by the Secretary of Health and Human Services on September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Edwin Echegoyen, Acting Director, Office of Management/Executive Officer, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Silver Spring, MD 20993, 301–796–3300.

I. Summary

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; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Center of Drug Evaluation and Research.

This reorganization consists of the following Offices: Office of New Drugs (OND), Office of Translational Science (OTS), and Office of Pharmaceutical Quality (OPQ) within the Center for Drug Evaluation and Research and revises their functional statements. The proposed organizational changes align with the ReImagine HHS strategic shift moving to the 21st century: Maximizing Talent, Integrated Assessments, Benefit Risk Monitoring, and Leveraging the Power of Data. CDER will meet the definition of Maximizing Talent by focusing on growing our scientific leadership. This will result in clearly designed pathways to regulatory approval and enhanced emphasis on multidisciplinary teams. The proposed reorganization will integrate assessments to critically, collaboratively, and consistently assess whether information in submissions meets statutory and regulatory requirements. OND, OPQ, and OTS will establish Benefit-Risk Monitoring to unify the post-market safety surveillance framework leading to operational excellence by aligning the therapeutic focus. Each of these offices will incorporate Leveraging the Power of Data to provide access to analytical tools and systems to help the reviewers evaluate and interpret submitted data, thereby improving and streamlining the processes which will impact the critical analyses leading to efficiencies and effectiveness in CDER's scientific regulatory review.

Under Part D, FDA, the Center for Drug Evaluation and Research (CDER) has been restructured as follows:

Standard Administrative Codes (SAC). ORGANIZATION—CDER is headed by the Director and includes the following organizational units:

Office of Regulatory Policy (SAC)
Office of Management (SAC)
Office of Communications (SAC)
Office of Compliance (SAC)
Office of Manufacturing Quality (SAC)
Office of Unapproved Drugs and Labeling Compliance (SAC)
Office of Scientific Investigations (SAC)
Office of Program and Regulatory Operations (SAC)
Office of Medical Policy (SAC)
Office of Prescription Drug Promotion (SAC)
Office of Medical Policy Initiatives (SAC)
Office of Translational Sciences (SAC)
Office of Biostatistics (SAC)
Office of Clinical Pharmacology (SAC)
Office of Computational Science (SAC)
Office of Study Integrity and Surveillance (SAC)
Office of Administrative Operations (SAC)
Office of Executive Programs (SAC)
Office of Surveillance and Epidemiology (SAC)
Office of Medication Error Prevention and Risk Management (SAC)
Office of Pharmacovigilance and Epidemiology (SAC)
Office of New Drugs (SAC)
Office of Administrative Operations (SAC)
Office of Cardiology, Hematology, Endocrinology & Nephrology (SAC)
Office of Drug Evaluation Science (SAC)
Office of Immunology & Inflammation (SAC)
Office of Infectious Diseases (SAC)
Office of Neuroscience (SAC)
Office of New Drug Policy (SAC)
Office of Nonprescription Drugs (SAC)
Office of Oncologic Diseases (SAC)
Office of Program Operations (SAC)
Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine (SAC)
Office of Regulatory Operations (SAC)
Office of Specialty Medicine (SAC)
Office of Therapeutic Biologics and Biosimilars (SAC)
Office of Strategic Programs (SAC)
Office of Program and Strategic Analysis (SAC)
Office of Business Informatics (SAC)
Office of Generic Drugs (SAC)
Office of Research Standards (SAC)
Office of Bioequivalence (SAC)
Office of Generic Drug Policy (SAC)
Office of Regulatory Operations (SAC)
Office of Pharmaceutical Quality (SAC)
Office of Administrative Operations (SAC)
Office of Biotechnology Products (SAC)
Office of Lifecycle Drug Products (SAC)
Office of New Drug Products (SAC)
Office of Pharmaceutical Manufacturing Assessment (SAC)
Office of Policy for Pharmaceutical Quality (SAC)
Office of Program and Regulatory Operations (SAC)
Office of Quality Surveillance (SAC)
Office of Testing and Research (SAC)

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.

Alex M. Azar, II,

Secretary.

[FR Doc. 2019–26952 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) III Review.

Date: January 29–30, 2020.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washington Blvd., Gaithersburg, MD 20878.

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Bethesda, MD 20892, 240–276–5085, *tandlea@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review III.

Date: February 6–7, 2020.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Rockville, MD 20850, 240–276–5864, *jennifer.schiltz@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP 7: NCI Clinical and Translational R21 and Omnibus R03.

Date: February 12–13, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Robert Stephen Coyne, Ph.D., Scientific Review Officer, National Cancer Institute, NIH, Division of Extramural Activities, Special Review Branch, 9609 Medical Center Drive, Room 7W236, Rockville, MD 20850, 240–276–5120, *coyners@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–3: NCI Clinical and Translational R21 and Omnibus R03.

Date: February 13–14, 2020.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Hasan Siddiqui, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W240, Rockville, MD 20850, 240–276–5122, *hasan.siddiqui@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP–1: SBIR Contract Review.

Date: February 19–20, 2020.

Time: 6:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, Rockville, MD 20850.

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W260, National Cancer Institute, NIH, Bethesda, MD 20892–9745, 240–276–5856, *nadeem.khan@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Research Specialist Award R50.

Date: February 27–28, 2020.

Time: 5:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W242, Bethesda, MD 20892, 240–276–6372, *zouzhiq@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Transition to Independence SEP.

Date: March 10, 2020.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W602, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Delia Tang, M.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Bethesda, MD 20892, 240–276–6456, *tangd@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Quantitative Imaging Methods and Resources (UG3/UH3, U24).

Date: March 13, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 6W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850, 240–276–7684, *saejeong.kim@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; HIV-Associated Malignancy Research.

Date: March 26–27, 2020.

Time: 5:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, Rockville, MD 20852.

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W260, National Cancer Institute, NIH, Bethesda, MD 20892–9745, 240–276–5856, *nadeem.khan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 10, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–27003 Filed 12–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of Siglec-6-Specific Chimeric Antigen Receptor (CAR) for the Treatment Acute Myeloid Leukemia (AML), Chronic Lymphocytic Leukemia (CLL), and Other Forms of Acute and Chronic B- and T-Cell Leukemia and Lymphoma

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to T–CURX GmbH (T–CURX), located in Würzburg, Germany.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before December 31, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Abritee Dhal, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 3W610, MSC 9702, Bethesda, MD 20892–9702, (for business mail), Rockville, MD 20850–9702, Telephone: (240) 276–6154; Facsimile: (240) 276–5504; Email: *abritee.dhal@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 61/178,688 entitled ''A Panel Of Fully