U.S. Food and Drug Administration
Certification to Accompany Drug, Biological Product, and Device Applications/Submissions

0910-0616

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85, amended the Public Health Service Act (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 (ClinicalTrials.gov) previously established by the National Institutes of Health/National Library of Medicine (NIH/NLM), including expanded information on clinical trials and information on the results of clinical trials. The provisions include responsibilities for the Food and Drug Administration (FDA) as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One provision, 42 U.S.C. § 282(j)(5)(B), 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, or under section 351 of the PHS Act, or submission of a report under section 510(k) of the FD&C Act, such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

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 42 U.S.C. 282(j)(5)(B), 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. Violations are subject to civil money penalties.

The HHS regulations at 42 CFR part 11 (published on September 20, 2016, see 81 FR 64981) is associated with this information collection. FDA has provided guidance related to this information collection, as well as an updated electronic form to assist with this data collection.

2. Purpose and Use of the Information Collection

The collection of information required under 42 U.S.C. 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act, can be submitted electronically or manually to FDA.

This information will be submitted to FDA with new investigational and marketing applications/submissions and certain additional submissions to such applications for human drugs, biological products, and devices. It will be used by the Federal Government to confirm that sponsors/applicants/submitters have complied with the certification provisions in the law with regard to any applicable clinical trials referenced in the investigational or marketing applications/submissions with which the certification is submitted. The information also will provide a means of correlating the clinical trials contained in the applications/submissions to FDA with the information contained in the ClinicalTrials.gov data bank.

3. Use of Improved Information Technology and Burden Reduction

The Agency is not yet equipped to receive all investigational and marketing applications/submissions electronically; therefore, this reporting requirement will not mandate the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology for this certification form. However, the form is designed to be able to be electronically completed and, if desired, electronically submitted by the applicant/submitter. Because the form will accompany an investigational or marketing application/submission, the form will be submitted in the same manner as the application/submission that it accompanies. There are Center-wide efforts to moving to e-submission of applications, and we have worked very closely with those efforts and have updated the certification form so that it allows for the use of additional continuation pages, drop down menus, and electronic signatures. We believe these efforts increase the usability of the certification form and make submission easier for the end user. FDA estimates that 70% of respondents will use electronic means to fulfill the agency's information collection. FDA has revised the form to reference the new regulations at 42 CFR part 11.

FDA has revised the instructions for this information collection so as to require that users provide information only related to clinical trials for which the sponsor is the "responsible party" of the applicable clinical trial being provided in the application/submission (as these terms are defined in 42 U.S.C. §282(j), section 402(j) of the Public Health Service Act and it implementing regulations at 42 CFR part 11). We believe that this will decrease burden to the extent that sponsors are not submitting information on the form related to clinical trials for which they did not conduct.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed information collection is not otherwise available to FDA. Such information is only available from the individuals or entities responsible for submitting such information to the ClinicalTrials.gov data bank, or from the product applicants/submitters

and product application/submission holders referenced in their applications/submissions. The information will vary for each drug, biological product, or device application/ submission. Only the submitter of the medical product application/submission has the ability to certify that the requirements of 42 U.S.C. § 282(j), section 402(j) PHS Act have been met or are not applicable to the clinical trials being referenced in the application/ submission being submitted to FDA.

FDA is the only Agency that reviews, approves, and/or clears medical product applications/submissions (including investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs) biologics license applications (BLAs), premarket notification (510(k)s), humanitarian device exemptions (HDEs), and premarket approval (PMAs)). We, thus, have not undertaken literature searches or contacted staff of other organizations with respect to this information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that the number of small businesses required to respond to this information collection is 7,045. This estimate was derived from 2015 U.S. census data for the number of small businesses identified under North American Industry Classification System (NAICS) # 325412 Pharmaceutical Preparation Manufacturing, NAICS # 325413 In-Vitro Diagnostic Substance Manufacturing, NAICS # 325414 Biological Product (except Diagnostic) Manufacturing, NAICS # 334510 Electromedical and Electrotherapeutic Apparatus Manufacturing, NAICS # 339112 Surgical and Medical Instrument Manufacturing, NAICS # 339113 Surgical Appliance and Supplies Manufacturing, NAICS # 339114 Dental Equipment and Supplies Manufacturing, and NAICS # 339115 Ophthalmic Goods Manufacturing.

The reporting requirements of this statute are those mandated by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act, as enacted by Title VIII, FDAAA. They will not be a burden to small businesses. However, FDA also aids small businesses in dealing with any requirements through the Office of Small Manufacturers Assistance and through the scientific and administrative staffs within the agency.

6. Consequences of Collecting the Information Less Frequently

The information is collected if a sponsor/applicant/submitter submits certain applications or reports to FDA under sections 505, 510(k), 515, or 520(m) of the FD&C Act or under section 351 of the PHS Act. If the collection is not conducted, or is conducted less frequently, the sponsor/applicant/submitter will not be in compliance with 42 U.S.C. 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act. In order to lessen the burden, we issued our January 2009 Guidance which clarified which applications/submissions required certification; this guidance excluded annual reports and labeling supplements which reduces the burden. This guidance was revised in June 2017 to reference the requirements of the new regulations at 42 CFR part 11. These changes are reflected in the table provided.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER on 09/22/2017 (82 FR 44417). There were no comments were received.

9. Explanation of Any Payment or Gift to Respondents

   No gifts or payments are to be offered in regard to this information collection.

10. Assurance of Confidentiality Provided to Respondents

    All information received by FDA is subject to the confidentiality and privacy provisions in the Freedom of Information Act (5 U.S.C. § 552), the Privacy Act (5 U.S.C. § 552a), and the agency's regulations about public information (21 CFR Part 20).

11. Justification for Sensitive Questions

    There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

    The information required under 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act, will be submitted with applications/submissions currently submitted to FDA under 21 CFR part 312 and 314 (human drugs) approved under OMB control numbers 0910-0014 and 0910-0001, respectively, 21 CFR part 312 and 601 (biological products) approved under OMB control numbers 0910-0014 and 0910-0338 and 21 CFR parts 807 and 814 (devices) approved under OMB control numbers 0910-0120 and 0910-0231, respectively.

    Table 1 below provides an estimate of the annual reporting burden for the submission of information from calendar year 2013 to satisfy the requirements of 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act.

Table 1 – Estimated Annual Reporting Burden

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	Total hours
CDER						
New Applications (IND)	1,669		1	1,669	0.25 (15 minutes)	417
Clinical Protocol Amendments (IND)	15,285		1	15,285	0.25 (15 minutes)	3,821
New Marketing Applications/Resubmissions (NDA/BLA)		198	1	198	0.75 (45 minutes)	149
Clinical Amendments to Marketing Applications		1,067	1	1,067	0.75 (45 minutes)	800
Efficacy Supplements/Resubmissions		219	1	219	0.75 (45 minutes)	164
CBER						
New Applications (IND)	381		1	381	0.25 (15 minutes)	95
Clinical Protocol Amendments (IND)	456		1	456	0.25 (15 minutes)	114
New Marketing Applications/Resubmissions (NDA/BLA)		54	1	54	0.75 (45 minutes)	41
Clinical Amendments to Marketing Applications		0	1	0	0.75 (45 minutes)	0
Efficacy Supplements/Resubmissions (BLA Only)		34	1	34	0.75 (45 minutes)	26
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data)		330	1	330	0.75 (45 minutes)	247
OGD						
Original Applications		1,036	1	1,036	0.75 (45 minutes)	777
BE Supplements/Amendments		698	1	698	0.75 (45 minutes)	524
Total						7,175

We believe the estimate of 7,175 hours per year accurately reflects the burden. We recognize that some 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. From our experience with current submissions, individual and entities (i.e. industry) have made completion and submission of the certification form part of their standard practice (i.e. part of their SOPs, retain electronic copies of submissions and simply update NCT numbers on subsequent forms). In addition, we have participated in numerous conferences on the requirements and the form and have received positive feedback about the implementation of this activity.

We do not believe there is a new recordkeeping burden associated with the submission of this certification form. Current recordkeeping levels should be sufficient to complete and submit the certification form.

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by regulatory affairs professionals. We have estimated the hourly wage rate for regulatory affairs professionals as $93.58. The estimated wage rate of $46.79 for a Regulatory Affairs Professional was derived from an average of the annual wage rates listed in several sources including Salary.com, PayScale.com.com, Indeed.com, SimplyHired.com and Glassdoor.com. The hourly wage rate assumes a 40-hour work week. This estimated wage rate was then multiplied by a factor of 2 to account for benefits and overhead.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	7,175	$93.58	$671,436

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no other capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal Government for this information is not able to be specifically identified. The form is required to accompany other applications and submissions and is submitted as part of the entire package of documents.

15. Explanation for Program Changes or Adjustments

The increase in burden reflects a change in the overall number of research and marketing applications/submissions received by FDA since the previous estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collection requirements will not be published, tabulated, or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exceptions are requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.