

under a potential future funding opportunity (Phase III). During Phase II, ACF will engage a contractor to: Conduct a cross-site process evaluation. Data collected for the process evaluation will be used to assess grantees' organizational capacity to implement

and evaluate the model interventions and to monitor each grantee's progress toward achieving the goals of the implementation period.

Data for the process evaluation will be collected through: Interviews during site visits.

*Respondents:* Grantee agency directors and staff; partner agency directors and staff. Partner agencies may vary by site, but are expected to include child welfare, mental health, and youth housing/homelessness agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Total/annual burden hours
Grantee Site Visit-Semi-Structured Interview Topic Guide .....	60	1	1.5	90
Estimated Total Annual Burden Hours .....	.....	.....	.....	90

*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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration, for Children and Families.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[OMB NO.: 0970-0402]

**Submission for OMB Review; Comment Request**

*Title:* Mother and Infant Home Visiting Program Evaluation (MIHOPE): Long-Term Follow-Up.

*Description:* The Administration for Children and Families (ACF), in partnership with the Health Resources and Services Administration (HRSA), both of the U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Mother and Infant Home Visiting Program Evaluation Long-Term Follow-Up project (MIHOPE-LT). The purpose of MIHOPE-LT is to conduct follow-up studies that assess the long-term impact of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program. The design of MIHOPE-LT calls for multiple follow-up points including when the participating children are in kindergarten, 3rd grade, early adolescence, and late adolescence. This **Federal Register** Notice is specific to the first follow-up study. Data collected

during the first follow-up study (when the children from the MIHOPE sample are of kindergarten age) will include the following: (1) A one-hour survey with the child's primary caregiver (who will be the mother if she is available), (2) direct assessments of child development, (3) a semi-structured interview with the caregiver, (4) surveys with the child's teacher, (5) a direct assessment of the caregiver, and (6) 15 minutes of videotaped interactions between the caregiver and child. In addition to collecting these data, the MIHOPE-LT project will also maintain up-to-date consent forms for the collection of administrative data. Future information collection requests and related **Federal Register** Notices will describe future data collection efforts for this project.

Data collected during the kindergarten follow-up study will be used to estimate the effects of MIECHV-funded programs on seven domains: (1) Maternal health; (2) child health; (3) child development and school performance; (4) child maltreatment; (5) parenting; (6) crime or domestic violence; and (7) family economic self-sufficiency.

*Respondents:* The respondents in this follow-up study will include 4,115 families who participated in MIHOPE and 4,115 teachers of the focal children from those families.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Survey of caregivers .....	4115	1372	1	1	1372
Direct assessments of children .....	4115	1372	1	1.5	2058
Semi-structured interview with caregivers .....	100	33	1	2	66
Survey of the focal children's teachers .....	4115	1372	1	0.5	686
Direct assessments of caregivers .....	4115	1372	1	0.25	343
Videotaped caregiver-child interactions .....	8230	2743	1	0.25	686

*Estimated Total Annual Burden Hours:* 5,211.

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

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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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1638]

#### **Pediatric HIV Infection: Drug Development for Treatment; 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 “Pediatric HIV Infection: Drug Development for Treatment.” This guidance provides general recommendations on the development of drug products for the treatment of human immunodeficiency virus (HIV) infection in pediatric patients (birth to younger than 17 years of age).

**DATES:** Submit either electronic or written comments on the draft guidance by July 13, 2018 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 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-D-1638 for “Pediatric HIV Infection: Drug Development for Treatment; Draft Guidance for Industry; Availability.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Yodit Belew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6322, Silver Spring,