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

0910-0389

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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.
Premeeting Packages (Reporting)	After the Agency makes a fast track designation a sponsor or applicant may submit a premeeting 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) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding Section 506 (21 U.S.C. 356). 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 FD&C Act. The guidance discusses collections of information that are specified under section 506 of the FD&C 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) premeeting packages; and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting 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 FD&C 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 FD&C Act, the PHS Act, or the implementing regulations.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package, which may include additional information supporting a request to participate in certain fast track programs. The premeeting 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 FD&C Act, the PHS Act, or implementing regulations.

Under Section 506(c) of the FD&C 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 FD&C 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. Purpose and Use of the Information 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. Use of Improved Information Technology and Burden Reduction

To improve the use of information technology in the submission of marketing applications for human drugs and related reports, FDA has developed and issued guidances for industry on electronic submissions. These guidance documents are available on FDA's Web site at: http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

4. Efforts to Identify Duplication and Use of Similar 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. Impact on Small Businesses or Other Small Entities

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 and the Center for Drug Evaluation and Research, Office of Communications provide assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

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

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

8a. Publication in the FEDERAL REGISTER

In accordance with 5 CFR 1320.8 (d), FDA published a 60-day notice for comment in the Federal Register of April 13, 2011 (76 FR 20679). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA under the guidance would be consistent with the Freedom of Information Act (FOIA) 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 FOIA and FDA regulations.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Respondents to this information collection are sponsors and applicants who seek fast track designation under Section 506 of the FD&C Act. The Agency estimates the total annual number of respondents submitting requests for fast track designation to the CBER and the CDER is approximately 97, and the number of requests received is approximately 118 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 77 from 64 respondents, and for each of these granted requests a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package.

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

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
Designation Request	97	1.22	118	60	7,080
Premeeting Packages	64	1.20	77	100	7,700
Total					14,780

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12b. Annualized Cost Burden Estimate

There are labor costs associated with preparing and submitting designation requests and premeeting packages. Assuming a loaded wage rate of

approximately $85 per hour, we estimate these costs to be approximately $1,256,300.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pharmaceutical industry average wage grade for preparing and submitting this information collection	14,780	$85.00	$1,256,300
Total			$1,256,300

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

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

14. Annualized Cost to the 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. Explanation for Program Changes or Adjustments

The adjustment in burden is the result of an increase in the number of designation requests and premeeting packages submitted over the past 3 years.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

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 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 d. _ Farms b. P Business or other for-profit e. _ Federal Government c. _ Not-for-profit institutions 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 161 b. Total annual responses 195 1. Percentage of these responses collected electronically c. Total annual hours requested 14,780 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 b. Total annual costs (O&M) c. Total annualized cost requested d. Current OMB inventory e. Difference f. Explanation of difference 1. Program change 2. Adjustment
15. Purpose of information collection *(Mark primary with "P" and all others that apply with "X")* a. P Application for benefits e. _Program planning or b. _Program evaluation Management c. _General purpose statistics f. x Research d. _Audit 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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