Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–14932 Filed 7–12–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0531]

Submission for OMB Review; Formative Data Collections for ACF Program Support

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) plans to submit a request to the Office of Management and Budget (OMB) to extend approval of the existing overarching generic clearance for Formative Data Collections for ACF Program Support (OMB #0970–0531; expiration date 7/31/2022). ACF proposes minor updates to the description of potential generic information collections under the overarching generic and to the estimated number of respondents.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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 goals of the generic information collections under this approval are to obtain information about program and grantee processes or needs and to inform the following types of activities, among others:

- Delivery of targeted assistance and/or workflows related to program and grantee processes. This could include the development and refinement of recordkeeping and communication systems.
- Planning for provision of programmatic or evaluation-related training or technical assistance (T/TA).
- Obtaining input on the development of program performance measures from grantees or others with experience or vested interest.
- Obtaining feedback about processes and/or practices to inform ACF program development or support, or ACF research.
- Use of rapid-cycle testing activities to strengthen programs in preparation for summative evaluations.
- Creating public resources with information about ACF-funded programs, systems, or activities.

ACF uses a variety of techniques such as semi-structured discussions, focus groups, surveys, templates, open-ended requests, and telephone or in-person interviews in order to reach these goals.

Information collected under this overarching generic is meant to inform ACF activities and may be incorporated into documents or presentations that are made public such as through conference presentations, websites, or social media. The following are some examples of ways in which we may share information resulting from these data collections: technical assistance plans, presentations, infographics, project specific reports, or other documents relevant to those involved with or interested in ACF programs such as federal leadership and staff, grantees, local implementing agencies, and/or T/TA providers.

Information may also be used to create public resources for users (clients, programs, researchers). Following standard OMB requirements, the Office of Planning, Research, and Evaluation will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

The proposed types and the purpose of generic information collections submitted under this umbrella generic remain the same. Minor revisions are based on experiences over the past 3 years. These include:

- Updated burden estimates
- Broadened the description to make clearer the intention to broadly include respondents with knowledge, experience, or interest in ACF programs to allow ACF to learn about needs and processes related to ACF programs from those not necessarily funded by ACF
- Included specification about requesting information for efforts to consolidate publicly available information to build public resources for ACF programs, grantees, clients, or others who may use or be interested in services funded by ACF.

Respondents: Example respondents include current or prospective service providers, training or T/TA providers, grantees, contractors, current and potential participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF programs, key groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, state or local government officials, or others involved in or prospectively involved in ACF programs.

Burden Estimates

At the time of this extension request, 30 GenICs are ongoing, with a total of 13,652 burden hours. See Attachment B for a list of all previously approved, ongoing GenICs. The following estimates are specific to new collections over the next three years.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in 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

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)
Templates and Open-ended Requests	1,000	1	10	10,000

Estimated Total Annual Burden Hours: 40,500.

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–2020–E–2361; FDA–2020–E–2362; and FDA–2020–E–2363]

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

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 ENSPRYNG 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 biological 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 September 12, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicants for extension acted with due diligence during the regulatory review period by January 9, 2023. 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 September 12, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 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 Nos. FDA–2020–E–2361; FDA–2020–E–2362; and FDA–2020–E–2363 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ENSPRYNG.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration,