Assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in PDUFA V

A. Background

The timely review of the safety and effectiveness of new drugs and biologics is central to FDA's mission to protect and promote the public health. Prior to enactment of the Prescription Drug User Fee Act (PDUFA) in 1992, FDA's drug review process was relatively slow and not very predictable compared to other countries. As a result of concerns expressed by both industry and patients at the time, Congress enacted PDUFA, which provided the added funds through user fees that enabled FDA to hire additional reviewers and support staff and upgrade its information technology systems. In return for additional resources, FDA agreed to certain review performance goals, such as completing reviews of New Drug Applications (NDAs) and Biologics License Applications (BLAs) and taking regulatory actions on them in predictable timeframes. These changes revolutionized the drug approval process in the United States and enabled FDA to speed the application review process for new drugs and biologics without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs and biologics prior to approval.

PDUFA provides FDA with a source of stable, consistent funding that has made possible our efforts to focus on promoting innovative therapies and help bring to market critical products for patients. When PDUFA was originally authorized in 1992, it had a five year term. The program has been subsequently reauthorized every five years with the most recent reauthorization occurring in 2007 for fiscal years 2008-2012. To prepare for reauthorization of PDUFA for a new five year period, FDA conducted negotiations with the regulated industry and held regular consultations with public stakeholders including patient advocates, consumer advocates, and healthcare professionals between July 2010 and May 2011. Following these discussions, related public meetings, and agency requests for public comment, FDA published proposed recommendations for PDUFA V for fiscal years 2013-2017. The proposed recommendations include an FDA commitment to implement a new review program for New Molecular Entity (NME) NDAs and original BLAs to enhance review transparency and communication on these complex applications between FDA and applicants.

PDUFA V NME NDA and Original BLA Review Program

FDA's existing review performance goals for priority and standard applications, 6 and 10 months respectively, were established in 1997. Since that time, additional requirements in the drug review process and scientific advances in drug development have made those goals increasingly challenging to meet, particularly for more complex applications like NME NDAs and original BLAs that generally are discussed in an FDA advisory committee meeting. FDA further recognizes that increasing communication between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process.

To promote greater 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 NME NDAs and original BLAs in PDUFA V. The Program provides opportunities for increased communication by building in mid-cycle communications and late-cycle meetings between FDA and applicants. 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 NME NDAs and original BLAs received from October 1, 2012, through September 30, 2017[1]. The goal of the Program is to improve the efficiency and effectiveness of the first cycle review process by increasing communication with sponsor before application submission to improve the quality and completeness of submissions, and by increasing communications during review. This will provide applicants with opportunities 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 new drugs and biologics. 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 NME NDAs and original BLAs. 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 PDUFA 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 PDUFA 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 PDUFA 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

[1] NME NDAs and original BLAs that receive a Refuse-to-File action and are resubmitted during this time period will be included in the program. NME NDAs and original BLAs received in PDUFA V that are filed over protest will not be included in the program.

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 PDUFA V 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 corporate databases, construct and analyze a baseline data set of NME NDAs and original BLAs received and acted on 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 corporate 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 NME NDA and original BLAs reviewed under the Program.

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

    4. Determine the nature of relationships between 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 the NME NDAs and original BLAs received by CDER and CBER and reviewed under the Program in PDUFA V[2]. This evaluation will include an analysis of review process management, communication between FDA and applicants, submission quality, and

[2] Applications received during PDUFA V that are filed over protest will not be reviewed under the Program.

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 IND 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, and other tasks deemed necessary to conduct a thorough assessment of the impact of the Program on the review of NME NDAs and original BLAs in PDUFA V. The standards for scientific review and regulatory decision-making are not the subject of this evaluation.

- Interim and Final Assessment Cohorts

The PDUFA V Commitment Letter specifies that an interim and final assessment must be conducted of the Program. The interim assessment must be published by March 31, 2015, and the final assessment must be published by December 31, 2016. 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 three 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 December 31, 2014, 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 standard and priority applications received in FY 2013, standard applications received in FY 2014 by December 31, 2013, and priority applications received in FY 2014 by April 30, 2014.

The final assessment shall be cumulative and include all applications that have reached at least a first cycle action as of September 30, 2016, 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 standard and priority applications received in FYs 2013-2015 and priority applications received in FY 2016 by January 30, 2016.. To understand the expected size of the interim and final assessment cohorts, the most recent five-year average of NME NDA and BLA receipts is 41 applications (15 priority and 26 standard) per year according to FDA's PDUFA Performance Reports (FY 2007-2011).

The PDUFA V Commitment Letter stipulates specific metrics and other evaluative measures to be tracked as part of the quality system that is used for review management (Section II.A.9) and as part of the assessment of the program (Section II.B). 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 both tracked elements in the quality system, the specified assessment metrics, and any other identified metrics as appropriate.

Quality System (Section II.A.9)

1. Conduct of pre-NDA/BLA meeting and agreement on content of complete application
2. Submission of any components of the application within 30 calendar days of receipt of the original application (as per pre-NDA/BLA meeting agreement)
3. Issuance of the 74-day letter
4. Completion of mid-cycle communication with sponsor
5. Completion of primary and secondary reviews
6. Discipline Review (DR) letters issued
7. Exchange of late cycle meeting package
8. Conduct of late-cycle meeting

Assessment of the Program (Section II.B)

1. Submission of a complete application at the time of original submission
2. Number of unsolicited amendments submitted by the applicant
3. Timing and adequacy of Day 74 letters
4. Mid-cycle communications
5. Provision of late-cycle meeting memorandum outlining potential issues and questions for AC meeting consideration and discipline review letters
6. Specific milestones of the Program as described in Section IIA
7. Time to approval
8. Percentage of applications approved on the first review cycle
9. Percentage of application reviews extended due to major amendments
10. Post-action assessment of the completeness and thoroughness of the submitted application, Day 74 letter, mid-cycle communication, DR letters, and late cycle meeting.
11. Adherence by the applicant and FDA to the current GRMP guidance

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. This period will last not more than two weeks and will take place at FDA's headquarters at White Oak, MD and satellite offices in Rockville, MD.

3. The majority of the required 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 prior analyses as a guide for these additional potential measures. For example, Section II.B.11 of the commitment letter refers to adherence by the applicant and FDA to the GRMP guidance. In 2011, FDA published an independent contractor evaluation of GRMP Implementation that analyzed adherence to selected GRMP activities (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM272446.pdf).

    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 IND 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 pre-submission meetings, mid-cycle communications, and late-cycle meetings as well as the quality and completeness of applicant submissions and FDA communications 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 pre-submission meeting, mid-cycle communication and the late-cycle meeting for each application reviewed under the Program. The mid-cycle communication will take place by telephone, while FDA expects that the pre-submission and late cycle meetings will generally be face-to-face meetings conducted at FDA Headquarters in White Oak, MD or at satellite offices in Rockville, MD. The contractor shall be physically present for all face-to-face FDA-applicant meetings and may participate by telephone for all mid-cycle communications held by telephone. The length of these meetings is estimated to be 1-2 hours 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, 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

    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 convene discussion groups and/or conduct separate interviews of FDA staff and applicants to obtain additional perspectives on the impact of the Program using the interview guide developed in Key Task 8. This information shall be aggregated and made anonymous 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 NME NDAs and original BLAs received and acted on prior to implementation of the Program during FYs 2010-2012 that had at least a first cycle action by December 31, 2012. 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 PDUFA V, 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 pre-submission 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.

    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.

    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, the FDA Technical Advisory Group (TAG) 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 June 30, 2015. Tasks and deliverables that support the final assessment shall be completed by March 30, 2017. The interview guide and data collection instrument specified in Deliverable 11 shall be modified as necessary throughout the evaluation based on accumulated Program experience. The interim and final assessments specified in Deliverables 20 and 33 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 shall be redacted as appropriate to protect commercial confidential 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.

<u>Other Criteria for Acceptance of Deliverables</u>

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 TAG 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 and TAG 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 or TAG 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 2003 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 pre-submission 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 NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	8	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	December 31, 2012
9	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA Collect and analyze data on a baseline set of NME NDAs and original BLAs received and acted on during FYs 2010-2012 that had at least a first cycle action by December 31, 2012	9	Interim report and presentation to FDA on: • Findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate • Draft analysis of baseline set of NME NDAs and original BLAs received and acted on during FYs 2010-2012 that had at least a first cycle action by December 31, 2012	March 31, 2013
10	Develop draft interview guide data collection instrument for interviews of FDA staff and sponsors of applications reviewed under the Program	10	Draft written interview guide and data collection instrument	April 30, 2013
11	Revise interview guide and data collection instrument for interviews of FDA staff and sponsors of applications reviewed under the Program	11	Revised written interview guide and data collection instrument	May 15, 2013

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 NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA Revise analysis of baseline set of NME NDAs and original BLAs received and acted on during FYs 2010-2012 that had at least a first cycle action by December 31, 2012	12	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate Revised analysis of baseline set of NME NDAs and original BLAs received and acted on during FYs 2010-2012 that had at least a first cycle action by December 31, 2012	June 30, 2013
13	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	13	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	September 30, 2013
14	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	14	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	December 31, 2013
15	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	15	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	March 31, 2014
16	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	16	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	June 30, 2014

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
17	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	17	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	September 30, 2014
18	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	18	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	December 31, 2014
19	Develop draft interim assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2012 that had at least a first cycle action by December 31, 2014	19	Presentation to TAG and submission of draft interim assessment	January 31, 2015
20	Revise interim assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2012 that had at least a first cycle action by December 31, 2014	20	Revised interim assessment	February 15, 2015
21	Evaluate written comments submitted to the public docket	21	Written comment analysis	June 15, 2015
22	Develop draft presentation materials for interim assessment public meeting	22	Draft presentation materials for interim assessment public meeting	June 15, 2015
23	Revise presentation materials for interim assessment public meeting	23	Revised presentation materials for interim assessment public meeting	June 22, 2015
24	Present findings of interim assessment and proposed recommendations for Program modification in public meeting	24	Public meeting presentation	June 30, 2015
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
25	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	25	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	March 31, 2015
26	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	26	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	June 30, 2015
27	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	27	• 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	July 15, 2015
28	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	28	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	September 30, 2015

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
29	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	29	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	December 31, 2015
30	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	30	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	March 31, 2016
31	Collect and analyze data on NME NDAs and original BLAs received beginning on October 1, 2012 (FY 2013) through at least the first cycle action for each application, report to FDA	31	Interim report and presentation to FDA TAG on findings to date for NME NDAs and original BLAs reviewed under the Program, providing a quantitative and/or qualitative assessment of the data collected as appropriate	June 30, 2016
32	Develop draft final assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2012 that had at least a first cycle action by September 30, 2016	32	Presentation to TAG and submission of draft final assessment	October 31, 2016
33	Revise final assessment of the Program that includes quantitative and qualitative data analyses of all applications received since October 1, 2012 that had at least a first cycle action by September 30, 2016	33	Revised final assessment	November 15, 2016
34	Evaluate written comments submitted to the public docket	34	Written comment analysis	March 15, 2017
35	Develop draft presentation materials for final assessment public meeting	35	Draft presentation materials for final assessment public meeting	March 15, 2017
36	Revise presentation materials for final assessment public meeting	36	Revised presentation materials for final assessment public meeting	March 22, 2017

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
37	Present findings of final assessment and any proposed recommendations for further Program enhancement	37	Public meeting presentation	March 30, 2017
Status Updates				
38	Progress updates with the FDA Project Manager (phone)	--	--	Biweekly from project initiation
39	Monthly progress updates with the FDA TAG (phone)	--	--	Monthly from project initiation
40	Quarterly updates with the FDA PAG (face-to-face meeting)	--	--	Quarterly 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 April 30, 2017. The estimated period of performance is 55 months.

G. Place of Performance

The majority of the work will be performed at the Contractor's site. 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 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