DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Expedited OMB Review and Public Comment; Proposed Information Collection Activity; Administration and Oversight of the Unaccompanied Alien Children Program

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; U.S. Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting expedited review of an information collection request from the Office of Management and Budget (OMB) and inviting public comments on the proposed collection. The request consists of several forms that allow the Unaccompanied Alien Children (UAC) Program to monitor care provider facility compliance with federal laws and regulations, legal agreements, and ORR policies and procedures; and perform other administrative tasks.

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, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be incorporated into the submission under normal procedures.

The components of this information request include:

1. Care Provider Facility Tour Request (Form A–1A): This instrument is used by advocacy groups, faith-based organizations, researchers, government officials, and other stakeholders to request tours of ORR care provider facilities. After the request is received, ORR documents its decision and details regarding date and location of the tour, if applicable, and provides the completed form to the requester. This instrument was previously approved under OMB No. 0970–0498.

2. Notice to UAC for Flores Visits (Forms A–4 & A–4s): This instrument is used by care provider facilities to notify UAC of upcoming visits by Flores counsel (lawyers and volunteers from the organization that originally participated in the creation of the Flores Settlement Agreement) and allow UAC to add their name to a sign-up sheet if they are willing to speak with Flores counsel.

3. Authorization for Release of Records (Form A–5): This instrument is used by attorneys, legal service providers, child advocates, government agencies, and other stakeholders to request UAC case file records. In most cases, requesters are required to obtain the signature of the subject of the record request (UAC or their parent/legal guardian or sponsor) and a witness.

4. Program Level Event (PLE) Report (Form A–9): This instrument is used by ORR care provider programs to inform ORR of events that may affect the entire care provider facility, such as an active shooter or natural disaster. An updated PLE Report is required for events that occur over multiple days or if the situation changes regarding the event.

5. Emergency Significant Incident Report (SIR) and Addendum (Forms A–10A & A–10B): This instrument is used by ORR care provider programs to inform ORR of urgent situations in which there is an immediate threat to a child's safety and well-being that require instantaneous action. In some cases, an Emergency SIR Addendum may be required to provide additional information obtained after the initial report.

6. Significant Incident Report (SIR) and Addendum (Forms A–10C & A–10D): This instrument is used by ORR care provider programs to inform ORR of situations that affect, but do not immediately threaten, the safety and well-being of a child. In some cases, an SIR Addendum may be required to provide additional information obtained after the initial report.

7. Sexual Abuse Significant Incident Report (SA/SIR) and Addendum (Forms A–10E & A–10F): This instrument is used by ORR care provider programs to inform ORR of allegations of sexual harassment, sexual abuse, and inappropriate sexual behavior. In some cases, an SA/SIR Addendum may be required to provide additional information obtained after the initial report.

8. UAC Satisfaction Survey (Forms A–11 & A–11s): This instrument is used by ORR care provider programs to collect information from UAC regarding their experience while in ORR custody.

9. UAC Satisfaction Survey Aggregate Data: This instrument is used by ORR care provider programs to report aggregate data from UAC Satisfaction Survey forms submitted to ORR on a quarterly and annual basis. ORR uses this information to identify areas where it can make programmatic improvements.

10. Hotline Alert (A–12): This instrument is used by ORR's National Call Center to inform ORR of allegations sexual harassment, sexual abuse, inappropriate sexual behavior, and physical abuse that occurred while the UAC was in ORR custody.

Respondents: ORR grantee and contractor staff; advocacy groups, faith-based organizations, researchers, and government officials; attorneys, legal service providers, child advocates, and government agencies; and other stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual burden minutes
Care Provider Facility Tour Request (Form A–1A)	200	1	10	2,000
Notice to UAC for Flores Visits (Forms A–4 & A–4s)	20	1	15	300
Authorization for Release of Records (Form A–5)	4,000	1	10	40,000
Program Level Event Report (Form A–9)	1,500	1	20	30,000
Emergency Significant Incident Report (Form A–10A)	1,640	1	20	32,800

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual burden minutes
Emergency Significant Incident Report Addendum (Form A–10B)	1,360	1	15	20,400
Significant Incident Report (Form A–10C)	80,340	1	20	1,606,800
Significant Incident Report Addendum (Form A–10D)	25,630	1	15	384,450
Sexual Abuse Significant Incident Report (Form A–10E)	5,980	1	20	119,600
Sexual Abuse Significant Incident Report Addendum (Form A–10F)	4,190	1	15	62,850
UAC Satisfaction Survey (Form A–11 & A–11s)	72,840	1	20	1,456,800
UAC Satisfaction Survey Aggregate Data	235	4	240	225,600
Hotline Alert (Form A–12)	80	1	15	1,200

Estimated Annual Burden Total: 3,982,800.

Comments: 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.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement*, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–07995 Filed 4–15–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3995]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Information on Pediatric Uses of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 18, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0748. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Submission of Information on Pediatric Uses of Medical Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure Under Section 515A of the Federal Food, Drug, and Cosmetic Act—21 CFR 814

OMB Control Number 0910–0748—Extension

Section 515A(a) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360e-1) (FD&C Act) requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

These requirements apply to applicants who submit humanitarian device exemption requests (HDEs), premarket approval applications (PMAs) or PMA amendments or supplements, or a product development protocol (PDP).

FDA expects to receive approximately 47 original PMA/PDP/HDE applications each year, 1 of which FDA expects to be HDEs. This estimate is based on the average of FDA's receipt of new PMA applications. The Agency estimates that 11 of the estimated 47 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive approximately 928 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and part 814 (21 CFR part 814).

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and part 814. We believe that because the applicant is required to organize and submit only readily available information, no more than 8 hours will be required to comply. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the required information is a supplement to be 2 hours. FDA estimates that the total estimated burden is 2,392 hours.

Additionally, the document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff'' describes how to