DDM
Display Date 1-24-08
Publication Date 1-25-08
Certifier N. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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: Oncologic 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 12, 2008, from 8 a.m. to 5 p.m. and on March 13, 2008, from 8 a.m. to 4 p.m.

Location: Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., Gaithersburg, MD, 301–948–8900.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. 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

oc0822

2008-4345

NM1

timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On March 12, 2008, the committee will discuss: (1) Biologic license application (BLA) 125268, proposed trade name NPLATE (romiplostim), Amgen Inc., proposed indication for the treatment of thrombocytopenia in adults with chronic immune (idiopathic) thrombocytopenia purpura who are nonspelenectomized and have had an inadequate response or are intolerant to corticosteroids and/or immunoglobulins; or patients who are splenectomized and have an inadequate response to splenectomy, and (2) supplemental biologics license application (sBLA) 103949/5153, PEGINTRON (peginterferon alfa-2b), Schering Corp., proposed indication for adjuvant treatment of melanoma. On March 13, 2008, the committee will discuss the cumulative data, including recent study results, on the risks of erythropoeisis-stimulating agents when administered to patients with cancer. Agents to be discussed include ARANESP (darbepoetin alfa), EPOGEN (epoetin alfa), PROCRIT (epoetin alfa, Amgen, Inc.), and MIRCERA (methoxy polyethylene glycol-epoetin beta, Hoffman-La Roche Inc.). This is a followup to the May 10, 2007, Oncologic Drugs Advisory Committee Meeting.

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/*

ohrms/dockets/ac/acmenu.htm, click on the year 2008 and scroll down to the appropriate advisory committee 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 February 27, 2008. 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. on March 12, 2008, and between approximately 1 p.m. to 2 p.m. on March 13, 2008. Those desiring to make 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 February 19, 2008. 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 February 20, 2008.

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 Nicole Vesely 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/oc/advisory/default.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: 1/17/08

oc0822

January 17, 2008.

Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL