Dated: November 29, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–26340 Filed 12–2–22; 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; Procedural Justice-Informed Alternatives to Contempt Demonstration (OMB #0970–0505)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to add additional data collection activities as part of the rigorous evaluation of the Procedural Justice-Informed Alternatives to Contempt (PJAC) Demonstration. The proposed revision to conduct additional data collection is part of a research supplement that builds on the PJAC study to understand the role of bias in child support program enforcement actions.

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 *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OCSE is proposing to conduct additional data collection activities as part of the PJAC Demonstration. In September 2016, OCSE issued grants to five state child support agencies to provide alternative approaches to the contempt process with the goal of increasing noncustodial parents' compliance with child support orders by building trust and confidence in the child support agency and its processes. OCSE also awarded a grant to support a rigorous evaluation of PJAC. The PJAC Demonstration is designed to help grantees and OCSE to learn whether incorporating principles of procedural justice into child support business practices increases reliable child support payments, reduces arrears, minimizes the need for continued enforcement actions and sanctions, and reduces the use of contempt proceedings.

The PJAC demonstration will yield information about the efficacy of applying procedural justice principles via a set of alternative services to the current use of a civil contempt process to address nonpayment of child support. As a part of the evaluation, PJAC will build evidence about disparity and bias in the child support system, with a focus on the use of enforcement actions used to coerce child support payments. The research will measure the extent to which bias is embedded within child support policies and practices. The information gathered may help inform future policy decisions to better understand and reduce disparities within the child support program.

The research will document disparities and differences in treatment by race and ethnicity, gender, and income within the child support system in up to three states participating in the PJAC demonstration. Key elements of the study include a quantitative analysis of disparities in the initiation of a child support case, setting of order amounts, order modifications, and use of punitive enforcement actions, including civil contempt; semi-structured interviews with staff from child support agencies and selected partner organizations; and separate semi-structured interviews with study participants to learn about their experiences with and perceptions of bias in the child support process, specifically in the use of enforcement actions.

OCSE is proposing to conduct additional data collection activities as part of the PJAC Demonstration, which include the following: a topic guide for interviews about experiences of bias with noncustodial parents and a topic guide for interviews about experiences of bias with child support staff and partners.

Data collection activities that were previously approved by OMB, following public comment, are the staff data entry on participant baseline information, study Management Information Systems (MIS) to track receipt of services, staff and community partner interview topic guide, the noncustodial parent participant interview protocol, the staff survey, the staff time study, and the custodial parent interview protocol. These instruments are currently in use and this request will extend approval to continue data collection. Supporting materials, including burden estimates related to approved instruments are available at *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202202-0970-013.* The following burden table includes information for the proposed new interviews.

Respondents: Respondents for the new data collection instruments include study participants and child support program staff and partners at three of the six PJAC demonstration sites.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Topic list for interviews about experiences of bias with staff and partners	90	1	1.5	135	45
Topic guide for interviews about experiences of bias with noncustodial parents	90	1	1	90	30

Estimated Total Annual Burden Hours: 75.

Authority: 42 U.S.C. 1315.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–26328 Filed 12–2–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–3101]

Abbreviated New Drug Applications: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions; 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 revised draft guidance for industry entitled ''ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions.'' For purposes of implementing the Generic Drug User Fee Amendments of 2022 (GDUFA III), the Pre-Submission Facility Correspondence (PFC) process was revised as part of the performance goals and program enhancements agreed to by FDA and industry, as described in the GDUFA Reauthorization Performance Goals and Program Enhancements, Fiscal Years 2023 through 2027 (GDUFA III commitment letter). FDA assesses facility information submitted in a PFC to inform the Agency's decision regarding the need for facility inspections that support assessment of the abbreviated new drug application (ANDA). A complete and accurate PFC allows the Agency to begin the facility assessment process in advance of the planned ANDA submission for priority ANDAs, allowing the Agency more time to make preapproval inspection decisions. A PFC meeting the conditions outlined in the revised draft guidance will qualify the ANDA for a shorter, 8-month priority review goal. This revised draft guidance describes the content, timing, and assessment of a complete and accurate PFC for purposes of GDUFA III. Additionally, this revised draft guidance provides information on the Agency's rationale for and current approach to assessing a PFC and replaces the previous draft guidance for industry, ''ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence),'' issued in November 2017.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 6, 2023. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by February 3, 2023.

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–2017–D–3101 for ''ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions.'' 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. Send one self-addressed adhesive