

EXHIBIT 11

PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022

I. ENSURING THE EFFECTIVENESS OF THE HUMAN DRUG REVIEW PROGRAM

- A.** Review Performance Goals
- B.** Program For Enhanced Review Transparency And Communication For NME NDAs And Original BLAs
- C.** First Cycle Review Management
- D.** Review Of Proprietary Names To Reduce Medication Errors
- E.** Major Dispute Resolution
- F.** Clinical Holds
- G.** Special Protocol Question Assessment And Agreement
- H.** Meeting Management Goals
- I.** Enhancing Regulatory Science And Expediting Drug Development
- J.** Enhancing Regulatory Decision Tools To Support Drug Development And Review
- K.** Enhancement And Modernization Of The FDA Drug Safety System

II. ENHANCING MANAGEMENT OF USER FEE RESOURCES

- A.** Resource Capacity Planning And Modernized Time Reporting
- B.** Financial Transparency And Efficiency

III. IMPROVING FDA HIRING AND RETENTION OF REVIEW STAFF

- A.** Completion Of Modernization Of The Hiring System Infrastructure And Augmentation Of System Capacity
- B.** Augmentation Of Hiring Staff Capacity And Capability
- C.** Complete Establishment Of A Dedicated Function To Ensure Needed Scientific Staffing For Medical Product Review
- D.** Set Clear Goals For Drug Review Program Hiring
- E.** Comprehensive And Continuous Assessment Of Hiring And Retention

IV. INFORMATION TECHNOLOGY GOALS

- A.** Objective
- B.** Improve The Predictability And Consistency Of PDUFA Electronic Submission Processes
- C.** Enhance Transparency And Accountability Of FDA Electronic Submission And Data Standards Activities

V. IMPROVING FDA PERFORMANCE MANAGEMENT

**VI. PROGRESS REPORTING FOR PDUFA VI AND CONTINUING PDUFA V
INITIATIVES**

VII. DEFINITIONS AND EXPLANATION OF TERMS

PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022

This document contains the performance goals and procedures for the Prescription Drug User Fee Act (PDUFA) reauthorization for fiscal years (FYs) 2018-2022, known as PDUFA VI. It is commonly referred to as the “goals letter” or “commitment letter.” The goals letter represents the product of FDA’s discussions with the regulated industry and public stakeholders, as mandated by Congress. The performance and procedural goals and other commitments specified in this letter apply to aspects of the human drug review program that are important for facilitating timely access to safe, effective, and innovative new medicines for patients. While much of FDA’s work is associated with formal tracked performance goals, the Agency and industry mutually agree that it is appropriate to manage some areas of the human drug review program with internally tracked timeframes. This provides FDA the flexibility needed to respond to a highly diverse workload, including unanticipated public health needs. FDA is committed to meeting the performance goals specified in this letter and to continuous improvement of its performance regarding other important areas specified in relevant published documents¹ that relate to preapproval drug development and post-approval activities for marketed products. FDA and the regulated industry will periodically and regularly assess the progress of the human drug review program throughout PDUFA VI. This will allow FDA and the regulated industry to identify emerging challenges and develop strategies to address these challenges to ensure the efficiency and effectiveness of the human drug review program.

Unless otherwise stated, goals apply to cohorts of each fiscal year (FY).

¹ Refer to the Good Review Management Principles and Practices for PDUFA Products guidance (hereinafter referred to as “GRMP guidance”) available at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079748.pdf> and the Good Review Management Principles and Practices for Effective IND Development and Review MAPP (hereinafter referred to as “GRMP MAPP”) available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM349907.pdf>

I. ENSURING THE EFFECTIVENESS OF THE HUMAN DRUG REVIEW PROGRAM

A. REVIEW PERFORMANCE GOALS

1. NDA/BLA Submissions and Resubmissions²

- a. Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60 day filing date.
- b. Review and act on 90 percent of priority NME NDA and original BLA submissions within 6 months of the 60 day filing date.
- c. Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt.
- d. Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt.
- e. Review and act on 90 percent of Class 1 resubmitted original applications within 2 months of receipt.
- f. Review and act on 90 percent of Class 2 resubmitted original applications within 6 months of receipt.

2. Original Efficacy Supplements

- a. Review and act on 90 percent of standard efficacy supplements within 10 months of receipt.
- b. Review and act on 90 percent of priority efficacy supplement within 6 months of receipt.

3. Resubmitted Efficacy Supplements

- a. Review and act on 90 percent of Class 1 resubmitted efficacy supplements within 2 months of receipt.
- b. Review and act on 90 percent of Class 2 resubmitted efficacy supplements within 6 months of receipt.

² Refer to Section I.B for a description of the review program for NME NDAs and original BLAs.

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