

populations to support indications in the pediatric population. If extrapolation is found to be appropriate, FDA believes that statistical modeling and methods can be used to increase the precision of pediatric inferences.

This guidance should be used in conjunction with other device-specific guidances to help ensure that medical devices intended for use in pediatric population provide reasonable assurance of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on extrapolation of data for pediatric uses. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1827 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 parts 801 and 809 have been approved under OMB control number 0910-0485 (medical device labeling); the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078 (investigational device exemptions); the collections of information in 21 CFR part 814 have been approved under OMB control

number 0910-0231 (subparts A through E, premarket approval).

V. Reference

The following reference have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA guidance entitled "Premarket Assessment of Pediatric Medical Devices," March 24, 2014, available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm>.

VI. 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>.

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-10482 Filed 5-5-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-D-0147 (formerly Docket No. 2002D-0449)]

Administrative Applications and the Phased Review Process; 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 guidance for industry (GFI) #132 entitled "Administrative Applications and the Phased Review Process." This guidance defines the "phased review process" for reviewing application-level information during the investigational period of new animal

drug development, and an "administrative" new animal drug application (NADA) or abbreviated new animal drug application (ANADA), the content, the procedures a sponsor should follow to submit such an application, and the intended time frame for its review.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Katherine Weld, Center for Veterinary Medicine (HFV-108), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0846, Katherine.Weld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 6, 2002 (67 FR 67631), FDA published the notice of availability for a draft guidance entitled "The Administrative New Animal Drug Application Process" giving interested persons until January 21, 2003, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance was updated to clarify current processes and include information about generic new animal drugs. The guidance announced in this notice finalizes the draft guidance dated November 6, 2002.

To be legally marketed, a new animal drug must be the subject of either an approved application under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b), a conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc), or an index listing under section 572 of the FD&C Act (21 U.S.C. 360ccc-1). Sections 512(b)(1) and 512(n)(1) of the FD&C Act describes the information that must be submitted to FDA, specifically the Center for

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.

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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 200¹ 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.