

### 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.*

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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, [PRStaff@fda.hhs.gov](mailto:PRStaff@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

collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct

or sponsor, and a person is not required to respond to, a collection of

information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Infant Formula Requirements .....	0910–0256	3/31/2023
Export of Medical Devices; Foreign Letters of Approval .....	0910–0264	10/31/2025
Center for Devices and Radiological Health Appeals Processes .....	0910–0738	10/31/2025
Review Transparency & Communication for New Molecular Entity NDAs & Original BLAs .....	0910–0746	10/31/2025

Dated: October 24, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB Number 0915–0327—Revision.

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than November 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the Acting HRSA Information Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–9094.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision.

*Abstract:* Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS (Secretary) that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program), and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity. A 60-day notice was

published in the **Federal Register** on June 14, 2022, vol. 87, No. 114; pp. 35983–85. There were five comments. Some comments addressed policy issues that are outside the scope of this information collection request. HRSA responded to technical comments that pertained to the ICR and revised the draft instruments based on the comments received.

*Need and Proposed Use of the Information:* To ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency and integrity, HRSA developed a process of registration for covered entities to enable it to address specific statutory mandates. Specifically, section 340B(a)(9) of the PHS Act requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

In addition, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary in order to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except several forms have been revised to increase program efficiency and integrity. Below are descriptions of each of the forms and revisions that are captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS).