to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–12695 Filed 5–26–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Affordable Care Act Tribal Maternal, Infant and Early Childhood Home Visiting Program Annual Report Guidance.

OMB No.: 0970–0409.

Description: Section 511(e)(8)(A) of the Social Security Act, as added by Section 2951 of the Affordable Care Act and amended by the Protecting Access to Medicare Act of 2014 and the Medicare Access and CHIP Reauthorization Act of 2015, requires that grantees under the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program for states and jurisdictions submit an annual and final report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511 (h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, has awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting discretionary grants support 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; establish, measure, and report on progress toward meeting performance measures in six legislatively-mandated benchmark areas; and participate in rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

Tribal Home Visiting grantees have been notified that in every year of their grant, after the first year, they must comply with the requirement for submitting an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period. In order to assist grantees with meeting the requirements of the Annual Report to the Secretary, ACF created guidance for grantees to use when writing their annual reports. ACF is requesting approval to renew and update the existing Tribal Home Visiting Guidance for Submitting an Annual Report to the Secretary (OMB Control No. 0970–0409) that will include instructions for grantees to submit either an annual or final report (in the final year of the grant) on the progress of their program to the Secretary, depending on the reporting period.

This Report Shall Address the Following:

- Update on Home Visiting Program Goals and Objectives
- Update on the Implementation of Home Visiting Program in Targeted Community(ies)
- Update on progress toward meeting Legislatively Mandated Benchmark Requirements
- Update on Rigorous Evaluation Activities
- Update on Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Update on Dissemination Activities
- Update on Technical Assistance Needs

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Managers (The information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total annual burden hours
Annual/Final Report to the Secretary (depending on reporting period)	25	1	1	50	1250

Estimated Total Annual Burden Hours: 1,250.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF 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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for

the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–12693 Filed 5–26–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Risperidone; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry on risperidone injection entitled ''Draft Guidance on Risperidone.'' The recommendations provide specific guidance on the design of studies to support abbreviated new drug applications (ANDAs) for risperidone injection. This draft guidance is the second revision of a previously issued draft guidance on the same subject.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 27, 2015.

ADDRESSES: 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. 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific bioequivalence (BE) recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of a second revision of draft BE recommendations for risperidone injection.

FDA initially approved new drug application 021346 for Risperdal Consta Long-Acting Injection in October 2003. There are no approved ANDAs for this product. In February 2010, FDA issued a draft guidance for industry on BE recommendations for generic risperidone injection. In August 2013, we issued a revised draft guidance on the same subject. We are now issuing a second revision of the draft guidance for industry on BE recommendations for generic risperidone injection (Draft Guidance on Risperidone).

In February 2011, Johnson & Johnson Pharmaceutical Research and Development, LLC, manufacturer of Risperdal Consta, the reference listed drug, submitted a citizen petition requesting that FDA require that any ANDA referencing Risperdal Consta meet certain requirements, including requirements related to demonstrating BE (Docket No. FDA–2011–P–0086). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the revised draft BE recommendations in responding to the petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for risperidone injection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12847 Filed 5–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 27, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of