be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Karl Koerper

OPRE Reports Clearance Officer.

[FR Doc. 2014–02949 Filed 2–11–14; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a public workshop entitled ''Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products.'' The purpose of the public workshop is to bring together a broad range of stakeholders to discuss current and future standards development activities involving cellular therapies and regenerative medicine products. This public workshop is being rescheduled due to the government shutdown.

Date and Time: The public workshop will be held on March 31, 2014, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. Please visit the following Web site for location, parking, security, and travel information: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Sherri Revell, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, email: *CBERPublicEvents@fda.hhs.gov* (Subject line: SESDCTRMP Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Sherri Revell (see *Contact Person*) or email to *CBERPublicEvents@fda.hhs.gov* (Subject line: SESDCTRMP Workshop Registration) by March 24, 2014. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

Streaming Webcast of the Public Workshop: For those unable to attend in person, FDA will Webcast the public workshop. To join the Webcast of the public workshop, please go to: *https://collaboration.fda.gov/sesdctrmpworkshop/.* If you have never attended an Adobe Connect meeting before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* Get a quick overview: *http://www.adobe.com/go/connectpro_overview.* Registration is not required for those attending via Adobe Connect.

If you need special accommodations due to a disability, please contact Sherri Revell (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Standardization efforts concerning the clinical development of cellular therapies and regenerative medicine products have generated a great deal of interest. These efforts include standards development, expert opinion position papers, and professional practice guidelines. However, relatively little is done to coordinate the various existing efforts. In the public workshop, FDA hopes to bring together a broad range of stakeholders of cellular therapies and regenerative medicine products in order to:

- Inform stakeholders about the types of standards and standards organizations that are available currently, the role that the Federal Agencies play in standards development, and the potential role that stakeholders can play in standards development.
- Provide a high-level overview of current standards development activities in the fields of cellular therapy and regenerative medicine and the regulatory application of standards.
- Provide opportunity for discussion of areas of high interest for current or future standards development in the fields of cellular therapy and regenerative medicine and to explore ways to minimize redundancy and maximize collaboration.

We encourage all who have an interest in the development of cellular therapies and regenerative medicine products to attend the public workshop.

This public workshop is being rescheduled due to the government shutdown. It was originally scheduled for October 7, 2013 (see 78 FR 43889, July 22, 2013). Those who registered for the original workshop date must register again for the rescheduled date (see *Registration*).

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03015 Filed 2–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 31, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under

the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 31 Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *AIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss new drug applications (NDAs) 205–435 and 205–436, tedizolid phosphate tablets and tedizolid phosphate injection, submitted by Trius Therapeutics, respectively, for the proposed indication of treatment of acute bacterial skin and skin structure infections.

During the afternoon session, the committee will discuss NDA 021–883, dalbavancin hydrochloride for intravenous injection, submitted by Durata Therapeutics International B.V., for the proposed indication of treatment of acute bacterial skin and skin structure infections.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 17, 2014. Oral presentations from the public will be scheduled between approximately 10:45 a.m. to 11:15 a.m., and 3:45 p.m. to 4:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 7, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 10, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 6, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–02942 Filed 2–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 20, 2014, from 11:30 a.m. to approximately 3:20 p.m.

Location: Rockwall II, Conference Room 1033, 5515 Security Lane, Rockville, MD 20852. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room.

Contact Person: Prabha Atreya or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 20, 2014, the committee will meet in open session to hear updates of the research programs in the Laboratory of Respiratory and Special Pathogens, Division of Bacterial, Parasitic and Allergenic Products, and in the Laboratory of Hepatitis Viruses, Division of Viral Products, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/*