SUPPORTING STATEMENT for
Fast-track Drug Development Programs-
Designation, Development, and Application review
0910-0389

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting an extension of OMB approval of the information collection provisions contained in a document entitled "Guidance for Industry: Fast-track Drug Development Programs - Designation, Development, and Application Review." The information collection provisions are as follows:

Request for fast-track designation (Reporting)	All manufacturers of drug and biological drug products seeking to have a product designated as one in a fast-track drug development program would submit a request for fast-track designation as an amendment to an IND or as a supplement to an application.
Pre-meeting Packages (Reporting)	After the agency makes a fast-track designation a sponsor or applicant may submit a pre-meeting package which may include additional information supporting a request to participate in certain fast-track programs.

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) (Tab B) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356) (Tab C). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under section 112(b), FDA issued guidance to industry on fast-track policies and procedures outlined in section 506 of the act. The guidance discusses collections of information that are specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving collection of information: (1) Fast-track designation requests, (2) pre-meeting packages, and (3) requests to submit portions of an application. Of these, fast-track designation requests and pre-meeting packages, in support of receiving a fast-track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation.

Under section 506(a)(1) of the act, an applicant who seeks fast-track designation is required to submit a request to the agency showing that the product: (1) Is intended for a serious or life-threatening condition; and (2) the product has the potential to address an unmet medical need. Mostly, the agency expects that information to support a designation request will have been gathered under existing provisions of the act, the PHS Act, or the implementing regulations.

After the agency makes a fast-track designation, a sponsor or applicant may submit a pre-meeting package, which may include additional information supporting a request to participate in certain fast-track programs. The pre-meeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast-track designation, the agency expects that most sponsors or applicants will have already gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations.

Under section 506(c) of the act, a sponsor must submit sufficient clinical data for the agency to determine, after preliminary evaluation, that a fast-track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that is not required under section 506(c) or any other provision of the act. All forms referred to in the guidance have valid OMB control numbers that include: FDA Form 1571 (OMB Control No. 0910-0014); FDA Form 356h (OMB Control No. 0910-0338); and FDA Form 3397 (OMB Control No. 0910-0297).

2. How, By Whom, Purpose of Collection

FDA uses the information to determine whether a particular drug or biological product should be designated as a drug in a fast-track drug development program and whether a drug or biological product so designated continues to meet the criteria for fast-track designation.

3. Consideration Given to Information Technology

FDA has issued the following guidance documents, among others, to explain the process for submitting information to the agency in electronic format:

- "Providing Regulatory Submissions in Electronic Format -- NDAs." This guidance provides information on how to submit a complete archival copy of an NDA in electronic format and applies to the submission of original NDAs as well as to the submission of supplements and amendments to NDAs. Among other things, the guidance provides recommendations on how to submit "labeling text" in electronic format. "Labeling text" is the term used in the guidance to mean labeling required under 21 CFR 201.100(d)(3), including all text, tables, and figures required by or included under those sections. The guidance recommends that labeling text be submitted as a PDF file.

- "Providing Regulatory Submissions in Electronic Format--General Considerations." This guidance includes a description of the types of electronic file formats that we are able to accept to process, review, and archive electronic regulatory submissions. The guidance also states that documents submitted in electronic format should, among other things, enable you to: (1) Easily view a clear and legible copy of the information; (2) print each document page by page, as it would have been provided in paper, while maintaining fonts, special orientations,

table formats, and page numbers; and (3) copy text and images electronically into common word processing documents. To achieve these and other goals, the guidance recommends that all electronic regulatory submissions be submitted as PDF files.

- "Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format." This guidance provides information to assist applicants in submitting documents in electronic format for review and archive purposes as part of a BLA, product license application (PLA), or establishment license application (ELA).

- "Providing Regulatory Submissions in Electronic Format-—Prescription Drug Advertising and Promotional Labeling." This draft guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products.

- "Providing Regulatory Submissions in Electronic Format—ANDAs." This guidance discusses issues related to the electronic submission of ANDAs and supplements and amendments to those applications.

- "Providing Regulatory Submissions in Electronic Format-—Annual reports for NDAs and ANDAs." This draft guidance discusses issues related to the electronic submission of annual reports for NDAs and ANDAs.

- "Providing Regulatory Submissions in Electronic Format-—Postmarketing Periodic Adverse Drug Experience Reports." This guidance discusses general issues related to the electronic submission of postmarketing periodic adverse drug experience reports for NDAs, ANDAs, and BLAs.

- "Providing Regulatory Submissions in Electronic Format-—Human Pharmaceutical Product Applications and Related Submissions." This draft guidance discusses issues related to the electronic submission of ANDAs, BLAs, INDs, NDAs, master files, advertising material, and promotional labeling.

- "Providing Regulatory Submissions in Electronic Format-—General Considerations." This draft guidance discusses general issues common to all types of electronic regulatory submissions.

- "Providing Regulatory Submissions in Electronic Format-—Content of Labeling." This draft guidance discusses issues related to the submission of the content of labeling in electronic format for marketing applications for human drug and biological products.

These guidance documents and others are available at FDA's web site http://www.fda.gov/cder/guidance/index.htm.

4. Identification of Information

FDA is the only agency that requires the filing of a request for designation as a product in a fast-track drug development program. No other component of FDA or other government agencies requires similar information or data to be filed. This information is not available from any other source.

5. Small Businesses

While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. The CBER, Office of Communications, Training, and Manufacturers Assistance and the CDER, Office of Training and Communications provide assistance to small businesses subject to FDA's regulatory requirements.

6. Less Frequent Information Collection

Sponsors and applicants may request that FDA designate a product as one in a fast-track drug development program. Once such designation is received, a sponsor or applicant may submit a pre-meeting package, which may include additional information supporting a request to participate in certain fast-track programs. Less frequent information collections would not provide the necessary information needed by FDA to make the appropriate determination. There are no technical obstacles to reducing the burden.

7. Information Collection Circumstances

An applicant may be required to submit to FDA proprietary trade secrets or other confidential information when submitting a drug or biological product license application or supplement. FDA has instituted security measures to protect confidential information received from manufacturers and will, to the extent permitted by law, protect this information.

8. Consultation with Persons Outside FDA

In accordance with 5 CFR 1320.8 (d), FDA published a notice in the Federal Register of May 6, 2008, (73 FR 25016), providing for a 60-day comment period on the information collection. FDA received no comments pertaining to the information collection provisions.

9. Payment or Gift

No payment or gift was provided to respondents.

10. Confidentiality Provisions

The confidentiality of information received by FDA under the guidance would be consistent with the Freedom of Information Act and the FDA's regulations under 21 CFR Part 20. Manufacturers seeking to market a drug or biological product in interstate commerce may be required to include proprietary or trade information in an application submitted for FDA approval. However, such proprietary or trade information is deleted from any information released by FDA under the Freedom of Information Act and FDA regulations.

11. Privacy

Questions of a sensitive nature are not applicable to this information collection.

12. Burden of Information Collection

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the act. The agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research is approximately 64, and the number of requests received is approximately 77 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request.

Not all requests for fast track designation may meet the statutory standard. Of the requests for fast track designation made per year, the agency granted 60 from 54 respondents, and for each of these granted requests a pre-meeting package was submitted to the agency. FDA estimates that the preparation hours is approximately 100 hours per pre-meeting package.

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

Table 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request	64	1.28	77	60	4,620
Premeeting Packages	54	1.11	60	100	6,000
Total					**10,620**

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

13. Costs to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	10,620	$50.00	$531,000.00

The estimated cost to respondents is $531,000.00. The cost estimate is based on the hourly pay rate of $50.00 for a regulatory affairs specialist who is responsible for preparing the submissions. The salary estimates include benefits but no overhead costs.

14. Costs to Federal Government

The cost of the review of New Drug Applications, Biologics License Applications, and supplemental applications under existing regulations is not expected to be increased by the procedures for fast-track designation and application review described in the guidance document.

15. Reason for Change

There is no change in burden.

16. Statistical Reporting

There are no tabulated results to publish for this information collection.

17. Display of OMB Approval Date

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

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

There are no exceptions to Section 19 of OMB Form 83-I.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request
Food and Drug Administration

2. OMB control number
a. 0910-0389 b. [ ] None

3. Type of Information Collection (check one)
a. [ ] New Collection
b. [ ] Revision of a currently approved collection
c. [x] Extension of a currently approved collection
d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired
e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired
f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (check one)
a. [x] Regular Submission
b. [ ] Emergency - Approval requested by MM/DD/YYYY
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date
a. [x] Three years from approval date b. [ ]Other Specify MM/DD/YYYY

7. Title
Guidance for Industry: Fast Track Drug development Programs – Designation, Development, and Application Review

8. Agency form number(s) *(if applicable)*
N/A

9. Keywords
Drug, Biologics, Reporting Requirements

10. Abstract This guidance is intended to articulate how FDA plans to work with sponsors to achieve expedited development and rapid review of new drugs or biological products intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the condition. The guidance also meets the requirements of section 112 of the Food and Drug Administration Modernization Act of 1997, which amended the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351 et seq.) by adding new section 506 ("Fast Track Products").

11. Affected public (Mark primary with "P" and all others that apply with "x")
a. _ Individuals or households
b. P Business or other for-profit
c. _ Not-for-profit institutions
d. _ Farms
e. _ Federal Government
f. _ State, Local or Tribal Govt

12. Obligation to respond (*check one*)
a. [ ] Voluntary
b. [x] Required to obtain or retain benefits
c. [ ] Mandatory

13. Annual recordkeeping and reporting burden

a. Number of Respondents	118
b. Total annual responses	10,620
1. Percentage of these responses collected electronically	
c. Total annual hours requested	10,620
d. Current OMB inventory	
e. Difference	
f. Explanation of difference	
1. Program change	
2. Adjustment	

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs	**0**
b. Total annual costs (O&M)	**0**
c. Total annualized cost requested	**0**
d. Current OMB inventory	**0**
e. Difference	**0**
f. Explanation of difference	
1. Program change	_____
2. Adjustment	x

15. Purpose of information collection *(Mark primary with "P" and all others that apply with "X")*
a. P Application for benefits
b. _Program evaluation
c. _General purpose statistics
d. _Audit
e. _Program planning or Management
f. x Research
g. _Regulatory or compliance

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [ ] Recordkeeping b. [ ] Third party disclosure
c. [x] Reporting
1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually
5. [ ] Biennially 8. [ ] Other (describe)

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)
Name:

	Phone:

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