Food and Drug Administration
Expedited Programs for Serious Conditions – Drugs and Biologics
Guidance for Industry (GFI)
OMB Control No. 0910-0765
Supporting Statement

## A. Justification

1. Circumstances Making the Collection of Information Necessary

The information collection supports agency guidance entitled, "*Expedited Programs for Serious Conditions – Drugs and Biologics*." The guidance discusses FDA policies and procedures intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious and life-threatening conditions, including: (1) Fast track designation including rolling review, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation.

*Priority Review Designation Request*: The guidance explains that a sponsor may expressly request priority review of an 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*: The guidance describes the process for sponsors to request breakthrough therapy designation. Section 506(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by section 902 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 provides 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.

2. Purpose and Use of the Information Collection

The information collection for the priority review designation request provides a means for sponsors to expressly request priority review of an application to shorten the amount of time for FDA review of a marketing application. The guidance describes that FDA determines whether an application qualifies for priority review for every application, however, an applicant may expressly request priority review. The information will be used by FDA to assess whether drug products meet the qualifying criteria for priority review designation.

The information collection for the breakthrough therapy designation request provides a means for sponsors to request breakthrough therapy designation to expedite drug development and review. The information will be used by FDA to assess whether drug products meet the qualifying criteria for breakthrough therapy designation.

3. Use of Improved Information Technology and Burden Reduction

Sponsors may use electronic means to submit a priority review designation request and a breakthrough therapy designation request when practicable. Approximately 95% of priority review and 80% of breakthrough therapy designation requests are submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Approximately 10% of respondents are small businesses. To assist small businesses, FDA provides industry guidance on its website and has established small business assistance contacts within a number of agency components including the Center for Drug Evaluation and Research (CDER).

6. Consequences of Collecting the Information Less Frequently

The guidance describes FDA recommendations and current thinking on whether an application qualifies for priority review. Frequency of collection is determined by the frequency with which respondents submit applications to the agency.

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 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), in the Federal Register of November 29, 2016 (81 FR 85973), a 60-day notice was published for public comment on this information collection. We received no comments that pertained to the information collection analysis.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the FD&C Act.

11. Justification for Sensitive Questions

The information collection does not include questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

We estimate the burden of the information collection as follows:

12a. Annualized Hour Burden Estimate

The guidance references agency regulations covered by related information collections: OMB Control Nos. 0910-0001, -0297, -0338, -0389, and -0686. This information collection covers those recommendations of the guidance that may pose additional burden as described below.

We estimate that approximately 48 sponsors will prepare and submit a total of approximately 80 priority review designation submissions in accordance with 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, as reflected in row 1. We further estimate that approximately 87 sponsors 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, as reflected in row 2. Finally, and although included in our previous estimate, burden for information collection on promotional materials under 21 CFR 314.550 is now included under OMB Control No. 0910-0001; *New Drug Applications*.

Table 1 – Estimated Annual Reporting Burden[1]

| Guidance on Expedited Programs | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burdens per Response | Total Hours |
|---|---|---|---|---|---|
| Priority Review Designation Request | 48 | 1.7 | 80 | 30 | 2,400 |
| Breakthrough Therapy Designation Request | 87 | 1.29 | 113 | 70 | 7,910 |
| Total | | | | | 10,310 |

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

12b. Annualized Cost Burden Estimate

The cost estimates for priority review designation requests and breakthrough therapy designation requests is based on an average pharmaceutical industry loaded wage rate of $85.00 per hour for developing and submitting the requests. Multiplied times the total hour burden estimated above, the total cost burden to respondents is $876,350.

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

FDA staff reviews priority review and breakthrough therapy designation requests to determine whether the qualifying criteria described in the guidance are met. We estimate it takes a GS-12 and a GS-15 approximately 10 hours and 81 hours cumulatively (combining individual scientific disciplines as appropriate) to complete a priority review. Thus, the estimated annual cost to the Federal government is approximately $50,137.25 for the review of priority review designation requests and $207,376.20 for the review of breakthrough therapy designation requests, for a total of $257,513.45.

15. Explanation for Program Changes or Adjustments

FDA has adjusted its estimate to reflect submissions received by the agency over the past three years. We have also removed an individual IC – IC 3; "*Promotional Materials*," as a review of the collection shows that the burden is accounted for under OMB Control No. 0910-0001; *New Drug Applications*. Overall, therefore, the collection shows a decrease of **18** responses and **9,580** hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no such plans.

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

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.