information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the October ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, October 21, 2020 according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by October 22, 2020. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

Written Public Comment: Written comments must be received on or before October 29, 2020. Written public comments submitted by 72 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–20705 Filed 9–18–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Family Level Assessment and State of Home Visiting (FLASH–V) Outreach and Recruitment Study (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) Office of Planning, Research, and Evaluation is requesting public comment on new data collection activities to gather information about how Maternal, Infant, and Early Childhood Home Visiting (MIECHV) state and territory local implementing agencies (LIAs) and tribal grantees recruit families for program participation and work with their community referral partners to recruit families. The project is designed to examine challenges programs experience reaching caseload capacity and promising strategies to address how challenges might be overcome.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The ACF Office of Planning, Research, and Evaluation is proposing a new information collection to learn more about how MIECHV-funded home visiting programs recruit families for home visiting services. The voluntary study will include a national survey of MIECHV-funded program managers, semi-structured interviews with program staff, and a review of program outreach and recruitment materials. This descriptive work will capture how programs identify and recruit families to home visiting services. The study will also capture how outreach and recruitment challenges and accomplishments related to capacity have changed since COVID–19 and identify strategies programs have used to address associated challenges. The activities and products from this project will help ACF and the Health Resources and Services Administration to identify actionable bottlenecks in the outreach and recruitment process to allow for the development and testing of strategies to improve the delivery of MIECHV funded services.

Respondents: MIECHV funded state, territory, or tribal grantee administrators; program administrators; program managers; and frontline staff.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Request for LIA Contact Information from MIECHV Leads	56	1	.25	14	7
LIA Survey	779	1	.50	390	195
Interview Protocol Local Implementing Agency	120	1	.75	90	45

Estimated Total Annual Burden Hours: 247 hours.

Authority: Social Security Act Title V § 511 [42 U.S.C. 711]. As extended by the Bipartisan Budget Act of 2018 (Pub. L. 115–123) through FY 22.

John M. Sweet Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–20733 Filed 9–18–20; 8:45 am]

BILLING CODE 4182–74–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1825]

Investigational COVID–19 Convalescent Plasma; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Investigational COVID–19 Convalescent Plasma.'' The guidance document provides recommendations to healthcare providers and investigators on the use of investigational convalescent plasma for the treatment of the Coronavirus Disease 2019 (COVID–19) during the public health emergency. The guidance announced in this notice supersedes the guidance of the same title dated April 2020 and updated in May 2020. The guidance includes a discussion to facilitate the availability of investigational convalescent plasma when blood establishments, hospitals, and healthcare providers collect plasma that does not meet the Conditions of Authorization of the Emergency Use Authorization (EUA). The guidance also provides recommendations for healthcare providers who wish to administer and study convalescent plasma under an investigational new drug (IND) application.

DATES: The announcement of the guidance is published in the **Federal Register** on September 21, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–1825 for ''Investigational COVID–19 Convalescent Plasma.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Investigational COVID–19 Convalescent Plasma.'' The guidance provides recommendations to healthcare providers and investigators on the use of investigational convalescent plasma for the treatment of COVID–19 during the public health