U.S. Food And Drug Administration
Center for Drug Evaluation and Research and
Center for Biologics Evaluation and Research

PDUFA V
Information Technology Assessment

FY 2013

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1.0 Introduction

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides the Food and Drug Administration (FDA) with the necessary resources to maintain a predictable and efficient review process for human drug and biological products. Under the PDUFA reauthorization, FDA is required to report progress in meeting a set of performance goals each fiscal year.

This report assesses FDA's progress on the commitments identified under the requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA), Section 1136, Electronic Submission of Applications, which gives FDA the authority to require the electronic submission of certain information and data in standardized formats. Section 1136 addresses submissions to New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and certain Biologics License Applications (BLAs) and Investigational New Drug Applications (INDs) under the PDUFA program.

This report details FDA's progress in FY 2013 toward achievement of the objectives defined in Sections XII Improving the Efficiency of Human Drug Review through Required Electronic Submission and Standardization of Electronic Drug Application Data and section XIV Information Technology Goals of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017 (a document commonly referred to as the PDUFA V Commitment letter).

2.0 Supporting Regulatory Operations

Activity in FY 2013 involved continuing the Agency's efforts in providing reliable access to the FDA Electronic Submissions Gateway (ESG). The FDA ESG, an Agency-wide solution that enables the secure transmittal and receipt of electronic regulatory submissions, has been operational since May 2006.

The electronic submission process encompasses the following: the receipt, acknowledgment of receipt, and any processing errors (to the sender) along with Center/Office routing, notification, and finally access to the electronic submission by the respective review teams.

Goals: Supporting Regulatory Operations	
To strengthen the Electronic Submissions Gateway to support the long-term exchange and review of drug and biologics applications.	
Objectives	**Current Progress**
Ensure the ESG is stable and can meet current demand and projected future increases in submission loads.	• Updated ESG to Interchange 5.10.1. to improve the stability of the ESG. • Increased capacity of ESG through additional infrastructure to ensure adequate capacity for current and projected submission activity, to support the 2013 ESG submission volume increased by 22 percent. • Conducting analysis on the long-term operation and governance needs of the ESG consistent with the needs of the FDA and its broad stakeholder community to ensure continued viability.
Future Milestones	
• Complete the analysis of the Electronic Submission Gateway Operations in FY 2014. • Implement the recommendations arising from the ESG analysis, as appropriate.	

3.0 Electronic Regulatory Submissions

PDUFA V calls for a consistent approach to the creation and review of regulatory submissions. Efforts to meet this goal in FY 2013 involved developing draft guidance to improve consistency of submission processing, ensure access to documents and data, and facilitate evaluation of information contained in submissions. FDA also continued to update technical specifications and IT-related guidance documents in support of an electronic environment.

Goals: Electronic Regulatory Submissions	
To provide a consistent approach to the creation and review of regulatory submissions.	
Objectives	**Current Progress**
Publish draft eCTD guidance by FY 2013.	• Published draft guidance for industry on "Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications."
Enhance Electronic Common Technical Document (eCTD) formation to provide additional capabilities.	• Announced a minor change to the updated Module 1 release to incorporate specifications and headings that reflect a change in section 1.15.2.1. This change adds material-id and issue attributes to facilitate the processing of Electronic Common Technical Document (eCTD) promotional submissions. • Implemented release to the automated software tool (GS Validate) to capture and report on the compliance with the eCTD submission standard.
Future Milestones	
• Publish by FY 2015 the revised draft and final guidance for industry on Providing Regulatory Submissions in Electronic Format Using the eCTD Specifications. • Implement major Module 1 release by September 2014. • Implement eCTD version 4.0 by FY 2016. • Require NDA, BLA, and ANDA submissions in eCTD format by FY 2017. • Require commercial INDs be submitted in eCTD format by FY 2018.	

4.0 Data Standards

FDA coordinates the development of data standards by working with Standards Development Organizations (SDOs), industry, other government agencies and other stakeholders, subsequently implementing these standards internally through the Centers. FDA supports an open, consensus-based process for the development, implementation and maintenance of data standards. Open, consensus-based data standards are necessary to integrate, analyze, report, and share regulatory information.

Goals: Data Standards	
To define and implement standards supporting drug efficacy, drug safety, manufacturing, product identification, and other areas.	
Objectives	**Current Progress**
4.0 Data Standards: • Require the electronic submission of data in standardized formats.	• Published draft guidance requiring submissions under NDAs, ANDAs, and certain BLAs and INDs to be submitted in electronic format. • Published revised draft guidance on providing regulatory submission in electronic format – Standardized Study Data. • Published draft Study Data Technical Conformance Guide. • Published draft Data Standards Catalog. • Published the Data Standards Strategy, version 1.0.
4.1 Study Data Standards: • Continue developing and implementing open, consensus-based standards to support efficacy analysis of distinct therapeutic areas in new drug review.	• Collaborated with the Coalition for Accelerating Standards and Therapies (CFAST) to progress development of Therapeutic Areas Data Standards. • Published Therapeutic Area (TA) Initiative project plan, version 1.0. • Awarded grants to further development of multiple Therapeutic Areas.
4.2 Individual Case Safety Report Submission Standards: • Conduct pilot testing of E2B (R3) formatted ICSRs. • Issue regional guidance and specifications to describe the electronic submissions process and requirements applicable for its regulatory processes.	• Conducted regional pilot testing with industry partners using the R3 eSubmitter tool. • Published E2B (R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide (Drugs, Biologics, and Vaccines). • Developed draft guidance on providing regulatory submission in electronic format – Post-marketing Individual Case Safety Reports (ICSRs) for Vaccines. • Developed draft guidance on providing regulatory submission in electronic format – Post-marketing Lot Distribution Reports for CBER-Regulated Biologics.

4.3 Identification of Medicinal Products IDMP • Implement International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) standards with reliable and robust repositories and processes to support efficient, consistent, and timely decision making in the regulation of medicinal product throughout the product development lifecycle.	• Planning to launch a pilot publication by the end of the 2nd quarter of fiscal year 2014.
4.4 Drug Quality and Facilities: • Issue draft guidance for pre-market manufacturing establishment information.	• Developed draft guidance, which is targeted for publication in 2014.
Future Milestones	
• Publish final guidance requiring submissions under NDAs, ANDAs, and certain BLAs and INDs to be submitted in electronic format by FY 2015. • Publish final guidance on providing regulatory submission in electronic format – Standardized Study Data by FY 2015. • Publish final Study Data Technical Conformance Guide by FY 2015. • Publish final Data Standards Catalog by FY 2015. • Publish Data Standards Strategy, version 2.0 by FY 2015. • Publish Therapeutic Area (TA) Initiative project plan, version 2.0 by Q3, 2014. • Publish draft guidance requiring electronic submission of post-market ICSRs to VAERS by FY 2014. • Publish draft guidance requiring electronic submission of post-market Lot Distribution Report to CBER by FY 2014. • Conduct E2B (R3) pilot testing in FY 2014. • Publish FDA Regional E2B (R3) implementation guidance Technical Specification in FY 2014. • Accept electronic submissions using E2B (R3) in FY 2015.	

5.0 Metrics and Measures

The PDUFA metrics measure progress and achievement of PDUFA V objectives in alignment with the PDUFA V performance goals and the PDUFA V IT Plan.

Goals: Metrics and Measures	
To report progress and assess the implementation of PDUFA V IT goals.	
Objectives	**Current Progress**
Report progress towards achievement of targeted metrics and measures defined in Section XIV.A of the PDUFA Reauthorization Performance Goals and Procedures FY 2013 through FY 2017.	• Planning to publish the PDUFA V IT Metrics and Measures Report on FDA's Web site by the end of the 2nd quarter of FY 2014.
Report IT financial metrics per the PDUFA V Commitment Letter.	• Published financial metrics in the PDUFA Financial Reports submitted to Congress for fiscal year 2013 on PDUFA program activities, collections, and spending.
Future Milestones	
Continue measuring and reporting progress toward achievement of the objectives as defined in Section XIV of the PDUFA Reauthorization Performance Goals and Procedures FY 2013 through FY 2017, Commitment Letter.	

6.0 Communications and Technical Interactions

FDA uses a multi-tiered approach to improve communications and distribute IT and data standards information to industry at regular intervals. FDA continues to improve communications between FDA and industry stakeholders in order to promote effective relationships. Among these activities, FDA employs both formal and informal written correspondence, electronic media, and interpersonal person-to-person communications.

Goals: Communications and Technical Interactions	
To disseminate information to industry stakeholders to help improve the PDUFA IT program.	
Objectives	**Current Progress**
Update and publish periodically a 5-year plan for business process improvement enabled by IT investments.	• Published the draft PDUFA V IT Plan on FDA's Web site and published a notice of availability in the Federal Register with a 60-day public comment period. • Published the FY 2013 PDUFA V Information Technology Assessment on FDA's Web site.
Meet with industry stakeholders to discuss prospective implementation of the plan,	• Conducted quarterly meetings with industry stakeholders discussing prospective

progress toward the long-term goal, potential impacts that future activities may have on FDA or stakeholders, and potential revisions to the plan.	implementation of the PDUFA V IT plan, progress toward the long-term goal, potential impacts that future activities may have on FDA or stakeholders, and potential revisions to the PDUFA V IT Plan.
Future Milestones	
• Review public comments on the draft PDUFA V IT Plan. • Publish final PDUFA V IT Plan by end of FY 2014. • Continue meeting to improve communications and distribute IT and data standards information to industry at regular intervals.	