TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Traineeship Program	1,000	1	1,000	1	1,000
Total					1,250

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00220 Filed 1–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4804]

Agency Information Collection Activities; Proposed Collection; Comment Request; Expedited Programs for Serious Conditions—Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection pertaining to ''Expedited Programs for Serious Conditions—Drugs and Biologics.''

DATES: Submit either electronic or written comments on the collection of information by March 11, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 11, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–4804 for ''Expedited Programs for Serious Conditions—Drugs and Biologics.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601

Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Expedited Programs for Serious Conditions—Drugs and Biologics

OMB Control Number 0910–0765—Extension

This information collection supports regulations governing FDA expedited programs for serious conditions. These provisions are set forth in 21 CFR part 312, subpart E and 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 is a resource for information on FDA's policies and procedures related to the following expedited programs for serious conditions: (1) fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation, and 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, provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval, and priority review.

In addition, we developed Agency guidance entitled ''Expedited Programs for Regenerative Medicine Therapies for Serious Conditions,'' (February 2019) describing the criteria for participation in the Regenerative Medicine Advanced Therapy (RMAT) program. The RMAT expedited program was approved as part of the 21st Century CURES Act, signed December 13, 2016. An RMAT product is intended to treat, modify, reverse, or cure serious or life-threatening diseases or conditions, and preliminary clinical evidence indicate that the drug has the potential to address unmet medical needs for such diseases or conditions. This is a Center Biologics Evaluation and Research (CBER) program and is included as an expedited program available for serious conditions.

For a sponsor or applicant who seeks fast track, priority, breakthrough, RMAT or accelerated approval designation review, approval is required to submit a request showing that the drug product: (1) is intended for a serious or life-threatening condition and (2) has the potential to (a) address an unmet medical need, (b) demonstrate substantial improvement over available therapy, or (c) fill an unmet need to be approved based on a surrogate endpoint. 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 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 should be sufficient to permit a reviewer to assess whether the criteria for fast track, priority, breakthrough, RMAT or accelerated approval designation have been met.

After we make an expedited programs designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain expedited 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 expedited programs designation, we expect that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, NDA, or 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.

The guidance documents are available on our website at *www.fda.gov/regulatory-information/search-fda-guidance-documents* and were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER					
Priority Review Designation Requests (Expedited Programs for Serious Conditions Guidance (EPSC) Section VIII)	81	1.53	124	30	3,720
Breakthrough Therapy Designation Requests (EPSC Section VI)	71	1.08	77	70	5,390
Fast Track Designation Requests (EPSC Section V)	235	1.18	277	60	16,620
Accelerated Approval Designation (EPSC Section VII)	26	1.27	33	100	3,300
Premeeting Packages (21 CFR 312.82)	163	1.01	165	100	16,500
CDER Subtotal			676		45,530
CBER					
Priority Review Designation Request (EPSC Section VIII)	8	1	8	30	240
Breakthrough Therapy Designation Request (EPSC Section VI)	15	1.1	17	70	1,190
Fast Track Designation Requests (EPSC Section VII)	64	1.2	77	60	4,620
RMAT Designation Requests (Regenerative Medicine Therapies for Serious Conditions Guidance (RMAT) Section III)					
Guidance p 6)	33	1.1	36	60	2,160
Premeeting Packages (RMAT Section V)	146	1.9	277	100	27,700
CBER Subtotal			415		35,910
Total			1,091		81,440

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

Based on FY 2022 receipts, we estimate that for Center for Drug Evaluation and Research (CDER) products, 81 respondents will submit 124 requests for priority review designation annually, and we assume 30 hours are needed to prepare such a request. We estimate 71 respondents will submit 77 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 235 respondents will submit 277 requests for fast-track designation requests annually, and we assume 60 hours are required to prepare such a request. We estimate 26 respondents will submit 33 accelerated approval designation requests annually and we assume 100 hours are required to prepare such a request. Finally, CDER received 165 pre-meeting package submissions from 163 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Similarly, also based on FY 2022 receipts, we estimate that for CBER products, 8 applicants will submit 8 requests for priority review designation annually, and we assume 30 hours are required to prepare such a request. We estimate 15 respondents will submit 17 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 64 respondents will submit 78 requests for fast-track designation annually, and we assume 60 hours is required to prepare such a request. We also estimate 33 respondents will submit 35 requests for RMAT designation annually and assume that 60 hours are needed to prepare each RMAT designation request. Finally, CBER received 283 pre-meeting package submissions from 146 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 143 responses and 10,350 hours to reflect actual submissions we have received. We attribute these changes to increased interest in the expedited programs, new expedited programs, and an increase in the number of submissions we received over the last few years.

Dated: January 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00217 Filed 1–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Bureau of Health Workforce Performance Data Collection, OMB No. 0915–0061—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 8, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent