ACF to fulfill the ongoing legislative mandate for program evaluation specified in the Foster Care Independence Act of 1999. Respondents: Semi-structured interviews will be held with program leaders, partners and stakeholders, and front-line staff as well as young adults being served by the programs.

### ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Total number of respondents</th>
<th>Average burden hours per respondent</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outreach email for discussion with program administrators and staff</td>
<td>16</td>
<td>8</td>
<td>64</td>
</tr>
<tr>
<td>Outreach email for Focus Group Recruiters</td>
<td>12</td>
<td>6</td>
<td>72</td>
</tr>
<tr>
<td>Discussion Guide for program leaders</td>
<td>48</td>
<td>24</td>
<td>1152</td>
</tr>
<tr>
<td>Discussion Guide for program partners and stakeholders</td>
<td>60</td>
<td>30</td>
<td>1800</td>
</tr>
<tr>
<td>Discussion Guide for program front-line staff</td>
<td>104</td>
<td>52</td>
<td>548</td>
</tr>
<tr>
<td>Focus Group Guide for program participants</td>
<td>160</td>
<td>80</td>
<td>12800</td>
</tr>
<tr>
<td>Compilation and Submission of Administrative Data Files</td>
<td>48</td>
<td>24</td>
<td>1152</td>
</tr>
</tbody>
</table>

**Estimated Total Annual Burden Hours:** 1,056.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C St. SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPReinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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.

Emily B. Jabbour, ACF/OPRE Certifying Officer.

[Federal Register: 2018, Volume 83, Number 184, Friday, September 21, 2018, Page 47923]
• 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–2018–N–3160 for “Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting: Establishment of a Public Docket; Request for Comments.” 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.
• 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.” FDA 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT:
Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: kalyani.bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA’s website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss the efficacy, safety, and risk-benefit profile of new drug application (NDA) 210417 for buprenorphine and samidorphan sublingual tablets, submitted by Alkermes, Inc., for adjunctive treatment of major depressive disorder.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/AdvisoryCommitteeMeetingCalendar. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see ADDRESSES) on or before October 18, 2018, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 18, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 11, 2018.

Persons attending FDA’s advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Kalyani Bhatt (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under 5 U.S.C. app. 2).

Dated: September 18, 2018.
Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–20571 Filed 9–20–18; 8:45 am]
BILLING CODE 4164–01–P