DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1167]

Controlled Correspondence Related to Generic Drug Development; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development.'' This guidance provides information regarding the process by which generic drug manufacturers and related industry can submit controlled correspondence to FDA requesting information related to generic drug development and the Agency's process for providing communications related to such correspondence. This guidance also describes the process by which generic drug manufacturers and related industry can submit requests to clarify ambiguities in FDA's controlled correspondence response and the Agency's process for responding to those requests. This guidance finalizes the draft guidance of the same title issued on December 22, 2022. This guidance replaces the guidance ''Controlled Correspondence Related to Generic Drug Development'' issued on December 17, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on March 18, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2014–D–1167 for ''Controlled Correspondence Related to Generic Drug Development.'' Received comments 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.'' The Agency 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 to 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 this 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1672, Silver Spring, MD 20993–0002, 240–402–6902.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development.'' This guidance provides information regarding the process by which generic drug manufacturers and related industry can submit to FDA controlled correspondence requesting information related to generic drug development and the Agency's process for providing communications related to such correspondence. This guidance also describes the process by which generic drug manufacturers and related industry can submit requests to clarify ambiguities in FDA's controlled correspondence response and the Agency's process for responding to those requests. In accordance with the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III commitment letter), FDA agreed to certain review goals and procedures for

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]

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,*