TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

	Investigational Applications	Marketing Applications	Hours per Response	Total Hours
CDER/CBER (manufacturing supplement)	----	2,500	.75	1,875
CDER/CBER (labeling supplement)	----	1,273	.75	955
CDRH (supplement)	----	2,705	.75	2,029
Total				24,419

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe the estimate of 24,419 hours per year accurately reflects the burden. We recognize that individuals or entities less familiar with FDA forms and the clinical trials data bank (*ClinicalTrials.gov*) may require greater than 15 and 45 minutes (depending on the type of application/submission) per response.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 28, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4158 Filed 3–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of January 25, 2008 (73 FR 4580). The amendment is being made to reflect a change in the *Date and Time*, *Agenda*, and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 2008, FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on March 12 and 13, 2008.

On page 4580, in the third column, the *Date and Time* portion of the meeting is amended to read as follows:

Date and Time: The meeting will be held on March 12 and 13, 2008, from 8 a.m. to 4 p.m.

On page 4580, beginning in the third column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: On March 12, 2008, the committee will discuss 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 (ITP) who are nonsplenectomized 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. 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.

On page 4581, beginning in the first column, the *Procedure* portion of the meeting is amended to read as follows:

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 1 p.m. to 2 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: February 26, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–4157 Filed 3–4–08; 8:45 am]

BILLING CODE 4160–01–S