individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals, to serve as a nonvoting industry representative. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19496 Filed 9–8–23; 8:45 am]

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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) is announcing the year two opportunity for a limited number of applicants to participate in a Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) program to facilitate the expedited CMC development of products under an investigational new drug application (IND), where warranted, based on the anticipated clinical benefit of earlier patient access to the products. FDA has implemented this pilot program to facilitate CMC readiness for selected Center for Biologics Evaluation and Research (CBER)- and Center for Drug Evaluation and Research (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 FDA guidance, as applicable. This notice outlines the eligibility criteria and process for submitting a request to participate in the pilot.

DATES: Starting October 2, 2023, FDA will accept requests to participate in 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 Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7256, Silver Spring, MD 20993–0002, 240–402–5683.

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 allowing streamlining of 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 entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014) (Ref. 2), as applicable.

FDA (CBER and CDER) is continuing to conduct a CDRP to facilitate the CMC development of selected products under INDs that have expedited clinical development timeframes, based on the anticipated clinical benefits of earlier patient access to the products. This includes products with Breakthrough Therapy (BT), Fast Track (FT), and Regenerative Medicine Advance Therapy (RMAT) designations. For sponsors participating in the pilot, FDA will provide product-specific CMC advice during product development, to include two additional CMC-focused Type B meetings, as well as a limited number of additional CMC-focused discussions, based on readiness and defined CMC milestones. 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.

II. Participation

FDA will continuously accept requests to participate in the CDRP program. 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. Taking into consideration lessons learned from the prior year, FDA will publish in the **Federal Register** a notice to announce pilot programs for each of the remaining FYs of the CDRP program. 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.''

To promote innovation and understanding in this area, lessons learned through the pilot may be presented by FDA (*e.g.,* in a public workshop) as case studies, including when the product studied in the pilot has not yet been approved by FDA. FDA intends to conduct a public workshop and issue a strategy document focused on CMC aspects of expedited development incorporating lessons from the CDRP. To be eligible for the pilot, the sponsor and FDA will reach an agreement on the information to be publicly disclosed. Generally, FDA does not anticipate that the case studies will need to include information, such as the sponsor's name or product information, that can specifically identify a unique product.

Participation in the pilot program, including such agreement on information disclosure, is voluntary and at the discretion of the sponsor. Where feasible, FDA will notify a sponsor in advance when it plans to include some aspect of their experience in the program in a public discussion (*e.g.,* a slide presentation, a white paper).

A. Eligibility Criteria

To be considered for the pilot program, participants must meet the following eligibility criteria:

1. Joint CBER and CDER Eligibility Criteria

- Participant must have an active commercial IND (see the definitions of commercial INDs 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 entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (February 2020) (Ref. 3).
- INDs for combination products (21 CFR 3.2(e)(1)) 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, at the time of application to the pilot, the IND clinical program has not yet reached the end of Phase 2 to allow the pilot to have sufficient time to have an impact on CMC readiness (*e.g.,* 2 years from anticipated marketing application submission). However, in extenuating circumstances, requests for exceptions may be considered, where the development programs would still benefit from the pilot—examples of what could constitute such circumstances include:
  - Cases where the clinical development is following an innovative trial design
  - The product is intended to treat a rare disease
- 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'' under *What To Submit in a Request To Participate in the Pilot* 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 BT or 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 the anticipated clinical benefits of earlier patient access. This would include INDs for products with a BT or FT designation; IND sponsors of other products that meet this criterion may also apply to the pilot, with their 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.

1. CMC Development Plan

To focus pilot resources where they should 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 description of their CMC development plan that includes a timeline for CMC development aligned with when the clinical development program is expected to be complete:

(1) The plan should describe the current state of CMC development, including any ongoing activities not already included in the IND.

(2) The plan should include a projected timeline for product development that aligns with the anticipated clinical development timeline, showing the CMC tasks and activities intended to yield complete CMC data and information to be included in the marketing application. This part of the plan should cover the following CMC-related areas:

- Available product characterization and preliminary identification of critical quality attributes.
- Description of the current drug substance and drug product manufacturing process and control strategy (including identification and development of assays), and a description of and plan for the proposed commercial scale manufacturing and control strategy, including any necessary microbial control strategy.
- Identification of manufacturing facilities, including any contract facilities, along with the facilities' recent inspection history (including foreign regulatory inspections, where applicable).
- Plans for ensuring product availability for commercial launch.
- Drug substance and drug product stability assessment plan.
- Overall plan for process validation (*e.g.,* stage 1 and stage 2 as described in FDA's guidance for industry entitled ''Process Validation: General Principles and Practices'' (Ref. 4)).

(3) Given the expedited clinical timeframe, mapping out a plan for manufacturing readiness within the same overall timespan may reveal potential challenges in accomplishing CMC activities within the allotted time that is typically needed during CMC development to prepare a marketing application that can support approval. The plan should highlight these areas (exemplified in the bulleted list above, and any additional CMC challenges that may require FDA input), to facilitate FDA engagement regarding the types of supportive data and information that might be used to address these challenges. 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 (Ref. 5)).

2. Proposed Plan and Timing for Meetings With FDA

The CMC Development Plan should include proposed timing (*i.e.,* month and year) for the two additional CMC-specific Type B meetings afforded by the pilot, as well as any other meetings and discussions foreseen.

C. Selection Criteria and Process

FDA intends to select participant CBER and CDER INDs based on the criteria outlined below. Review of requests is planned to occur quarterly, or as needed, depending on the requests to participate in the pilot that are received during the period. FDA intends to issue a letter to notify each sponsor of FDA's decision on their request to participate within 180 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, (4) sponsor's overall manufacturing experience, and (5) sponsor's experience with the particular product type, class, or the type of manufacturing process. FDA may give additional consideration to less-experienced sponsors. Overall, FDA intends to seek balance and diversity in product types, sponsors, 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 be able to discuss their product development strategies and goals with FDA review staff during predesignated Type B meetings and a limited number of additional CMC-focused discussions. As part of the CMC readiness pilot, two dedicated CMC meetings will be granted, and sponsors will have an opportunity for followup discussions to address questions arising from the meeting or meeting minutes, or if additional clarifications are needed.

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 draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (December 2017) (Ref. 6), CDER MAPP 6025.6: Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics (July 2014) (Ref. 7), CBER SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products (March 2023) (Ref. 8), and CBER SOPP 8212: Breakthrough Therapy Products—Designation and Management (August 2023) (Ref. 9).

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*. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 at *https://www.fda.gov/media/151712/download*.
2. FDA guidance for industry ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014): *https://www.fda.gov/media/86377/download*.
3. FDA guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (February 2020): *https://www.fda.gov/media/135373/download*.
4. FDA guidance for industry ''Process Validation: General Principles and Practices'' (January 2011): *https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf*.
5. CDER MAPP 5015.13: *Quality Assessment for Products in Expedited Programs: https://www.fda.gov/media/162786/download?attachment*.
6. FDA draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (December 2017): *https://www.fda.gov/media/109951/download*.
7. CDER MAPP 6025.6: *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics* (July 2014): *https://www.fda.gov/media/89155/download*.
8. CBER SOPP 8101.1: *Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* (March 2023).
9. CBER SOPP 8212: *Breakthrough Therapy Products—Designation and Management* (August 2023).

Dated: September 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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