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 the CDRP and opportunities for its improvement. FDA then issued the strategy document based on the experience and learnings from the CDRP and workshop, as well as on the experience from other submissions for products with accelerated clinical development timelines.

II. Participation

FDA will accept requests to participate in the CDRP program continuously throughout the fiscal year. FDA will select no more than nine proposals per fiscal year, with approximately two-thirds being CBER-regulated products and one-third CDER-regulated products. FDA will

renew the CDRP program each fiscal year and announce the opening of the pilot program in the *Federal Register* for the remainder of this PDUFA VII period (until the end of FY 2027). However, once enrolled in the pilot a participating firm will continue to be enrolled in the program until their marketing application is filed. Sponsors who are interested in participating in the pilot program should submit a request to participate in the pilot as an amendment to their IND. The cover letter should state "Request To Participate in the CMC Development and Readiness Pilot."

A. Eligibility Criteria

The following eligibility criteria apply for consideration for participation in the pilot program:

1. Joint CBER and CDER Eligibility Criteria

- An active commercial IND (see the definition of commercial IND at https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/research-investigational-new-drug-applications-what-you-need-know).
- IND has been submitted in, or converted to, Electronic Common Technical Document (eCTD) format, unless the IND is of a type granted a waiver from eCTD format as per FDA's guidance for industry titled "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (September 2024) (Ref. 4).
- INDs for combination products (21 CFR 3.2(e)) are eligible; products that require significant cross-Center interactions (e.g., complex combination products) may be less likely to be selected for the pilot.
- In general, there should be enough time remaining before submission of the marketing application to allow the pilot to have an impact on CMC readiness.

- CMC-related information is provided to demonstrate a commitment to pursue a CMC development plan that aligns with the expedited clinical development program (see "CMC Development Plan" in section II.B of this document for details).
- Due to the differences in product complexity between CBER- and CDER-regulated products, the following eligibility and selection criteria differ between the Centers.

2. CBER-Specific Eligibility Criteria

- IND is an existing, CBER-regulated IND intended for submission as an application for licensure of a biological product under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)) for cellular therapies, gene therapies, and other products regulated by the Office of Therapeutic Products/CBER or vaccines regulated by the Office of Vaccines Research and Review/CBER.
- IND has a Breakthrough Therapy (BT) or Regenerative Medicine Advance Therapy (RMAT) designation.

3. CDER-Specific Eligibility Criteria

- IND is an existing, CDER-regulated IND for a product intended for submission as an application for: (1) approval of a new drug submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or (2) licensure of a biological product under section 351(a) of the PHS Act.
- IND has an expedited clinical timeframe warranted based on anticipated clinical benefits of earlier patient access. This would include INDs with BT or Fast Track designations as well as other INDs that meet this criterion, with eligibility to be determined by FDA.

B. What To Submit in a Request To Participate in the Pilot

To participate in the CDRP, sponsors should submit a written request as an amendment to the IND. In addition to providing a point of contact and noting any expedited program designations the IND has received to date, the request should include the following information.

CMC Development Plan

To focus pilot resources where they will be most useful and have an impact on the timeliness with which CMC readiness is achieved, prospective applicants to the pilot program should include in their Request to Participate a brief description of their CMC development plan, with a prospective timeline for CMC development that would align with when the clinical development program is expected to be complete:

- The plan should list the remaining CMC tasks and activities anticipated to be necessary, with estimated timeframes. This part of the plan should cover the following CMC-related areas:
    - Currently available product characterization and preliminary identification of critical quality attributes.
    - Summary of the current drug substance and drug product manufacturing process and control strategy (including assays, noting any that are still under development).
    - A brief description of the proposed commercial scale manufacturing and control strategy, including any necessary microbial control strategy--focusing on important differences from clinical scale.
    - Identification of potential commercial manufacturing facilities, including any contract facilities, or, at least, the type (in house, contract manufacturing organization) of facilities anticipated.
    - Plans for ensuring product availability at approval.
    - Drug substance and drug product stability assessment plan.
    - Strategy for process validation (see FDA's guidance for industry titled "Process Validation: General Principles and Practices" (January 2011) (Ref. 5)).
- Given the expedited clinical timeframe, mapping out a plan for manufacturing readiness within the same overall timespan may reveal potential challenges in accomplishing CMC readiness. The plan should highlight any anticipated CMC challenges--whether related to the bullets above or otherwise. This will facilitate FDA engagement and collaboration.

Participants in the pilot should plan to discuss these challenges with FDA during the pilot. For CDER-regulated products, see MAPP 5015.13, "Quality Assessment for Products in Expedited Programs" (July 2025) (Ref. 6).

- The CMC Development Plan should include proposed timing (i.e., month and year) for the first CMC-specific Type B meeting afforded by the pilot.

C. Selection Criteria and Process

FDA intends to select CBER and CDER INDs based on the criteria outlined below. Requests will be acknowledged and reviewed when received. FDA intends to issue a Proceed to Disclosure Agreement letter, if selected into the pilot, or deny letter within 90 days of receipt.

In selecting INDs for the pilot program, FDA intends to consider factors such as: (1) anticipated clinical benefits of facilitating earlier patient access to the product, (2) novelty of the product, (3) complexity of the product or its manufacturing process, including technology, and (4) anticipated CMC challenges. Overall, FDA intends to seek balance and diversity in product types and therapeutic indications to obtain a variety of relevant experience and learnings from the pilot.

D. FDA-Sponsor Interactions During the Pilot

During this CDRP program, sponsors will have the ability to discuss their product development strategies and goals with FDA review staff during the two dedicated Type B meetings, as well as in additional CMC-focused discussions. Besides additional interactions and collaboration with FDA, for those INDs in the pilot, FDA will assemble a team to support the CMC development and readiness of the IND, e.g., participating in the meetings and other discussions under the pilot.

In preparation for a meeting, sponsors should submit written questions along with a background information package clearly marked as a "PDUFA VII CDRP meeting" as part of the cover letter to enable FDA review staff to address the questions. The briefing package should be submitted to the corresponding IND. Meetings associated with the pilot should be

requested by sponsors. For additional information on meetings and other communications between the sponsors and FDA, see the FDA guidance for industry titled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" (August 2026) (Ref. 7), CDER MAPP 6025.6: "Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics" (Rev. 1) (February 2024) (Ref. 8), CBER "SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products" (December 2025) (Ref. 9), and CBER "SOPP 8212: Breakthrough Therapy Products--Designation and Management" (April 2026) (Ref. 10).

III. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). To the extent this information collection involves 10 or more respondents within any 12-month period, the collections of information are subject to the PRA. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501-3521). The collections of information for NDAs, formal meetings with sponsors and applicants for PDUFA products, and the PDUFA VII Commitment Letter have been approved under OMB control number 0910-0001. The collections of information for INDs have been approved under OMB control number 0910-0014. The collections of information for BLAs have been approved under OMB control number 0910-0338. The collections of information pertaining to CGMP requirements have been approved under OMB control number 0910-0139. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910-0765.

IV. References

The following references are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-

7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027." Available at https://www.fda.gov/media/151712/download.

2. FDA, Guidance for Industry: "Expedited Programs for Serious Conditions--Drugs and Biologics" (May 2014). Available at https://www.fda.gov/media/86377/download.

3. FDA's Strategy Document on Facilitating Chemistry, Manufacturing, and Controls Readiness for Products with Accelerated Clinical Development (July 2026). Available at https://www.fda.gov/media/193747/download?attachment.

4. FDA, Guidance for Industry: "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (Rev. 8) (September 2024). Available at https://www.fda.gov/media/135373/download.

5. FDA, Guidance for Industry: "Process Validation: General Principles and Practices" (Rev. 1) (January 2011): https://www.fda.gov/media/71021/download.

6. CDER MAPP 5015.13: "Quality Assessment for Products in Expedited Programs" (Rev. 1) (July 2025). Available at https://www.fda.gov/media/187958/download?attachment.

7. FDA, Guidance for Industry: "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" (August 2026): https://www.fda.gov/media/172311/download.

8. CDER MAPP 6025.6: "Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics" (Rev. 1) (February 2024). Available at https://www.fda.gov/media/89155/download.

9. CBER “SOPP 8101.1: “Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products” (December 2025). Available at https://www.fda.gov/media/84040/download?attachment.

10. CBER “SOPP 8212: Breakthrough Therapy Products--Designation and Management” (April 2026). Available at https://www.fda.gov/media/98351/download?attachment.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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