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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for fidaxomicin tablets.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*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.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier OMB # 0990–0424–30D for reference.

Information Collection Request Title: Positive Adolescent Futures (PAF) Study

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Positive Adolescent Futures (PAF) Study will provide information about program design, implementation, and impacts through a rigorous assessment of program impacts and implementation of two programs designed to support expectant and parenting teens. These programs are located in Houston, Texas and throughout the state of California. This revised information collection request includes the 24-month follow-up survey instrument related to the impact study. The data collected from this instrument in the two study sites will provide a detailed understanding of program impacts about two years after youth are enrolled in the study and first have access to the programming offered by each site.

Need and Proposed Use of the Information: The data will be used to determine program effectiveness by comparing outcomes on repeat pregnancies, sexual risk behaviors, health and well-being, and parenting behaviors between treatment (program) and control youth. The data will also be used to understand whether the programs are more effective for some youth than others. The findings will be of interest to the general public, to policymakers, and to organizations interested in supporting expectant and parenting teens.

Likely Respondents: The 24-month follow-up survey data will be collected through a web-based survey or through telephone interviews with study participants. The mode of survey administration will primarily be based on the preference of the study participants. The survey will be completed by 1,515 respondents across the two study sites. Clearance is requested for three years.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
24-month follow-up survey of impact study participants	505	1	30/60	252.5
Total				252.5

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2016–20129 Filed 8–23–16; 8:45 am]

BILLING CODE 4168–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

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

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

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

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: Office on Women's Health: IPV Provider Network Cross-Site Evaluation.