TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
821.25(b)	12	46,260	555,120	1	555,120
821.25(c) [2]	12	1	12	63	756
821.25(c)(3)	12	1,124	13,488	1	13,488
Total					569,364

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
821.30(a) and (b)	17,000	1	17,000	1	17,000
821.30(c)(2) and (d)	17,000	1	17,000	1	17,000
Total					34,000

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

Dated: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11072 Filed 5–5–11; 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; 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 requirements for certain FDA applications or submissions to be accompanied by a certification, Form FDA 3674, to ensure all applicable statutory requirements have been met.

DATES: Submit either electronic or written comments on the collection of information by July 5, 2011.

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 Office of Management and Budget (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., P150–400B, Rockville, MD 20850, 301–796–3794, *jonnalynn.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from 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 extension of an existing 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 extension of the 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)) 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 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, 2013; 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). The 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 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 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.

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 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

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.

[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**.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center Activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
CDER						
New Applications (IND)	1,752		1	1,752	15/60	438
Clinical Protocol Amendments (IND)	11,769		1	11,769	15/60	2,943
New Marketing Applications/Resubmissions (NDA/BLA)		157	1	157	45/60	118
Clinical Amendments to Marketing Applications		1,466	1	1,466	45/60	1,100
Efficacy Supplements/Resubmissions		166	1	166	45/60	125
CBER						
New Applications (IND)	281		1	281	15/60	70
Clinical Protocol Amendments (IND)	1,471		1	1,471	15/60	368
New Marketing Applications/Resubmissions		8	1	8	45/60	6
Clinical Amendments to Marketing Applications		17	1	17	45/60	13
Efficacy Supplements/Resubmissions (BLA only)		25	1	25	45/60	19
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data)		892	1	892	45/60	669
OGD						
Original Applications		854	1	854	45/60	641
BE Supplements/Amendments		495			45/60	372
Total						6,882

[1] There are no capitol costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Dated: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11073 Filed 5–5–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0126]

Guidance for Industry on the Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications." The guidance is intended to assist abbreviated new drug application (ANDA) applicants in complying with the requirements in the final rule on the submission of bioequivalence data that published in the **Federal Register** in January 2009 (74 FR 2849, January 16, 2009). The final rule requires ANDA applicants to submit data from all bioequivalence studies (BE studies) the applicant conducts on a drug product formulation submitted for approval, including both studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria. The guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs and is applicable to BE studies conducted during both preapproval and postapproval periods.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650),