orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before November 2, 2023, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. 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 25, 2023. 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 26, 2023.

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 Takyiah Stevenson (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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19407 Filed 9–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3137]

Endpoints and Trial Designs To Advance Drug Development in Kidney Transplantation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting on ''Endpoints and Trial Designs To Advance Drug Development in Kidney Transplantation.''

DATES: The public meeting will be held on November 9, 2023, from 8 a.m. to 4:30 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the 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 parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Ozlem Belen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 6118, Silver Spring, MD 20993–0002, 301–796–0676.

SUPPLEMENTARY INFORMATION:

I. Background

The goal of this public meeting is to facilitate discussion among FDA, academicians, and industry representatives on endpoint and trial designs to promote drug development in kidney transplantation. The last drug FDA approved for use in prophylaxis of organ rejection in kidney transplant was belatacept in 2011. It is well established that kidney transplantation offers a clear survival and quality-of-life advantage to patients with end-stage kidney disease. The current treatment options have resulted in excellent short-term graft and patient survival but not without long-term side effects. FDA recognizes the importance of offering safe and effective drugs with a tolerable adverse effect profile to preserve kidney allografts for patients. This public meeting aims to discuss current and future potential endpoints and trial designs that can promote development in this area of unmet need.

II. Topics for Discussion at the Public Meeting

The topics of discussion include:

- Efficacy endpoints for prophylaxis of kidney transplant rejection trials: current state of primary endpoints and future potential endpoints.
- Biopsy proven acute rejection efficacy failure: long-term impact, impact of treatment, and grade of rejection.
- Noninferiority trials: identifying clinically important noninferiority margin, safety, and secondary efficacy endpoints.
- Enrichment as a tool in trial design: identifying target populations.

III. Attending the Public Meeting

Registration: If you wish to attend the public meeting (either in person or via Zoom), please register by October 26, 2023, at 4 p.m. Eastern Time. Visit the registration page here: *https://kidney-transplantation-workshop.eventbrite.com.*

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 7:30 a.m. Eastern Time. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact *ONDPublicMTGSupport@fda.hhs.gov* no later than October 18, 2023.

Streaming Webcast of the Public Meeting: This public meeting will also be virtual via Zoom. Zoom links will be sent using the email provided by persons who register. We will post a link to the archived recording on *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/endpoints-and-trial-designs-advance-drug-development-kidney-transplantation-11092023?check_logged_in=1*

approximately 1 week after the public meeting.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov*. A link to the transcript will also be available at *https://www.fda.gov/about-fda/office-immunology-and-inflammation-division-rheumatology-and-transplant-medicine-drtm.*

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19405 Filed 9–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Advisory Council) has scheduled public meetings. Information about the Advisory Council and the agenda for these meetings can be found on the ACBSCT website at: *https://bloodstemcell.hrsa.gov/about/advisory-council.*

DATES: Thursday, September 28, 2023, 2:00 p.m.–6:00 p.m. Eastern Standard Time; and Thursday, October 26, 2023, 2:00 p.m.–6:00 p.m. Eastern Standard Time.

ADDRESSES: Both meetings will be held virtually by webinar. A link to register and join each meeting will be posted at least 10 days prior to the meeting date at: *https://bloodstemcell.hrsa.gov/about/advisory-council.*

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Designated Federal Official, at the HRSA Health Systems Bureau, Division of Transplantation, 5600 Fishers Lane, 8W–67, Rockville, MD 20857; 301–443–8036; or *ACBSCTHRSA@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Council provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. 274k (section 379 of the Public Health Service Act), as amended, and Public Law 109–129, as amended. The Advisory Council may transmit its recommendations through the Administrator of HRSA on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory.

The agenda for the September 28, 2023, meeting is being finalized and may include the following topics: the Department of Health and Human Services' periodic review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering potential inclusion of such new therapies in the C.W. Bill Young Cell Transplantation Program; criteria for defining a high-quality cord blood unit for banking specifications; the unmet needs in blood stem cell transplantation and cellular therapy; strategies to improve rates of donation for adult blood stem cell donors; and other areas to increase blood stem cell donation and transplantation. The agenda for the October 26, 2023, meeting will be determined based on discussion, priorities, and/or action items from the September 28, 2023 meeting. All agenda items will be posted on the Advisory Council's website no later than 10 days prior to the respective meeting dates. Agenda items are subject to change as priorities dictate. Refer to the Advisory Council's website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the Advisory Council should be sent to Shelley Tims Grant, using the contact information above at least 3 business days prior to the meeting. Individuals who plan to attend and need special assistance or other reasonable accommodations should notify the Advisory Council at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–19398 Filed 9–7–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Drug Abuse, September 12, 2023, 10:30 a.m. to September 12, 2023, 05:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on August 21, 2023, FR Doc 2023–17889, 88 FR 56847.

This notice is being amended to change the open session start time from 12:45 p.m. to 1:00 p.m. The open session will now be held from 1:00 p.m. to 5:00 p.m. on September 12, 2023. The meeting is partially closed to the public.

Dated: September 1, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–19406 Filed 9–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services announces a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

The meeting will provide information on federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED).

DATES: October 18, 2023, 10:00 a.m. to 4:00 p.m. (EDT)/Open.

ADDRESSES: The meeting is open to the public and can be accessed virtually only by accessing: *https://www.zoomgov.com/j/1608742409?pwd=NjdoRlpGU2NoOHpaTzZVWXR3N0k4UT09*, or by dialing 646–828–7666, webinar ID: 160 874 2409, passcode: 446018. Agenda with call-in information will be posted on the