



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-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. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on November 4, 2021, from 9:30 a.m. to 5:20 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtu.be/2Xz4YzkWNDs>.

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, or 240-402-8106, 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.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 4, 2021, for Topic I, the committee will meet in open session to hear an overview of the research programs of the Plasma Derivatives Branch, Division of Plasma Protein Therapeutics, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER). For Topic II, the committee will meet in open session to hear an overview of the research programs of the Laboratory of Cellular Hematology, Division of Blood Components and Devices, Office of Blood Research and Review (OBRR), CBER. For Topic III, the committee will meet in open session to hear an overview of the research programs of the Laboratory of Emerging Pathogens, Division of Emerging & Transfusion Transmitted Diseases, OBRR, CBER. After the open sessions, the meeting will be closed to the public for committee deliberations.

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: On November 4, 2021, the meeting is open to the public, from 9:30 a.m. to 11:30 a.m. for Topic I; 12:50 p.m. to 2:10 p.m. for Topic II; and 3:10 p.m. to 4:30 p.m. for Topic III. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be submitted to the contact person on

or before October 28, 2021. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:30 a.m. for Topic I; 1:50 p.m. and 2:10 p.m. for Topic II; and 4:10 p.m. and 4:30 p.m. for Topic III. Those individuals interested in making formal 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 October 20, 2021. 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 October 21, 2021.

Closed Committee Deliberations: On November 4, 2021, from 11:30 a.m. to 12:20 p.m. for Topic I; 2:10 p.m. to 3 p.m. for Topic II; and 4:30 p.m. to 5:20 p.m. for Topic III, the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigator's research programs along with other information, will be discussed during this session. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

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 (BPAC@fda.hhs.gov) 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/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> 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: September 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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