United States Food and Drug Administration

Certification to Accompany Drug, Biological Product, and Device Applications/Submissions

OMB Control No. 0910-0616

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA, us or we) in its administration and enforcement of requirements related to the registration and reporting of certain clinical trial information. 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 certain clinical trials and information on the results of these clinical trials. The provisions include responsibilities for the 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 requests extension of OMB approval for form FDA 3674 and guidance document "Form FDA 3674 - Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions," (https://www.fda.gov/media/105405/download) under OMB control number 0910-0616.

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. The information is used by FDA 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 provides 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 the certification required by section 402(j)(5)(B) of the PHS Act. However, FDA developed Form FDA 3674 to assist respondents with submitting this certification to the Agency. This 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 80% of respondents will use electronic means to fulfill the agency's information collection.

4. Efforts to Identify Duplication and Use of Similar Information

This information 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)).

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 6,888. This estimate was derived from 2017 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.

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 May 14, 2020 (85 FR 28955). There were no comments received on this information collection.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3674 (Certification of Compliance) is name, title, address, city, state, zip/postal code, country, telephone number, and fax number. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

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 (expires March 31, 2022) and 0910-0001 (expires March 31, 2021), respectively, 21 CFR part 312 and 601 (biological products) approved under OMB control numbers 0910-0014 and 0910-0338 (expires February 28, 2023) and 21 CFR parts 807 and 814 (devices) approved under OMB control numbers 0910-0120 (expires June 30, 2023) and 0910-0231 (expires March 31, 2023), respectively.

Table 1 below provides an estimate of the annual reporting burden for the submission of information from calendar year 2019 to satisfy the requirements of 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act.

FDA Center Activity	Number of respondents (investigational applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER New Applications (IND)	1,661	1	1,661	0.25 (15 minutes)	415
CDER Clinical Protocol Amendments (IND)	11,328	1	11,328	0.25 (15 minutes)	2,832
CDER New Marketing Applications/Resubmissions (NDA/BLA)	220	1	220	0.75 (45 minutes)	165
CDER Clinical Amendments to Marketing Applications	701	1	701	0.75 (45 minutes)	526
CDER Efficacy Supplements/Resubmissions	257	1	257	0.75 (45 minutes)	193
CDER Abbreviated New Drug Applications (ANDA) - Original Applications	892	1	892	0.75 (45 minutes)	669
CDER ANDA Bioequivalence Supplements/ Amendments	765	1	765	0.75 (45 minutes)	573
CBER New Applications (IND)	639	1	639	0.25 (15 minutes)	160
CBER Clinical Protocol Amendments (IND)	581	1	581	0.25 (15 minutes)	145
CBER New Marketing Applications/Resubmissions (NDA/BLA/PMA)	32	1	32	0.75 (45 minutes)	24
CBER Clinical Amendments to Marketing Applications	1	1	1	0.75 (45 minutes)	1
CBER Efficacy Supplements/Resubmissions (BLA Only)	38	1	38	0.75 (45 minutes)	28
CBER Abbreviated New Drug Applications (ANDA) - Original Applications	1	1	1	0.75 (45 minutes)	1
CBER ANDA Bioequivalence Supplements/ Amendments	1	1	1	0.75 (45 minutes)	1
CDRH New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data)	324	1	324	0.75 (45 minutes)	243
Total					5,976

We believe the estimate of 5,976 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 of the form and have received positive feedback about the implementation of this activity.

For CBER's clinical amendments to marketing applications and ANDA bioequivalence supplements/amendments we do not expect any submissions. However, for PRA purposes we estimate one burden hour as a placeholder should these line items increase in future submissions.

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 $107.28. The estimated wage rate of $53.64 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	5,976	$107.28	$641,105

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 adjustment (decrease) in burden is due to a decrease in the overall number of research and marketing applications/submissions received by FDA since the previous submission.

Additionally, the number of ICs in ROCIS decreased from seven to one.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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.