Assessment of the Program for Enhanced Review Transparency and Communication for biosimilar biological products (original 351(k) BLAs) in BSUFA II

A. Background

The Biosimilar User Fee Act (BsUFA) was first enacted by Congress in 2012 and authorizes FDA to collect user fees, including fees for biosimilar biological product applications (hereafter referred to as 351(k) applications). FDA dedicates BsUFA user fees to the efficient review of 351(k) applications and to facilitate the development of safe and effective biosimilar biological products for the American public. For example, the user fees enable FDA to hire reviewers and support staff and upgrade its information technology systems. In the BsUFA commitment letter, FDA agrees to certain review performance goals, such as completing reviews of 351(k) applications and taking regulatory actions on them in predictable timeframes. The BsUFA user fees enable FDA to expedite the process for the review of 351(k) applications without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of biosimilar products prior to approval.

As directed by statute, FDA prepared recommendations for the reauthorization of BsUFA for a new five-year period by conducting negotiations with the regulated industry and holding regular consultations with public stakeholders including patient advocates, consumer advocates, and healthcare professionals. Following these discussions, related public meetings, and agency requests for public comment, FDA published proposed recommendations for BsUFA II for fiscal years 2018-2022. The proposed recommendations include an FDA commitment to implement a new review program for 351(k) applications to promote the efficiency and effectiveness of the first-cycle review process and minimize the number of review cycles necessary for approval of these complex applications.

BsUFA II Original 351(k) Review Program

FDA recognizes that increasing communication between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process. To enhance review transparency and improve communication between the FDA review team and the applicant, FDA has proposed a new review model (hereafter referred to as "the Program") for the review of all original Biologics License Applications (BLAs) submitted under section 351(k) of the Public Health Service Act ("351(k) BLAs") in BsUFA II.

The Program will allow for additional communication between FDA review teams and the applicants of biosimilar biological products in the form of BPD Type 4 (pre-351(k) application) meetings, mid-cycle communications, and late-cycle meetings. The Program also allows for FDA and the applicant to agree on a formal communication plan (FCP), which modifies communications under the Program. To accommodate this increased interaction during regulatory review and to address the need for additional time to review these complex

applications, FDA's review clock will begin after the 60-day administrative filing review period for applications reviewed under the Program.

The Program will apply to all 351(k) applications received from October 1, 2017, through September 30, 2022. The goal of the Program is to promote the efficiency and effectiveness of the first-cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality biosimilar and interchangeable biological products. The goal of the additional communication with the sponsor is to improve the quality and completeness of submissions before the applicant submits an application and to provide applicants with opportunities during the review process to clarify previous submissions and provide additional data and analyses that are readily available, potentially avoiding the need for an additional review cycle when FDA's concerns can be promptly resolved without compromising FDA's traditional high standards for approval. An efficient and effective review process that allows for timely responses to FDA questions can help ensure timely patient access to safe, effective, and high quality biosimilar and interchangeable biological products. To understand the Program's effect on the review of these applications, interim and final assessments by an independent contractor are key components of the Program. These assessments are the subject of this task order.

B. Key Objectives

The primary objective of this evaluation task order is to determine the impact of the Program on the efficiency and effectiveness of review of 351(k) applications. For an application that otherwise meets FDA's high standards for approval, an optimal review allows for resolution of all issues (e.g., negotiation of labeling, risk evaluation and mitigation strategies (REMS) and postmarketing requirements and/or commitments) that must precede the issuance of an approval action letter on or before the original BsUFA goal date. Subsequent review cycles are sometimes necessary for applications that contain outstanding deficiencies or require additional discussions between FDA and the applicant. This represents an inefficient use of resources if resolution of these issues could have been achieved prior to the first-cycle BsUFA goal date. The Program builds in specific opportunities for communication between FDA and the applicant regarding the content of a complete application prior to submission and any deficiencies identified during application review while also building in additional time during review to address any deficiencies that can be resolved prior to the first-cycle BsUFA goal date. Despite these modifications to the review process, the first review cycle alone may be unable to accommodate substantial application deficiencies, a delay in an applicant's response to an information request that could address the identified deficiencies, or any activities that contribute to review performance that are attributable to FDA. Therefore, it will be important for the program assessment to examine attributes beyond those of the Program in assessing the review performance for these applications.

Because the features of the Program occur throughout the review cycle, the assessment shall be performed while these applications are under FDA review and finalized soon after the

review is completed. This prospective analysis will examine the set of metrics described in the BsUFA II commitment letter in addition to the attributes of the applications and the review process that factored into the timing of the regulatory outcome of the application. These metrics are further described in Section C.

- Key Objectives of the Assessment

    1. Using information from FDA's databases, construct and analyze a baseline data set of 351(k) applications received prior to implementation of the Program. This set of applications shall be used to assess the impact on the key evaluation measures for applications reviewed under the Program.

    2. Using information from FDA's databases as well as other databases (e.g., database or other tracking mechanism developed by contractor) for applications reviewed under the Program, collect and analyze data on all 351(k) applications reviewed under the Program.

    3. Determine the nature of relationships among attributes of the Program and the regulatory outcome and its timing in the first review cycle.

    4. Determine the nature of relationships among other attributes of the review process and applications that are reviewed under the Program and the timing of the regulatory outcome in the first review cycle.

    5. Collect and analyze applicant and FDA review staff feedback on applications reviewed under the Program, including any best practices, key concerns, or challenges with regard to the enhanced communication and review of these applications.

C. Scope of Work

The evaluation covers 351(k) applications received by CDER and CBER and reviewed under the Program in BsUFA II.[1] This evaluation will include an analysis of review process management, communication between FDA and applicants, submission quality, and other factors that contribute to the efficiency of FDA's review process. The contractor shall draw on many sources of information, such as FDA tracking databases, documentation of FDA-sponsor interactions during the biosimilar Biological Product Development (BPD) phase, follow-up to review events, direct feedback through interviews with FDA staff and applicants and other records of review activity. The contractor shall assess the interactions between FDA and applicants by examining documents and by analyzing events in the review process as they occur or soon after occurrence. The scope of this contract will cover all aspects of data collection, analysis, evaluation, interviewing of key FDA staff and applicants, reporting, documentation,

[1] Applications received during BsUFA II that are filed over protest will not be reviewed under the Program.

and other tasks deemed necessary to conduct a thorough assessment of the impact of the Program on the review of 351(k) applications in BsUFA II. The standards for scientific review and regulatory decision-making are not the subject of this evaluation.

- Interim and Final Assessment Cohorts

The BsUFA II Commitment Letter specifies that an interim and final assessment must be conducted of the Program. The interim assessment must be published by December 31, 2020, and the final assessment must be published by June 30, 2022. Because a key measurement of the Program's success will be first-cycle review performance, FDA has determined that only applications on which the agency has taken at least a first-cycle action will be included in each evaluation. To allow time for completion of the analysis, report generation, and publication in the Federal Register, the cutoff date for inclusion in each analysis shall occur approximately four months before the publication date specified in the Commitment Letter.

Therefore, the interim assessment shall include all applications that have reached at least a first-cycle action as of August 31, 2020, as well as any applications that have received a refuse-to-file action or have been withdrawn after filing by this date. The set of applications evaluated as part of the interim assessment will likely include applications received in FY 2018 and FY 2019 by August 31, 2019.

The final assessment shall be cumulative and include all applications that have reached at least a first-cycle action as of January 15, 2022, as well as any applications that have received a refuse-to-file action or have been withdrawn after filing by this date. The set of applications evaluated as part of the final assessment will likely include applications received in FYs 2018 – 2021. To understand the expected size of the interim and final assessment cohorts, FDA estimates 12 new 351(k) applications and 5 resubmission 351(k) applications per year in FYs 2018 – 2022.

The BsUFA II Commitment Letter stipulates specific metrics and other evaluative measures to be tracked as part of the assessment of the Program (Section I.B.8). These are noted below. The interim and final assessment reports and public meeting presentations associated with each assessment shall include the contractor's analysis of the specified assessment metrics, and any other identified metrics as appropriate.

<u>Assessment of the Program</u> (Section I.B)

1. Adherence by the applicant and FDA to the current good review management principles and practices (GRMPs) guidance or the GRMPs guidance as updated in accordance with Section I.D (BsUFA II Commitment Letter), as applicable

2. Conduct of BPD Type 4 (pre-351(k) application) meeting
3. Development of and adherence to formal communication plan (if applicable)
4. Completeness and quality of the submitted application
5. Number of unsolicited amendments submitted by the applicant
6. Timing and adequacy of Day 74 letters
7. Conduct of the mid-cycle communication
8. Any discipline review letter letters issued
9. Late-cycle meeting background package
10. Conduct of the late-cycle meeting
11. Conduct of post-advisory committee meeting
12. Timing of inspection completion
13. Time to approval
14. Percentage of applications that are approved during the first review cycle
15. Percentage of application reviews that are extended due to a major amendment
16. Number of review cycles for applications that are ultimately approved
17. Time to resubmission for applications that receive a complete response in the first review cycle

This assessment will also include a de-identified analysis of:

- Issues typically discussed during the mid-cycle communication and the late-cycle meeting
- Ability of the additional FDA-applicant communications to (a) achieve resolution of these issues during the remainder of the review clock, or (b) allow the applicant to better prepare for a resubmission of the application.

D. Key Tasks

1. The contractor shall participate in a project kick-off meeting to review the task order, including the project timeline, scope, and schedule of deliverables. At this meeting, the contractor shall present its proposed overall approach and workplan to FDA. The contractor shall revise the proposed approach based on feedback from FDA.

2. The contractor shall participate in an orientation period to become familiar with the details of FDA's review process, GRMPs, and the implementation details of the Program.

3. The majority of the metrics specified in the commitment letter and in Section C of this document shall be tracked using FDA's corporate databases. For any specified or other appropriate identified measures that cannot be tracked and evaluated using these databases, the contractor shall develop a tracking tool (e.g., database) for capturing and analyzing this information as part of the assessment.

    a. In some cases, the contractor may refer to existing documents as a guide for these additional potential measures. For example, Section I.D of the commitment letter refers to adherence by the applicant and FDA to the GRMP guidance.

    b. In other cases, the contractor shall refer to the regulatory history of the product under review as an aid in assessing certain measures related to the Program. For example, in evaluating the completeness and thoroughness of submitted applications, an understanding of prior FDA-sponsor interactions (e.g., through the contractor's review of minutes of milestone development meetings) that occurred during the BPD phase will be important. The contractor shall acquire this understanding through review of minutes of milestone development meetings and any prior agreements reached between FDA and the sponsor or advice provided by FDA during drug development (e.g., expectations of submission of certain data to support the application).

    c. Following the interim assessment and implementation of any recommended modifications to the Program, the contractor shall revise the tracking tool developed for the interim assessment.

4. The contractor shall develop a proposed approach to the evaluation of FDA-applicant interactions in BPD Type 4 (pre-351(k) application) meetings, mid-cycle communications, and late-cycle meetings, content and use of formal communication plan, quality and completeness of applicant submissions, FDA communications and inspections timing related to applications reviewed under the Program. The contractor shall present the proposed approach to FDA and subsequently revise it based on any FDA feedback.

5. The contractor shall develop a proposed approach to quantitative and qualitative analysis of all data collected on applications reviewed under the Program, including proposed evaluation methodologies for both qualitative and quantitative data. The contractor shall present the proposed approach to FDA and subsequently revise it based on any FDA feedback.

6. The contractor shall attend and observe all FDA-applicant interactions at the BPD Type 4 (pre-351(k) application) meeting, mid-cycle communication, late-cycle meeting, and post-AC meeting for each application reviewed under the Program. The contractor shall also attend and observe all FDA-applicant interactions under an FCP. If the BPD Type 4 meeting was held prior to the start of BsUFA II, the contractor shall rely on meeting minutes to assess FDA-applicant agreements and interactions. The mid-cycle communication will take place by telephone, while FDA expects that BPD Type 4 (pre-351(k) application) meetings and late-cycle meetings will generally be face-to-face meetings conducted at FDA Headquarters in White Oak, MD. The late-cycle meeting may be held by teleconference if FDA and the applicant agree. The contractor shall be physically present for all face-to-face FDA-applicant meetings and shall participate by telephone for meetings held by telephone. The length of these meetings is estimated to be 60 – 90 minutes each.

7. The contractor shall review and evaluate the quality (e.g., completeness and thoroughness) of FDA and applicant documents, including the original submission, Day 74 letter (timing and adequacy), DR letters, and the late-cycle meeting background package.

8. The contractor shall develop a guide and a data collection instrument for conducting interviews of FDA review staff and sponsors of applications reviewed under the Program. The draft guide and collection instrument shall be submitted to FDA and subsequently revised based on any FDA feedback. At a minimum, the questions in the interview guide shall be designed to elicit the following information:

    a. Effect of additional communication during review including additional interactions that occur as part of a formal communication plan

    b. Best practices in reviewing applications under the Program

    c. Key concerns about the Program

    d. Suggestions for future implementation of the Program

    e. Additional data to consider tracking and evaluating in future implementation.

9. Following regulatory action on each application reviewed under the Program, the contractor shall conduct separate interviews of FDA review team and applicants to understand each party's perspectives on the review of the application, including whether issues were or should have been identified at the BPD meetings to facilitate application

review using the interview guide developed in Key Task 8. These interviews should have particular focus on the benefits and drawbacks of additional communication under the Program, including instances when the FDA and applicant agreed to an FCP. This information shall be aggregated and anonymized prior to inclusion in the interim and final assessments and in any presentation materials at the public meetings described in Key Task 13. The information from these interviews will be used to supplement the analysis conducted on the tracked elements of the Program.

10. The contractor shall establish a baseline for the assessment by analyzing data on 351(k) applications received prior to implementation of the Program. This will encompass 351(k) applications received during FYs 2013 - 2017 (BsUFA I) that had at least a first-cycle action by December 31, 2017. This set of applications shall be used to assess the impact of the Program on key evaluation measures such as the percentage of applications approved on the first cycle, time to approval, percentage of application reviews extended due to major amendments, number of unsolicited amendments, and other appropriate Program measures. This baseline cohort will mature during BsUFA II, and the contractor shall update the baseline analysis as part of the interim and final assessments specified in Key Task 11.

11. Using quantitative and qualitative data collected from FDA's databases, the contractor-developed database, review of FDA and sponsor documents, direct observation at FDA-sponsor meetings, and interviews of FDA staff and sponsors, the contractor shall conduct the appropriate analyses to evaluate the impact of the Program on the efficiency and effectiveness of the review process. The analysis shall include events that occur between the BPD Type 4 (pre-351(k) application) meeting and first action on the application. The conduct of the analysis shall be ongoing, culminating in the interim and final assessments of the Program. The baseline analysis specified in Key Task 10 shall constitute the reference data set for the interim and final assessments. At a minimum, the analysis for both the interim and final assessments shall address the following areas:

    a. Relationships between specific tracked elements of the Program and the outcome of the first-cycle review, with a focus on the effect of additional FDA-applicant communications under the Program on the review process.

    b. Identification of elements that contribute to first-cycle approval actions versus elements that contribute to an eventual approval action after multiple cycles of review.

    c. Case study analysis of applications reviewed under the Program that leads to identification of best practices in communication and transparency during FDA-sponsor interactions and during application review.

    d. Proposed recommendations to improve to success of the Program, including recommendations to enhance the quality of FDA-applicant interactions and

communications and the quality of submitted applications to improve the efficiency and effectiveness of the review process.

e. Use of an FCP, including whether any discussion of an FCP occurred at the BPD 4 meeting, and the outcome (and associated rationale) of that discussion. The contractor shall also qualitatively assess the effect of the FCP on the efficiency of the review process. For those applications where FDA and the applicant agreed on an FCP, the contractor shall evaluate the implementation of the FCP in the review process, any modifications to the FCP during the review process, and the rationale for those changes.

Draft versions of the interim and final assessment shall be submitted to FDA and subsequently revised based on any FDA feedback. The final assessment shall also include a sub-analysis that examines the impact of any modifications to the Program implemented after the interim assessment. In this case, the reference data set shall be the applications evaluated as part of the interim assessment. The sub-analysis shall address 11a and 11b above.

12. After publication of the interim and final assessments and the close of the public comment period, the contractor shall evaluate all written comments submitted to the docket.

13. The contractor shall present the findings of the interim and final assessments at the public meetings conducted on each assessment. These presentations shall include the contractor's analysis of any comments submitted to the public docket. Draft presentation materials shall be submitted to FDA in advance of the public meetings and revised based on any FDA feedback.

14. The contractor shall brief the FDA Project Manager and the FDA Program Advisory Group (PAG) at regular intervals throughout data collection and analysis.

E. Key Deliverables

The tasks and deliverables related to the interim assessment of the Program shall be completed by March 31, 2021. Tasks and deliverables that support the final assessment shall be completed by September 30, 2022. The interview guide and data collection instrument specified in Deliverable 6 shall be modified as necessary throughout the evaluation based on accumulated Program experience. The interim and final assessments specified in Deliverables 18 and 27 shall also be submitted in Adobe Acrobat portable document format, compliant with Sec. 508 of the Rehabilitation Act suitable for posting on FDA's website. The posted versions of these assessments will only contain publicly releasable information.

In all cases where revised deliverables are expected to follow draft versions, any revisions made shall be based on accuracy in interpretation of data and delivery of a high quality final work product. Any differences of opinion between the contractor and FDA with respect to the deliverables shall be noted in the final deliverable.

Other Criteria for Acceptance of Deliverables

FDA will review contractor deliverables in accordance with specifications and requirements stated in the schedule of deliverables below and any directives issued during the life of this project. The acceptance of deliverables and satisfactory work performance required herein shall be based upon the timeliness, accuracy, and suitability of the deliverable. The specific deliverables and schedule for delivery shall be agreed upon in the project work plan.

All face-to-face meetings with the FDA PAG will take place at FDA's White Oak Campus. For status updates with the FDA Project Manager and the FDA PAG that can occur by telephone, FDA will provide the teleconference information. It is expected that the contractor will deliver all reports and presentations electronically at least three business days prior to the FDA PAG progress update meetings.

- All deliverables and associated work shall be submitted to the FDA Project Manager.
- All deliverables associated with a presentation to the FDA PAG shall be submitted three business days in advance of the meeting.
- All deliverables submitted under this task order shall be submitted in electronic format using appropriate Microsoft Office products (e.g., Office 2010 or later).
- All workbooks, calculations, and references used in developing deliverables shall be submitted with the deliverable to FDA.

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
Interim Assessment				
1	Initiate project in kick-off meeting with FDA; present proposed project approach and workplan	1	Presentation to FDA of the proposed overall approach and workplan that describes the key project milestones, project schedule and proposed staffing	1 week after initiation
2	Revise overall approach and workplan based on FDA feedback	2	Revised overall approach and workplan	2 weeks after initiation
3	Participate in an orientation Program to review process, GRMPs, and the implementation details of the Program	3	Completion of orientation Program	3 weeks after initiation

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
4	Develop proposed tracking tool to capture relevant data not tracked by FDA's databases Develop proposed approach to the evaluation of FDA-applicant interactions Develop proposed approach to the evaluation of the quality and completeness of applicant submissions and FDA communications	4	Presentation to FDA on: • Database or other proposed mechanism, including a list of proposed tracked attributes or metrics • Proposed approach to evaluation of FDA-applicant interactions in BPD Type 4 (pre-351(k) application) meetings, mid-cycle communications, and late-cycle meetings • Proposed approach to evaluation of quality and completeness of the applicants' submissions and FDA's communications related to applications reviewed under the Program	4 weeks after initiation
5	Revise tracking tool to capture relevant data not tracked by FDA's databases Revise approach to the evaluation of FDA-applicant interactions Revise approach to the evaluation of the quality and completeness of applicant submissions and FDA communications	5	Revised approach to tracking of specific attributes or metrics, evaluation of FDA-applicant interactions, and quality and completeness FDA and applicant documents related to applications reviewed under the Program	5 weeks after initiation
6	Develop proposed approach to quantitative and qualitative analysis of all data collected on applications reviewed under the Program, including proposed evaluation methodologies for both qualitative and quantitative data	6	Presentation to FDA on: Proposed approach to quantitative and qualitative analysis of all data collected on applications reviewed under the Program, including proposed evaluation methodologies for both qualitative and quantitative data	6 weeks after initiation

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
7	Revise approach to quantitative and qualitative analysis of all data collected on applications reviewed under the Program, including evaluation methodologies	7	Revised approach to quantitative and qualitative analysis of all data collected on applications reviewed under the Program, including evaluation methodologies	7 weeks after initiation
8	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018) through at least the first-cycle action for each application, report to FDA	8	Interim report and presentation to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	January 31, 2018
9	Develop draft interview guide data collection instrument for interviews of FDA staff and sponsors of applications reviewed under the Program	9	Draft written interview guide and data collection instrument	December 31, 2017
10	Revise interview guide and data collection instrument for interviews of FDA staff and sponsors of applications reviewed under the Program	10	Revised written interview guide and data collection instrument	January 15, 2018
11	Collect and analyze data on 351(k) applications received beginning on October 1, (FY 2018) through at least the first-cycle action for each application, report to FDA Collect and analyze data on a baseline set of 351(k) applications received during FYs 2013 - 2017 (BsUFA I) that had at least a first-cycle action by December 31, 2017	11	Interim report to and presentation to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate Draft analysis of baseline set of 351(k) applications received during FYs 2013 2017 (BsUFA I) that had at least a first-cycle action by December 31, 2017	May 31, 2018

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
12	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018) that had at least a first-cycle action by December 31, 2017 Revise analysis of baseline set of 351(k) applications received during FYs 2013- 2017 (BsUFA I) that had at least a first-cycle action by December 31, 2017	12	Interim report to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate Revised analysis of baseline set of 351(k) applications received during FYs 2013- 2017 (BsUFA I) that had at least a first-cycle action by December 31, 2017	September 30, 2018
13	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018) through at least the first-cycle action for each application	13	Interim report and presentation to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	March 31, 2019
14	Collect and analyze data on 351(k) applications received October 1, 2017 (FY 2018) through at least the first-cycle action for each application	14	Interim report to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	September 30, 2019
15	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018) through at least the first-cycle action for each application	15	Interim report and presentation to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	March 31, 2020
16	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018) through at least the first-cycle action for each application	16	Interim report to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	September 30, 2020

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
17	Develop draft interim assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2017 (FY 2018) and baseline 351(k) applications received during FYs 2013 - 2017 (BsUFA I) that had at least a first-cycle action by August 31, 2020	17	Presentation to PAG and submission of draft interim assessment	October 31, 2020
18	Revise interim assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2017 (FY 2018) that had at least a first-cycle action by August 31, 2020	18	Revised interim assessment	November 30, 2020
19	Develop draft presentation materials for interim assessment public meeting	19	Draft presentation materials for interim assessment public meeting	February 26, 2021
20	Revise presentation materials for interim assessment public meeting	20	Revised presentation materials for interim assessment public meeting	March 15, 2021
21	Evaluate written comments submitted to the public docket	21	Written comment analysis	April 15, 2021
22	Present findings of interim assessment and proposed recommendations for Program modification in public meeting	22	Public meeting presentation	March 31, 2021
Continuation of Evaluation for the Final Assessment				

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
23	Develop appropriate changes to tracking tool, other evaluation approaches, and quantitative and qualitative analytic approaches to accommodate any modifications to the Program resulting from the interim assessment	23	• Modified approach to tracking of specific attributes or metrics, evaluation of FDA-applicant interactions, and quality and completeness FDA and applicant documents related to applications reviewed under the Program • Modified approach to quantitative and qualitative analysis of all data collected on applications reviewed under the Program • Note: These deliverables represent modifications to the deliverables specified in Deliverables #5 and 7 to address changes made to the Program after the interim assessment	April 30, 2021
24	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018) through at least the first-cycle action for each application, report to FDA	24	Interim report and presentation to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	May 31, 2021
25	Collect and analyze data on 351(k) applications received beginning on October 1, 2017 (FY 2018)) through at least the first-cycle action for each application, report to FDA	25	Interim report to FDA PAG on findings to date for 351(k) applications reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	November 30, 2021
26	Develop draft final assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2017 (FY 2018) that had at least a first-cycle action by January 15, 2022	26	Presentation to PAG and submission of draft final assessment	January 15, 2022

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
27	Revise final assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2017 (FY 2018) that had at least a first-cycle action by February 28, 2022	27	Revised final assessment	February 15, 2022
28	Evaluate written comments submitted to the public docket	28	Written comment analysis	May 15, 2022
29	Develop draft presentation materials for final assessment public meeting	29	Draft presentation materials for final assessment public meeting	March 30, 2022
30	Revise presentation materials for final assessment public meeting	30	Revised presentation materials for final assessment public meeting	April 15, 2022
31	Present findings of final assessment and any proposed recommendations for further Program enhancement	31	Public meeting presentation	April 30, 2022
Status Updates				
32	Progress updates with the FDA Project Manager (phone)	--	--	Biweekly from project initiation
33	Progress updates with the FDA PAG (email communication)	--	--	Periodically from project initiation
34	Progress updates with the FDA PAG (face-to-face meeting)	--	--	Periodically from project initiation

F. Period of Performance

Performance of this task order shall commence on the task order execution date and shall not extend beyond May 31, 2022. The estimated period of performance is 56 months.

G. Place of Performance

The contractor will be expected to travel on-site to FDA's White Oak headquarters located in Silver Spring, MD, to attend orientation sessions, FDA-sponsor meetings, FDA PAG progress updates, interviews with FDA staff, and other activities that can't be conducted virtually. FDA will provide hoteling space on an as-needed basis, but contractors should also expect to work from their employer's premises.

FDA will provide laptops, remote access tokens, badges, and access to relevant FDA data systems. FDA badges and government furnished equipment will be provided to the contractor

within one month following the date of award. Immediately after award of the contract, the contractor will provide a complete list of all personnel to FDA.

H. Evaluation Criteria

The following evaluation criteria will be used in assessing the technical proposals for the work specified in this statement of work:

1. Technical understanding of the work described in this statement of work
2. Approach to conducting the work and meeting requirements
3. Qualification of key personnel