II. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: *August 20, 2013.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20697 Filed 8–23–13; 8:45 am]

BILLING CODE 4160–01–P

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Draft Guidance for Industry on Bioequivalence Recommendations for Risperidone Injection; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Draft Guidance on Risperidone.'' The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for risperidone injection.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 25, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific bioequivalence (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 BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. FDA finalized that guidance and announced its availability in the **Federal Register** of June 11, 2010 (75 FR 33311). This notice announces the availability of revised draft BE recommendations for risperidone injection.

New drug application 021346 for Risperdal Consta (risperidone) Long-Acting Injection was initially approved by FDA in October 2003. In February 2010, FDA issued a draft guidance for industry on BE recommendations for generic risperidone injection (Draft BE Recommendations for Risperidone Injection). FDA is now issuing a revised version of the Draft BE Recommendations for Risperidone Injection (Revised Draft BE Recommendations).

In February 2011, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. submitted a citizen petition requesting that FDA require that any ANDA referencing Risperdal Consta (risperidone) Long-Acting Injection 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 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 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 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20696 Filed 8–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Implementation of the Revised International Guiding Principles for Biomedical Research Involving Animals

SUMMARY: The National Institutes of Health (NIH) is providing guidance to Public Health Service (PHS) awardee institutions on implementation of the revised International Guiding Principles for Biomedical Research Involving Animals (''Guiding Principles''). The NIH is seeking input from the public on any concerns they may have regarding the revised Guiding Principles.

DATES: Public concerns regarding the revised Guiding Principles must be submitted electronically at *http://grants.nih.gov/grants/rfi/rfi.cfm?ID=35* by September 30, 2013 in order to be considered.

FOR FURTHER INFORMATION CONTACT: Office of Laboratory Animal Welfare, Office of Extramural Research, National Institutes of Health, Suite 360, 6705 Rockledge Drive, Bethesda, MD 20892–7982, phone: 301–496–7163, email: *olaw@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NIH Office of Laboratory Animal Welfare (OLAW) oversees PHS-funded animal activities by the authority of the Health Research Extension Act of 1985 (*http://grants.nih.gov/grants/olaw/references/hrea1985.htm*) and the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy; *http://grants.nih.gov/grants/olaw/references/phspol.htm*). The PHS Policy requires that institutions have an approved Animal Welfare Assurance before conducting activities involving live vertebrate animals. Institutions outside the United States that receive PHS funding are required to have a Foreign Assurance (*http://grants.nih.gov/grants/olaw/sampledoc/foreign.htm*) that commits the institution to follow the International Guiding Principles for Biomedical Research Involving Animals (''Guiding Principles''). The Guiding Principles were revised in December 2012 by a partnership between the Council for International Organizations for Medical Science (CIOMS) and the International Council for Laboratory Animal Science (ICLAS).

PHS-Assured institutions outside the United States are encouraged to adopt the revised Guiding Principles as soon as possible, and full implementation is expected after October 1, 2013. OLAW will confirm an institution's adoption of the Guiding Principles at the next renewal of the Foreign Assurance.

II. Electronic Access

The December 2012 revision of the Guiding Principles is available for download at *http://grants.nih.gov/grants/olaw/Guiding_Principles_2012.pdf* (PDF).

Dated: August 19, 2013.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2013–20740 Filed 8–23–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 16, 2013.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Insitute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 715, Msc 5452, Bethesda, MD 20892, (301) 594–8843, *barnardm@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–20658 Filed 8–23–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: September 16–17, 2013.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Lakshmi Ramachandra, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700–B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, *Ramachandral@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers of Excellence for Translational Research (CETR) (U19).

Date: September 17–19, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–402–3938, *lr228v@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–20659 Filed 8–23–13; 8:45 am]

BILLING CODE 4140–01–P