Board of Governors of the Federal Reserve System, January 5, 2016.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2016–00153 Filed 1–7–16; 8:45 am]

**BILLING CODE 6210–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) PAR15–352, Occupational Safety and Health Training Project Grants.

*Time and Date:* 8:00 a.m.–7:00 p.m., January 26–28, 2016 (Closed).

*Place:* Internet Assisted Meeting (IAM)/Virtual Meeting.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters for Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to Occupational Safety and Health Training Project Grants, FOA PAR15–352, initial review.

*Contact Person For More Information:* Donald Blackman, Ph.D., Scientific Review Officer, CDC, 2400 Century Center Parkway NE., 4th Floor, Room 4204, Mailstop E–74, Atlanta, Georgia 30345, Telephone: (404) 498–6185, *DYB7@CDC.GOV.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Catherine Ramadei,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2016–00113 Filed 1–7–16; 8:45 am]

**BILLING CODE 4163–18–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Risk of Transmission of Hepatitis B Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry; Availability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 Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry.'' The draft guidance document provides establishments that make donor eligibility determinations for donors of human cells, tissues, 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 draft guidance, when finalized, is intended to supplement 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:** 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 April 7, 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–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; 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:** Jessica T. Walker, 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 Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry.'' The draft guidance document 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/Ps 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 antigen (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 with an indication for screening donor blood samples for 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/Ps donors should be tested using an FDA-licensed HBV NAT. The draft guidance, when finalized, is intended to supplement previous FDA recommendations to HCT/P establishments concerning donor testing for HBsAg and total anti-HBc, in the 2007 Donor Eligibility Guidance.

This 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 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 draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 5, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–00149 Filed 1–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0001]**

### Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 25, 2016, from 8 a.m. to 6 p.m. and February 26, 2016, from 8 a.m. to 1 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.