DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0426]

Submission for OMB Review; Comment Request; Child and Family Services Plan (CFSP), Annual Progress and Services Review (APSR), and Annual Budget Expenses Request and Estimated Expenditures (CFS–101)

Description: Under title IV–B, subparts 1 and 2, of the Social Security Act (the Act), States, Territories, and Tribes are required to submit a Child and Family Services Plan (CFSP). The CFSP lays the groundwork for a system of coordinated, integrated, and culturally relevant family services for the subsequent five years (45 CFR 1357.15(a)(1)). The CFSP outlines initiatives and activities the State, Territory, and Tribes will carry out in administering programs and services to promote the safety, permanency, and well-being of children and families, including, as applicable, those activities conducted under the John H. Chafee Foster Care Independence Program (Section 477 of the Act) and the State grant authorized by the Child Abuse Prevention and Treatment Act. By June 30 of each year, States, Territories, and Tribes are also required to submit an Annual Progress and Services Report (APSR) and a financial report called the CFSP–101. The APSR is a yearly report that discusses progress made by a State, Territory or Tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains new and updated information about service needs and organizational capacities throughout the five-year plan period. The CFSP–101 has three parts. Part I is an annual budget request for the upcoming fiscal year. Part II includes a summary of planned expenditures by program area for the upcoming fiscal year, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by program area, and the geographic areas served for the last complete fiscal year.

Respondents: States, Territories, and Tribes must complete the CFSP, APSR, and CFS–101. States and Territories must also report data annually on caseworker visits with children in foster care. Tribes are exempted from the caseworker visits reporting requirement of the CFSP/APSR. There are approximately 189 Tribal entities that currently receive IV–B funding. There are 53 States (including Puerto Rico, the District of Columbia, and the U.S. Virgin Islands) that must complete the CFSP, APSR, and CFS–101. There are a total of 242 possible respondents.

**ANNUAL BURDEN ESTIMATES**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>APSR</td>
<td>242</td>
<td>1</td>
<td>80</td>
<td>19,360</td>
</tr>
<tr>
<td>CFSP</td>
<td>48.4</td>
<td>1</td>
<td>120.25</td>
<td>5,820.10</td>
</tr>
<tr>
<td>CFS–101, Parts I, II, and III</td>
<td>242</td>
<td>1</td>
<td>5</td>
<td>1,210</td>
</tr>
<tr>
<td>Caseworker Visits</td>
<td>53</td>
<td>1</td>
<td>99.33</td>
<td>5,264.48</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 31,654.59.

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, 330 C Street SW., Washington, DC 20201. Attn: Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@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, Email: OIRAthankyou@omb.eop.gov, Attn: Desk Officer for the Administration for Children and Families.

Mary Jones, ACF/OPRE Certifying Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1003]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2018 Experiential Learning Program (ELP). This training is intended to provide CDRH and other FDA staff with an opportunity to understand laboratory practices, quality system management, patient perspective/input, and challenges that impact the medical device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities, and others to participate in this formal training program for CDRH and other FDA staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit electronic proposals for participation in the ELP within the dates provided at the ELP Web site at: https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

ADDRESSES: For access to the docket to read background documents, 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.

FOR FURTHER INFORMATION CONTACT: Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5261, Silver Spring, MD 20993–0002, 240–402–2246, Christian.Hussong@fda.hhs.gov or ELP Management, ELP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Additionally, CDRH assures patients and providers have timely and continued access to high-quality, safe, and effective medical devices. Since CDRH has identified Partnering with Patients and Promoting a Culture of Quality and Organizational Excellence as strategic priorities, for the 2018 ELP, our goal is to specifically understand the perspective of our stakeholders and understand implementation of these topics within their institutions. The Center encourages applicants to consider including opportunities to discuss patient perspective and incorporating quality system design and management in their proposals as they contribute to the success of the device development life cycle.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH and other FDA staff a better understanding of the products they review, how they are developed, the voice of the patient, challenges related to quality systems development and management in the product life cycle, and how medical devices fit into the larger health care system. CDRH is formally requesting participation from industry, academia, and clinical facilities, medical device incubators and accelerators, health technology assessment groups, and those that have previously participated in the ELP or other FDA site visit programs.

Additional information regarding the CDRH ELP, including the table of areas of interest, submission dates, a sample request, and an example of the site visit agenda, is available on CDRH’s Web site at: https://www.fda.gov/sciencecareeropportunities/ucm380676.htm.

II. CDRH ELP

A. Areas of Interest

In the ELP training program, groups of CDRH and other FDA staff will observe operations in the areas of research, device development, in making coverage decisions and assessments, incorporating patient information and reimbursement, manufacturing, and health care facilities. The areas of interest for visits include various topics identified by managers at CDRH and other areas within FDA. These areas of interest are listed on the ELP Web site and are intended to be updated quarterly.

To submit a proposal addressing one of the Center’s training needs, visit the link for the table of areas of interest at: https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/UCM380676.htm. Once you have determined an area of interest to address in your ELP proposal, follow the instructions in section III to complete the site visit request template and agenda provided at: https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392998.pdf and at: https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf.

Submit all proposals at ELP@fda.hhs.gov within the dates provided at the ELP Web site at: https://www.fda.gov/sciencecareeropportunities/ucm380676.htm.

B. Site Selection

CDRH and FDA will be responsible for its own staff travel expenses associated with the site visits. CDRH and FDA will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH and FDA’s priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding (if applicable). If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history, and must be listed in the proposal along with a Facility Establishment Identifier number, if applicable.

III. Request To Participate

Information regarding the CDRH ELP, including a sample request and an example of a site visit agenda, and submission dates is available on CDRH’s Web site at: https://www.fda.gov/sciencecareeropportunities/ucm380676.htm. Proposals to participate should be submitted to ELP@fda.hhs.gov, within the dates provided, at the ELP Web site at https://www.fda.gov/sciencecareeropportunities/ucm380676.htm.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5569]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is