DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369 (Formerly Docket No. 2007D–0168)]

Draft Guidance for Industry on Bioequivalence Recommendations for Paliperidone Palmitate Extended-Release Injectable Suspension; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Bioequivalence Recommendations for Paliperidone Palmitate.'' The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for paliperidone palmitate extended-release injectable suspension.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 3, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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: Kris Andre, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration,7519 Standish Pl., Rockville, MD 20855,240–276–9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''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/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for paliperidone palmitate extended-release injectable suspension.

New drug application 022264 for INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension was initially approved by FDA in July 2009. In August 2011, FDA issued a draft guidance for industry on BE recommendations for generic paliperidone palmitate (Draft BE Recommendations for Paliperidone Palmitate). FDA is now issuing a revised version of the Draft BE Recommendations for Paliperidone Palmitate Extended-Release Injectable Suspension (Revised Draft BE Recommendations).

In May 2013, Janssen Research & Development, LLC, submitted a citizen petition requesting that FDA require that any ANDA referencing INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension meet certain conditions, including conditions related to demonstrating BE (Docket No. FDA–2013–P–0608). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Revised Draft BE Recommendations in responding to the citizen 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 paliperidone palmitate extended-release injectable suspension. 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 either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

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

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–29080 Filed 12–4–13; 8:45 am]

BILLING CODE 4160–01–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 within 60 days of this notice.

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: Rural Health Network Development Planning Performance Improvement and Measurement System Database

OMB No. 0915–xxxx—[NEW]

Abstract: The purpose of the Rural Health Network Development Planning (Network Planning) program, authorized by Section 330A(f) of the Public Health Service Act, 42 U.S.C. 254c(f), as amended by section 201, Public Law 107–251 of the Health Care Safety Net Amendments of 2002, is to assist in the development of an integrated healthcare network, if the network participants do not have a history of collaborative efforts.

The Network Planning program helps to promote the planning and development of healthcare networks in order to: (i) Achieve efficiencies; (ii) expand access to, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole. This program brings together key parts of a rural health care delivery system, particularly those entities that may not have collaborated in the past under a formal relationship, to work together to establish and improve local capacity and coordination of care. This grant program supports one year of planning with the primary goal of helping networks create a foundation for their infrastructure and focusing member efforts to address important regional or local community health needs.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data. These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including (a) network infrastructure; (b) network collaboration; (c) sustainability; and (d) network assessment. Several measures will be used for this program.

Likely Respondents: The respondents would be Network Planning grant recipients.

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
Performance Improvement and Measurement System (PIMS) Database	21	1	21	1	21
Total	21	1	21	1	21

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.

Dated: November 22, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–29038 Filed 12–4–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a conference call of the Interagency Autism Coordinating Committee (IACC).

The IACC Full Committee will have a conference call meeting on Friday, December 13, 2013. The committee will discuss and finalize the 2013 IACC Strategic Plan Update. The conference call will be publicly accessible in listen-only mode.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open—Conference Call.

Date: December 13, 2013.

Time: 12:00 p.m. to 1:30 p.m. *Eastern Time*—Approximate end time.

Agenda: To discuss and finalize the 2013 IACC Strategic Plan Update.

Written Public Comments: Due by 5:00 p.m. ET on Tuesday, December 10, 2013.

Place: Conference call only; No in-person meeting.

Conference Call: Dial: 888–390–8568, Access code: 8162989.

Cost: The conference call is free.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 6182A, Rockville, MD 20852, Phone: (301) 443–6040, Email: *IACCPublicInquiries@mail.nih.gov.*

Please Note:

The meeting will be open to the public through a conference call phone number. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please send an email to *helpdeskiacc@gmail.com* or by phone at 415–652–8023.

Written Public Comments:

Written public comments may be submitted to: Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC,