

Concurrently, nomination materials for prospective candidates should be sent to FDA by March 16, 2020.

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of a pool of nonvoting industry representatives should be sent electronically to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993-0002, 301-796-5960, email: [margaret.ames@fda.hhs.gov](mailto:margaret.ames@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for a pool of nonvoting industry representatives for the Committee. The list of needed expertise on May 1, 2020, is identified below:

- (1) Cybersecurity
  - (2) Communication of Benefit and Risk Information to Patients; Medical Device Labeling
  - (3) Digital Health Technology/Artificial Intelligence
  - (4) Health of Women/Pediatrics (Vulnerable Population Groups)
  - (5) Patient Engagement
  - (6) Patient Preference Elicitation
  - (7) Patient-reported Outcomes Development, Validation, and Use in Regulatory Studies or Clinical Practice
  - (8) Postmarket Studies, including Observational and Registry-based Studies
- FDA is publishing separate documents regarding:
1. Request for Nominations for Voting Members for the Patient Engagement Advisory Committee
  2. Request for Nominations for Consumer Representative for the Patient Engagement Advisory Committee

### I. General Description of the Committee's Duties

The Committee provides advice on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance

and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues are among the topics that may be considered by the Committee. Members are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects. The Commissioner of Food and Drugs (the Commissioner), or designee, shall have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic(s).

### II. Qualifications

Persons nominated for the Patient Engagement Advisory Committee should be full-time employees of firms that manufacture medical device products, or consulting firms that represent manufacturers or have similar appropriate ties to industry.

### III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest must send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes or curriculum vitae. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate or candidates (to serve in a pool of individuals with varying areas of expertise) to represent industry interest for the Committee, within 60 days after the receipt of the FDA letter. The interested organizations are not bound by the list of nominees in selecting a candidate or candidates. However, if no individual is selected within 60 days, the Commissioner will select temporary nonvoting members (or

pool of individuals) to represent industry interests.

### IV. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a temporary nonvoting industry representative. Nominations must include a cover letter and a current, complete resume or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**). Nominations should specify the advisory committee for which the nominee is recommended within 30 days of publication of this document (see **DATES**). In addition, nominations should acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the Committee. Only interested industry organizations participate in the selection process. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 7, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-0008]

### Blood Products Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee (BPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues related to blood and products derived from blood.

Matters considered at the meeting will include current strategies to reduce the risk of Zika virus (ZIKV) transmission by blood and blood components, an update on the Transfusion Transmissible Infections Monitoring System (TTIMS), and testing blood donations for hepatitis B surface antigen. The meeting will be open to the public.

**DATES:** The meeting will be held on April 2, 2020, from 8:30 a.m. to 3:45 p.m. and April 3, 2020, from 8:30 a.m. to 12:30 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to <https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://collaboration.fda.gov/bpacapril20/>.

**FOR FURTHER INFORMATION CONTACT:** Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054, [christina.vert@fda.hhs.gov](mailto:christina.vert@fda.hhs.gov), or 240-402-8106, [joanne.lipkind@fda.hhs.gov](mailto:joanne.lipkind@fda.hhs.gov), respectively, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via webcast. The webcast will

be available at the following link for both days: <https://collaboration.fda.gov/bpacapril20/>.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On April 2, 2020, in the morning, the BPAC will meet in open session to discuss and make recommendations on strategies to reduce the risk of ZIKV transmission by blood and blood components. The committee will discuss whether universal testing of blood donations for ZIKV is an appropriate strategy considering the decline of ZIKV cases in the United States and worldwide. In the afternoon, the committee will meet in open session to hear an update on the TTIMS. Sponsored by the FDA, the National Institutes of Health National Heart, Lung and Blood Institute, and the Department of Health and Human Services Office of the Assistant Secretary for Health, TTIMS collects incidence, prevalence and risk factor data for certain transfusion-transmitted infections, including human immunodeficiency virus, in U.S. blood donations. On April 3, 2020, the committee will meet in open session to discuss and make recommendations on testing for hepatitis B surface antigen (HBsAg) in blood donations. The committee will discuss whether testing for HBsAg can be discontinued considering the sensitivity of hepatitis B virus nucleic acid testing and hepatitis B anti-core testing of blood donations in the United States.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 25, 2020. On April 2, 2020, oral presentations from the public will be scheduled between approximately 10:50 a.m. to 11:20 a.m. and 3:15 p.m. to 3:45 p.m. On April 3, 2020, oral presentations from the public will be scheduled between approximately 11 a.m. to 11:30 a.m. Those individuals interested in making

oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 17, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 7, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915-0184-Revision**

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

**ACTION:** Notice.