Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Since 2005, Congress has authorized dedicated funding for discretionary awards from ACF's Office of Family Assistance to support HMRF programs. Per the 2020 HMRF Notice of Funding Opportunities issued by ACF, HMRF grant recipients that are carrying out local evaluations are required to submit a final evaluation report to ACF at the end of their grant. The final reports must document the research questions, measures, study design, planned and actual implementation of the program, analytic methods for their evaluation, and evaluation findings.

OPRE is conducting the HMRF Local Evaluation Technical Assistance (LETA) projects, jointly referred to as the HMRF–LETA projects, to support federally funded programs in evaluating their healthy relationship and family stability services to adult couples, adult individuals, fathers, and youth. As part of the HMRF–LETA project, grant recipients receive technical assistance to support planning and executing a local evaluation and analyzing and reporting local evaluation findings.

The purpose of the current information collection request is to provide standardized report templates and table shells to grant recipients to document their evaluation's analysis and findings. A structured final report template will facilitate grant recipients' efficient and consistent reporting of evaluation findings in their final reports. The completed draft reports will be reviewed by the HMRF–LETA teams to determine whether the analysis and reports meet standards set by ACF, and to develop recommendations for grant recipients to improve the analysis and reports before final submission to ACF. Grant recipients will finalize and submit their final reports to ACF, as required. This request includes the time to develop and submit the reports.

Respondents: The respondents are HMRF grant recipients conducting a local evaluation. There are currently 79 grant recipients conducting local evaluations: 50 evaluations using descriptive designs (''descriptive evaluations'') and 29 evaluations using impact designs (''impact evaluations'').

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Descriptive Evaluation Final Report Template	50	1	40	2,000
Impact Evaluation Final Report Template	29	1	30	870
Impact Evaluation Final Report Table Shells	29	1	10	290

Estimated Total Annual Burden Hours: 3,160.

Authority: 42 U.S.C. 603(a)(2).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28555 Filed 12–5–24; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2033]

Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' Accelerated approval is one of FDA's expedited programs intended to facilitate and expedite development and review of certain drugs and biological products for serious or life-threatening conditions. This guidance provides information on FDA's policies and procedures for the accelerated approval program, including discussions of which products may be candidates for accelerated approval, the standards for granting accelerated approval, and the procedures for withdrawing accelerated approval. When finalized, this draft guidance will replace the accelerated approval-related content in the final guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' issued on May 30, 2014 (the 2014 final guidance). Additional programs to expedite product development are covered in the 2014 final guidance as well as other guidances.

DATES: Submit either electronic or written comments on the draft guidance by February 4, 2025. 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–2024–D–2033 for ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' Received comments 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 a.m. and 4 p.m., 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926 or 301–796–2500, *dat.doan@fda.hhs.gov;* 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; or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567, *Paul.Kluetz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' Accelerated approval allows drugs for serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. Accelerated approval is one of FDA's expedited programs intended to facilitate and expedite development and review of new drugs to address an unmet medical need in the treatment of a serious or life-threatening condition.

In 1992, FDA issued accelerated approval regulations. In 1997, Congress codified the accelerated approval program in the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), adding section 506 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356). In 2012, Congress amended section 506 of the FD&C Act via the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) to provide that FDA should consider the ''severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.'' In 2014, FDA issued a final guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics,'' which provides information on FDA's policies and procedures for four expedited programs (fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation), as well as threshold criteria applicable to concluding that a drug is a candidate for these expedited programs.

Section 506(c) of the FD&C Act was most recently amended by the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), which granted FDA additional authorities and imposed on FDA additional obligations regarding the accelerated approval pathway. Among other revisions, section 3210 of the Consolidated Appropriations Act, 2023 requires FDA to set forth conditions, not later than the date of accelerated approval, for confirmatory trials, which ''may include enrollment targets, the study protocol, and milestones, including the target date of study completion.'' Congress also revised the provisions in section 506(c) of the FD&C Act related to the expedited withdrawal of approval of a product approved under accelerated approval, including by adding new procedures for expedited withdrawal. Section V of this draft guidance describes these recently added procedures for the expedited withdrawal of approval of a product approved under accelerated approval.

This draft guidance addresses the accelerated approval process, including granting accelerated approval (*e.g.,* discussion of endpoints, evidentiary criteria, confirmatory trials and other conditions of accelerated approval), and withdrawal of accelerated approval. Changes from the 2014 final guidance include early consultation on novel endpoints, timely conduct of confirmatory trials, other aspects of confirmatory trials, and the expedited withdrawal of accelerated approval. Other changes include a revised title and editorial changes for clarity, as well as updated references and contact information for FDA. When finalized, this guidance will replace the accelerated approval-related content contained in the 2014 final guidance issued on May 30, 2014 (79 FR 31117).

Additionally, via the Consolidated Appropriations Act, 2023, Congress gave FDA the authority to require, as appropriate, that a confirmatory trial be underway prior to accelerated approval or within a specified time period after the date of accelerated approval. The

Agency intends to address this authority in a separate guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information including information submitted to FDA in support of maintaining an accelerated approval. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a separate issue of the **Federal Register**. This notice will encompass the collection of information discussed in the guidance relating to expedited procedures for the withdrawal of accelerated approval of drugs and biologics. Those procedures include the sponsor's submission of their objections to withdrawal as well as their supporting data and evidence. This collection of information is not included in any currently approved information collection.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 10, 12–16, and 19 pertaining to administrative practice and procedures have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 312 relating to clinical trials associated with accelerated approval pathways have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications, including accelerated approval of new drugs for serious or life-threatening conditions, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338. 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.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 27, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28392 Filed 12–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Public Comment Request: Request for Information Regarding HRSA Sickle Cell Disease Programs

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of request for public comment.

SUMMARY: HRSA's Maternal and Child Health Bureau Sickle Cell Disease (SCD) Programs are requesting input from the public to inform future SCD program development.

DATES: Submit comments no later than January 6, 2025.

ADDRESSES: Submit electronic comments to *scdprograms@hrsa.gov.* Please submit your response only one time.

FOR FURTHER INFORMATION CONTACT: Oriana Sanchez, Public Health Analyst, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; *scdprograms@hrsa.gov* or call (347) 415–1458.

SUPPLEMENTARY INFORMATION: SCD is a group of inherited red blood cell disorders affecting an estimated 100,000 individuals in the United States. The Centers for Disease Control and Prevention report that SCD is a lifelong condition disproportionately affecting Black (1 of every 365 births) and Hispanic Americans (1 of every 16,300 births) with cases also occurring in individuals of Mediterranean, Middle Eastern, and Asian descent. SCD causes the body to produce red blood cells that are crescent shaped which impedes blood flow and cause anemia, severe pain, organ damage and other complications. Without access to comprehensive and routine services, life expectancy is greatly reduced for individuals with SCD. HRSA currently funds a portfolio of three coordinated programs with several recipients to improve outcomes of individuals with SCD and their families: the SCD Newborn Screening Follow-up Program (authorized by 42 U.S.C. 701(a)(2) (sec. 501(a)(2) of the Social Security Act)) funds 25 community-based organizations, the SCD Treatment Demonstration Program (authorized by 42 U.S.C. 300b–5(b) (sec. 1106(b) of the Public Health Service Act)) funds five regional organizations, and one Hemoglobinopathies National Coordinating Center (authorized by 42 U.S.C. 300b–5(b) (sec. 1106(b) of the Public Health Service Act).

Together the programs strengthen the SCD system of care and support by (1) educating patients, families, and clinicians to improve knowledge and capacities; (2) linking individuals and families to evidence-based care; and (3) fostering partnerships between clinicians, community organizations, and other stakeholders to improve the ability to deliver coordinated, comprehensive care across the lifespan. HRSA's SCD portfolio seeks to support and strengthen regional networks of SCD care, education, and social services across the United States. More information about the HRSA SCD programs is available online at: *https://mchb.hrsa.gov/programs-impact/programs/sickle-cell.*

Responses

HRSA is seeking responses that address the following questions. A response to each question is not required. When drafting responses, highlight strategies that HRSA should consider or prioritize to meet the needs of individuals with SCD and their families within the United States.