related to cessation and should address the following questions:

1. How can researchers increase enrollment for traditionally underrepresented populations in clinical trials (*e.g.,* racial and ethnic minority populations, LGBTQ+ populations, rural populations)?
2. Would there be interest in an externally led Patient Focused Drug Development (PFDD) meeting to better understand the challenges and barriers to smoking cessation from individuals trying to quit and what additional endpoints can be evaluated in smoking cessation clinical trials?
3. What are some novel targets that could facilitate cigarette cessation product development?
4. What challenges are researchers and/or drug developers facing in their efforts to identify novel targets for smoking cessation therapies?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://advancingsmokingcessation.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting in person must register by October 15, 2024, 11:59 p.m. Eastern Time. Persons interested in attending this public meeting virtually must register by October 21, 2024, 9 a.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

For special accommodations due to a disability, please visit the registration website: *https://advancingsmokingcessation.eventbrite.com.* Please submit special accommodation requests no later than October 7, 2024.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate requests to make public comments.

Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Eastern Time on October 21, 2024. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement describing the general nature of the evidence or arguments they wish to present and the names and email addresses of proposed participants, on or before October 1, 2024, by 5 p.m. Eastern Time. Topics should address the questions listed in II., Section 6. Individuals making formal oral presentations will not have the capacity to present slides during the public comment session. Individuals may submit presentation materials to the docket on or before November 21, 2024.

Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in person may be limited. If the number of registrants requesting to speak in person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in person. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants as soon as possible to provide speakers with adequate time to prepare. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please visit the following website for more information: *https://advancingsmokingcessation.eventbrite.com.*

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

(Notice of this meeting is given pursuant to 21 CFR 10.65.)

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21678 Filed 9–20–24; 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 three 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, 2024, FDA will accept requests to participate in year three 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 James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 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 entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014) (Ref. 2), as applicable.

FDA (CBER and CDER) is continuing to administer the CDRP 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.

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.''

To promote innovation and understanding in this area, FDA will hold a public workshop and issue a strategy document focused on CMC aspects of expedited development incorporating lessons from the CDRP. At the workshop, sponsors may be asked to present lessons learned from the pilot. FDA may also present summary lessons and case studies. Generally, FDA does not anticipate that the case studies will need to include information, such as the sponsor's name, that can identify a unique product or product-specific manufacturing process information. Case studies will focus on FDA-sponsor interactions and problem solving, and address scientific and technical issues only in general terms. However, as described in the FDA PDUFA VII Commitment Letter for FYs 2023 Through 2027, to be eligible for the pilot, the sponsor must reach agreement with FDA on the information that could be publicly disclosed. 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 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 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)) 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 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 entitled ''Process Validation: General Principles and Practices'' (Ref. 4)).
- 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'' (Ref. 5).
- 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 draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (September 2023) (Ref. 6), CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024) (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.* 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'' 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'' (Rev. 7) (February 2020): *https://www.fda.gov/media/135373/download.*

4. FDA guidance for industry ''Process Validation: General Principles and Practices'' (Rev. 1) (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'' (December 2022): *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'' (Rev. 1) (September 2023): *https://www.fda.gov/media/172311/download.*

7. CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024): *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 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21674 Filed 9–20–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3805]

The Accreditation Scheme for Conformity Assessment Program; Draft Guidances for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three draft guidance documents for the Accreditation Scheme for Conformity Assessment Program entitled ''The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.'' In accordance with amendments made by the FDA User Fee Reauthorization Act of 2022 (FUFRA), part of the Medical Device User Fee Amendments of 2022 (MDUFA V), FDA was directed to conclude the Pilot Accreditation Scheme for Conformity Assessment Program by the end of fiscal year 2023 and continue to operate the program (hereafter referred to as the ASCA Program) consistent with the amended FD&C Act. FDA is publishing these draft guidance documents which, when finalized, are intended to provide updates to improve the ASCA Program. These draft guidance documents are not final nor for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 22, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2019–D–3805 for ''The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation