strategies, objectives, and priorities; and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

Matters To Be Considered: Day One: The agenda will focus on the secondary peer review of extramural research grant applications received in response to two (2) Notice of Funding Opportunities (NOFO): CE19–004, ''Etiologic and Effectiveness Research to Address Polysubstance Impaired Driving'' and CE19–005, Research Grants for Preventing Violence and Violence Related Injury (R01). Day Two: The agenda will include discussions on The Injury Center's Role in Addressing Public Health Concerns Related to Marijuana; Impaired Driving, Dating Matters and Health Economics and Policy Research at the National Center for Injury Prevention and Control. Agenda items are subject to change as priorities dictate.

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.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–10143 Filed 5–15–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE19–005, Research Grants for Preventing Violence and Violence Related Injury; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—*RFA–CE19–005, Research Grants for Preventing Violence and Violence Related Injury;* May 14–15, 2019, 8:30 a.m.–5:30 p.m., EDT.

Atlanta Marriott Buckhead and Conference Center, 3405 Lenox Road NE, Atlanta, GA 30326 which was published in the **Federal Register** on Thursday, February 21, 2019, Volume 84, Number 35, page 5445.

The meeting is being amended to change the date to July 16–17, 2019, 8:30 a.m.–5:30 p.m., EDT and to change the location to the Georgian Terrace, 659 Peachtree Street NE, Atlanta, GA 30308. The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Mikel L. Walters, M.A., Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, (404) 639–0913; *mwalters@cdc.gov*.

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.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–10164 Filed 5–15–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0389]

Submission for OMB Review; Comment Request

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Form 1: Demographic and Service Utilization Data.

Description: Description: The Bipartisan Budget Act of 2018 (Pub. L. 115–123). Section 511(h)(2)(A) of Title V of the Social Security Act, created the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) and authorized the Secretary of HHS (in Section 511(h)(2)(A)) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, awards grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs assessments, plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

In Year 1 of the cooperative agreement, grantees must (1) conduct a comprehensive community needs and readiness assessment and (2) develop a plan to respond to identified needs. Following each year that Tribal MIECHV grantees implement home visiting services, they must submit Form 1: Demographic and Service Utilization Data. The Form 1 data are used to help ACF better understand the population receiving services from Tribal MIECHV grantees and the degree to which they are using services, as well as better understanding of the Tribal MIECHV workforce. Overall, this information collection will provide valuable information to HHS that will guide understanding of the Tribal MIECHV Program and the provision of technical assistance to Tribal MIECHV Program grantees.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Grantees

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal MIECHV Form 1	25	1	500	12,500

Estimated Total Annual Burden Hours: 12,500.

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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–10167 Filed 5–15–19; 8:45 am]

BILLING CODE 4184–77–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by July 15, 2019 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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://*