4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2396]

# Lessons Learned From the Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual-only public workshop entitled "Lessons Learned From the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Program." This workshop fulfills a commitment in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII) to hold a public meeting to discuss best practices and lessons learned from this pilot program. Convened by the Duke-Robert J. Margolis, MD Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement between FDA and Duke-Margolis, the workshop will feature sponsors and FDA experience under this pilot program and will solicit input on future directions for FDA policy and programs to facilitate expedited CMC development of products under an investigational new drug application (IND), where indicated based upon the anticipated clinical benefits.

DATES: The public workshop will be held virtually on September 10, 2025, from 1:00 p.m. to 5:00 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by October 15, 2025. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

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 PM Eastern Standard Time (EST) on October 15, 2025. 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-2022-N-2396 for ‘‘Lessons Learned from the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) program; Public Workshop; Request for Comments.’’ 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 AM and 4 PM EST, 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: 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.

SUPPLEMENTARY INFORMATION:

## I. Background

Development programs for the Center for Biologics Evaluation and Research (CBER)- and the Center for Drug Evaluation and Research (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.

As described in the PDUFA VII Commitment Letter for fiscal years (FYs) 2023 Through 2027, FDA implemented the CDRP program to facilitate CMC readiness for selected CBER- and CDER-regulated products with 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, such as those described in the FDA guidance for industry entitled "Expedited Programs for Serious Conditions—Drugs and Biologics" (May 2014), as applicable. Under this CDRP program, participating sponsors are able to discuss their product development strategies and goals with

FDA review staff during two dedicated Type B meetings, as well as additional CMC-focused discussions.

This public workshop fulfills FDA's commitment under the PDUFA VII letter (available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027; see section N.4.c.) to hold a public meeting focused on CMC aspects of expedited development including case studies, lessons learned, and stakeholder input regarding the CDRP, and to solicit industry and public feedback.

## II. Topics for Discussion at the Public Workshop

This public workshop is intended as an information gathering step in support of the strategy paper FDA will subsequently develop. That strategy paper will outline FDA's planned policy and programmatic response to support expediting CMC readiness when the clinical benefit of an investigational-stage product warrants it. The public workshop will feature discussions on CMC aspects of expedited development, including case studies, illustrating best practices and lessons learned from the CDRP. The workshop will also provide a forum for industry and the public to make recommendations on expediting CMC development.

Workshop updates, agenda, and background materials, if any, will be made available prior to the workshop at the CDRP web page https://www.fda.gov/drugs/pharmaceutical-quality-resources/chemistry-manufacturing-and-controls-development-and-readiness-pilot-cdrp-program.

## III. Participating in the Public Workshop

*Registration:* To register for the public workshop, please visit the following website: https://healthpolicy.duke.edu/events/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-0. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration will end at 11:59 p.m. Eastern Time on September 9, 2025. Registration is free, and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will

receive a confirmation email after they register. If you need special accommodations due to a disability, please contact Margolisevents@duke.edu no later than 5:00 p.m. Eastern Time on August 27, 2025. Please note, closed captioning will be available automatically.

*Transcript*: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may also be viewed at the Dockets Management Staff (see ADDRESSES).

Dated: August 14, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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