The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 26, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–23640 Filed 10–28–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Building Capacity To Evaluate Child Welfare Community Collaborations To Strengthen and Preserve Families (CWCC) Cross-Site Process Evaluation (OMB #0970–0541)

AGENCY: Office of Planning, Research, and Evaluation (OPRE); Administration for Children and Families (ACF); Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families at HHS is requesting an extension to continue data collection for an evaluation of the initiative, Community Collaborations to Strengthen and Preserve Families (also referred to as Child Welfare Community Collaborations [CWCC]). The cross-site process evaluation will provide insight to ACF about the various factors that promote or impede the implementation of child welfare community collaborations.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The evaluation involves seven data collection activities. Initial interviews with Project Directors and leaders from partner organizations and initial interviews with staff from lead and partner organizations have been completed. This request includes the remaining five activities:

- *Survey Invitee Template:* This template requests the Project Director of each CWCC grant to fill out a Survey Invitee Template to gather contact information for leaders and staff from lead and partner organizations who the evaluation team will invite to complete the Collaboration Survey (see below).
- *Collaboration Survey:* This electronic survey documents perceptions that leaders and staff from the CWCC lead and partner organizations have regarding their organizational/group processes, implementation activities, and progress towards goals. This survey is administered to staff at all grantee and partner organizations on an annual basis during each cohort's grant period.
- *Site Visit Planning Template:* Each project director (or their designee) will complete a Site Visit Planning Template to schedule site visit activities prior to each annual site visit.
- *Two Site Visit Discussion Guides:* To systematically document the approaches and strategies used by the first two cohorts of CWCC grantees (fiscal year (FY) 18 and FY 19 awardees), the evaluation team will conduct follow-up interviews with: (1) Project Directors from lead grantee organizations and leaders from partner organizations, and (2) Staff from the lead and partner organizations. These interviews will take place during site visits. Each grantee will participate in four site visits in total. As noted above, the first two have already been completed.

Respondents: Leadership and staff from CWCC lead (grantee) organizations and from partner organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents (over request period)	Number of responses per respondent (total over request period)	Average burden hours per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Cohort 1 Data Collection for FY 18 grantees					
Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Follow-Up Interviews	12	1	1.5	18	9
Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Follow-Up Interviews	36	1	1	36	18
Survey Invitee Template	4	1	1	4	2
Annual Collaboration Survey	268	1	.5	134	67
Site Visit Planning Template	4	1	2	8	4
Cohort 2 Data Collection for FY19 grantees					
Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Follow-Up Interviews	27	2	1.5	81	41
Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Follow-Up Interviews	81	2	1	162	81
Survey Invitee Template	9	2	1	18	9
Annual Collaboration Survey	990	2	.5	990	495
Site Visit Planning Template	9	2	2	36	18

Estimated Total Annual Burden Hours: 744.

Authority: Section 105(b)(5) of the Child Abuse Prevention and Treatment Act of 1978 (42 U.S.C 5106(b)(5)), as amended by the CAPTA Reauthorization Act of 2010 (Pub. L. 111–320).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–23673 Filed 10–28–22; 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 or Agency) is announcing the 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 (IND) application, where warranted, based upon the anticipated clinical benefit of earlier patient access to the products. FDA is implementing 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 April 1, 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 20903–0002, 301–796–0871; or Stephen Ripley, 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 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 is implementing 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) (Ref. 2), as applicable.

Starting in FY 2023, FDA (CBER and CDER) will conduct a CDRP to facilitate the CMC development of selected products under INDs which have expedited clinical development timeframes, based upon 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

Starting April 1, 2023, FDA will accept requests to participate in the CDRP program and select no more than nine proposals, with approximately two thirds being CBER-regulated products and one third CDER-regulated products. Taking into consideration lessons from the prior year, FDA will publish in the **Federal Register** a notice to announce pilot programs for each of the 3 following fiscal years. 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. Participation in the pilot program is voluntary and at the discretion of the sponsor. To be eligible for the pilot, the sponsor's written request should include the following statement:

''We, <sponsor's name>, acknowledge that certain information relevant to the CDRP may be publicly disclosed.''