

found on our website. New users of the CDER NextGen Portal must register for an account. For designation requests submitted by email, the Agency recommends using automated read receipt to verify receipt of the email.

Sponsors and others who plan to email information to FDA that is private, sensitive, proprietary, or commercial confidential are strongly encouraged to send it from an FDA-secured email address so the transmission is encrypted. The Agency will assume the addresses of emails received or email addresses provided as a point of contact are secure when

responding to those email addresses. Sponsors and others can establish a secure email address link to FDA by sending a request to SecureEmail@fda.hhs.gov. There may be a fee to a commercial enterprise for establishing a digital certificate before encrypted emails can be sent to FDA.

Respondents to the information collection are sponsors who develop investigational drugs and biologicals for commercial use and who seek orphan drug designation, and upon approval or licensure, orphan drug exclusivity.

In the **Federal Register** of April 16, 2026 (91 FR 20460), we published a 60-

day notice requesting public comment on the proposed collection of information. One comment was received encouraging FDA to offer more incentives toward the development of drug products to treat specific conditions and we appreciate this comment. At the same time, the comment did not suggest any modification to the estimates in our 60-day notice nor appear to question the Agency's need for the information collection.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR part or section; activity	Number of respondents	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
Part 316 associated records	864	1	1,080	135	145,800
§§ 316.20, 316.21, 316.26 (Form FDA 4035)	864	1	1,080	32	34,560
§ 316.22; Notifications of changes in agents	305	1	305	0.5	153
§ 316.24(a); Deficiency letters and granting orphan-drug designation	756	1	756	2	1,512
§ 316.27; Submissions to change ownership of orphan-drug designation	110	1	110	3	330
§ 316.30; Annual reports	2,210	1	2,210	3	6,630
§ 316.36; Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug	1	3	3	15	45
Guidance Recommendations: Meeting requests to OOPD and related submission packages	800	1.5	1,200	4	4,800
Total			6,744		193,830

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our burden figures on the number of submissions received and include those activities relating to: (1) requesting orphan drug designation; (2) responding to deficiencies letters with submissions of amendments; (3) keeping files current with contact information for agents and transfer of ownership, when applicable; (4) submitting annual reports while products have designation status; and (5) requesting and preparing for both informal and formal meetings. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government, we account for these activities cumulatively in table 1 above. Our burden estimate reflects a nominal increase of approximately 9% annually.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-19284 Filed 9-18-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-10430]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our reporting

requirements contained in FDA regulations governing state petitions for exemption from preemption.

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 20, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2026-N-10430 for "Agency Information Collection Activities; Proposed Collection; Comment Request; State Petitions for Exemption from Preemption." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT:

Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8758, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice

of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Petitions for Exemption from Preemption—21 CFR 100.1

OMB Control Number 0910-0277—Extension

This information collection supports FDA regulations. Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343-1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(c) (21 CFR 100.1(c)) provides prerequisites a petition must satisfy for an exemption from preemption. Section 100.1(d) sets forth the information a State is required to submit in such a petition. The petition may be submitted either as: (1) an original and one copy or (2) an original and a computer-readable disk containing the petition. Contents of the disk should be in a standard format. The petition must be submitted to the Dockets Management Staff at the address provided in the section "Written/Paper Submissions." The information required under § 100.1 enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

Description of Respondents: The respondents to this collection of information are State and local governments who regulate food labeling and standards of identity.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.1; petition for exemption from preemption	1	1	1	40	40

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.1 is minimal because petitions for exemption from preemption are seldom submitted by States. In the next 3 years, we estimate that one or fewer petitions will be submitted annually.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19282 Filed 9–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2396]

Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing year five of the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP). This program facilitates the expedited CMC development of products under an investigational new drug application (IND) based on the anticipated clinical benefit of earlier patient access to the products. FDA has implemented this pilot program to assist with CMC readiness for products regulated by both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that have accelerated clinical development timelines. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, as applicable. This notice outlines the eligibility criteria and

process for submitting a request to participate in the pilot.

DATES: Starting October 1, 2026, FDA will accept requests to participate in year five of the CDRP program. See the “Participation” section of this document for eligibility criteria, instructions on how to submit a request to participate, and selection criteria and process.

FOR FURTHER INFORMATION CONTACT:

Tanya Clayton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0871; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

For general questions about the CDRP Program for CBER: industry.biologics@fda.hhs.gov.

For general questions about the CDRP Program for CDER: cder-opq-opro-crad-inquiries@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Development programs for CBER- and CDER-regulated drugs and biologics intended to diagnose, treat, or prevent a serious disease or condition where there is an unmet medical need may have accelerated clinical development timelines. Yet, marketing applications for products in expedited development programs still need to meet FDA’s approval standards, including manufacturing facility compliance with current good manufacturing practice (CGMP). Products with accelerated clinical development activities may face challenges in expediting CMC development activities to align with the accelerated clinical timelines.

Successfully expediting CMC readiness may require additional interactions with FDA during product development and, if applicable, warrant the use of science- and risk-based regulatory approaches to streamline CMC development activities so that clinical benefits of earlier patient access to these products can be realized.

As described in the FDA Prescription Drug User Fee Act (PDUFA) VII Commitment Letter for fiscal years (FYs) 2023 Through 2027 (Ref. 1), FDA implemented the CDRP program to facilitate CMC readiness for selected

CBER- and CDER-regulated products with accelerated clinical development timelines in FY 2023. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, such as those described in the FDA guidance for industry titled “Expedited Programs for Serious Conditions—Drugs and Biologics” (May 2014) (Ref. 2), as applicable.

FDA (CBER and CDER) is continuing to administer the CDRP throughout the PDUFA VII program to facilitate the CMC development of selected products under INDs which have expedited clinical development timeframes, based on the anticipated clinical benefits of earlier patient access to the products. For sponsors participating in the pilot, FDA will provide product-specific CMC advice during product development, including two additional CMC-focused Type B meetings, as well as additional CMC-focused discussions. To support these interactions, once a sponsor is admitted to the pilot, FDA will expand the IND quality assessment team so as to ensure it has representation from the full complement of relevant disciplines. The increased communication between FDA review staff and sponsors is intended to ensure a mutual understanding of approaches to completing CMC activities, including what information should be provided at the appropriate timepoint (*i.e.*, at the time of new drug application (NDA) or biologics license application (BLA) submission, prior to the end of the review cycle, or post-approval) to ensure CMC readiness for a marketing application.

To promote innovation and understanding in this area, FDA held a public workshop on September 10, 2025, and issued a strategy document on July 23, 2026, focused on CMC aspects of expedited development incorporating lessons from the CDRP (Ref. 3). The public workshop explored the benefits and challenges of expedited CMC development. During the workshop, FDA participants described the aims of, and experience with, the CDRP. Participating sponsors and industry experts discussed their experience with