

ADDRESSES: 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: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

Authority: Sec. 413, Pub. L. 115–31.

Emily B. Jabbour,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Descriptive Study of the Unaccompanied Refugee Minors Program (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; ACF; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) at the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of a project to better understand the range of child welfare services and benefits provided through the Unaccompanied Refugee Minors (URM) Program.

DATES: *Comments due within 60 days of publication.* 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.

ADDRESSES: 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 Street 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.

SUPPLEMENTARY INFORMATION: The information collection activities to be submitted in the package include:

1. Survey of State Refugee Coordinators (SRCs) from the 15 states with URM programs.
2. Survey of URM Program Directors from all 22 URM programs.

3. Survey of Private Custody Child Welfare Agency Administrators from nine states with private custody arrangements.

4. Interviews with URM Program Managers from six URM programs.

5. Interviews with URM Program Staff (e.g. case managers, data managers) from six URM programs.

6. Interviews with Child Welfare Agency Administrators who have contact with six URM programs.

7. Interviews with Community Partners including leadership and line staff from local organizations, such as health care and mental health care providers, legal aid organizations, and faith-based groups serving the URM population at six URM program sites.

8. Interviews with Community Partners in the field of education, such as school administrators and counselors, and organizations providing English language education and support at six URM program sites.

9. Focus Groups for URM Youth from six URM programs.

10. Focus Groups for URM Foster Families from six URM programs.

Respondents: State Refugee Coordinators and supporting staff, URM Program Directors and supporting staff, Child Welfare Agency Administrators and supporting staff, URM program staff (case workers, data managers, and other staff), staff from community partner organizations (e.g. health and mental health service providers, education service providers, faith-based organizations), URM youth, and URM foster families.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Survey of State Refugee Coordinators	37.5	1	0.67	25
Survey of URM Program Directors	55	1	1	55
Survey of Private Custody Child Welfare Agency Administrators	21	1	0.67	14
Interviews with URM Program Managers	9	1	1.5	14
Interviews with URM Program Staff	36	1	1.25	45
Interviews with Child Welfare Agency Administrators	26	1	1	26
Interviews with Community Partners [General]	48	1	1	48
Interviews with Community Partners [Education]	12	1	1	12
Focus Groups with URM Youth	54	1	1.5	81
Focus Groups with URM Foster Families	54	1	1.5	81

Estimated Total Annual Burden Hours: 401.

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.

Authority: Section 1110 of the Social Security Act.

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–20068 Filed 9–14–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2973]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA research in obtaining information from medical specialty groups and/or medical experts regarding compounded drug products that contain certain bulk drug substances to support establishment of a list of bulk drug substances under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by November 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 No. FDA–2018–N–2973 for "Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act." 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." 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.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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this