U.S. Food and Drug Administration
Guidance for Industry Fast Track Drug Development Programs —
Designation, Development, and Application Review

OMB Control Nos. 0910-0389 and 0910-0765

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) guidance. Under Section 506 of the Federal Food, Drug, and Cosmetic Act (FFDCA or the act)(21 U.S.C. 356), FDA is authorized 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. Accordingly, FDA has issued the guidance document entitled "*Guidance for Industry on Expedited Programs for Serious Conditions – Drugs and Biologics*," currently approved under OMB Control No. 0910-0765. The guidance provides a single resource for information on FDA policies and procedures related to expedited review programs for serious conditions and is intended to facilitate and expedite development and review of new drugs and biologics[1] to address unmet medical needs in the treatment of serious and life-threatening conditions. This guidance includes the following programs:

Fast track designation – explains that all manufacturers of drug and biological drug products seeking to have a product or indication designated for fast track drug development under section 506 of the FFDCA submit a request for fast track designation as an amendment to an investigational new drug application (IND) or as a supplement to a drug or biologic marketing application. After FDA 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. The agency expects that most sponsors or applicants will have already gathered such information to meet existing requirements for fast track designation or meetings under the FFDCA, the Public Health Service Act, or implementing regulations.

Priority Review Designation Request – explains that a sponsor may expressly request priority review of a marketing application. Under the Prescription Drug User Fee Act (PDUFA), FDA agreed to specific goals for improving the drug review time and created a two tiered system of review times – standard review and priority review. A priority review means that the time it takes FDA to review a marketing application is reduced.

Breakthrough Therapy Designation Request – describes the process for applicants to request breakthrough therapy designation. Section 506(a) of the FFDCA, as added by section 902 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 provides

[1] For this GFI, all references to new drugs or drug products include both human drugs and biological products regulated by CDER and CBER.

for the designation of a drug as a breakthrough therapy if it meets the qualifying criteria. Section 902 of FDASIA instructs FDA to take actions appropriate to expedite the development and review of a breakthrough therapy.

Accelerated Approval – describes the qualifying criteria, relevant terms and the conditions of the accelerated approval pathway. Under section 506(c) of the FFDCA, a product for a serious or life-threatening disease or condition may be granted accelerated approval if FDA determines that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) or other clinical benefit. Products granted approval under the accelerated approval pathway, require postmarketing confirmatory trials to verify and describe the anticipated effect on IMM or other clinical benefit. This approval pathway is used primarily in settings in which the disease course is long and an extended period of time is required to measure the intended benefit of treatment and there are few, if any, alternatives for treatment.

As discussed in our 60- and 30- day Federal Register notices, and because the previously separate information collection elements are now addressed in a single agency guidance, we are requesting consolidation of OMB Control No. 0910-0389 into 0910-0765. Upon OMB approval of this request, FDA will discontinue collection 0910-0389.

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

We are unaware of duplicative information collection. Respondents should note that information collection provisions related to accelerated approval of applications for drugs and biologics are currently approved under OMB Control Nos. 0910-0001 and 0338 respectively, and that while the subject guidance document references information collection found in existing agency regulations and approved under separate ICRs (e.g., OMB Control Nos. 0910-0001; 0297; and 0686), this information collection supports those recommendations found in the guidance that may pose additional burden not already covered by other collections. Those collection elements are discussed in this supporting statement more fully above and in detail throughout the guidance document, available at: https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf

5. Impact on Small Businesses or Other Small Entities

While FDA cannot apply different standards with respect to statutory requirements, we do provide 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. In addition, FDA provides guidance for small business on its website at www.fda.gov.

6. Consequences of Collecting the Information Less Frequently

Information collection is consistent with applicable statutory requirements and existing regulations, and determined by respondents who wish to submit information to FDA consistent with guidance recommendations. 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

In accordance with 5 CFR 1320.8 (d), FDA published a 60-day notice for comment in the Federal Register of November 8, 2017 (82 FR 51847). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is 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

We estimate the burden for the information collection as follows:

12a. Annualized Hour Burden Estimate

As reflected in Table 1 below, we estimate 48 applicants will prepare and submit a total of approximately 82 priority review designation submissions in accordance with recommendations found in the guidance, and that the added burden for each submission will be approximately 30 hours to develop and submit to FDA as part of the application. We further estimate 87 applicants will prepare a total of approximately 113 breakthrough therapy designation submissions in accordance with the guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit.

We also estimate that in accordance with the guidance, approximately 187 requests for fast track designation will be received from approximately 140 applicants. Of these applicants, 107 will also submit approximately 132 fast track premeeting packages. Each designation request adds 60 hours of added information collection burden to prepare and submit it as part of the review application. Premeeting packages require approximately 100 hours information collection burden per request.

Table 1-- Estimated Annual Reporting Burden[1]

Guidance for Industry: Expedited programs for serious conditions – Drugs and Biologics	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority review designation request	48	1.7	82	30	2,400
Breakthrough therapy designation request	87	1.29	113	70	7,910
Designation Requests	140	1.33	187	60	11,220
Premeeting Packages	107	1.23	132	100	13,200
TOTAL					34,730

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

12b. Annualized Cost Burden Estimate

We assume labor costs for priority review, breakthrough therapy, and fast track designation requests based on an average pharmaceutical industry loaded wage rate of $85.00 per hour for developing and submitting the requests. Multiplied by the total hour burdens estimated above, the total cost burden to respondents for these expedited programs for serious conditions is estimated as $2,952,050.

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

We estimate that costs of the information collection are absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

The information collection reflects both agency adjustments and revision. There is an adjustment of 24,420 burden hours and 321 annual responses for an overall increase. This is attributable to an increase in submissions. Also, and as discussed previously in this supporting statement and included in the burden table under ***Question 12***, we have revised the collection to consolidate burden from the two IC elements previously captured under OMB Control No. 0910-0389.

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 the certification.