[2] In accordance with 45 CFR 96.85, each State's estimated median income for a four-person family is multiplied by the following percentages to adjust for family size for LIHEAP: 52 percent for one person, 68 percent for two persons, 84 percent for three persons, 100 percent for four persons, 116 percent for five persons, and 132 percent for six persons. For each additional family member above six persons, add 3 percentage points to the percentage for a six-person family (132 percent), and multiply the new percentage by the State's estimated median income for a four-person family.

[3] These figures were calculated by the Division of Energy Assistance (DEA). DEA calculated these figures by multiplying the estimated State median income for a four-person family for each State by 60 percent.

[FR Doc. E8–4190 Filed 3–4–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0144]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the certification to accompany human drug, biological product, and device applications or submissions (Form FDA 3674).

DATES: Submit written or electronic comments on the collection of information by May 5, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Certification to Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)—(OMB Control Number 0910–0616)—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) will be submitted in the form of a certification with applications and submissions currently submitted to FDA under part 312 (21 CFR part 312) and 21 CFR part 314 (human drugs) and approved under OMB control numbers 0910–0014 (expires May 31, 2009) and 0910–0001 (expires May 31, 2008), respectively; submitted to FDA under part 312 and 21 CFR part 601 (biological products) and approved under OMB control numbers 0910–0014 and 0910–0338 (expires June 30, 2010); and submitted to FDA under 21 CFR parts 807 and 814 (devices) and approved under OMB control numbers 0910–0120 (expires August 31, 2010) and 0910–0231 (expires November 30, 2010), respectively.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) amended the PHS Act by adding section 402(j) (42 U.S.C. 282(j)). The new provisions require additional information to be submitted to the clinical trials data bank (*ClinicalTrials.gov*)[1] previously established by the National Institutes of Health/National Library of Medicine, including expanded information on clinical trials and information on the results of clinical trials. The provisions include new responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One new provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The proposed collection of information is necessary to satisfy the previously mentioned statutory requirement.

The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and

[1] (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties.

Investigational New Drug Applications

FDA's Center for Drug Evaluation and Research (CDER) received 1,837 investigational new drug applications (INDs) and 24,581 new IND amendments in fiscal year (FY) 2004. CDER anticipates that IND and amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 227 new INDs and 6,689 new IND amendments in FY 2004. CBER anticipates that IND and amendment submission rates will remain at or near this level in the near future.

The estimated total number of submissions (new INDs and new submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act is 26,418 for CDER plus 6,916 for CBER, or 33,334 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to type the necessary information.

Based on its experience reviewing INDs and consideration of the previously mentioned information, FDA estimated that approximately 15.0 minutes on average would be needed per response for certifications which accompany IND applications and submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained an NCT number from *ClinicalTrials.gov* prior to making the submission to FDA. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions

CDER and CBER received 214 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 8,535 NDA/BLA amendments in FY 2004. CDER and CBER received 259 efficacy supplements/resubmissions to previously approved NDAs/BLAs; 2,500 manufacturing submissions; and 1,273 labeling submissions in FY 2004. CDER and CBER anticipate that new drug/biologic and efficacy supplement submission rates will remain at or near this level in the near future.

FDA's Center for Devices and Radiological Health (CDRH) received 51 new applications for premarket approvals (PMA); 3,635 premarket notification submissions under section 510(k) of the FD&C Act; and 9 applications for humanitarian device exemptions (HDE), for a total of 3,695 new applications/submissions in FY 2004. CDRH received 2,267 PMA/510(k)/HDE amendments in FY 2004. CDRH received 2,705 PMA/510(k)/HDE supplements in FY 2004. CDRH anticipates that application, amendment, and supplement rates will remain at or near this level in the near future.

The estimated total number of new submissions (new marketing applications/submissions, amendments, and supplements) subject to the mandatory certification requirements under section 402(j)(5)(B) of the PHS Act is 12,781 for CDER and CBER plus 8,667 for CDRH, or 21,448 new submissions per year. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to type the necessary information and compile a list of relevant NCT numbers.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, and 510(k)s, and consideration of the previously mentioned information, FDA estimated that approximately 45.0 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, and 510(k) applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Table 1 of this document provides an estimate of the annual reporting burden for the submission of information to satisfy the requirements of section 402(j)(5)(B) of the PHS Act.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Investigational Applications	Marketing Applications	Hours per Response	Total Hours
CDER (new application)	1,837	----	.25	459
CBER (new application)	227	----	.25	57
CDER (amendment)	24,581	----	.25	6,145
CBER (amendment)	6,689	----	.25	1,672
CDER/CBER (new application/resubmission)	----	214	.75	161
CDRH (new application)	----	3,695	.75	2,771
CDER/CBER (amendment)	----	8,535	.75	6,401
CDRH (amendment)	----	2,267	.75	1,700
CDER/CBER (efficacy supplement/resubmission)	----	259	.75	194

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