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This guidance finalizes the draft guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development'' issued on December 22, 2022 (87 FR 78691). FDA considered comments received on the draft guidance as the guidance was finalized.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]

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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]

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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,*