risk of transmission of ZIKV by Whole Blood and blood components. The guidance does not apply to the collection of Source Plasma, which is used for further manufacture of plasma-derived products. If, based upon the available scientific evidence, the risk of ZIKV transmission by blood and blood components significantly changes, FDA may update the recommendations as warranted. In making this determination, FDA will consider available epidemiologic and other scientific evidence.

The guidance supersedes the February 2016 guidance entitled, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus; Guidance for Industry" and the March 2016 guidance entitled, "Questions and Answers Regarding 'Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry'" no later than 12 weeks after the date of the issuance of this guidance.

Implementation of the guidance will be immediate for blood establishments that collect Whole Blood and blood components in States and territories with local transmission of ZIKV by mosquitos, and will be phased in over 4 to 12 weeks in other States and territories using a tiered, risk-based approach. Blood establishments should follow the recommendations in the February 2016 guidance until they fully implement the recommendations in the guidance document currently being issued.

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.

The global ZIKV epidemic expanded in the region of the Americas by early

2015 when the first local transmission was reported in Brazil. Local transmission of ZIKV has also been reported in areas outside of the Americas, including the Pacific Islands of Samoa, American Samoa, Marshall Islands and Tonga, and Cape Verde in Africa, and there are now at least 50 countries and territories worldwide with active local transmission of the virus.

The first local transmission of ZIKV in the United States was reported from Puerto Rico in December 2015, and soon thereafter local transmission was also reported in American Samoa and the U.S. Virgin Islands. In July 2016, the first cases of local transmission of ZIKV occurring in the continental United States were reported from Miami-Dade County in Florida. The possibility of further geographic spread of ZIKV exists in regions where the *Aedes aegypti*, and possibly the *Aedes albopictus*, mosquito is present. In January 2016, ZIKV disease was added to the list of nationally notifiable conditions in the United States as a subtype of Arboviral diseases.

The most common ZIKV disease symptoms include fever, arthralgia, maculopapular rash, and conjunctivitis. In addition, neurological manifestations and congenital anomalies have been associated with ZIKV disease outbreaks. ZIKV infection has been associated with Guillain-Barré syndrome. ZIKV infection during pregnancy is a cause of microcephaly and other serious fetal brain anomalies. Other problems have been detected in pregnancies and among fetuses and infants infected with ZIKV before birth, such as miscarriage, stillbirth, absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth; however, the full clinical spectrum of the effects of ZIKV infection during pregnancy is not yet known.

FDA has identified ZIKV as a transfusion-transmitted infection under § 630.3(l) and RTTI under § 630.3(h)(2). This determination is based on the severity of the disease, risk of transfusion-transmission by blood and blood components, the availability of appropriate screening measures, and significant incidence and prevalence affecting the potential donor population.

The guidance recommends that blood establishments test all donations collected in the United States and its territories with an investigational individual donor nucleic acid test (ID-NAT) for ZIKV under an investigational new drug application (IND), or when available, a licensed test. Alternatively, blood establishments may implement pathogen reduction technology for

platelets and plasma using an FDA-approved pathogen reduction device as specified in the Instructions for Use of the device. If an FDA-approved pathogen reduction device becomes available for Whole Blood or red blood cells, blood establishments may implement pathogen reduction technology for such products rather than testing the donations. Blood establishments implementing these measures may discontinue providing donor educational material with respect to ZIKV and screening donors for ZIKV risk factors such as travel history and deferring them as previously recommended in the February 2016 guidance. Under 21 CFR 630.10(a), if a donor volunteers a recent history of ZIKV infection, a blood establishment must not collect blood or blood components from that donor. For such donors, the guidance recommends a deferral period of 120 days after a positive viral test or the resolution of symptoms, whichever timeframe is longer.

FDA recommends that blood establishments implement the recommendations in the guidance as follows: (1) Blood establishments that collect Whole Blood and blood components in U.S. States and territories with one or more reported locally acquired mosquito-borne cases of ZIKV should implement the recommendations immediately. Blood establishments should cease blood collection until testing or the use of pathogen reduction technology is implemented, consistent with the recommendations in the guidance. As of the date of issuance of the guidance, the recommendations applies to blood establishments that collect Whole Blood and blood components in Florida and Puerto Rico; (2) because of their proximity to areas with locally acquired mosquito-borne cases of ZIKV or because of other epidemiological linkage to ZIKV, such as the number of travel-associated cases reported in a State, blood establishments that collect Whole Blood and blood components in Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina, and Texas should implement the recommendations as soon as feasible, but not later than 4 weeks after the guidance issue date; and (3) blood establishments that collect Whole Blood and blood components in all other States and territories should implement the recommendations as soon as feasible, but not later than 12 weeks after the date of the issuance of this guidance.

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 "Revised 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.

## 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; the collections of information in 21 CFR 606.100(b) and 606.160(b)(1) have been approved under OMB control number 0910–0795; and the collections of information in 21 CFR 606.122 and 630.30 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: August 25, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

**NAME:** National Advisory Committee on Rural Health and Human Services.