Quality Branch 3; and established Data Quality Branch 4.

In the Division of Talent Services IV (DTS IV) realigned the ORA Branch 1 functions to DTS III and retitled as the Recruitment and Staffing Branch 10; realigned the ORA Branch 2 functions to DTS III and retitled as the Recruitment and Staffing Branch 11; and abolished DTS IV.

In the Division of Talent Sourcing and Staffing (DTSS) realigned the Corporate Recruitment and Title 38 Branch functions and resources to the OTS Immediate Office Executive Resources Staff and retitled as the Scientific Programs and Executive Resources Staff; realigned the Scientific Staffing and Outreach Branch functions and resources to the OTS Immediate Office Scientific Talent Recruitment Staff and retitled as the Science, Technology, Engineering, and Mathematics Outreach Staff; realigned the Customer Care and Data Quality Branch functions and resources to DTS III and retitled as the Data Quality Branch 1; and abolished DTSS.

Under Part D, FDA, OO, OTS has been restructured as follows:

DCNJ. ORGANIZATION. The Office of Talent Solutions is headed by the FDA Chief Talent Officer and includes the following organizational units:

Business Operations Staff
Policy, Programs, and Accountability Staff
Scientific Programs and Executive Resources Staff
Science, Technology, Engineering, and Mathematics Outreach Staff
Division of Talent Solutions I
Recruitment and Staffing Branch 1
Recruitment and Staffing Branch 2
Recruitment and Staffing Branch 3
Recruitment and Staffing Branch 4
Special Hiring and Pay Branch
Division of Talent Solutions II
Recruitment and Staffing Branch 5
Recruitment and Staffing Branch 6
Recruitment and Staffing Branch 7
Recruitment and Staffing Branch 8
Recruitment and Staffing Branch 9
Classification Branch 1
Classification Branch 2
Division of Talent Solutions III
Recruitment and Staffing Branch 10
Recruitment and Staffing Branch 11
Delegated Examining Branch
Data Quality Branch 1
Data Quality Branch 2
Data Quality Branch 3
Data Quality Branch 4

Under Part D, FDA, OO has been restructured as follows:

DCNK. ORGANIZATION. The Office of FDA Commissioned Corps (OFCC) is headed by the Director of FDA Commissioned Corps.

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm*

(Authority: 44 U.S.C. 3101.)

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–01567 Filed 1–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Operations (OO), Office of Enterprise Management Services (OEMS) has modified its structure. This new organizational structure was approved by the Deputy Secretary of Health and Human Services on September 26, 2022, and effective on September 26, 2022.

FOR FURTHER INFORMATION CONTACT: Tiffany Branch, Associate Director for Management, Office of Enterprise Management Services, Office of Operations, Food and Drug Administration, 3 White Flint North, 11601 Landsdown Street, North Rockville, MD 20852, 240–402–3156.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect reorganization of OEMS.

This reorganization realigned the FDA History Office function from the Office of the Commissioner (OC), Office of External Affairs (OEA) to OO, OEMS and revised the OEA and OEMS functional statements to this function realignment.

The Food and Drug Administration, Office of Operations, Office of Enterprise Management Services has been restructured as follows:

DCNA. ORGANIZATION. OEMS is headed by the Director of Enterprise Management Services and includes the following organizational units:

Division of Compliance and Conflict Prevention
Division of Human Capital
Division of Information Governance
FDA History Office
Division of Resources Management
Division of Vendor Management

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

(Authority: 44 U.S.C. 3101).

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–01566 Filed 1–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2174]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on March 9, 2023, from 12 p.m. to 5 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. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–2174. Please note that late, untimely filed comments will not be considered. The docket will close on March 8, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 8, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before February 24, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

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–2022–N–2174for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–5343, email: *ODAC@fda.hhs.gov,* 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 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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss supplemental biologics license application (BLA) 761121/S–008, for POLIVY (polatuzumab vedotin-piiq) for injection, submitted by Genentech, Inc. The proposed indication (use) for this product is in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). This product was approved under 21 CFR 601.41 (subpart E, accelerated approval regulations) for use in combination with bendamustine and a rituximab product for the

treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, after at least two prior therapies. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a product after it receives accelerated approval. The new proposed indication is based on the confirmatory study, POLARIX (Study GO39942), conducted to fulfill post-marketing requirement 3630–1 detailed in the June 10, 2019, approval letter, available at *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761121Orig1s000ltr.pdf.* Based on the results of the POLARIX study, the committee will discuss the benefit-risk profile of POLIVY in patients with previously untreated DLBCL.

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 February 24, 2023, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 3:15 p.m. to 4:15 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 February 14, 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 February 15, 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 Yvette Waples (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: January 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01553 Filed 1–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA DK22–003 Promoting Organ and Tissue Donation Among Health Disparity Populations (R01—Clinical Trial Optional).

Date: March 9, 2023.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, 6707 Democracy Blvd. Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD 20892, 301–594–2242, *jerkinsa@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 20, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–01541 Filed 1–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Analytics and Statistics for Population Research Panel B Study Section.

Date: February 22–23, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria De Jesus Diaz Perez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000G, Bethesda, MD 20892, (301) 496–4227, *diazperezm2@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cell Structure and Function 1 Study Section.

Date: February 23–24, 2023.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.