SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to facilitate improvements in the treatment of rare diseases and conditions, consistent with the requirements under section 3202 of the Food and Drug Omnibus Reform Act of 2022 (FDORA). Section 3202 of FDORA requires FDA to conduct a number of activities related to improving the treatment of rare diseases and conditions, including the convening of one or more public meetings to address increasing and improving engagement with rare disease patients, rare disease patient groups, and experts on small population studies, in order to improve the understanding of patient burden, treatment options, and the side effects of treatments (see section 3202(d)(2) of FDORA).

II. Topics for Discussion at the Public Meeting

The purpose of this public meeting is to highlight and build upon existing actionable approaches for engaging patients, patient groups, and related experts when developing necessary evidence for rare disease drug approvals. The meeting will address approaches to increasing and improving engagement with rare disease patients, groups representing such patients, rare disease experts, and experts on small population studies, to improve the understanding of how to best understand patients' experiences living with a rare disease and how to incorporate those experiences and priorities throughout the drug development process. This includes understanding patient perspectives on the burden of their condition and any existing treatment options, as well as how their current health status and risk of disease progression may impact willingness to accept risks from treatment side effects.

Meeting updates, the agenda, and background materials (if any) will also be made available at *https://duke.is/4/7yuu* prior to the meeting.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://duke.is/4/7yuu.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration will end at 11:59 p.m. Eastern Time on December 13, 2023.

Registration is free and persons interested in attending this public meeting must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact *Margolisevents@duke.edu* no later than November 30, 2023. Please note, closed captioning will be available automatically.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://duke.is/4/7yuu.* The transcript will also be available at *https://www.regulations.gov* and may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25500 Filed 11–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a virtual meeting. The meeting will be open to the public via webcast. The committee will discuss and vote on recommendations related to surge capacity for blood and blood products.

DATES: The meeting will take place virtually on January 11, 2024 from approximately 9:00 a.m.—5:00 p.m. Eastern Time (ET). Meeting times are tentative and subject to change. The confirmed times and agenda items for the meeting will be posted on the ACBTSA web page at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2024-01-11/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the ACBTSA; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Rockville, MD, 20852. Email: *ACBTSA@hhs.gov.* Phone: 202–795–7608.

SUPPLEMENTARY INFORMATION: On the day of the meeting, please go to *https://www.hhs.gov/live/index.html* to view the meeting. The public will have an opportunity to present their views to the ACBTSA by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide written public comment should review instructions at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2024-01-11/index.html* and respond by midnight January 3, 2024, ET. Written public comments will be accessible to the public on the ACBTSA web page prior to the meeting.

Background and Authority: The ACBTSA is a discretionary Federal advisory committee and is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. app), which sets forth standards for the formation and use of advisory committees. The ACBTSA functions to provide advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national survey and data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.

Dated: November 2, 2023.

James J. Berger,

Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2023–25572 Filed 11–17–23; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.