Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts

OMB Control No. 0910-0746
SUPPORTING STATEMENT Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Pursuant to the requirements of the Paperwork Reduction Act (44 USC 35) and Public Law, No. 112-144, 126 Stat. 993 (also known as the Food and Drug Administration Safety and Innovation Act, or FDASIA), the Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information request that FDA committed to in Section II.B of the Prescription Drug User Fee Act **(**PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017 letter ("Commitment Letter"). In accordance with earlier sections of the Commitment Letter, FDA established a new review model for enhanced review transparency and communication for new molecular entity (NME) new drug applications (NDAs) and original biologics license applications (BLAs) for fiscal years (FYs) 2013 to 2017; this new review model is called "the Program." Section II.B of the Commitment Letter states that the Program will be assessed by an independent contractor and that the assessment will "include interviews of the sponsor."

Since 1992, FDA has reviewed and acted on NME NDAs and original BLAs in accordance with timeliness and other requirements established in PDUFA. Each 5-year reauthorization of PDUFA has incorporated additional provisions to enhance and improve the process for the review of human drugs and biological products. As part of its commitments in PDUFA V, FDA established the Program, a new review model to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the agency. The Program applies to all NME NDAs and original BLAs that are received from October 1, 2012, through September 30, 2017.

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the interim and final assessments must be conducted by an independent contractor and that they must include interviews of pharmaceutical manufacturers who submit NME NDAs and original BLAs to the Program in PDUFA V. The independent contractor for the Program assessments is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf.

In accordance with the PDUFA V Commitment Letter, FDA proposes to have ERG conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process, including any best practices or challenges experienced in the Program. ERG will not ask applicants for any confidential business information, nor will ERG ask applicants to evaluate the performance of FDA staff. Instead, interviews will focus on applicant experiences with the new review process under the Program. Some applicants might perceive their individual feedback about the new review process to be sensitive given that they might interact with FDA about other NDAs/BLAs in the future. To address these potential concerns, ERG will not share any identifying information with FDA and will include only anonymized, aggregated interview results in the interim and final assessment reports and presentations at public meetings held regarding each assessment. FDA will publish ERG's assessments (with interview results and findings) for public comment.

The independent assessments, including information from applicant interviews, will be of great interest to FDA's stakeholders, including the regulated industry, patient and consumer groups, healthcare professionals, and Congress. Equally importantly, these assessments will be critical in determining whether and how to refine Program implementation to improve the likelihood of success of the Program.

2. Purpose and Use of the Information Collection

The contractor for the independent assessment has prepared a draft protocol and script for scheduling and conducting interviews with applicants after their NDA/BLA receives a first review cycle action from FDA. The protocol ensures that ERG is aware of all applicants who are candidates for interviews and schedules and conducts post-action interviews in a timely, consistent manner using good interview practices. The script includes rating-scale questions and open-ended questions aimed at obtaining a thorough understanding of applicants' experiences and insights about the review process for their application under the Program.

To design and prepare for this information collection, FDA consulted with the contractor, ERG, which has program evaluation and interview experts on staff. Similarly, ERG consulted corporate experts outside its independent assessment project team to obtain input and feedback on this information collection.

The contractor will analyze rating-scale question responses to determine the extent to which applicants as a group believe that Program practices contribute to review process transparency, efficiency, and predictability. ERG will analyze open-ended responses to identify practices that applicants perceive as enhancing review process transparency, practices that applicants perceive as increasing the efficiency of the review process, and aspects of Program implementation that might benefit from improvement. In addition, ERG will consider how interview responses might explain or provide context for results from other parts of the independent assessment, such as metrics pertaining to pre-submission meetings, mid-cycle communications, late-cycle meetings, and other Program

elements. In this way, ERG will use interview responses to complement and supplement data on Program parameters obtained through other means. ERG will synthesize and interpret the results to develop a set of findings and recommendations for the Program to be included in interim and final assessment reports and presentations.

In turn, FDA will use the independent assessment results, findings, and recommendations to:

- Determine the success of the Program in achieving established goals.
- Determine whether and how to refine implementation of the Program during the remainder of PDUFA V.
- Demonstrate compliance with the commitment to conduct the independent assessments and publish them for public comment.
- Share information about the Program with the regulated community, the public health community, Congress, and the general public.

3. Uses of Improved Technology and Burden Reduction

ERG will not employ any web-based resources in soliciting sponsor and FDA feedback. While online surveys can be distributed quickly and easily to a large volume of respondents, they are not the best vehicle for discussing the nuances of respondent's individual experiences, insights, and reasoning. Even surveys with open-ended questions do not permit immediate follow-up exchanges to clarify or elucidate responses; any follow-up requires additional contact with respondents, increasing burden. Interviews provide the more detailed and nuanced feedback needed for this independent assessment in a way that minimizes burden.

ERG will also minimize the burden by offering to conduct interviews by telephone or videoconference if meeting in person is burdensome. Finally, the interview instrument has been designed to elicit the desired feedback in as short an interview time as possible.

4. Efforts to Identify Duplication and Use of Similar Information

No other Agency or program is interviewing sponsors of NME NDAs/original BLAs as part of the required assessments of the Program in PDUFA V. Members of FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Program Advisory Group have met to discuss/identify any similar efforts. This effort is expected by the regulated industry based on the requirements specified in the PDUFA V Commitment Letter.

5. Impact on Small Businesses or Other Small Entities

The contractor for the independent assessment will not ask small businesses or entities to travel, pay for telephone charges, or incur other unusual expenses. To avoid such expenses

and minimize burden, ERG will conduct interviews by telephone if the applicant will not be in or near Silver Spring, MD during the desired interview timeframe.

6. Consequences of Collecting the Information Less Frequently

There would be several consequences of not collecting the data as proposed. First, the requirements of the PDUFA V agreement between FDA and the regulated industry would not be met. Second, FDA would lack applicant perspectives on best practices and potential improvements for the Program to help ensure the success of the Program during PDUFA V. Third, the regulated industry, FDA's other stakeholders, and the public would lack a key piece of information about the effectiveness of the Program in achieving its stated goals. Finally, applicants would not have the opportunities they expect to share their opinions about the review process under the Program.

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

There are no special circumstances for the collection of 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 public comment in the Federal Register of December 10, 2015 (Vol. 80 FR 76699). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts for participating in this information collection.

10. Assurance of Confidentiality Provided to Respondents

While there is no express assurance of confidentiality that cannot be supported by law, the design of the data collection will allow responses to be anonymous. Interviewees will be assured of the privacy, to the extent available under law, of their responses through language placed prominently on all interview materials as well as introductory comments made by the interviewer. Interviewers will be trained on the privacy of responses and will be prepared to describe the policy in detail, provide examples, and respond to any related questions from participants. For example, the interviewer will explain that each individual's answers will be combined with those of others and presented in summary form only, and that FDA will not have access to the names of participants.

All responses that could identify specific sponsors will be kept only by the contractor, ERG, for use in analysis. Any data received by FDA will not contain personal identifiers, thus precluding individual identification. Public use data files produced at the end of the study will follow the current OMB checklist on confidentiality to ensure that they can be

distributed to the general public for analysis without restrictions and without identification of interviewees.

11. Justification for Sensitive Questions

The interview script contains no questions of a sensitive nature. Some interview questions ask applicants for frank assessments of the review process under the Program, which might be perceived as sensitive to some applicants. This information is crucial to understanding the extent to which the Program achieves its goals of improving communication and transparency in application reviews, what practices contribute to transparent review, and what practices can be refined to improve review transparency and communication. The contractor will keep private the identity of individual applicants, as well as each applicant's responses to interview questions; all interview materials will emphasize this. No individual applicant will be identified as an interviewee to FDA.

12. Estimates of Annualized Burden Hours and Costs

12a. Annual Burden Estimate

FDA estimates the total annual burden of this information collection to be 210 hours, as outlined in Table 1.

Table 1. Estimated Annual Reporting Burden

Portion of Study	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Hours
Pre-test	5	1	1.5	7.5
Interviews	135	1	1.5	202.5
Total				210.0

12b. Annualized Cost Burden Estimate

FDA estimated the annualized cost to respondents to be the burden hours estimate multiplied by the median hourly wage estimate (Source: Occupational Employment Statistics, Bureau of Labor Statistics). FDA used the median wage estimate ($90.00) for Physicians and Surgeons, All Others, Standard Occupational Code (SOC) 29-1069, because this wage falls in the middle of the range of wages for NDA/BLA managers in the pharmaceutical industry. FDA multiplied this median wage by 1.4 to capture benefits, resulting in a loaded hourly median wage rate of $126.00.

Table 2. Annualized Cost to Respondents

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
NME NDA / Original BLA Sponsors	210.0	$126.00	$26,460.00

13. Estimates Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to the Federal Government

This 5-year independent assessment of the Program encompasses several evaluation methodologies, including interviews with sponsors of NME NDAs and original BLAs under the Program. The interview effort involves development of an interview protocol and script, implementation of the interviews, and analysis of results to develop findings and recommendations about FDA's Program. The annualized cost to the Federal government is estimated to be $50,000, which is the total contractor cost of conducting the interview portion of the independent assessment project. Of the $265,000 allotted over five years to this interview process, approximately $15,000 was budgeted for interview development costs (e.g., instrument development, implementation design, etc.) and $250,000 was budgeted for interview implementation and analysis. There are no other costs to the Federal government for implementation.

15. Explanation for Program Changes or Adjustments

This is renewal of an existing data collection wherein the burden remains unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

The contractor conducting the independent assessment will present results, including interview results, in two reports:

- Assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs in PDUFA V: Interim Report

- Assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs in PDUFA V: Final Report

FDA will publish these reports, or links to the reports, in the Federal Register.

Table 3. Schedule for Project Tasks

Tasks	Schedule
Draft post-action interview protocol and script	January 25, 2013
Finalize post-action interview protocol and script	May 8, 2013
Conduct post-action interviews	Approximately 2 weeks after applications receive a first review cycle action from FDA (throughout PDUFA V)
Analyze interview information	Quarterly throughout PDUFA V
Prepare interim assessment report	February 15, 2015 (PREPARED 3-27-2015)
Prepare final assessment report	November 15, 2016

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

Not applicable. The collection instrument will display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.