

Families 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 by emailing *infocollection@acf.hhs.gov*. All requests should identify the title of the information collection. Written comments and recommendations for the proposed information collection should be sent directly to the following: Administration for Children and

Families, Paperwork Reduction Project, Email: *infocollection@acf.hhs.gov*, Attn: Desk Officer for the Administration for Children and Families.

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 submitted within 180 days of the approval for this request. Any edits resulting from public comment will be incorporated into the submission under normal procedures.

The Medical Complaint form is to be updated in response to the COVID-19 outbreak. Two fields were added to capture the COVID-19 diagnosis and related public health interventions.

Respondents: ORR Grantee Staff.

Annual Burden Estimates: The following burden estimates were previously approved by OMB for data collection under OMB #0970-0509. The addition of this data element does not increase reporting or record keeping burden.

ESTIMATED OPPORTUNITY BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical Complaint Form	120	836	0.13	13,042

Total: 13,042.

ESTIMATED RECORDKEEPING BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical Complaint Form	120	836	0.08	8,026

Total: 8,026.

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al.*, Case No. CV 85-4544-RJK [C.D. Cal. 1996])

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970-0466]

Expedited OMB Review and Public Comment: Information Collection Activity; Initial Medical Exam Form and Initial Dental Exam Form

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; 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 revisions. The request consists of the addition of questions to the Initial Medical Exam Form to track instances of COVID-19.

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 in this notice.

ADDRESSES: Copies of the proposed collection of information can be obtained by emailing *infocollection@acf.hhs.gov*. All requests should identify the title of the information collection. Written comments and recommendations for the proposed information collection should be sent directly to the following: Administration for Children and Families, Paperwork Reduction Project, Email: *infocollection@acf.hhs.gov*, Attn: Desk Officer for the Administration for Children and Families.

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 submitted within 180 days of the approval for this request. Any edits resulting from public comment will be incorporated into the submission under normal procedures. The Initial Medical Exam Form is to be updated in response to the COVID-19 outbreak. Three fields were added to capture travel history, COVID-19 diagnosis, and related public health interventions.

Respondents: ORR Grantee Staff.
Annual Burden Estimates: The following burden estimates were

previously approved by OMB for data collection under OMB #0970-0466. The addition of these data elements does not

increase reporting or record keeping burden.

ESTIMATED OPPORTUNITY BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	297	0.22	9,801

Total: 9,801.

ESTIMATED RECORDKEEPING BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	297	0.08	3,564

Total: 3,564.

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al.*, Case No. CV 85-4544-RJK [C.D. Cal. 1996])

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-0567]

Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.” This guidance provides recommendations regarding the use of restricted delivery systems to limit unintentional ingestion of oral liquid drug products (e.g., oral solution, oral suspension) by children. The recommendations in this guidance apply broadly to oral liquid drug and biological products. FDA’s recommendations are intended to minimize the potential for harm due to unintentional ingestions.

DATES: Submit either electronic or written comments on the draft guidance by May 18, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 Division of Dockets Management, FDA will post your