

U.S. Food and Drug Administration

SUPPORTING STATEMENT FOR

Guidance for Industry: Fast Track Drug Development Programs Designation, Development, and Application Review

OMB No. 0910-0389

SECTION A - Justification

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting OMB emergency approval of the information collection requirements contained in a "Guidance for Industry" document entitled "Fast Track Drug Development Programs Designation, Development, and Application Review" (Attachment A). The information collection requirements for which approval is requested are as follows:

Request for fast track designation (Reporting) reviewed

All manufacturers of drug and biological drug products seeking to have a product designated and 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.

Additional reports (Reporting)

Additional reports would only be required after designation as a drug in a fast track drug development program was received. Submission of several of the reports would depend on which fast track programs benefits a sponsor or applicant would seek to access.

The guidance is designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the condition. The guidance also describes how a product may be designated as one in a fast track drug development program and the benefits that may be accessed by sponsors or applicants under FDA's fast track program. Under section 506(a)(1) of the act, an applicant who seeks fast track designation is required to submit a request to the agency. In order to receive a fast track designation, the requestor must establish that the product meets the statutory standard for designation, i.e., that: (1) The product is intended for a serious or life-threatening condition; and (2) the product has the potential to address an unmet medical need. In most cases, the agency expects that information to support a designation request will have been gathered pursuant to existing provisions of the act, the PHS Act, or the implementing regulation and such information, if already submitted to the agency, may be summarized in a fast track designation request. The guidance also recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation, which may include, clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous but should be sufficient

to permit a reviewer to assess whether the criteria for fast track designation have been met. After the Agency makes a fast track designation, a sponsor or applicant may submit a pre-meeting package, which may include additional information to support a request to participate in certain fast track programs. As with the request for fast track designation, the agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

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 which include: FDA Form 1571 (OMB Clearance No. 0910-0104, expires December 31, 1999); FDA Form 356h (OMB Clearance No. 0910-0338, expires April 30, 2000); and FDA Form 3397 (OMB Clearance No. 0910-0297, expires April 30, 2001).

FDA is issuing the guidance to describe how it plans to work together with sponsors and applicants to achieve expedited development and rapid review of new therapies that will advance the care of patients with serious life-threatening illnesses. The guidance is also intended to meet the requirements of Section 112 of the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115) (Attachment B), which amends the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 351 et seq.) by adding new section 506 (?Fast Track Products?) (Attachment C). Section 506 directs FDA to facilitate the development and expedite the review of drug products that are intended to treat unmet medical needs and directs FDA to issue guidance describing its policies and procedures pertaining to such products.

2. How, by Whom, and for what Purpose Information Used

FDA would use 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 drug so designated continues to meet the criteria for fast track designation.

3. Consideration Given to Information Technology

One of FDA's continuing objectives is to improve the speed and quality of its review and approval programs. In order to reach a decision to approve an application the agency must evaluate all information and data provided by applicants that support the safety, purity, potency, and efficacy of the proposed product. To make the review process more efficient for industry and FDA, CBER and CDER are utilizing electronic information systems technology. CBER accepts "Computer Assisted Product License Applications" (CAPLA) and CDER encourages sponsors to use "Computer Assisted New Drug Applications" (CANDA). FDA believes the increased use of computer assisted application will enhance the timeliness, effectiveness, and efficiency of the review process and reduce burdensome, nonessential hard-copy handling and storage. FDA is not aware of any other improved technology to reduce the burden.

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 the agency or other government agencies requires similar information or data to be filed. This information is not available from any

other source.

5. **Small Businesses**

FDA believes that its duty requires the equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research, Office of Communications, Training, and Manufacturers Assistance provides 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 only need submit information as necessary to access other benefits of fast track designation. 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. **Special Collection Circumstances**

An applicant may be required to submit to FDA proprietary trade secrets or other confidential information when submitting a 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. **Outside Consultations**

In accordance with 5 CFR 1320.8 (d) FDA is publishing a notice in the Federal Register providing a short comment period on the information collection. Comments regarding the content or format of the guidance document may be submitted to the FDA at any time. The agency will periodically review comments received and incorporate any comments as appropriate.

9. **Payments or Gift**

No payment or gift was provided to respondents.

10. **Confidentiality Provisions**

The confidentiality of information received by FDA under the proposed rule would be consistent with the Freedom of Information Act and the agency's regulations under 21 CFR Part 20. Manufacturers seeking to market a biological product in interstate commerce may be required to include proprietary or trade information in a license 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 Hours

The estimated annual burden for this information collection is 9,000 hours.

Estimated Annual Reporting Burden¹

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request	60	1	60	60	3,600
Pre-Market Packages	54	1	54	100	5,400
Total	114		114		9,000

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

The agency estimates that the aggregate annual number of respondents submitting requests for fast track designation to CBER and CDER will be approximately 60. To obtain this estimate, FDA extrapolated from the number of requests for fast track designation actually received by the CBER and CDER in a six month period since November 21, 1997, the date of enactment of the Modernization Act. Within this time period, CBER received 9 requests and CDER received 20. FDA estimates that the number of hours needed to prepare a request for fast track designation may generally range 40 and 80 hours per request, depending on the complexity of each request, and an average of 60 hours per request. Not all requests for fast track designation may meet the statutory standard. The agency estimates that approximately 90 percent of all annual requests (approximately 54 respondents) for fast track designation would be granted. Of those respondents who receive fast track designation for a product, FDA expects that all will submit a pre-meeting package and that a pre-meeting package would generally need more preparation time than needed for a designation request because the issues may be more complex and the data may need to be discussed more fully. FDA estimates that the preparation hours may generally range between 80 and 120 hours, with an average of 100 hours per package as indicated in the chart below. This estimate does not include the actual time needed to conduct studies and trials or other needed research from which the reported information is obtained.

Cost to Respondent

Activity	No. Of Hours	Cost per Hour	Total Cost
Reporting	9,000	\$38.00	\$342,000

The cost estimate is based on the hourly pay rate of \$38.00 for a regulatory affairs specialist who would be responsible for preparing the reports. The salary estimates include benefits but no overhead costs.

13. Cost to Respondents Resulting from the Collection of Information

There are no capital and start-up, and operation, maintenance and purchase costs associated with the information collection.

14. **Annualized Cost to FDA**

An estimate of the total cost to the Federal Government associated with the review of New Drug Applications, Biological License Applications (Product License Applications and Establishment License Applications), and supplemental applications is provided in the table below. The estimate is based on full-time equivalents (FTEs) associated with the review of applications and supplements to applications and the average annual salaries for CBER and CDER reviewers. The cost estimate for the review of information submitted under existing regulations is \$34,109, 598.00, which is not expected to be increased by the procedures for fast track designation and application review described in the guidance document.

The amount of time and expense incurred by the government is due to the review of all material submitted with an application. This information is essential to determine the safety and effectiveness of products as required by FDA's mission to protect the public health. This information may include clinical data, safety updates, samples submitted for evaluation by the agency, case report tabulations, case report forms, and patient information.

Applications¹	Number of FTEs	Average Annual Reviewer Salary	Total Cost
NDA ²	327	\$70,834.00	\$23,162,718.00
ELA ³ and PLA ⁴	168	\$65,160.00	\$10,946,880.00
Total Cost to Government			\$34,109, 598.00

¹ Includes original applications and supplements to approved applications.

² New Drug Application

³ Establishment License Application

⁴ Product License Application

15. **Reason for Change**

There is no change in burden as this is the first submission of the "Guidance for Industry: Designation, Development, and Application Review for Products in Fast Track Drug Development Programs."

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. Exceptions to "Certification for Paperwork Reduction Act Submissions"

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

SECTION B - Collection of Information Employing Statistical Methods

The collection of data does not employ statistical methods.

[Information Collection Requests](#)

[GUIDELINES TO OBTAIN OMB APPROVAL FOR COLLECTIONS OF INFORMATION REQUIREMENTS](#)