Dated: August 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20221 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Fidaxomicin; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry on generic fidaxomicin tablets entitled ''Draft Guidance on Fidaxomicin.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for fidaxomicin tablets.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 24, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Fidaxomicin.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), 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 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for generic fidaxomicin tablets.

FDA initially approved new drug application (NDA) 201699 for DIFICID (fidaxomicin) in May 2011. Currently, there are no approved ANDAs for this product. We are now issuing a draft guidance for industry on BE recommendations for generic fidaxomicin tablets (''Draft Guidance on Fidaxomicin'').

On May 6, 2015, Cubist Pharmaceuticals, Inc. submitted a

citizen petition requesting that ''FDA impose scientifically-appropriate standards for demonstrating BE for ANDAs and 505(b)(2) new drug applications'' citing to DIFICID as the reference listed drug. FDA has reviewed the issues raised in the citizen petition and is responding to the citizen petition (Docket No. FDA–2015–P–1595, available at *http://www.regulations.gov*).

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 the design of BE studies to support ANDAs for fidaxomicin tablets. 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. Electronic Access

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

Dated: August 18, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–20146 Filed 8–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, notice is hereby given of the following meeting of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT).

DATES:

September 13, 2016, from 8:00 a.m. to 4:00 p.m. Eastern Time.

September 14, 2016, from 8:00 a.m. to 12:30 p.m. Eastern Time.

ADDRESSES: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Executive Secretary, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 8W60, Rockville, MD 20857; telephone (301) 443–6839.

SUPPLEMENTARY INFORMATION:

Status: The meeting will be open to the public.

Purpose: Pursuant to Public Law 109–129, 42 U.S.C. 274k (session 379 of the Public Health Service Act, as amended), the ACBSCT advises the Secretary of the Department of Health and Human Services and Administrator, Health Resources and Services Administration (HRSA), on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory Program.

Agenda: The Council will discuss trends in the usage of various sources of blood stem cells used in unrelated blood stem cell transplants, utilization of cord blood, blood stem cell transplantation for treatment of sickle cell disease, and late effects in blood and marrow transplantation, among other topics. The Council will also receive a program update from the HRSA Division of Transplantation (DoT). Agenda items are subject to change as priorities indicate.

After Council discussions, members of the public will have an opportunity to provide comment. Because of the Council's full agenda and timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACBSCT meeting.

The draft meeting agenda will be posted on *www.ACBSCTmeeting.org.* Those participating at this meeting should pre-register by visiting *www.ACBSCTmeeting.org.* The deadline to pre-register for this meeting is Friday, September 9, 2016. Registration will be confirmed on site. For all logistical questions and concerns, please contact Susie Gingrich, Leonard Resource Group, at (202) 289–8322 or send an email to *sgringrich@lrginc.com.*

Participants can also join this meeting via teleconference by:

1. (Audio Portion) Calling the Conference Phone Number (1–800–832–0736) and providing the Participant Passcode (1337210); and

2. (Visual Portion) Connecting to the ACBSCT Adobe Connect Pro Meeting using the following URL *https://lrg.adobeconnect.com/acbsct/* and entering as GUEST: (Copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should plan to call and connect 15 minutes prior to the meeting for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *http://www.adobe.com/go/meeting_test.* In order to obtain a quick overview, go to the following URL: *http://www.adobe.com/go/connectpro_overview.* Call (202) 289–8322 or email Susie Gingrich at *sgringrich@lrginc.com* if you are having trouble connecting to the meeting site.

Public Comment: It is preferred that persons interested in providing an oral presentation email a written request, along with a copy of your presentation, to Robert Walsh, Executive Secretary, at *RWalsh@hrsa.gov.* Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are encouraged to combine their comments and present them through a single representative.

The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may request it during the public comment period. Public participation and ability to comment will be limited as time permits.

Jason E. Bennett

Director, Division of the Executive Secretariat.

[FR Doc. 2016–20198 Filed 8–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OMB # 0990–0424–30D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, Office of Adolescent Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before September 23, 2016.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.