manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 100 of these manufacturers may use an AP in any given year.

In the **Federal Register** of May 23, 2011 (76 FR 29764), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
374(g)	100	1	100	15	1,500

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

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24582 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0275]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 26, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0616. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. 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)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and is already approved by OMB. The OMB control numbers and expiration dates for submitting Form FDA 3674 under the following parts are: 21 CFR parts 312 and 314 (human drugs) are 0910–0014, expiring August 31, 2011, and 0910–0001, expiring May 31, 2011; 21 CFR parts 312 and 601 (biological products) are 0910–0014 and 0910–0338, expiring December 31, 2011; 21 CFR parts 807 and 814 (devices) are 0910–0120, expiring December 31, 2013, and 0910–0231, expiring December 31, 2013.

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

One 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, Form FDA 3674, 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 extension of the 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 organizations submitting applications or reports to FDA under the listed

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

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.

In January 2009, FDA issued ''Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007'' available at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.* This guidance identified the applications and submissions that FDA considered should be accompanied by the certification form, Form FDA 3674. The applications and submissions noted in the guidance are reflected in the burden analysis.

I. Investigational New Drug Applications

FDA's Center for Drug Evaluation and Research (CDER) received 1,752 investigational new drug applications (INDs) and 11,769 clinical protocol IND amendments in fiscal year (FY) 2010. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 281 new INDs and 1,471 clinical protocol IND amendments in FY 2010. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

The estimated total number of submissions (new INDs and new protocol submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act, is 13,521 for CDER plus 1,752 for CBER, or 15,273 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 enter the necessary information on the form.

Based on its experience with current submissions, FDA estimates that approximately 15.0 minutes on average would be needed per response for certifications which accompany IND applications and clinical protocol amendment submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained a NCT number from *http://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.

II. Marketing Applications/Submissions

In 2010, CDER and CBER received 165 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 1,483 NDA/BLA amendments for which certifications are needed. CDER and CBER received 191 efficacy supplements/resubmissions to previously approved NDAs/BLAs in FY 2010. CDER and CBER anticipate that new drug/biologic applications/resubmissions 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 a total of 892 new applications for premarket approvals (PMA), 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments, for a total of 424 new applications/submissions in FY 2010. CDRH anticipates that application, amendment, supplement, and annual report submission rates will remain at or near this level in the near future.

FDA's Office of Generic Drugs (OGD) received 854 abbreviated new drug applications (ANDAs) in FY 2010. OGD received 495 bioequivalence amendments/supplements FY 2010. OGD anticipates that application, amendment, and supplement submission rates will remain at or near this level in the near future.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, 510(k)s, and ANDAs and experience with current submissions of Form FDA 3674, FDA estimates that approximately 45.0 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, 510(k), and ANDA marketing 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.

In the **Federal Register** of May 6, 2011 (76 FR 26305), FDA published a 60-day notice requesting public comment on the proposed collection of information. There were four comments submitted in response to the 60-day **Federal Register** notice. Only two comments were directly related to the information collection. One comment was unrelated to the information collection. The remaining comment requested that FDA define a term contained in section 402(j)(1)(A)(ii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(ii)). The implementation of this provision, including defining any statutory terms, is the responsibility of NIH. NIH has indicated in the Unified Agenda that proposed rulemaking is anticipated in 2011. In addition, NIH has provided an elaboration of the definition of that term on its Web site at *http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.*

One of the comments that directly addressed the information collection commented on the utility of the information collected through Form FDA 3674 and requested that FDA consider a means to associate the NCT number with the study numbers. Since the enactment of FDAAA, FDA has been involved in a technological effort designed to accomplish what has been suggested by the comment. FDA is currently involved in designing a software/computer system that can link the information provided on the Form FDA 3674 with actions taken in relation to that study, a future marketing application, and future actions taken in relation to the approved medical product. Part of this effort is designed to provide NIH information which will be displayed on its Web site for each clinical trial for which specific information is provided. An additional aspect for the effort is designed to link this information internally for various purposes including compliance efforts. This commenter also proposed changes to the timing of the certification submissions accompanying INDs based upon the requirements for submission of clinical trial information to *http://ClinicalTrials.gov.* FDA appreciates the comment but has implemented the statutory requirements in the most efficient manner possible. The statute requires FDA to obtain the certification upon submission of an IND despite the fact that submission of clinical trial information to *http://ClinicalTrials.gov* generally is not required at the time an IND is required to be submitted. In order to collect information on trials that are not applicable clinical trials, as suggested by the comment, either a

statutory change or, possibly, rulemaking would be required.

The remaining comment contended that the estimates FDA used in its burden estimates should be adjusted significantly upward. We do not agree with the comment's conclusions. FDA has based the burden hours on the totality of the time needed for the information collection and not (as claimed by the commenter) on the completion of the form itself. As noted in our previous information collection and this one, we anticipated that entities submitting Form FDA 3674 would implement systems that would simplify collection of the information. We have received feedback based on submitters' experience over the past 3½ years that suggests these types of systems have been implemented. Furthermore, given the responsibilities required for registering and updating trials on *http://ClinicalTrials.gov* and current FDA requirements, unrelated to Form FDA 3674, for submission of trial information for marketing applications, the information required for completion of this form should be easy to compile. FDA's experience in responding to calls on the form and questions presented at meetings and conferences does not accord with the practices noted in this comment and does not support the burden estimates proposed by the comment. In fact, the only other comment submitted directly related to the information collection indicated that the ''estimate of the burden of the proposed collection of information, including the validity of the methodology and assumption used, seems reasonable.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center activity	No. of respondents (investigational applications)	No. of respondents (marketing applications)	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER						
New Applications (IND)	1,752		1	1,752	0.25 (15 min.)	438
Clinical Protocol Amendments (IND)	11,769		1	11,769	0.25 (15 min.)	2,943
New Marketing Applications/Resubmissions (NDA/BLA)		157	1	157	0.75 (45 min.)	118
Clinical Amendments to Marketing Applications		1,466	1	1,466	0.75 (45 min.)	1,100
Efficacy Supplements/Resubmissions		166	1	166	0.75 (45 min.)	125
CBER						
New Applications (IND)	281		1	281	0.25 (15 min.)	70
Clinical Protocol Amendments (IND)	1,471		1	1,471	0.25 (15 min.)	368
New Marketing Applications/Resubmissions		8	1	8	0.75 (45 min.)	6
Clinical Amendments to Marketing Applications		17	1	17	0.75 (45 min.)	13
Efficacy Supplements/Resubmissions (BLA only)		25	1	25	0.75 (45 min.)	19
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data)		892	1	892	0.75 (45 min.)	669
OGD						
Original Applications		854	1	854	0.75 (45 min.)	641
BE Supplements/Amendments		495			0.75 (45 min.)	372
Total						6,882

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

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24581 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Gastrointestinal 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: Gastrointestinal 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 17, 2011, from 8 a.m. to 5 p.m.

Location: Holiday Inn Washington-College Park, The Ballroom, 10000 Baltimore Ave., College Park, MD. The hotel telephone number is 301–345–6700.

Contact Person: Minh Doan, 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, *e-mail: GIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 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 November 17, 2011, the committee will provide recommendations to the Agency on the design and size of premarketing cardiovascular safety development programs necessary to support approval of products in the class of serotonin (5-hydroxytryptamine) receptor 4 agonists for the proposed indications of chronic idiopathic (of unknown cause) constipation, constipation predominant irritable bowel syndrome, gastroparesis, and gastroesophageal reflux disease that does not respond to a proton pump inhibitor.

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 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 2, 2011. 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 October 25, 2011. 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 26, 2011.

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 Minh Doan 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 20, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–24603 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Gastrointestinal 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: Gastrointestinal 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 16, 2011, from 8 a.m. to 5 p.m.

Location: Holiday Inn Washington-College Park, The Ballroom, 10000 Baltimore Ave., College Park, MD. The hotel telephone number is 301–345–6700.

Contact Person: Kristine T. Khuc, 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, *e-mail: GIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 timely notice. Therefore, you should