

enough to provide timely notice. Therefore, you should always check the FDA'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 October 28, 2022, the committee will discuss biologics license application 761176, for ¹³¹I-omburtamab solution for injection, submitted by Y-mAbs Therapeutics, Inc. The proposed indication (use) for this product is for the treatment of neuroblastoma with central nervous system/leptomeningeal metastases.

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 on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 14, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 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 5, 2022. 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 6, 2022.

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 Philip Bautista (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: August 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Organ Transplantation

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), HHS is hereby giving notice that the Advisory Committee on Organ Transplantation (ACOT or Committee) has been renewed. The effective date of the charter renewal is August 31, 2022.

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant (Designated Federal Officer); HRSA Division of Transplantation, HRSA, 5600 Fishers Lane, 08W67, Rockville, Maryland 20857; 301-443-8036; or sgrant@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACOT provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities pursuant to 42 U.S.C. 217a;

section 222 of the Public Health Service Act. ACOT may provide advice to the Secretary on proposed Organ Procurement and Transplantation Network policies and such other matters as the Secretary determines.

The renewed charter for ACOT was approved on August 25, 2022. The filing date of the renewed charter is August 31, 2022. The renewal of the ACOT charter gives authorization for the committee to operate until August 31, 2024.

A copy of the ACOT charter is available on the ACOT website at <https://www.hrsa.gov/advisory-committees/organ-transplantation>. A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is <http://www.facadatabase.gov/>.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

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

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a meeting. The meeting will be open to the public via webcast. For this meeting, the TBDWG will (1) review the final draft of chapters for the report and (2) further discuss plans for developing the next report to the HHS Secretary and Congress on federal tick-borne activities and research, taking into consideration the 2018 and 2020 report. The 2022 report will address a wide range of topics related to tick-borne diseases, such as, surveillance, prevention, diagnosis, diagnostics, and treatment; identify advances made in research, as well as overlap and gaps in tick-borne disease research; and provide recommendations regarding any appropriate changes or improvements to such activities and research.

DATES: The public can view the meeting online via webcast on October 4-5, 2022