

TABLE 3—ESTIMATED ONE-TIME REPORTING BURDEN <sup>1</sup>

Information collection activity	Number of respondents	Number of responses per respondent	Total one-time responses	Average burden per response	Total hours
Initial VQIP application .....	100	1	100	80	8,000
Initial VQIP application w/additional information .....	100	1	100	100	10,000
Total .....					18,000

<sup>1</sup> There are no capital or operating and maintenance costs associated with the collection of information.

The guidance will inform food importers of application procedures for VQIP. We estimate that up to 200 qualified importers will be accepted in the first year of VQIP. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for the VQIP

program. For the purpose of this analysis, we assume that 50 percent of all applications received will require additional information and it would take an additional 20 person-hours by the importer to provide that information. Therefore, we estimate that 100 importers will spend 8,000 hours

(80 hours/importer × 100 importers) and 100 importers will spend 10,000 hours (100 hours/importer × 100 importers) to submit their initial VQIP applications for a total one-time reporting burden of 18,000 hours (see table 3).

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Information collection activity	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subsequent year VQIP application .....	200	1	200	20	4,000
Request to reinstate participation .....	2	1	2	10	20
Total .....					4,020

<sup>1</sup> There are no capital or operating and maintenance costs associated with the collection of information.

The guidance states that each VQIP participant will submit to FDA a notice of intent to participate in VQIP on an annual basis. We expect that each of the expected 200 importers in VQIP would apply in the subsequent year to participate in VQIP. We expect that an application to participate in VQIP in a subsequent year will take significantly less time to prepare than the initial application. We use 25 percent of the amount of effort to prepare and submit the initial application for acceptance in VQIP. Therefore, it is expected that, on average, each VQIP importer will spend 20 hours to complete and submit a VQIP application for each subsequent year. The annual burden of completing a subsequent year application to participate in VQIP status by 200 importers is estimated at 4,000 hours (200 applications × 20 hours/application) (see table 4).

Finally, we have added to the VQIP estimated annual reporting burden an estimate of the burden associated with importers' requests to reinstate participation in VQIP after their participation is revoked. We believe most participants will not need to use this provision, and we have included an estimate that reflects this. Upon implementation of the VQIP, we will reevaluate our estimate for future OMB submission and revise it accordingly.

Dated: August 12, 2016.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–D–5073]

#### Use of Nucleic Acid Tests To Reduce the Risk of Transmission of Hepatitis B Virus From 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 Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry.” The guidance document provides establishments that make donor eligibility determinations

for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), with recommendations concerning the use of FDA-licensed nucleic acid tests (NAT) in donor testing for hepatitis B virus (HBV) deoxyribonucleic acid (DNA). The guidance finalizes the draft guidance of the same title dated January 2016 and supplements previous FDA recommendations to HCT/P establishments concerning donor testing for hepatitis B surface antigen (HBsAg) and total antibody to hepatitis B core antigen (anti-HBc), in the document 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:** 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-2015-D-5073 for "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; 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:**

Angela Moy, 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 "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry." The guidance provides establishments that make donor eligibility determinations for

donors of HCT/Ps, with recommendations concerning the use of FDA-licensed NAT in donor testing for HBV DNA. FDA considers the use of FDA-licensed HBV NAT in testing HCT/P donors to be necessary to adequately and appropriately reduce the risk of transmission of HBV. The FDA-licensed HBV NAT can detect evidence of the viral infection at an earlier stage than the HBsAg and total anti-HBc tests. Therefore, FDA recommends the use of FDA-licensed HBV NAT for testing donors of HCT/Ps for evidence of infection with HBV.

HBV is a major global public health concern and has been transmitted by blood transfusions and tissue transplantation. Available literature has indicated possible transmissions of HBV by hematopoietic stem cells and blood with HBV NAT positive/hepatitis B surface antibody (anti-HBs) positive/HBsAg negative blood, irrespective of anti-HBc test results. In blood donors, adding the HBV NAT testing for HBV reduces the residual risk of transmission of HBV infection beyond that which can be achieved by screening donors using only HBsAg and total anti-HBc tests. In addition, it can detect breakthrough infections in previously vaccinated individuals who are exposed to the virus, and HBV mutants appear to be more likely detected by HBV NAT than by HBsAg assays.

In the United States, there are currently FDA-licensed HBV NAT assays intended to screen blood samples from donors of whole blood and blood components, other living donors (individual organ donors when specimens are obtained while the donor's heart is still beating), and blood specimens from cadaveric (non-heart-beating) donors. Some of these are multiplex assays that can simultaneously detect HIV, HCV, and HBV in a single blood specimen, thus improving the feasibility of routine NAT testing for HBV. By analogy to the experience in the blood donor setting, it is reasonable to expect that the residual risk of transmission of HBV infection would be reduced by adding HBV NAT to the testing strategy for HCT/P donors. HBV NAT's potential utility in further reducing risk of HBV transmission by transplantation is mainly restricted to the early HBsAg-negative phase of infection. In summary, the available scientific data and the availability of FDA-licensed assays support a recommendation that all HCT/P donors should be tested using an FDA-licensed HBV NAT.

In the **Federal Register** of January 8, 2016 (81 FR 937), FDA announced the

availability of the draft guidance of the same title dated January 2016. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2016 and supplements previous FDA recommendations to HCT/P establishments concerning donor testing for HBsAg and total antibody to anti-HBc, in the 2007 Donor Eligibility Guidance.

This 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 the "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products." 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: August 11, 2016.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0567]

#### **Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice, establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee of the Pediatric Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the

public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on September 14, 2016, from 8 a.m. to 5:30 p.m.

**ADDRESSES:** DoubleTree by Hilton Hotel Bethesda-Washington DC, 8120 Wisconsin Ave., Bethesda, MD 20814, 301-652-2000. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at [www.doubletreebethesda.com/](http://www.doubletreebethesda.com/). You may submit your 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, you 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*

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- 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 either the Docket No. FDA-2016-N-0567 for the "Pediatric Advisory Committee; Notice of Meeting;

Establishment of a Public Docket; Request for Comments"; or the Docket No. FDA-2016-N-2470 for the "Pediatric-focused Safety Reviews", which will be posted on the Internet, but not presented at the Pediatric Advisory Committee meeting. 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>.

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#### **FOR FURTHER INFORMATION CONTACT:**

Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240-402-3838,