c. Increasing access of members of the target populations to services relevant to individuals with paralysis
d. Increasing the empowerment, confidence, and independence of individuals living with paralysis
e. Strengthening support networks for individuals living with paralysis
f. Improving and increasing opportunities for community living for individuals living with paralysis and their caretakers

To gain an in-depth understanding of the perspectives of mentors and peers participating in the PFSP, QOL program subgrantees, and people who serve as regional champions in the Promotional Activities, Outreach, and Collaboration program, eight focus groups will be conducted with no more than eight people per focus group. Additionally, a web-based survey will be administered to a maximum of 330 PFSP peers, 150 PFSP mentors, and 850 people served by QOL subgrantees to understand respondents' experiences with the NPRC.

This data will contribute to documenting how each of the NPRC's major activities are delivered and the extent to which they improve the quality of life of people living with paralysis, their caregivers, and their support networks.

Findings can inform practice for the NPRC and other Resource Centers. This evaluation will also help to identify how the NPRC can better meet the stated goals of the Department of Health and Human Services (HHS) to, ''protect and strengthen equitable access to high quality and affordable healthcare,'' and to, ''strengthen social well-being, equity, and economic resilience.'' [1]

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

The eight focus groups together will include no more than 64 total individuals representing three major activities of the NPRC: the QOL Grants Program; the PFSP; and the Promotional Activities, Outreach, and Collaboration program. The burden for their participation is estimated at 1.5 hours per participant, for a total of 96 hours.

A maximum of 150 PFSP mentors, 330 PFSP peers, and 850 people served by QOL subgrantee programs are expected to respond to the web-based survey, for a total of 1,330 respondents. The approximate burden for survey completion is 15 minutes for the peer mentor survey, and 10 minutes for the peer survey and QOL end-user survey per respondent.

This results in a total survey burden estimate of 14,050 minutes (234.17 hours). The estimated survey completion burden includes time to review the instructions, read the questions, and complete responses.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours *
Focus groups	64	1	1.50	96.00
Survey—Peer Mentor	150	1	0.25	37.50
Survey—Peers	330	1	0.17	55.00
Survey—Quality of Life End-User	850	1	0.17	141.67
Total	1,394	1	2.09	330.17

* Annual burden hours were calculated from total minutes for each activity divided by sixty.

Dated: October 24, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–23484 Filed 10–27–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1261]

Clostridioides difficile Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention; Draft 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 draft guidance for industry entitled ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of *Clostridioides difficile* infection (CDI), reduction of recurrence, or prevention of CDI.

DATES: Submit either electronic or written comments on the draft guidance by December 27, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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'').

[1] *FY 2023 Evaluation Plan* (p. 3). (2022). U.S. Department of Health & Human Services. *https://aspe.hhs.gov/reports/fy-2023-hhs-evaluation-plan.*

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–D–1261 for ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' 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 the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ramya Gopinath, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6154, Silver Spring, MD 20993, 240–402–5328.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for treatment, reduction of recurrence, or prevention of CDI. Specifically, this guidance addresses FDA's current thinking regarding clinical trial design considerations such as trial populations and efficacy endpoints for treatment of CDI, reduction of recurrence, and prevention.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information relating to regulations found in 21 CFR parts 58, 312, 314, and 601 have been approved under OMB control numbers 0910–0119, 0910–0014, 0910–0001, and 0910–0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft 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: October 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23457 Filed 10–27–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0370; FDA–2011–D–0893; and FDA–2013–N–0093]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information