DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1143]

Use of Nucleic Acid Tests To Reduce the Risk of Transmission of West Nile Virus From Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; 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 ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry.'' The guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for testing living donors for West Nile Virus (WNV). Specifically, the guidance provides recommendations regarding the use of an FDA-licensed nucleic acid test (NAT) to test living donors of HCT/Ps for evidence of infection with WNV. The guidance does not provide recommendations regarding testing of cadaveric HCT/P donors for WNV. The guidance announced in this notice finalizes the draft guidance of the same title dated December 2015. This guidance supplements the donor screening recommendations for WNV (which will remain in place) in sections IV.E. (recommendations 15 and 16) and IV.F. (recommendation 5), and supersedes the ''West Nile Virus (WNV)'' section in Appendix 6 of the guidance entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated August 2007 (2007 Donor Eligibility Guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the guidance by December 12, 2016.

SUPPLEMENTARY INFORMATION:

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–2013–D–1143 for ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); 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.

I. Background

FDA is announcing the availability of a document entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry.'' The guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for testing living donors for WNV. The guidance does not provide recommendations regarding testing of cadaveric HCT/P donors for WNV. FDA believes that the use of an FDA-licensed NAT will reduce the risk of transmission of WNV from living donors of HCT/Ps and therefore recommends that you use an FDA-licensed NAT for testing living donors of HCT/Ps for infection with WNV as set forth in the guidance. The 2007 Donor Eligibility Guidance indicated that FDA may recommend routine use of an appropriate, licensed donor screening test(s) to detect acute infections with WNV using NAT technology, once such tests were available.

In the **Federal Register** of December 15, 2015 (80 FR 77645), FDA announced the availability of the draft guidance entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry'' dated December 2015 (December 2015 draft guidance). FDA received several comments on the draft guidance and those comments were considered as the guidance was developed.

In the **Federal Register** of February 28, 2007 (72 FR 9007), FDA announced the availability of the 2007 Donor Eligibility Guidance. FDA issued a revised version of this guidance under the same title, dated August 2007 (2007 Donor Eligibility Guidance).

The guidance announced in this notice finalizes the December 2015 draft guidance and supplements sections IV.E. (recommendations 15 and 16) and IV.F. (recommendation 5), and supersedes the ''West Nile Virus (WNV)'' section in Appendix 6 of the 2007 Donor Eligibility Guidance.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' 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. 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: September 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21969 Filed 9–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Healthy Start Evaluation and Quality Improvement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 13, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement OMB No. 0915–0338—Revision

Abstract: The National Healthy Start Program, funded through HRSA's Maternal and Child Health Bureau (MCHB), has the goal of reducing disparities in infant mortality and adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 2 decades to 100 grantees across 37 states and Washington, DC. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average and high rates for other adverse perinatal outcomes. These communities are geographically, racially, ethnically, and linguistically diverse low-income areas. Healthy Start covers services during the perinatal period (before, during, after pregnancy) and follows the woman and infant through 2 years after the end of the pregnancy. The Healthy Start program has five approaches including: (1) Improving women's health; (2) promoting quality services; (3) strengthening family resilience; (4) achieving collective impact; and (5) increasing accountability through quality assurance, performance monitoring, and evaluation.

MCHB seeks to implement a uniform set of data elements for monitoring and conducting a mixed-methods evaluation to assess the effectiveness of the program on individual, organizational, and community-level outcomes. Data collection instruments will include a National Healthy Start Program Survey; Community Action Network Survey; Healthy Start Site Visit Protocol; Healthy Start Participant Focus Group Protocol—these instruments have not been changed. The Preconception, Pregnancy and Parenting (3Ps) Information Form will also be used as a data collection instrument; however the 3Ps Information Form has been redesigned from one form into six forms. The six forms include: (1) Demographic Intake Form; (2) Pregnancy Status/History; (3) Preconception; (4) Prenatal; (5) Postpartum; and (6) Interconception/Parenting. The purpose of this redesign is to enhance the 3Ps Information Form to ensure collected data is meaningful for monitoring and evaluation, as well as screening and care coordination, and streamline previously separate data systems. The 3Ps Information Form was also redesigned to allow questions to be administered in accordance with the participant's enrollment/service delivery status and perinatal period. In addition to redesigning the 3Ps Information Form, HRSA deleted questions that are neither critical for