

in, or potentially interested in ACF programs and similar programs is vital to ensure ACF is responsive to the needs of those it serves and that resources are, and programming is appropriate, useful, and relevant for audiences. Information collections under this generic would gather information from individuals with diverse experiences and perspectives to inform ACF policies and programs. The information collected would allow for ongoing, two-way collaborative and actionable communications between ACF and its state, local and/or Tribal partners, program participants, communities served or affected by ACF programs, and or others experienced with or interested in ACF programs or similar programs.

ACF envisions using information collected to inform a variety of efforts and activities such as the improvement, planning, and implementation of research studies, program changes, development and dissemination of resources and products developed under ACF studies, regulatory activities, guidance, outreach and/or training activities.

The specific types of information gathering methods included under the umbrella of this clearance will vary, but will use well-established methodologies, including but not limited to:

- Semi-structured discussions or conference calls
- Focus groups
- Telephone or in-person interviews
- Questionnaires/Surveys
- Roundtable and/or Breakout Sessions
- Open-ended requests
- Contextualizing Existing Data

Data collection will take place through a variety of activities—both in-person and virtual—dependent on the specific project. ACF will submit individual requests under this clearance. ACF requests OMB provide a response on individual generic information collections within 10 business days.

Respondents: Respondents could include current or prospective service providers, T/TA providers, grant recipients, contractors, current and potential participants in ACF programs or other comparable groups and other

individuals with lived experience with ACF or similar programs, experts in fields pertaining to ACF programs, other key groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, state or local government officials, those in broader fields of study related to human services, or others involved in or prospectively involved in ACF programs.

Burden Estimates

The burden table below is illustrative. Estimates for the number of respondents and time per response have been made based on discussion with ACF program offices, but as this is a new umbrella generic, it may be possible that we will need to adjust estimates throughout the three-year approval period. If needed, ACF will submit a change request for these updates. While we will not exceed the total burden cap for this generic without requesting a change for updates, we may use more or less burden within each instrument type.

Example types of information collections	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Semi-Structured Discussions and Focus Groups	10,000	1	2	20,000
Interviews	4,500	1	1	4,500
Questionnaires/Surveys	8,000	1.5	.5	6,000
Templates and Open-ended requests	1,000	1	10	10,000
Estimated Totals	23,500			40,500

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (Office of Management and Budget #: 0970-0401)

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) proposes to extend data collection under the existing overarching Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (Office of Management and Budget (OMB) #0970-0401). There are no changes to the proposed types of information collection or uses of data,

but ACF is requesting an increase to the estimated number responses per respondent.

DATES: Comments due within 60 days of publication. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing OPREinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Executive Order 12862 directs federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. As outlined in Memorandum M-11-26, OMB worked with agencies to create a Fast Track Process to allow agencies to obtain

timely feedback on service delivery while ensuring that the information collected is useful and minimally burdensome for the public, as required by the Paperwork Reduction Act of 1995. ACF created this generic clearance in response to this effort by OMB.

To work continuously to ensure that the ACF programs are effective and meet our customers' needs, we use this Fast Track generic clearance process to collect qualitative feedback on our service delivery. This collection of information is necessary to enable ACF to garner customer and stakeholder feedback in an efficient, timely manner in accord with our commitment to improving service delivery. The information collected from our customers and stakeholders helps ensure that users have an effective, efficient, and satisfying experience with the programs. This feedback provides

insights into customer or stakeholder perceptions, experiences, and expectations; provides an early warning of issues with service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections allow for ongoing, collaborative, and actionable communications between ACF and its customers and stakeholders. They also allow feedback to contribute directly to the improvement of program management.

Per Memorandum M–11–26, information collection requests submitted under this Fast Track generic will be considered approved unless OMB notifies ACF otherwise within 5 days.

Respondents: ACF program participants, potential program

participants, stakeholders, and other customers.

Annual Burden Estimates

Burden Estimates—Approved Information Collection

The request to OMB will include an extension request for approved information collections that are planned to continue beyond May 2024. Find currently approved information collections here: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202305-0970-012.

Burden Estimates—New Requests

The following table includes burden estimates for new requests under this generic over the next 3 years. Based on the use of this generic clearance over the past 3 years, ACF is requesting an increase to the estimated number of responses per respondent from 1 to 2.

Type of collection	Total number of respondents	Average total number of responses per respondent	Average burden hours per response for types of collections	Total burden hours
Surveys	175,000	2	.5	50,000
Comment Cards/Forms			.25	
Feedback Questions			.083	
Focus Groups, Discussions, Cognitive Studies			1	

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Social Security Act, Sec. 1110. [42 U.S.C. 1310].

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2095 and FDA–2022–E–2096]

Determination of Regulatory Review Period for Purposes of Patent Extension; WELIREG

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for WELIREG and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a

redetermination by February 9, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 10, 2024. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: 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 p.m. Eastern Time at the end of February 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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