

UNITED STATES FOOD & DRUG ADMINISTRATION

Expedited Programs for Serious Conditions--Drugs and Biologics

OMB Control No. 0910-0765

SUPPORTING STATEMENT

**Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports regulations governing Food and Drug Administration (FDA) expedited programs for serious conditions. These provisions are set forth in 21 CFR part 312, subpart E ( 21 CFR part 312). The subpart E regulations are intended to speed the availability of new therapies to patients with serious conditions, especially when there are no satisfactory alternative therapies, while preserving appropriate standards for safety and effectiveness. The regulations call for earlier attention to drugs that have promise in treating such conditions, including early consultation with FDA for sponsors of such products. Respondents to the information collection are sponsors of drug or biologic product applications submitted to FDA. To assist respondents with the information collection, we developed agency guidance entitled, “*Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics*” (May 2014). The guidance describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. The guidance addresses the applicability of expedited programs to rare diseases, clarification on available therapy, and additional detail on possible flexibility in manufacturing and product quality. It also clarifies the qualifying criteria for breakthrough therapy designation and provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval.

A sponsor or applicant who seeks fast track designation is required to submit to us a request showing that the drug product: (1) is intended for a serious or life-threatening condition and (2) has the potential to address an unmet medical need. We expect that most information to support a designation request will have been gathered under existing requirements for preparing an investigational new drug (IND), new drug application (NDA), or biologics license application (BLA). If such information has already been submitted to us, the information may be summarized in the fast track designation request. A designation request should include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information 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 it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

Once FDA makes a fast track designation, a sponsor or applicant may submit a premeeting package that 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, we expect that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, an NDA, or a BLA. These may include descriptions of clinical safety and efficacy trials not conducted under an IND (e.g., foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to us, the information may be summarized in the premeeting package.

We therefore request extension of OMB approval for the information collection provisions associated with regulations in 21 CFR 312, subpart E as applicable in the Guidance for Industry on Expedited Programs for Serious Conditions--Drugs and Biologics” and discussed in this supporting statement.

## 2. Purpose and Use of the Information Collection

We use this information to determine whether a particular drug or biological product can 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 guidance for industry on electronic submissions. These guidance documents are available on our website 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

## 5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. At the same time, FDA provides assistance to small businesses in complying with statutory and regulatory requirements administered by the agency.

## 6. Consequences of Collecting the Information Less Frequently

Information collection is consistent with applicable statutory and regulatory requirements. 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), we published a 60-day notice for comment in the *Federal Register* of November 18, 2020 (85 FR 73487). Although we received one comment pertaining to scientific study, it was not responsive to the information collection topics solicited in our notice for comment under the PRA.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII) or other data of a personal nature. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity).

The PII submitted using Form 356h "Application to Market a New or Abbreviated New Drug for Human Use" includes name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. The PII submitted using Form 1571 "Investigational New Drug Application" (IND) includes name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. The PII submitted using Form 1572 "Statement of Investigator" includes name, and work email address for the primary contact at a business. Other potential PII submitted using Forms 356h, Form 1571 and Form 1572 includes identifying job title, credentials, and the country of the contact.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

The confidentiality of the information received by FDA is consistent with the Freedom of Information Act and regulations under 21 CFR Part 20. Manufacturers seeking to market a diagnostic radiopharmaceutical or a new indication for use for an approved diagnostic radiopharmaceutical may be required to reveal proprietary information or trade secrets to gain FDA approval of the product or new indication. However, such information is deleted from the application before it is released under the Freedom of Information Act and FDA regulations.

## 11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

## 12. Estimates of Annualized Burden Hours and Cost

### 12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Designation Requests	70	1.44	101	30	3,030
Breakthrough Therapy Designation Requests	119	1.31	156	70	10,920
Fast Track Designation Requests	205	1.273	261	60	15,660
RMAT Designation Requests	33	1.15	38	60	2,280
Fast Track Premeeting Packages	224	1.75	392	100	39,200
Total					71,090

1. There are no capitol, or operating and maintenance costs associated with the information collection.

Based on our review, we estimate that 70 respondents will submit 101 requests for priority review designation annually, and we assume 30 hours is needed to prepare such a request. We estimate 119 respondents will submit 156 requests for breakthrough designation annually, and we assume 70 hours is needed to prepare such a request. We estimate that 205 respondents will submit 261 requests for fast track designation requests annually, and we assume 60 hours is needed to prepare such a request. We estimate 33 respondents will submit 38 requests for RMAT designation annually, and assume that 60 hours is needed to prepare such a request. Finally, based on an average of 224 fast track designations annually, we received 392 pre-meeting package submissions and assume 100 hours is needed to prepare a pre-meeting package.

### 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. When we multiply the total burden hours estimated above, we assume a total cost to respondents for these expedited programs for serious conditions of \$6,042,650.

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

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

14. Annualized Cost to the Federal Government

Costs of the information collection to the Federal government are absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 389 responses and 35,325 hours to reflect submissions we have received.

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

We are 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.