

bioequivalence of clozapine products.² FDA recommends that such studies be performed only in patients who have not responded well to standard antipsychotic drug treatment and who have been receiving a maintenance dose of an approved clozapine product for at least 3 months. FDA is now issuing a draft guidance for industry on BE recommendations for generic clozapine that applies specifically to the ODTs.

Beckloff Associates, Inc., filed a citizen petition in December 2007, a citizen petition supplement in February 2009, and a second citizen petition in November 2010, requesting that FDA impose certain requirements for bioequivalence testing for ANDAs referencing FazaClo (clozapine) ODTs and modify the Clozapine Guidance (Docket Nos. FDA-2007-P-0188 and FDA-2010-P-0574). FDA is denying these petitions today.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on bioequivalence recommendations for clozapine. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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 documents at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

² The formatting of this guidance was updated in March 2011, but the content is unchanged. The March 2011 version is available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM249219.pdf>.

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; PAR Panel; Selected Topics and Transfusion Medicine.

Date: June 1-2, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health; 6701 Rockledge Drive; Bethesda, MD 20892; (Virtual Meeting).

Contact Person: Bukhtiar H Shah, DVM, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 4120, MSC 7802; Bethesda, MD 20892; 301-806-7314; shahb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel; Selected Topics and Transfusion Medicine.

Date: June 1-2, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health; 6701 Rockledge Drive; Bethesda, MD 20892; (Virtual Meeting).

Contact Person: Katherine M Malinda, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 4140, MSC 7814; Bethesda, MD 20892; 301-435-0912; Katherine_Malinda@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Child Psychopathology and Developmental Disabilities.

Date: June 2-3, 2015.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health; 6701 Rockledge Drive; Bethesda, MD 20892; (Virtual Meeting).

Contact Person: Jane A. Doussard-Roosevelt, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 3184, MSC 7848; Bethesda, MD 20892; (301) 435-4445; doussarj@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: June 3-4, 2015.

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

Agenda: To review and evaluate grant applications.

Place: The Warwick Allerton Hotel; 701 North Michigan Avenue; Chicago, IL 60611.

Contact Person: Boris P Sokolov, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 5217A, MSC 7846; Bethesda, MD 20892; 301-408-9115; bsokolov@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Molecular and Cellular Hematology Study Section.

Date: June 3-4, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion; 4300 Military Road NW.; Washington, DC 20015.

Contact Person: Luis Espinoza, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 6183, MSC 7804; Bethesda, MD 20892; 301-495-1213; espinozala@mail.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Cognition and Perception Study Section.

Date: June 4-5, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Historic Inns of Annapolis; 58 State Circle; Annapolis, MD 21401.

Contact Person: Dana Jeffrey Plude, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 3176, MSC 7848; Bethesda, MD 20892; (301) 435-2309; pluded@csr.nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; International and Cooperative Projects—1 Study Section.

Date: June 4, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Villa Florence Hotel; 225 Powell Street; San Francisco, CA 94102.

Contact Person: Hilary D Sigmon, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 5222, MSC 7852; Bethesda, MD 20892; (301) 594-6377; sigmonh@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group;

Psychosocial Development, Risk and Prevention Study Section.

Date: June 4–5, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel; 20 W Kinzie Street; Chicago, IL 60654.

Contact Person: Anna L Riley, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 3114, MSC 7759; Bethesda, MD 20892; (301) 435-2889; rileyann@csr.nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: June 4–5, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel; 405 Olive Way; Seattle, WA 98101.

Contact Person: Eugene Carstea, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 5194, MSC 7846; Bethesda, MD 20892; (301) 408-9756; carsteae@csr.nih.gov.

Name of Committee: Immunology Integrated Review Group; Transplantation, Tolerance, and Tumor Immunology Study Section.

Date: June 4–5, 2015.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel; 2660 Woodley Road NW.; Washington, DC 20008.

Contact Person: Jin Huang, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 4199, MSC 7812; Bethesda, MD 20892; 301-435-1230; jh377p@nih.gov.

Name of Committee: Immunology Integrated Review Group; Hypersensitivity, Autoimmune, and Immune-mediated Diseases Study Section.

Date: June 4–5, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel; 10 Thomas Circle, NW.; Washington, DC 20005.

Contact Person: Bahiru Gametchu, DVM, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 4204, MSC 7812; Bethesda, MD 20892; 301-408-9329; gametchb@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.

Date: June 4–5, 2015.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel; 2033 M Street NW.; Washington, DC 20036.

Contact Person: John Burch, Ph.D.; Scientific Review Officer; Center for

Scientific Review; National Institute of Health; 6701 Rockledge Drive, Room 3213, MSC 7808; Bethesda, MD 20892; 301-408-9519; burchjb@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

Date: June 4–5, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel; 711 Eastern Avenue; Baltimore, MD 21202.

Contact Person: Kathryn M Koeller, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 4166, MSC 7806; Bethesda, MD 20892; 301-435-2681; koellerk@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 29, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-10496 Filed 5-5-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Closed Loop Technologies; Clinical Trails.

Date: June 3, 2015.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: ELENA SANOVICH, Ph.D., SCIENTIFIC REVIEW OFFICER, REVIEW BRANCH, DEA, NIDDK, NATIONAL INSTITUTES OF HEALTH, ROOM 750, 6707 DEMOCRACY BOULEVARD, BETHESDA, MD 20892-2542, 301-594-8886, sanoviche@mail.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

Date: June 9–10, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

Contact Person: THOMAS A. TATHAM, Ph.D., SCIENTIFIC REVIEW OFFICER, REVIEW BRANCH, DEA, NIDDK, NATIONAL INSTITUTES OF HEALTH, ROOM 760, 6707 DEMOCRACY BOULEVARD, BETHESDA, MD 20892-5452, (301) 594-3993, tatham@mail.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DDK-C Conflicts.

Date: June 10, 2015.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

Contact Person: THOMAS A. TATHAM, Ph.D., SCIENTIFIC REVIEW OFFICER, REVIEW BRANCH, DEA, NIDDK, NATIONAL INSTITUTES OF HEALTH, ROOM 760, 6707 DEMOCRACY BOULEVARD, BETHESDA, MD 20892-5452, (301) 594-3993, tatham@mail.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; U54 Urology Research Center Applications.

Date: July 8–9, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: JASON D. HOFFERT, Ph.D., SCIENTIFIC REVIEW OFFICER, REVIEW BRANCH, DEA, NIDDK, NATIONAL INSTITUTES OF HEALTH, ROOM 741A, 6707 DEMOCRACY BOULEVARD, BETHESDA, MD 20892542, 301-594-5404, hoffertj@nidk.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: April 30, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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