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Bioequivalence Recommendations for Risperidone; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry on risperidone injection entitled ''Draft Guidance on Risperidone.''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 This draft guidance is the second revision of a previously issued draft guidance on the same subject.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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 27, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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

the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Medicare Rural Hospital Flexibility Grant Program Performance OMB No. 0915–0363–Rev.

Abstract: The Medicare Rural Hospital Flexibility Program (Flex) is authorized by Section 1820 of the Social Security Act (42 U.S.C. 1395i–4), as amended. The purpose of Flex is engaging state designated entities in activities relating to planning and implementing rural health care plans and networks; designating facilities as Critical Access Hospitals (CAHs); providing support for CAHs for quality improvement, quality reporting, performance improvements, and benchmarking; and integrating rural emergency medical services (EMS).

Specifically, the Flex program provides funding for states to support technical assistance activities in hospitals to improve the quality of health care provided by CAHs; improve the financial and operational outcomes of CAHs; improve the Community Health and Emergency Medical Service (EMS) Needs of CAHs; enhance the health of rural communities through community/population health improvement; improve identification and management of Time Critical Diagnoses (TCD) and engage EMS capacity and performance in Rural Communities; assist in the conversion of qualified small rural hospitals to CAH status; and support the financial and operational transition to value based models and health care transformation models in the health care system. State designated Flex Programs will act as a resource and focal point for these activities, ensuring residents in rural communities have access to high quality health care services. Measures and goals identified in the Flex program take into consideration existing measures and priorities HHS has set for hospitals, to avoid both conflict and duplication of efforts.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the Flex program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 2010. These measures cover principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Quality reporting; (b) quality improvement interventions; (c) financial and operational improvement initiatives; (d) population health management; and (e) innovative care models. Several measures will be used for this program and will inform FORHP's progress toward meeting the goals set in GPRA. Furthermore, obtaining this information is important for identifying and understanding programmatic improvement across program areas, as well as guiding future iterations of the Flex Program and prioritizing areas of need and support.

Likely Respondents: Respondents will be the Flex Program coordinator for each state participating in the Flex Program. There are currently 45 states participating in the Flex Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Medicare Rural Hospital Flexibility Grant Program	45	1	45	216	9,720
Total	45	1	45	216	9,720

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–12700 Filed 5–26–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: June 17, 2015 (9:30 a.m.–4:30 p.m.).

Place: Webinar/Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The ACICBL provides advice and recommendations to the Secretary of the Department of Health and Human Services (Secretary) concerning policy, program development, and other matters of significance related to interdisciplinary, community-based training grant programs authorized under sections 750–759, title VII, part D of the Public Health Service Act, as amended by the Affordable Care Act. The following sections are included under this part: 751—Area Health Education Centers; 752—Continuing Education Support for Health Professionals Serving in Underserved Communities; 753—Geriatrics Workforce Enhancement; 754—Quentin N. Burdick Program for Rural Interdisciplinary Training; 755—Allied Health and Other Disciplines; 756—Mental and Behavioral Health Education and Training, and 759—Program for Education and Training in Pain Care.