4164-01-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

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

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)) 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 April 30, 2015, and 0910-0001, expiring September 30, 2014; 21 CFR parts 312 and 601 (biological products) are 0910-0014 and 0910-0338, expiring January 31, 2017; 21 CFR parts 807 and 814 (devices) are 0910-0120, expiring January 31, 2017, and 0910-0231, expiring January 31, 2017.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (Public Law 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, http://www.clinicaltrials.gov/ (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) 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 1,564 investigational new drug applications (INDs) and 14,328 clinical protocol IND amendments in calendar year (CY) 2013. 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 451 new INDs and 492 clinical protocol IND amendments in CY 2013. 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 15,892 for CDER plus 943 for CBER, or 16,835 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 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://www.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 CY 2013, CDER and CBER received 226 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 932 NDA/BLA amendments for which certifications are needed. CDER and CBER received 198 efficacy supplements/resubmissions to previously approved NDAs/BLAs in CY 2013. 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 530 new applications for premarket approvals (PMA), 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments in CY 2013. 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 1,001 abbreviated new drug applications (ANDAs) in 2013. OGD received 989 bioequivalence amendments/supplements in 2013. 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 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.

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)	1,564		1	1,546	0.25 (15 minutes)	387
Clinical Protocol Amendments (IND)	14,328		1	14,328	0.25 (15 minutes)	3,582
New Marketing Applications/ Resubmissions (NDA/BLA)		191	1	191	0.75 (45 minutes)	143
Clinical Amendments to Marketing Applications		932	1	932	0.75 (45 minutes)	699
Efficacy Supplements/ Resubmissions		173	1	173	0.75 (45 minutes)	130
CBER						
New Applications (IND)	451		1	451	0.25 (15 minutes)	113
Clinical Protocol Amendments (IND)	492		1	492	0.25 (15 minutes)	123
New Marketing Applications/Resubmissions (NDA/BLA)		35	1	35	0.75 (45 minutes)	26
Clinical Amendments to Marketing Applications		0	1	0	0.75 (45 minutes)	1
Efficacy Supplements/ Resubmissions (BLA only)		25	1	25	0.75 (45 minutes)	19
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data)		530	1	530	0.75 (45 minutes)	398
OGD						
Original Applications		1,001	1	1,001	0.75 (45 minutes)	751
BE Supplements/ Amendments		989	1	989	0.75 (45 minutes)	742
Total						7,114

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

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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