Estimated Total Annual Burden Hours (Rounded from 523.98): 524.

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. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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*, *Attn:* Desk Officer for the Administration for Children and Families.

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–21226 Filed 9–28–18; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities, President's Committee for People With Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

DATES: Thursday, November 8, 2018 from 9:00 a.m. to 4:30 p.m.; and Friday, November 9, 2018 from 9:00 a.m. to 4:30 p.m. These meetings will be open to the general public.

ADDRESSES: These meetings will be held at the U.S. Access Board, located at 1331 F Street NW, Suite 800, Washington, DC 20004. Individuals who would like to participate via conference call may do so by dialing toll-free #: 1–888–949–2790, when prompted enter pass code: 1989852. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Ms. Allison Cruz, Director, Office of Innovation, via email at *Allison.Cruz@acl.hhs.gov,* or via telephone at 202–795–7334, *no later than* Monday, October 19, 2018. The PCPID will attempt to accommodate requests made after this date, *but cannot guarantee the ability to grant requests received after the deadline.* All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

FOR FURTHER INFORMATION CONTACT: Ms. Allison Cruz, Director, Office of Innovation, 330 C Street SW, Switzer Building, Room 1114, Washington, DC 20201. Telephone: 202–795–7334. Fax: 202–795–7334. Email: *Allison.Cruz@acl.hhs.gov*

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expanding employment opportunities; (B) connecting people to services; (C) supporting families and caregivers; (D) strengthening the networks; and (E) protecting rights and preventing abuse.

Agenda: The Committee Members will discuss preparation of the PCPID 2019 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Dated: September 24, 2018.

Mary Lazare,

Principal Deputy Administrator, Administration for Community Living.

[FR Doc. 2018–21319 Filed 9–28–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3275]

Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications; 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 ''Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to an IND, NDA, BLA, or ANDA.'' The draft guidance provides recommendations to industry and FDA staff regarding the content and submission procedures for use-related risk analyses, human factors validation study protocols and reports, threshold analyses, and comparative use human factors study protocols and reports.

DATES: Submit either electronic or written comments on the draft guidance by November 30, 2018 to ensure that the Agency considers your comments in this review.

ADDRESSES: You may submit comments 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