readiness and a stronger and safer drug supply chain including the following:

1. How are you using the stabilization period to:

a. Troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with upstream trading partners?

b. Troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with downstream trading partners?

2. What are the most significant challenges you have overcome? What strategies did you employ to overcome those challenges?

3. What aspects of your systems and processes have you successfully operationalized?

4. What are the next steps in your strategy to ensure successful implementation of the enhanced drug distribution security requirements by November 27, 2024?

Dated: November 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25609 Filed 11–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4718]

Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement.'' Convened by the Duke-Robert J. Margolis, MD Center for Health Policy (Duke-Margolis) in collaboration with FDA and supported by a cooperative agreement between FDA and Duke-Margolis, the workshop will focus on how best to understand patients' experiences living with a rare disease and how to incorporate those experiences, as well as patients' priorities for treatment goals, throughout the drug development process.

DATES: The public meeting will be held virtually on December 14, 2023, from 12 p.m. to 5 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by February 12, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually using the Zoom platform.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 12, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2023–N–4718 for ''Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Stuti Ganatra, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 301–796–8112, *PatientFocused@fda.hhs.gov.*

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.