UNITED STATES FOOD & DRUG ADMINISTRATION

Review Transparency and Communication in Reviews
of 351(k) Biologics License Applications in Biosimilars User Fee Act

OMB Control No. 0910-0746

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, we or us) programs, specifically, evaluation of those performance goals and procedures set forth in what is known as FDA's "*goals letter*" or "*commitment letter*" under the Prescription Drug User Fee Act (PDUFA) and, more recently, the Biosimilar User Fee Act (BsUFA). The *goals letter* is the result of agency, industry, and public input, as Congressionally mandated under the applicable statutes. Recently PDUFA was reauthorized, together with the Biosimilar User Fee Act of 2012. The documents entitled, "*PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*," and "*Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,*" represent the renewed performance goals agreed to by FDA in support of these respective programs. These documents are available at:

https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf; and
https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

To implement these performance goals, we established a review program (hereafter referred to as "*the Program*") to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products that we review. The Program goals are intended 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 extension of the Program to BsUFA II is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals.

The BsUFA II Commitment Letter specifies that an independent contractor can conduct the assessments and specifies that they include interviews of sponsors who submit 351(k) BLAs to the Program in BsUFA II. Currently, Eastern Research Group, Inc. (ERG) is the contractor for the assessments of the Program. In accordance with the PDUFA and BsUFA Commitment Letters, FDA contracted with ERG to 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 transparency and communication of reviews during the review process. ERG will anonymize and aggregate sponsor responses before inclusion in the assessments and presentation materials at public meetings, and we will publish the findings in the Federal Register.

Accordingly, we are requesting extension of OMB approval for the information collection provisions associated with the Program and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The ERG has prepared a protocol and script for scheduling and conducting interviews with applicants after their 351(k) 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 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 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 presubmission 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 BsUFA II;
- demonstrate compliance with the commitment to conduct the independent assessments
- and publish them for public comment; and
- share information about the Program with the regulated community, the public health community, Congress, and the general public.

3. Use of Improved Information 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. 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

We are unaware of duplicative information collection. Although there are many regulations applicable to drug and biologic applications submitted to the agency, this information collection provides for assessments of our Program independent of those activities and is consistent with goals articulated in the Commitment Letter.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. Respondents will not be asked to travel, or incur telephone charges or other unusual expenses.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with agency, industry, and Congressional timeframes, in accordance with the Program goals and Commitment Letter.

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

There are no special circumstances for this 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), we published a 60-day notice inviting public comment in the Federal Register of March 12, 2019 (84 FR 8877); 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

Although 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 (no responses will identify any individuals) 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.

After evaluation with our Privacy office, we have determined that the subject information collection does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA/CDER. Specifically, FDA/CDER does not intend to collect PII and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this proposed collection.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with the information collection.

12. Estimates of Annualized Burden Hours and Costs

12*a. Annualized Hour Burden Estimate*

We estimate the burden for the information collection as follows:

Table 1.--Estimated Annual Reporting Burden

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pre-test	5	1	5	1.5	7.5
Interviews	135	1	135	1.5	202.5
Total					210

We typically review 40 to 45 NME NDAs and original BLAs annually, and potentially twenty-

five (25) 351(k) BLAs per year. ERG interviews 1 to 3 sponsor representatives at a time for each application that receives a first-cycle action from FDA, up to 135 sponsor representatives per year. ERG conducts a pretest of the interview protocol with five respondents. We estimate it takes 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. Our estimate is based on our prior experience with the Program and communications with the regulated community.

12b. Annualized Cost Burden Estimate

To estimate the annualized cost to respondents, we multiplied the total number of burden hours by an hourly wage estimate of $90.00 (Source: Occupational Employment Statistics, Bureau of Labor Statistics). Using Standard Occupational Code (SOC) 29-1069, we used calculated a median figure representing a range of wages for NDA/BLA managers in the pharmaceutical industry. We also multiplied this median wage by 1.4 to capture benefits, resulting in a loaded hourly median wage rate of $126.00.

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

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

14. Annualized Cost to the Federal Government

The annualized cost to the Federal government is estimated to be $50,000, which represents the total contractor cost of conducting the interview portion of the independent assessment project. Out of a total allotment of $265,000 for a five year period, $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.

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

The ERG will present results, including interview results, in two reports:

- *Assessment of the Program for Enhanced Review Transparency and Communication for 351(k) BLAs in BsUFA II: Interim Repor*t; and

- *Assessment of the Program for Enhanced Review Transparency and Communication for 351(k) BLAs in BsUFA II: 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	October 2, 2017
Finalize post-action interview protocol and script	October 23, 2017
Conduct post-action interviews	Approximately 2 weeks after applications receive a first review cycle action from FDA (through)
Analyze interview information	Quarterly throughout BsUFA II
Prepare interim assessment report February 15, 2015	November 30, 2020
Prepare final assessment report	February 15, 2022

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

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.