the review of controlled correspondence received on or after October 1, 2022.

The GDUFA III commitment letter defines level 1 controlled correspondence and level 2 controlled correspondence, and this guidance provides additional details and recommendations concerning what inquiries FDA considers controlled correspondence for the purposes of meeting the Agency's performance goals under the GDUFA III commitment letter. In addition, this guidance provides details and recommendations concerning what information requestors should include in a controlled correspondence to facilitate FDA's consideration of and response to a controlled correspondence and what information FDA will provide in its communications to requestors that have submitted controlled correspondence. As described in the GDUFA III commitment letter, FDA has also agreed to review and respond to requests to clarify ambiguities in the controlled correspondence response, and the guidance provides information on how requestors can submit these requests and the Agency's process for responding to them.

This guidance finalizes the draft guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development'' issued on December 22, 2022 (87 FR 78691). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updating the guidance to clarify the role of a cover letter to a controlled correspondence; clarify that authorized agents submitting controlled correspondence should include the name of and contact information for the generic drug manufacturer or related industry they are representing; and explain that FDA intends to alert requestors whether their inquiry is a level 1 or level 2 controlled correspondence and if FDA changes the level of the controlled correspondence (*e.g.,* from level 1 to level 2) during substantive review. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Controlled Correspondence Related to Generic Drug Development.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information for controlled correspondence, covered product authorizations, and GDUFA III meetings are approved under OMB control number 0910–0727. The collections of information for risk evaluation and mitigation strategies and medication guides are approved under OMB control number 0910–0393. The collections of information for citizen petitions are approved under OMB control number 0910–0191. The collections of information for premarket approval of drug-device combination products as described in the draft guidance for industry entitled ''Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA'' have been approved under OMB control number 0910–0231.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05687 Filed 3–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0077]

Early Alzheimer's Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

Correction

In notice document 2024–05178, appearing on pages 17850 through 17851 in the issue of Tuesday, March 12, 2024, make the following correction:

On page 17850, in the second column, on the third line, ''May 13, 2024'' should read ''June 10, 2024''.

[FR Doc. C1–2024–05178 Filed 3–15–24; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research. The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed as below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov*).

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: May 6–7, 2024.

Time: May 6, 2024, 10:00 a.m. to 2:00 p.m.

Agenda: NICHD Director's Report, NCMRR Director's report; Scientific Presentation on Promoting Function and Inclusion for people with Spinal Cord Injury; Review of NINDS Traumatic Brain Injury Nomenclature Workshop; Concept Clearance.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892–7510 (Virtual Meeting).

Time: May 7, 2024, 10:00 a.m. to 2:30 p.m.

Agenda: Science Talk: Advocating for Cerebral Palsy Research; Update from NICHD Office of Health Equity; Pediatric Medical Device Public-Private Partnerships; Updates from The Advanced Research Projects Agency for Health; Updating the NIH Rehabilitation Research Plan; Words from Retiring Board Members; Planning for Next Board Meeting in December 2024.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Ralph M. Nitkin, Ph.D., Deputy, National Center for Medical Rehabilitation Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510, (301) 402–4206, *nitkinr@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory/nabmrr,*

where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 12, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–05653 Filed 3–15–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocast at the following link: *http://videocast.nih.gov/.*

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 Advisory Council on Minority Health and Health Disparities.

Date: May 30, 2024.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 31 Center Drive, Building 31C, Rooms 6 C, D, E, F, G, Bethesda, MD 20892.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: May 31, 2024.

Closed: 8:00 a.m. to 4:30 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.

Place: National Institutes of Health, 31 Center Drive, Building 31C, Rooms 6 C, D, E, F, G, Bethesda, MD 20892.

Contact Person: Paul Cotton, Ph.D., RDN, Director, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–402–1366, *paul.cotton@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NIMHD: *https://www.nimhd.nih.gov/about/advisory-council/,* where an agenda and any additional information for the meeting will be posted when available.

Dated: March 13, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–05701 Filed 3–15–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 1009 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 Institute of Neurological Disorders and Stroke Special Emphasis Panel; R25 Course on Clinical Trial Methods in Neurological Disorders (RFA–NS–23–030).

Date: April 3, 2024.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Steven G. Britt, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/HHS, NSC, 6001 Executive Blvd., Rockville, MD 20852, 301–480–1953, *steve.britt@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Clinical Trials in Neurology.

Date: April 4–5, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/HHS, NSC, 6001 Executive Blvd., Rockville, MD 20852, 301–435–6033, *rajarams@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: March 12, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–05656 Filed 3–15–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 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