Supporting Statement for
CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE APPLICATIONS/SUBMISSIONS

OMB No. 0910-xxxx

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 new 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, including expanded information on clinical trials and information on the results of clinical trials. The provisions include new 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 new 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.

Title VIII, FDAAA, is attached in its entirety.

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.

2. Purpose and Use of the Information Collection

The new 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 for human drugs, biological products, and devices. It will be used to confirm that sponsors/applicants/submitters have complied with the certification provisions in the new 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. 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.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed information collection is not already available to FDA. Such information is only available submitted to the data bank 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), 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

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 any application or report 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

This collection fully complies with 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), on December 12, 2007 (72 FR 70599), an emergency notice for public comment was published in the *Federal Register.*

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

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 May 31, 2009) and 0910-0001 (expires May 31, 2008), respectively, 21 CFR part 312 and 601 (biological products) approved under OMB control numbers 0910-0014 and 0910-0338 (expires June 30, 2010) and 21 CFR parts 807 and 814 (devices) approved under OMB control numbers 0910-0120 (expires August 31, 2010) and 0910-0231 (expires November 30, 2010), respectively .

Table 1 below provides an estimate of the annual reporting burden for the submission of information 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 [1]						
	Investigational Applications (IND)	Marketing Applications (NDA, BLA, PMA, HDE, 510(k))	Number of Responses per Respondent	Total Annual Number of Responses	Hours per Response	Total Hours
CDER (new application)	1,837	----	1	1,837	.25	459
CBER (new application)	227	----	1	227	.25	57
CDER (amendment)	24,581	----	1	24,581	.25	6,145
CBER (amendment)	6,689	----	1	6,689	.25	1,672
CDER/CBER (new application/ resubmission)	----	214	1	214	.75	161
CDRH (new application)	----	3,695	1	3,695	.75	2,771
CDER/CBER (amendment)	----	8,535	1	8,535	.75	6,401
CDRH (amendment)	----	2,267	1	2,267	.75	1,700
CDER/CBER (efficacy supplement/resubmission	----	259	1	259	.75	194
CDER/CBER (manufacturing supplement)	----	2,500	1	2,500	.75	1,875
CDER/CBER (labeling supplement)	----	1,273	1	1,273	.75	955
CDRH (supplement)	----	2,705		2,705	.75	2,029
Total						24,420

[1] There are no capital costs associated with this collection of information.

We believe the estimate, 24,420 hours per year accurately reflects the burden. We recognize that individuals or entities less familiar with FDA forms and the Clinical Trials Data Bank may require greater than 15 and 45 minutes (depending on the type of application/submission) per response.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

We believe that the collection of information will not result in a cost burden beyond the hours burden to respondents cited above.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal Government for this information is unknown at this time.

15. Explanation for Program Changes or Adjustments

This is a new collection of information and is necessary to satisfy the statutory requirement identified in section A1 of this document.

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 exemption is requested.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

No exceptions are requested.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.