DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Evaluation of the Child Welfare Capacity Building Collaborative: Part Two.

OMB No.: New Collection.

Description: This new data collection is the second part of a larger data collection effort being conducted for the evaluation of the Child Welfare Capacity Building Collaborative. The first group of instruments has already been submitted for this evaluation. This notice details the second group of instruments that will be used for data collection as part of this evaluation. The Evaluation of the Child Welfare Capacity Building Collaborative is sponsored by the Children's Bureau, Administration for Children and Families of the U.S. Department of Health and Human Services. The Capacity Building Collaborative includes three centers (Center for States, Center for Tribes, Center for Courts) funded by the Children's Bureau to provide national child welfare expertise and evidence-informed training and technical assistance services to State, Tribal and Territorial public child welfare agencies and Court Improvement Programs (CIP). The Centers offer a wide array of services including, but not limited to: Web-based content and resources, product development and dissemination, self-directed and group-based training, virtual learning and peer networking events, and tailored consultation and coaching. During the project period the Centers' services will be evaluated by both Center-specific evaluations and a Cross-Center Evaluation. The Center-specific evaluations are designed to collect data on Center-specific processes and outcomes. The Cross-Center Evaluation is designed to respond to a set of cross-cutting evaluation questions posed by the Children's Bureau. The Cross-Center Evaluation will examine: The extent to which key partners across and within the Centers are collaborating; whether the capacity building service interventions offered by the Centers are evaluable; the degree to which Centers follow common protocols; whether service interventions are delivered or performed as designed; how satisfied recipients are with the services received; how effective the service interventions were; which service approaches were most effective and under what conditions; and the costs of services.

The Cross-Center Evaluation is utilizing a longitudinal mixed methods approach to evaluate the Centers' services as they develop and mature over the course of the study period. Multiple data collection strategies will be used to efficiently capture quantitative and qualitative data to enable analyses that address each evaluation question. Proposed Cross-Center Evaluation data sources for this effort include: (1) A capacity survey to capture perceived changes in organizational capacity after receiving Center services; (2) a tailored services satisfaction survey administered in conjunction with the capacity survey to capture satisfaction with tailored services; (3) a foundational assessment to capture contextual data regarding the organizational health and functioning of child welfare agencies and courts; (4) a follow-up survey that will examine short-term and intermediate outcomes among CIPs that receive different levels of tailored services following continuous quality improvement (CQI) workshops; and (5) a key informant survey and interview to examine how capacity building services are incorporated into state and tribal activities to support implementation of Public Law 113–183. Center-specific data sources for this effort include (1) registration forms such as the webinar and learning management system (CapLEARN) registration forms and (2) service-specific feedback forms and interviews, such as the Center for States Tailored Services interviews and the Center for Courts Universal and Constituency Services survey.

Respondents: Respondents of data collection instruments will include (1) child welfare agency staff and stakeholders who directly receive services that have been tailored to the needs of their jurisdiction and (2) CIP coordinators, CIP Directors, and other project staff. The proposed data collection will span three years.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Capacity Survey	462	1	.3	138.60
Tailored Services Satisfaction Survey	462	1	.083	38.35
Foundational Assessment Survey	277	1	.1	27.7
CQI Workshop Follow-Up Survey	48	2	.12	11.52
Public Law 113–183 Key Informant Survey	52	1	.26	13.52
Public Law 113–183 Key Informant Interview	5	1	1	5
Center for Courts: Universal and Constituency Services	104	1	.41	42.64
Webinar Registration	4650	1	.03	139.5
Center for States: Tailored Services Interviews	60	1	1	60
Center for States: Assessment and Work Planning Survey	150	1	.25	37.5
CapLEARN Registration	600	1	.084	50.4

Estimated Total Annual Burden Hours: 564.73.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the

Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0882]

Generic Drug User Fees; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA), which authorizes FDA to collect fees and use them for the review of certain generic human drug applications and associated Type II active pharmaceutical ingredient (API) drug master files (DMFs), and for conducting associated inspections for fiscal years (FYs) 2018 through 2022. The legislative authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue to collect generic drug user fees for future fiscal years. Following discussions with the regulated industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) directs FDA to present the recommendations to the relevant Congressional committees, publish the recommendations for the reauthorized program in the **Federal Register**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held on October 21, 2016, from 9 a.m. to 5 p.m. Submit electronic or written comments to the public docket by November 7, 2016.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2012–N–0882 for ''Generic Drug User Fees; Public Meeting; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at *www.fda.gov/gdufa.*

FOR FURTHER INFORMATION CONTACT: Derek Griffing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993, 240–402–6980, email: *GenericDrugPolicy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations