U.S. Food And Drug Administration
Center for Drug Evaluation and Research and
Office of Regulatory Affairs

GDUFA
Information Technology/Informatics Plan
FY 2013 – FY 2017

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1.0 Introduction

This 5-year plan describes how the Food and Drug Administration (FDA) proposes to meet the information technology (IT) goals of the Generic Drug User Fee Act Amendments of 2012 (GDUFA), section 744G of the Food, Drug, and Cosmetic Act (FD&C Act) Authorization Program Performance Goals and Procedures for fiscal years[1] (FY) 2013 through 2017. The plan includes FDA's proposed approach for enhancing business processes, data quality and consistency, supporting technologies, and IT operations. Industry can use this information to adequately plan for, resource, and implement the necessary IT changes to enable efficient and consistent adoption of the data standardization, IT, and informatics changes described in the GDUFA Program Performance Goals and Procedures for FY 2013 through FY 2017.[2]

The plan considers assumptions, available resources, and statutory requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA)[3], signed into law on July 9, 2012. Section 1136 of FDASIA, which added section 745A to the FD&C Act, gives FDA the authority to require the electronic submission of certain information and data in standardized formats. Section 1136 applies to certain Investigational New Drug applications (INDs), Biologics License Applications (BLAs), and New Drug Applications (NDAs) as well as Abbreviated New Drug Applications (ANDAs). In addition, global collaborative initiatives, such as the International Conference on Harmonization (ICH) affect this plan.

Further, the plan relies on the development and acceptance of regulatory standards. Changes in those standards could result in changes to the plan; therefore, FDA intends to publish periodic draft revisions to the GDUFA plan to communicate minor updates and corrections.

Background

Signed into law on July 9, 2012, GDUFA is a newly authorized user fee program under FDASIA designed to speed the delivery of safe and effective generic drugs to the public. FDASIA also includes provisions that increase FDA's authorities and responsibilities to address issues such as drug shortages, drug supply chain, drug safety, drug security, and drug innovation. As generic drugs account for more than three-quarters of all prescriptions dispensed in the United States, GDUFA authorizes FDA to collect user fees from industry; such fees provide funding to expand and modernize FDA's generic drug regulatory process.

GDUFA requires FDA to meet established performance goals that cover a wide range of activities to enhance efficiency in the review process, hire personnel, decrease the

[1] Fiscal Year is 1 October through 30 September.
[2] http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.
[3] http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf.

backlog of applications, ensure consistency and frequency of inspections for domestic and foreign sites, improve communication, establish databases and IT systems, and advance regulatory science initiatives.

Vision

FDA is committed to achieving an automated standards-based information technology environment for the exchange, review, and management of information supporting the regulation of biological and human drug products. Our long-term vision is to share and leverage information that meets the increasing complexity and expected growth of the user fee program. The GDUFA IT Plan depicts FDA's IT strategic direction to enhance flexibility and interoperability across information systems, reducing redundancies and inefficiencies and improving access to accurate, timely, and consistent information.

To achieve this vision, IT investments must be aligned with business objectives and address all aspects related to discrete structural components within business, data, application, technical, security, and performance. The plan for optimally allocating resources towards this realization includes developing and implementing a comprehensive suite of strategic capabilities aimed at modernizing FDA's regulatory, surveillance, compliance, and enforcement oversight of drugs and biological products. In practice, IT is a key enabler that helps FDA meet its user fee goals.

Overview of the 5-Year Plan

FDA has governance processes in place to ensure the alignment of IT investments with the GDUFA commitments. These processes define decision-making authorities and assign accountability for executing decisions. Within FDA, the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Office of Regulatory Affairs (ORA) are accountable for meeting the GDUFA commitments and for allocating resources to support GDUFA. Each Center has an Information Technology Investment Review Board (ITIRB) that recommends and prioritizes IT investment decisions. Through this process, each Center's ITIRB selects, evaluates, and controls the proposed IT investments.

As part of the overall governance process, the ITIRBs monitor performance and risks associated with each investment and works closely with stakeholders to ensure these investments support GDUFA objectives, including reuse of common business processes, shared best practices, and employment of common authoritative data sources. FDA's User Fee Board reviews the total GDUFA allocation to ensure alignment with Agency GDUFA goals. The alignment between the Center ITIRBs and FDA's User Fee Board ensures good stewardship.

GDUFA IT/Informatics Goals

This 5-year plan discusses objectives and related key milestones for achieving the following GDUFA IT goals:

1. Supporting Regulatory Operations—describing the approach to strengthening the Electronic Submissions Gateway (ESG) to support the long-term exchange and review of drug and biologics applications.
2. Electronic Regulatory Submissions—providing a consistent approach to the creation and review of regulatory submissions.
3. Data Standards—defining and implementing standards supporting drug efficacy, drug safety, manufacturing, product identification, and other areas.
4. Metrics and Measures—tracking progress and assessing implementation of goals.
5. Communications and Technical Interactions—disseminating information to stakeholders to help improve the program.

FDA maintains many systems that support the User Fee Program. The milestones in this Plan depict when the program objectives, under the GDUFA Program Performance Goals and Procedures for Fiscal Years 2013 through FY 2017, are anticipated to be accomplished. However, many of these key milestones have dependencies that can affect the schedule, such as international guidelines, implementation timelines, and availability of resources.

2.0 Goal 1: Supporting Regulatory Operations

FDA plans to strengthen the Electronic Submissions Gateway (ESG) to support the long-term exchange and review of drug and biologics applications. The ESG has been critical to the success of FDA's electronic submission initiatives. Originally implemented in May 2006, the ESG has grown to support more than 1.4 million submissions a year. The ESG initially supported CDER, CBER, and the Center for Devices and Radiological Health (CDRH), but has since expanded to support seven centers and the Office of the Commissioner. In addition, FDA has been working with Health Canada through the Regulatory Cooperation Council (RCC) to enable Health Canada to use the ESG to receive regulatory submissions.

To ensure that the ESG is stable and can meet current demand and projected future increases in submission loads, FDA intends to analyze current ESG operations. This analysis will look at:

- Current program structure of the ESG
- Current ESG capacity and planning capabilities
- Effectiveness of the current ESG Communication Plan
- Adequacy of contingency planning and continuity of operations
- Long-term viability of the current technology and security provisions

The results of this analysis could lead to program changes that may become part of a future assessment of the GDUFA IT plan.

Table 1 shows the regulatory operations milestones for the objective.

Table 1: Supporting Regulatory Operations FY 2013 – FY 2017 Milestones

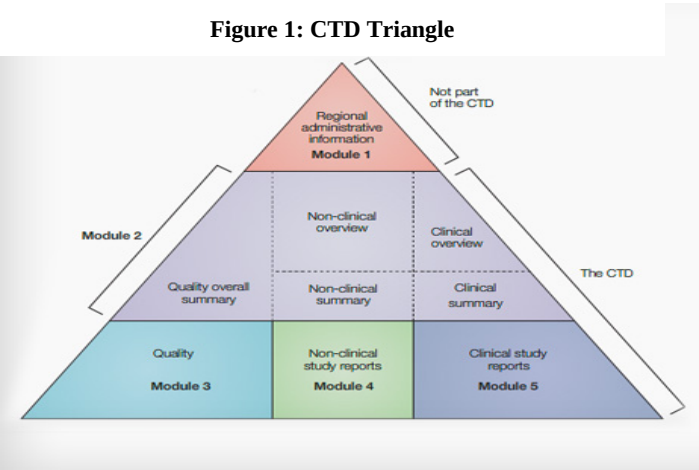
		FY13				FY14				FY15				FY16				FY17			
Objective(s)	**Milestones**	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Ensure the ESG is stable and can meet current demand and projected future increases in submission loads.	**Milestone 1.1:** Conduct analysis on the long-term operation and governance needs of the ESG consistent with the needs of FDA and its broad stakeholder community to ensure continued viability.	▽							▽												
	Milestone 1.2: Implement the recommendations arising from the ESG analysis, as appropriate.										▽										▽

3.0 Goal 2: Electronic Regulatory Submissions

FDASIA calls for a consistent approach to the creation and review of regulatory submissions. FDA ensures that the standardized format follows international guidelines. Since 2003, FDA has accepted electronic submissions using ICH's electronic Common Technical Document (eCTD) format.

The eCTD[4] derives from the ICH Common Technical Document (CTD) and allows for the electronic submission of the CTD from applicant to regulator. The eCTD contains an electronic table of contents also referred to as a backbone that manages all the metadata for an application. This backbone is broken down into five modules. Documents are placed appropriately into modules, which are graphically presented in Figure 1: CTD Triangle.[5]

Figure 1: CTD Triangle



[4] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.
[5] http://www.ich.org/products/ctd.html.

- **Module 1** references regional information such as forms, cover letters, labeling, and investigational brochures.
- **Module 2** references summaries such as quality, clinical, and non-clinical summaries.
- **Module 3** references quality information.
- **Module 4** references non-clinical information.
- **Module 5** references clinical information.

Module 1 is region specific. Modules 2, 3, 4, and 5 are harmonized. The current harmonized version of the eCTD is 3.2.2.

FDA intends to require submissions in a standardized electronic format. ANDA applications also follow the 24-month phase-in period under the GDUFA program.[6] The phase-in period for commercial INDs is 36 months.

FDA published the "Draft Revision of Guidance for Industry on Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" on January 3, 2013, and the comment period closed on March 4, 2013. The guidance specifies eCTD version 3.2.2 as the required harmonized format. After review of the public comments and internal discussions, FDA has decided to issue a second draft for public comment, which will affect the schedule for publishing of the final guidance. FDA published the updated draft guidance in July 2014 and intends to publish the final guidance by the fourth quarter of FY 2015. Per the requirements of FDASIA 1136, FDA intends to require submissions in eCTD format no sooner than 24 months after publication of the final eCTD guidance.

FDA has two initiatives to provide additional capabilities to the eCTD standard: the update of our U.S. regional Module 1 (M1) and development of the eCTD version 4 (v4.0). These initiatives enhance our electronic submission process and expand the eCTD capabilities. FDA published draft M1 specifications in October 2011 and published updated M1 specifications in August 2012. FDA continues work on the implementation of the updated M1 and plans to implement the updated M1 specifications by the end of FY 2015 Q2. The specification is posted on eCTD M1.[7]

ICH also continues work on eCTD v4.0. The next major version of the eCTD, version 4.0, uses the Health Level Seven International (HL7) Regulated Product Submission (RPS) standard. After RPS Release 2 becomes a normative HL7 standard, RPS will be submitted to the International Organization for Standardization (ISO) for approval.

[6] This requirement also applies to Master Files that are submitted for incorporation by reference into an NDA, BLA, or ANDA.

[7] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm.

ICH published the "ICH eCTD v4.0 DRAFT Implementation Guide v1.0" and conducted tests during the first half of 2013. The project documentation on ICH eCTD v4.0 Step 2 for testing page[8] includes a link to the U.S. regional eCTD v4.0 Web page. The next major eCTD v4.0 milestone is the HL7 RPS Normative re-ballot in September 2014. ICH continues testing and updating the ICH and regional implementation guides with a Step 4, adoption of the eCTD v4.0, in November 2015. The ICH timeline determines when FDA can start receiving eCTD v4.0 submissions, estimated to begin in 2017.

The eCTD v4.0 enhancements include:

- ***Message is managed through the use of controlled vocabularies:*** In developing eCTD 3.2 the rigid structure of the CTD was applied. The technology behind eCTD 3.2 makes it impossible to simply add a new heading. eCTD v4.0 is built on controlled vocabulary lists. To add a new heading only requires adding a new entry into the vocabulary lists.
- ***Complete standard:*** All regional administrative needs have been incorporated into eCTD v4.0, eliminating the need for a separate Module 1. All content differences with respect to Module 1 are handled by the controlled vocabularies.
- ***Simple reuse of previously submitted files:*** In eCTD v4.0, each file is assigned a unique identification number. To reuse that file, only a reference to that ID is needed.
- ***Enhanced lifecycle control:*** In eCTD v4.0, this core capability will be extended to support one-to-one, one-to-many, and many-to-one situations.
- ***Enhanced control of dossier:*** eCTD v3.2 requires that certain data (e.g., manufacturer) accompany documents in the dossier. These values change over time or may contain mistakes when they are submitted, e.g., the manufacturer's name changes or is misspelled. eCTD v4.0 provides the ability to correct this information.
- ***Enhanced identification of information contained with a submission:*** It is often very important to identify certain content (e.g., datasets) for further processing. eCTD v4.0 provides the capability to tag files based on the purpose. Regulatory authorities receiving these messages can use this information to properly process incoming submissions.
- ***Support for two-way communication:*** Currently, eCTD v3.2 supports only one-way communication from industry to regulatory authorities. eCTD v4.0 enables the exchange of FDA correspondence using the standardized electronic format.

Table 2 shows the electronic regulatory submissions milestones for each objective.

[8] http://estri.ich.org/new-eCTD/index.htm.

Table 2: Electronic Regulatory Submissions FY 2013 – FY 2017 Milestones

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Objective 1: Enhance eCTD formation to provide additional capabilities.	**Milestone 1.1:** Implement major Module 1 release.										▼										
	Milestone 1.2: Implement eCTD v4.0.																	▼			▼
	Milestone 1.2.1: ICH Step 2 adoption of eCTD v4.0									▼											
	Milestone 1.2.2: ICH Public Comment Period.									▼		▼									
	Milestone 1.2.3: Implement ICH Step 4.													▼							
Objective 2: Require submissions in a standardized format.	**Milestone 2.1:** Publish the revised draft and final guidance for industry on Providing Regulatory Submissions in Electronic Format Using the eCTD Specifications.									▼			▼	▼							
	Milestone 2.2: Require NDA, BLA, and ANDA submissions in eCTD format.																		▼		

4.0 Goal 3: Data Standards

FDA follows an open, consensus-based process to develop and maintain data standards. Open, consensus-based data standards are necessary to integrate, analyze, report, and share regulatory information. FDA's standards development and maintenance program aligns with three principles:

1. Ensure the use of high-quality data standards through the use of voluntary, consensus-based standards development processes in accredited standards development organizations (SDO) in place of government-unique standards unless such standards are inconsistent with law or otherwise impractical.
2. Reduce the burden of regulation through alignment with existing health IT initiatives, laws, regulations, and mandates such as Executive Orders.

3. Ensure the efficiency of data standards through the adoption or adaptation of other standards currently in use, when feasible.

FDA's new Data Standards Advisory Board will provide the overarching Agency framework for the management of data standards throughout their lifecycle, including policies, procedures, accountabilities, and decision-making. At the center level, CDER has well-defined data standards governance structures that ensure cross-center collaboration, communication, and alignment with respect to data standards development, implementation, and policy.

FDA collaborates with stakeholders (e.g., regulated industry, SDOs, academia, and medical-clinical societies, as well as other government agencies and FDA's review divisions) to develop new and refine existing data standards. FDA is committed to the consistent use of data standards in regulatory submissions and plans to develop a set of metrics to assess their impact on the efficiency of the review process. Further, FDA will develop a mechanism for the tracking and reporting of the number of submissions that comply and fail to comply with FDA-supported standards.

FDA has promoted and encouraged the submission of data in standard, electronic formats and to enable those data to be used efficiently and effectively in the process of reviewing drug marketing applications, safety reports, and other regulatory functions requiring data. Section 745A(a)(1) of the FD&C Act, passed in 2012 as part of Section 1136 of FDASIA, granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. In February 2014, FDA published two draft guidances focused on electronic submission requirements and standardized study data. The first guidance entitled "Providing Regulatory Submissions in Electronic Format — Submissions under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act" provides the implementation framework for the specification, in individual guidances, of the electronic requirements for certain submissions. The second guidance entitled "Providing Regulatory Submissions in Electronic Format — Standardized Study Data" specifies the formats for electronic submissions of study data contained in submissions under NDAs, ANDAs, BLAs and INDs.

Table 3 shows the data standards milestones for each objective.

Table 3: Data Standards FY 2013 – FY 2017 Milestones

		FY13				FY14				FY15				FY16				FY17			
Objective(s)	**Milestones**	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Require the electronic submission of data in standardized formats.	**Milestone 1.1:** Publish final guidance requiring regulatory submissions in electronic format –Submissions Under Section 745A(a).										▽										

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
	Milestone1.2: Publish final guidance requiring regulatory submissions in electronic format – Standardized Study Data.										▽										
	Milestone 1.3: Publish final Data Standards Catalog.										▽										
	Milestone 1.4: Publish final Study Data Standards Technical Conformance Guide.										▽										
	Milestone 1.5: Require ANDA submissions of data in standardized formats.																		▽		

4.1 Identification of Medicinal Products

FDA is working with the European Union (EU) to implement the ISO Identification of Medicinal Products (IDMP) standards that define, characterize, and identify each regulated Medicinal Product for human use from approval through postmarketing. FDA and the EU are collaborating with ISO to create and ballot a set of IDMP implementation guides balloting within ISO and HL7 and for public comment. The remaining IDMP implementation guides will be released starting in December 2014.

Following the finalization of the IDMP implementation guides in ISO and HL7, FDA plans to publish draft guidance on the use of the standards in regulatory submissions.

Table 4 shows the IDMP milestones for each objective.

Table 4: IDMP FY 2013 – FY 2017 Milestones

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Objective 1: 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.	**Milestone 1.1:** Successful ISO/HL7 balloting of IDMP implementation guides.					▼							▼								

4.2 Drug Quality and Facilities

FDA plans to issue draft guidance by the end of FY 2014 for the premarket submission of manufacturing establishment information using Structured Product Labeling (SPL) standards. In addition, FDA is assessing standardization needs and uses for drug quality data areas supporting Chemistry Manufacturing and Controls (CMC), product, and facility requirements. This assessment is likely to lead to other projects that may require additional guidance or standards development. Moreover, the assessment may support other efforts outlined in this plan such as IDMP implementation. FDA plans to solicit public input on standardization in these areas through *Federal Register* notices and public meetings.

Table 5 shows the drug quality and facilities milestones for each objective.

Table 5: Drug Quality and Facilities FY 2013 – FY 2017 Milestones

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Objective 1: Issue guidance for premarket manufacturing establishment information.	**Milestone 1.1:** Issue draft guidance for premarket manufacturing establishment information.								▼												
	Milestone 1.2: Issue final guidance for premarket manufacturing establishment information.													▼							

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Objective 2: Assess standardization needs and uses for drug quality data areas supporting Chemistry Manufacturing and Controls (CMC), product, and facility requirements.	**Milestone 2.1:** Implement the recommendations arising from the analysis, as appropriate.									▽											▽

4.3 Efficiency Enhancements

GDUFA outlines key efficiency enhancements to be undertaken by FDA between FY 2013 and FY 2017. Among these objectives, FDA plans to implement system enhancements supporting the issuance of complete response letters for ANDAs and associated Drug Master Files (DMFs); process improvements in completeness assessments (CAs) for Type II Active Pharmaceutical Ingredient (API) DMFs; efficiencies fostering inspection parity among foreign and domestic establishments; as well as other efficiency enhancements for improving generic drug review.

Table 6 shows the efficiency enhancements milestones for each objective.

Table 6: Efficiency Enhancements FY 2013 – FY 2017 Milestones

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Objective 1: Implement system enhancements supporting the issuance of complete response letters for ANDAs and associated DMFs; process improvements in completeness assessments (CAs) for Type II API DMFs; efficiencies fostering inspection parity among foreign and domestic establishments; as well as other efficiency enhancements for improving generic drug review.	**Milestone 1.1:** Establish facilities master data management.					▽			▽												
	Milestone 1.2: Establish a CMC knowledge repository and analytics.					▽			▽												
	Milestone 1.3: Implement a self-identification process.	▽			▽																
	Milestone 1.4: Finish first-cycle CAs within 45 calendar days from the receipt of a DMF fee payment.									▽			▽								
Objective 2: Develop a generic drug review platform to improve the management,	**Milestone 2.1:** Create a generic drug review platform.					▽			▽												

Objective(s)	Milestones	FY13 Q1	FY13 Q2	FY13 Q3	FY13 Q4	FY14 Q1	FY14 Q2	FY14 Q3	FY14 Q4	FY15 Q1	FY15 Q2	FY15 Q3	FY15 Q4	FY16 Q1	FY16 Q2	FY16 Q3	FY16 Q4	FY17 Q1	FY17 Q2	FY17 Q3	FY17 Q4
review, and inspection process for generic drug review standardized format.	**Milestone 2.2:** Integrate vital workflow processes.					▼															▼
	Milestone 2.3: Integrate review and inspection activities.									▼											▼

4.3.1 Facilities Master Data Management

GDUFA requires API and Finished Dosage Form (FDF) manufacturers as well as clinical and bioequivalence sites to submit certain facility-related information to FDA. To efficiently collect and manage this information, FDA intends to implement the use of the Data Universal Numbering System (DUNS) number as the unique facility identifier (UFI) for this facility information.

4.3.2 CMC Knowledge Repository and Analytics

FDA is developing a CMC Knowledge Repository to improve the efficiency and consistency of review and inspection. FDA plans to implement an integrated data warehouse and business intelligence solution in support of scientific analysis, regulatory decision-making, and publishing of key regulatory information. This approach provides a set of agile strategic informatics capabilities leveraging best-in-class commercial off-the-shelf software packages that can be configured to enable risk-based inspection and review across the entire drug life cycle.

4.3.3 Self-Identification Process

Generic drug facilities, and certain sites and organizations identified in a generic drug submission, are required by GDUFA to submit, update, or reconfirm identification information to FDA annually. Annual self-identification serves two purposes. First, self-identification is necessary to determine the universe of facilities required to pay user fees. Second, self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification enables quick, accurate, and reliable surveillance of generic drugs and facilitates inspections and compliance.

FDA will require generic drug facilities, and certain sites and organizations identified in a generic drug submission, to provide identification information in electronic format to FDA as specified under GDUFA. As such, FDA intends to develop an electronic self-identification process for enabling industry to submit their self-identification to FDA. To improve the management and collection of facility and site user-fee inspection and other programmatic information between the generic drug industry and FDA, FDA will design the self-identification process using the same electronic messaging standards currently

used for drug registration and listing information and for the content of labeling for ANDAs. These standards, along with FDA's overall informatics strategy for developing and issuing electronic data submission standards, are defined in the Data Standards section of this plan.

4.3.4 Generic Drug Review Platform

As part of its efforts to improve overall pharmaceutical quality, FDA intends to develop a generic drug review platform to improve the management, review, and inspection process for generic drug review. To strengthen the efficiency of lifecycle quality evaluations and regulation, FDA intends to establish a set of strategic informatics capabilities. These will apply best-in-class commercial off-the-shelf software configured to manage regulatory review activities throughout the entire drug life cycle. Using a cross-disciplinary approach, FDA will manage and improve the effectiveness of the review process. Specifically, FDA will integrate vital workflow processes across CDER. Among these objectives, FDA intends to focus resources to integrate review and inspection activities. These activities include strategies for improving the planning, execution, and tracking of established GDUFA timelines.

5.0 Goal 4: Metrics and Measures

FDA will track and report its progress towards achievement of targeted metrics and measures as established in the GDUFA Program Performance Goals and Procedures for FY 2013 through FY 2017. FDA will report these performance metrics in the annual GDUFA Performance Report, prepared by FDA's Office of Planning.
In addition, GDUFA requires FDA to report annually on the financial aspects of its implementation. Through this process, FDA will report its financial metrics in the GDUFA Financial Reports submitted to Congress each fiscal year on GDUFA program activities, collections, and spending.

Table 7 shows the metrics and measures milestones for each objective.

Table 7: Metrics and Measures FY 2013 – FY 2017 Milestones

		FY13				FY14				FY15				FY16				FY17			
Objective(s)	**Milestones**	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Track and report progress towards achievement of targeted metrics and	**Milestone 1. 1:** Report the GDUFA metrics on FDA's Website.	▼				▼				▼				▼				▼			

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
measures as established in the GDUFA Program Performance Goals and Procedures for FY 2013 through FY 2017.	**Milestone 1.2:** Publish the financial metrics in the GDUFA Financial Reports submitted to Congress each fiscal year on GDUFA program activities, collections, and spending.	▼				▼				▼				▼				▼			

6.0 Goal 5: Communications and Technical Interactions

FDA develops, updates, and publishes a 5-year GDUFA IT/Informatics Plan for business process improvement. To support improvements and to track these planning efforts, FDA will improve its processes for communicating timely, accurate, and consistent IT information. These processes include facilitating as well as participating in meetings and discussions to foster early and continued interactions between FDA and industry. As part of this process, FDA takes a collaborative approach to strengthening communications and sharing information technology data standards goals under GDUFA. FDA pursues opportunities for improving stakeholder collaboration through approaches aimed at reporting progress towards meeting these goals. The dissemination strategy also provides and obtains data from industry and other stakeholders that present important action-oriented information.

FDA intends to use a multi-pronged approach to improve communications and distribute IT/Informatics and data standards information to industry at regular intervals. For example, in preparation of the new self-identification requirements FDA conducted a series of informational sessions, which included webinars, public meetings, and technical walkthrough discussions. FDA will continue to communicate and collaborate with stakeholders by utilizing communication channels such as the FDA GDUFA Web site[9], meetings (public, small business), webinars, technical walkthroughs, and multiple-language factsheets to achieve the IT/Informatics goals set forth by FDASIA and the GDUFA Commitment Letter.

As part of the overall communications and technical interactions approach, FDA plans to make reports required under the GDUFA Commitment Letter available to industry on the FDA GDUFA Web site. Feedback to the initial strategic IT/Informatics Plan and guidances will be available on the *Federal Register* to allow the public to provide written comments.

Table 8 shows the communications and technical interactions milestones for each objective.

[9] http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm.

Table 8: Communications and Technical Interactions FY 2013 – FY 2017 Milestones

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Distribute IT and data standards information to industry at regular intervals.	**Milestone 1.1:** Publish the draft IT plan on FDA's Web site and publish a notice of availability in the *Federal Register* with a 60-day public comment period.																				
	Milestone 1.2: Finalize the IT plan and publish to FDA's Web site.																				
	Milestone 1.3: Periodically update and publish the IT plan, as determined by FDA.																				

7.0 Next Steps

The next steps for this plan involve conducting assessments, collecting feedback from stakeholders and updating plans. These steps depend on FDA interaction and agreement with international organizations' decisions, stakeholder involvement, and agency resources. To this end, FDA remains committed to working with industry to successfully implement and address implementation challenges for collaboratively meeting the GDUFA IT goals.

Appendix A: GDUFA IT/Informatics Goals and Objectives

The table below summarizes the GDUFA IT/Informatics goals and FDA objectives described throughout this document.

GDUFA IT/Informatics Goals	Objectives
Goal 1: Supporting Regulatory Operations—describing the approach to strengthening the ESG to support the long-term exchange and review of drug and biologics applications.	**Objective 1.1 :** Ensure the ESG is stable and can meet current demand and projected future increases in submission loads.
Goal 2: Electronic Regulatory Submissions—providing a consistent approach to the creation and review of regulatory submissions.	**Objective 2.1:** Enhance eCTD formation to provide additional capabilities. **Objective 2.2:** Require submissions in a standardized format.
Goal 3: Data Standards—defining and implementing standards supporting drug efficacy, drug safety, manufacturing, product identification, and other areas.	**Objective 3.1:** Require the electronic submission of data in standardized formats. **Objective 3.2**: 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. **Objective 3.3:** Issue guidance for premarket manufacturing establishment information. **Objective 3.4:** Assess standardization needs and uses for drug quality data areas supporting Chemistry Manufacturing and Controls (CMC), product, and facility requirements. **Objective: 3.5:** Implement system

GDUFA IT/Informatics Goals	Objectives
	enhancements supporting the issuance of complete response letters for ANDAs and associated DMFs; process improvements in completeness assessments for Type II API DMFs; efficiencies fostering inspection parity among foreign and domestic establishments; as well as other efficiency enhancements for improving generic drug review. **Objective 3.6:** Develop a generic drug review platform to improve the management, review, and inspection process for generic drug review.
Goal 4: Metrics and Measures—tracking progress and assessing implementation of goals.	**Objective 4.1:** Track and report progress towards achievement of targeted metrics and measures as established in the GDUFA Program Performance Goals and Procedures for FY 2013 through FY 2017.
Goal 5: Communications and Technical Interactions—disseminating information to stakeholders to help improve the program.	**Objective 5.1:** Distribute IT and data standards information to industry at regular intervals.

Appendix B: References

The documents listed below were referenced in the development of the GDUFA IT/Informatics Plan FY 2013 – FY 2017.

- The Food and Drug Administration Safety Innovation Act (FDASIA)
  http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf

- Generic Drug User Fee Act Program Performance Goals and Procedures
  http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf

- HHS Strategic Plan and Secretary's Strategic Initiatives FY 2014 - 2018
  http://www.hhs.gov/strategic-plan/priorities.html

- FDA Strategic Priorities 2011 - 2015
  Responding to the Public Health Challenges of the 21st Century
  http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf

- FDA Information Management and Office of Information Management Strategic Plan FY 2012 - FY 2016
  http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM325437.pdf

- Center for Biologics Evaluation and Research Strategic Plan FY 2012 - FY 2016
  Innovative Technology Advancing the Public Health
  http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm266867.pdf

- FDA Center for Drug Evaluation and Research Strategic Plan 2013 - 2017
  http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm376545.pdf