

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: Caleb Briggs, 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, email: ODAC@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 application (NDA) 204026, with the established name pomalidomide, application submitted by Celgene Corporation. The proposed indication (use) for this product is in combination with dexamethasone for patients with relapsed and refractory multiple myeloma who have received at least 2 prior regimens of established benefit, including both lenalidomide and bortezomib and have demonstrated disease progression on the last therapy.

During the afternoon session, the committee will discuss supplemental new drug application (sNDA) 021882/015, with the trade name EXJADE (deferasirox) tablets for oral suspension, application submitted by Novartis Pharmaceutical Corporation. The proposed indication (use) for this product is for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes (beta-thalassemia intermedia, HbE beta-thalassemia, and alpha-thalassemia) aged 10 years and older.

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 October 25, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 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 October 17, 2012. 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 October 18, 2012.

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 Caleb Briggs 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: September 13, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-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 November 29, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC-Silver Spring, The Ballroom, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's phone number is 301-589-5200.

Contact Person: Diane Goyette, 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, email: 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: The committee will discuss new drug application (NDA) 22407, VIBATIV (telavancin hydrochloride) sterile powder for injection, submitted by Theravance, Inc., for the requested

indication of nosocomial pneumonia (pneumonia contracted by hospitalized patients), including ventilator-associated pneumonia, caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae* (penicillin susceptible strains).

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 November 13, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 November 2, 2012. 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 November 5, 2012.

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

Dated: September 13, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the

National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: *Title:* Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI) (OMB No. 0925-0613). *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes. *Frequency of Response:* Up to 16 times per year. *Affected Public:* Private sector including businesses, other for-profit organizations, and non-profit institutions. *Type of Respondents:* Investigators, pharmacists, nurses, pharmacy technicians, and data managers. The annualized respondents' burden for record keeping is estimated to require 14,223 hours (see Table 1). There are no capital costs, operating costs, or maintenance costs.

TABLE 1—ESTIMATES OF ANNUAL BURDEN

| Type of respondents | Form | Number of respondents | Frequency of response | Average time per response (hours) | Total hour burden |
|--|---|-----------------------|-----------------------|-----------------------------------|-------------------|
| Investigators and Designee for Investigator Registration and DARF. | Statement of Investigator | 20,112 | 1 | 15/60 | 5,028 |
| | Supplemental Investigator | 20,112 | 1 | 10/60 | 3,352 |
| | Financial Disclosure | 20,112 | 1 | 5/60 | 1,676 |
| | Drug Accountability Record Form (DARF and DARF-Oral). | 3,907 | 16 | 4/60 | 4,167 |
| Totals | | | | | 14,223 |