

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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for fidaxomicin tablets.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Persons with access to the Internet may obtain the draft guidance at either 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]

BILLING CODE 4164-01-P

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]

BILLING CODE 4165-15-P

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.