Veterinary Medicine (CVM), as part of an NADA or ANADA, respectively.

CVM encourages sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This ''phased review'' of data submissions has created efficiencies for CVM and the animal pharmaceutical industry. These increased efficiencies have facilitated the approval of both pioneer and generic new animal drugs.

This guidance defines what an administrative (A)NADA is, defines and describes the phased review process, and briefly discusses how sponsors should submit an administrative (A)NADA and the time frame for review.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Administrative Applications and the Phased Review Process. It does 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032. The collections of information in section 512(n)(1) of the FD&C Act have been approved under OMB control number 0910–0669.

IV. 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.*

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10480 Filed 5–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1378]

Bioequivalence Recommendations for Clozapine Orally Disintegrating Tablets/Oral; 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 entitled ''Bioequivalence Recommendations for Clozapine,'' for the orally disintegrating tablets (ODTs). The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for clozapine ODTs.

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 comment on the 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 6, 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 documents.

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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

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 BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of one draft BE recommendation for clozapine ODTs.

Clozapine tablets, marketed under the name CLOZARIL, are the subject of new drug application (NDA) 19–758, held by Novartis Pharmaceuticals Corporation and approved by FDA on September 26, 1989. FazaClo ODTs were approved by FDA on February 19, 2004, under NDA 21–590, currently held by Jazz Pharmaceuticals III International LTD, based upon a finding that FazaClo ODTs were bioequivalent to CLOZARIL immediate-release tablets. FazaClo ODTs are available as yellow, orally disintegrating tablets of 12.5, 25, 100, 150, and 200 [1] milligrams (mg) of clozapine for oral administration without water. They are formulated to disintegrate once exposed to saliva and then are easily swallowed.

In June 2005, FDA published a guidance for industry entitled ''Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing'' (Clozapine Guidance) (70 FR 35447, June 20, 2005), which replaced a 1996 product-specific bioequivalence guidance for clozapine tablets. The 2005 Clozapine Guidance recommends that ANDA applicants employ multiple-dose, steady-state studies to evaluate the

[1] FDA approved the supplemental NDA for the 150 and 200 mg strengths on July 9, 2010.

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/GuidanceCompliance RegulatoryInformation/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.

[FR Doc. 2015–10478 Filed 5–5–15; 8:45 am]

BILLING CODE 4164–01–P

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;