

became effective: June 22, 2003. The applicant claims July 18, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 22, 2003, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 14, 2009. The applicant claims June 15, 2012, as the date the biologics license application (BLA) for RAXIBACUMAB (BLA 125349/0) was initially submitted. However, FDA records indicate that BLA 125349/0 was submitted on May 14, 2009.

3. *The date the application was approved:* December 14, 2012. FDA has verified the applicant's claim that BLA 125349/0 was approved on December 14, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 412 days of patent term extension.

### III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–31400 Filed 12–14–15; 8:45 am]

**BILLING CODE 4164–01–P**

## 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; Draft 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 draft 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); Draft Guidance for Industry.” The draft 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). The draft guidance recommends 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 draft guidance replaces the draft guidance entitled “Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated October 2013. The donor testing recommendations in the draft guidance, when finalized, will supplement the donor screening recommendations for WNV (which will remain in place) and supersede 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 draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 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 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); Draft 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:** 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 draft 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); Draft Guidance for Industry.” The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for testing living donors for WNV. The draft guidance recommends an FDA-licensed 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. 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. 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 October 24, 2013 (78 FR 63476), FDA announced the availability of the draft guidance entitled “Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated October 2013 (October 2013 draft guidance). FDA received several comments on the draft guidance and those comments were considered as this draft 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 draft guidance announced in this notice replaces the October 2013 draft guidance and when finalized, will supplement sections IV.E. (recommendations 15 and 16), IV.F. (recommendation 5), and supersede the “West Nile Virus (WNV)” section in

Appendix 6 of the 2007 Donor Eligibility Guidance.

The draft guidance is being issued 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 “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.” 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 draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 8, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-31405 Filed 12-14-15; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

[OMB Control Number 0917-0034]

**Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Indian Health Service published a 30 day **Federal Register** notice in the **Federal Register** (FR) on November 17, 2015 (80 FR 71813) to solicit comments from the general public on the information collection titled, “Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form,” Office of Management and Budget (OMB) Control Number 0917-0034. The notice was submitted before the 60 day FR notice comment period for the same information collection ends on December 8, 2015. Therefore, the correct date for the deadline to submit comments regarding the 30 day FR notice is January 9, 2016.