Prescription Drug User Fee Act (PDUFA) III Information Technology Five-Year Plan

FY 2003 Publication

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EXECUTIVE SUMMARY

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration's (FDA's) mission is to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way, and to monitor products for continued safety after they are in use. Decisions made by FDA affect every single American every day. In 2001, consumers spent nearly $1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA regulated products. Operating as a modern, scientifically up-to-date, responsive, and efficient agency, FDA can provide better protection for consumers and more effectively promote their health.

In the last decade, FDA has achieved great success in reforming and modernizing its regulatory processes and responsibilities as a result of drastic changes and improvements driven by the requirements of the Prescription Drug User Fee Act (PDUFA), the 1997 FDA Modernization Act (FDAMA), and other legislation. The additional resources provided by user fees, when combined with appropriations, have enabled FDA to modernize its information technology infrastructure and begin a monumental transformation from a paper-based to an electronic work environment. Much work remains to be done and, with the recent renewal of user fees for the fiscal year 2003-2007 timeframe ("PDUFA III") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA plans to make even greater progress, building on the foundation established in previous years.

The additional resources provided by user fees, when combined with appropriations, have enabled FDA to modernize its IT infrastructure and begin a monumental transformation from a paper-based to an electronic work environment.

This document is the first publication of the FDA's PDUFA III Information Technology Five-Year Plan. This Plan will show how FDA will apply PDUFA III IT funds toward building on the success of the last several years, while focusing on moving the medical drug and biologic products review processes toward a strong, homogeneous electronic work environment.

This plan will guide the direction and implementation of IT projects initiated to meet Agency program objectives and specific PDUFA III IT goals. We believe it communicates clearly to stakeholders, internal and external to the Agency, the steps FDA plans to take to achieve its objectives.

FDA considers the first year of the PDUFA III timeframe to be a period of considerable transition. Many near-term fundamental activities and strategic issues must be resolved by the Agency prior to committing resources to future, long-range systems development plans for the out years of PDUFA III. For example, due to a variety of external pressures, FDA is conducting studies to determine a strategy for consolidating IT infrastructure and services. Similarly, FDA is working to shift its IT decision-making and governance to an Agency-wide, less de-centralized model. Further, FDA must resolve security issues with standard, Agency-wide solutions for secure submissions, secure e-mail, and electronic signatures. In the first year to 18 months of PDUFA III, FDA will focus on completing these efforts to ensure that they are developed, published, and widely understood. Once these plans are implemented, FDA will be in a position to expand planning of specific systems development and infrastructure projects into the PDUFA III out-years.

The scope of information management and information technology efforts required for FDA to realize its vision is much greater than the efforts undertaken within the PDUFA III program alone. This plan, therefore, represents only a portion of the work to be accomplished at FDA, but it is imperative that these PDUFA activities map clearly to overall Agency business and IT strategic planning. Several of the strategies within this section must be accomplished not only to meet PDUFA III IT goals, but also Agency and DHHS goals. Therefore, the strategies presented here must be applied consistently across the Agency to achieve the maximum benefit of the efforts. PDUFA funding for these strategies, however, will be applied only in a manner that is commensurate to the proportion of PDUFA organizations to Agency-wide organizations.

FDA is developing this plan within an environment of significant challenges such as consolidation of administrative services, including information technology services. Given the dynamic nature of the current environment, FDA determined it would publish this first version of the PDUFA III IT Five-Year Plan and provide a near-term outlook. Subsequent versions of this plan will detail strategies and activities farther out into the 5-year timeframe.

Many levels of planning efforts are underway within the Department of Health and Human Services, the FDA, the Centers and Offices, and within the PDUFA Program. The strategies outlined in this plan are presented to show their alignment with overall Department, Agency, and Program goals and objectives. One strategy that supports goals and objectives at all levels is the establishment of a formal IT Governance process at FDA. Within this governance process, FDA will centralize accountability and funding for all PDUFA IT initiatives/activities for CBER, CDER, ORA and OC under the leadership of the CIO. The FDA CIO is responsible for ensuring IT investments support the Agency's common IT goals, fit into a common computing environment, and follow IT industry standard management practices and CMM principles. Establishing a formal PDUFA IT investment governance process that incorporates the oversight and approval by both the Agency CIO and Agency management is critical to the success of PDUFA IT investments.

The strategies outlined in this plan are presented to show their alignment with overall Department, Agency, and Program Goals.

The strategies FDA is pursuing within the PDUFA III IT Program are aligned and presented in this plan according to the CIO's PDUFA Program goals:

- Provide a governance framework, management, and oversight of IT decision-making;
- Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward; and
- Increase the efficiency of IT programs and services to better support all of its customers.

The following table summarizes the strategies the FDA will pursue in FY 2003-2004 and shows a mapping of those strategies to PDUFA III, Center/Office, Agency, and Departmental goals.

	PDUFA III IT	Center/Office					Agency					DHHS			
FDA IT STRATEGIES	PDUFA III IT Goals A-I (See Appendix A for Mapping)	Information Dissemination	Standards Development	Pre-Market Decision-Making	Post-Market Surveillance	Field Processes	Strong FDA	Risk Management	BioDefense	Consumer Information	Adverse Events and Medical	BioTerrorism	Nation's Health Science Research Enterprise	Quality of Health Care Services	Achieve Excellence in
Provide a governance framework, management, and oversight of IT decision-making															
Establish an IT Governance Process	**A, B, I**	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Review the efforts within the ERSR Program and move the Program forward															
Collaborate with standards organizations to define document and data standards	**C, D, E, F, I**	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Develop and publish guidance to Industry	**E, I**		✔	✔				✔						✔	
Evaluate ERSR Program and develop a target ERSR Architecture	**C, D, E, F, H, I**		✔	✔		✔	✔	✔						✔	
Define a path forward to meet electronic submissions requirements	**C, D, E, H, I**	✔		✔		✔	✔	✔					✔	✔	
Comply with ICH eCTD submission standards	**E, I**			✔			✔	✔						✔	
Provide Training for Reviewers on using Electronic Submissions and new tools	**E, I**			✔		✔	✔	✔						✔	
Continue the operation and maintenance of existing systems and services	**A, I**	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Increase the efficiency of IT programs and services															
Implement IT Consolidation	**A, C, F, I**			✔		✔	✔	✔					✔	✔	
Transfer Therapeutics Review from CBER to CDER	**A, F, I**			✔			✔	✔					✔	✔	
Standardize and improve project management techniques; advance software development maturity	**A, F, G, I**		✔			✔	✔	✔					✔	✔	✔
Develop an Enterprise Architecture	**A, C, F, H, I**	✔	✔			✔	✔	✔			✔		✔	✔	

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1.0 INTRODUCTION

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration's (FDA's) mission is to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way, and to monitor products for continued safety after they are in use. Decisions made by FDA affect every single American every day. In 2001, consumers spent nearly $1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA regulated products. Operating as a modern, scientifically up-to-date, responsive, and efficient agency, FDA can provide better protection for consumers and more effectively promote their health.

In the last decade, FDA has achieved great success in reforming and modernizing its regulatory processes and responsibilities as a result of drastic changes and improvements driven by the requirements of the Prescription Drug User Fee Act (PDUFA), the 1997 FDA Modernization Act (FDAMA), and other legislation. The additional resources provided by user fees, when combined with appropriations, have enabled FDA to modernize its information technology infrastructure and begin a monumental transformation from a paper-based to an electronic work environment. Much work remains to be done and, with the recent renewal of user fees for the fiscal year 2003-2007 timeframe ("PDUFA III") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA plans to make even greater progress, building on the foundation established in previous years.

This document is the first publication of the FDA's PDUFA III Information Technology Five-Year Plan. This Plan will show how FDA will apply PDUFA III IT funds toward building on the success of the last several years, while focusing on moving the medical drug and biologic products review processes toward a strong, homogeneous electronic work environment. Specifically, this Plan will show how FDA intends to:

- strengthen and improve information management within the new drug and biologic products review processes by facilitating faster, more-informed decision-making;
- improve FDA's ability to communicate, share, and disseminate information more clearly within the Agency and with other government organizations, the regulated industry, and the American Public; and
- seek more efficient and effective means for supplying technology tools and services to the FDA user community.

2.0 PURPOSE

This plan will help guide the direction and implementation of IT projects initiated to meet Agency program objectives and specific PDUFA III IT goals. Among the principal IT planning documents to be developed by the Agency during the PDUFA III timeframe, this document will communicate clearly to stakeholders, internal and external to the Agency, the steps FDA plans to take to achieve its objectives.

The Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) have collaborated with the Office of the Chief Information Officer (CIO) in the Office of the Commissioner (OC) to develop this FDA PDUFA III Information Technology Five-year Plan. Together, these offices will address their paramount concern: applying technology to the FDA regulatory review process in the most efficient and effective way possible to ensure reviewers have the information and tools that will allow them to make more informed and timely decisions.

FDA considers the first year of the PDUFA III timeframe to be a period of considerable transition. Many near-term fundamental activities and strategic issues must be resolved by the Agency prior to committing resources to future, long-range systems development plans for the out years of PDUFA III. For example, due to a variety of external pressures, FDA is conducting studies to determine a strategy for consolidating IT infrastructure and services. Similarly, FDA is working to shift its IT decision-making and governance to an Agency-wide, less de-centralized model. Further, FDA must resolve security issues with standard, Agency-wide solutions for secure submissions, secure-mail, and electronic signatures. In the first year to 18 months of PDUFA III, FDA will focus its efforts on completing these efforts to ensure that they are developed, published, and widely understood. Once these plans are implemented, FDA will be in a position to expand planning of specific systems development and infrastructure projects into the PDUFA III out-years.

Therefore, the purpose of this document is to communicate FDA's long-range goals under PDUFA III, and it will present tactical strategies for accomplishing near-term objectives toward those goals. The intent of this plan is to:

- communicate the link between IT efforts and the expected business outcomes and benefits;
- communicate vision and strategies FDA will follow for using PDUFA III IT funds;
- ensure our ability to baseline our plans and measure our future progress;
- provide a framework to govern PDUFA III IT decision-making;
- supply Agency IT governing bodies with an understanding of PDUFA III IT planned activities to ensure compatibility and harmonization with other Agency strategic technology initiatives; and
- provide an understanding for how this plan links to other Agency and Departmental planning documents.

This Plan will be revised periodically and re-published at least annually as strategies and approaches are defined and clarified.

3.0 VISION

The FDA vision is one in which our advances in information technology will help provide the American public with even more timely, well-informed decisions about regulated drug and biologic products. FDA depends on the application of advanced information technologies to ensure this vision is realized, and therefore, IT planning and decision-making will be a much more corporate collaboration than in previous years.

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The scope of information management and information technology efforts required for FDA to realize its vision is much greater than the efforts undertaken exclusively within the PDUFA III program. This plan, therefore, represents only a portion of the work to be accomplished at FDA. In addition, PDUFA activities must be aligned with the overall Agency business and IT strategic planning.

This Plan reflects that intent. The FDA views the PDUFA III goals as steps that would be taken by the Agency to reach the CIO's Office long-term vision of effective knowledge management capability. The long-term vision is not only to provide a seamless electronic submission process

for industry applications, but more importantly, to develop a fully integrated information management system across all FDA Centers and Offices with links to industry, the public and other government agencies for the sharing and processing of information.

4.0 CHALLENGES

During the last year or more, several major initiatives or external forces have converged, creating a particularly complex set of challenges for FDA. These challenges have a common theme in that they all have an information technology component, focus, or impact.

Early in FY 2003, FDA's new Commissioner identified a core set of strategic priorities for the Agency. These priorities focus on risk management, maintaining a strong-science-based organization, assisting in countering terrorist threats, providing information to constituents, and contributing to the reduction of adverse events and medical errors. The FDA strategic plan, structured around those five goals, highlights many very complex, advanced, and aggressive technical solutions and systems that will be required to achieve Agency goals.

One of those five priorities focuses on the critical role FDA plays in the country's efforts to counter terrorism. Among other responsibilities, FDA must take steps to ensure that regulated drugs and biologics are not used as vehicles of terrorism and to keep medically important products available to the American people despite any terrorist actions. These activities must be given an extremely high priority, and often demand immediate attention.

With the start of this Presidential Administration, DHHS Secretary Thompson instituted a "One Department" philosophy to govern management decisions. The Secretary stated that Information Technology (IT) is the key to providing better government services at reduced costs and that it is the foundation for efforts to re-engineer HHS. On May 31, 2001, the Secretary called for the development of the HHS Information Technology Strategic Five Year Plan. One of the goals articulated in the resulting Strategic Plan is the "aggregation and standardization of IT systems and services, resulting in significant consolidation within agencies and across the Department."

In line with the "One Department" philosophy, plans are underway to consolidate several other administrative functions in FDA. Until these plans are implemented, FDA must continue to operate during a very transitional period. Additionally, in this time of change, FDA must ensure an IT staffing capability that meets these changing needs. The Agency must also work to ensure that its staff is well trained and equipped with the skills necessary to deliver and maintain quality IT products.

Many other factors will influence FDA's strategy for accomplishing its IT goals. Financial and human resources, the number and types of product submissions, scientific advances, shifts in public expectations, changes in agency or industry priorities, major medical threats or breakthroughs, and other discontinuous changes might require FDA to reconsider its strategies in favor of unplanned but necessary adjustments.

FDA is developing this plan within this environment of significant challenges. Given the dynamic nature of current activities, FDA determined it would publish this first version of the PDUFA III IT Five-Year Plan and provide a near-term outlook. Subsequent versions of this plan will detail strategies and activities farther out into the 5-year timeframe.

5.0 ORGANIZATION

Players within the PDUFA III IT Program include the Office of the Chief Information Officer (OCIO), the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Office of Regulatory Affairs (ORA). CBER and CDER have direct responsibility for reviewing and approving biologic and drug product applications, respectively, as well as monitoring those products once they are on the market. ORA inspects the full range of FDA-regulated products—both before and after marketing.

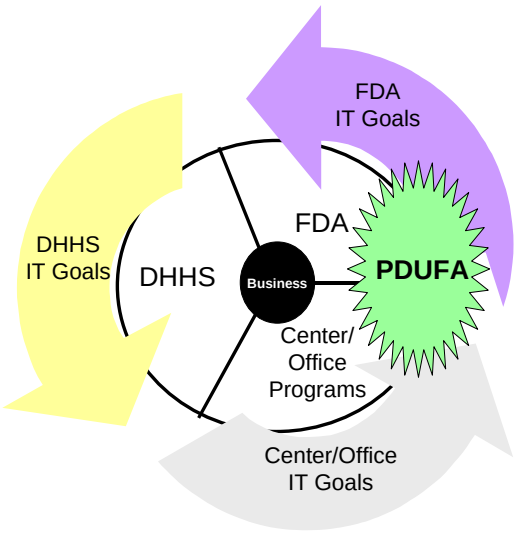
The OCIO provides Agency-wide information technology policy, guidance, support, and oversight to CBER, CDER, ORA and other FDA Centers. The OCIO is in the Office of the Commissioner's Office of Management and Systems and is responsible for managing the overall success of the IT portion of the PDUFA legislation. This office is also responsible for providing leadership in the provision of IT services across the Agency.

6.0 GOALS AND OBJECTIVES

This section presents the goals and objectives of the various governing layers within which FDA operates. First, it presents the goals, objectives, and strategic planning progress of the Department of Health and Human Services. FDA Agency level goals, objectives, and planning progress under the leadership of the new FDA Commissioner are then presented.

Next, specific information management/information technology goals and objectives for the FDA PDUFA Programs (CBER, CDER, ORA, OC) are presented. Accomplishment of these goals will be critical to the success of the Agency and Departmental goals.

Finally, the PDUFA business and information technology goals are presented.



6.1 Department Goals

DHHS has published a Strategic Plan for FY 2003-2008. It established eight strategic goals for accomplishing the DHHS mission to protect and improve the health and well being of the American public. These goals and accompanying objectives provide the focus for HHS investments of effort and resources over the next five years. Four of those eight goals relate directly to FDA's mission:

- *Goal 2: Enhance the ability of the Nation's Health Care System to Effectively Respond to Bioterrorism and Other Public Health Challenges.* To achieve this goal DHHS will focus efforts on:
    - ♦ Building the capacity of the health care system to prepare for and respond to public health threats, especially Bioterrorism; and
    - ♦ Initiating steps to ensure the safety of food, drugs, biological products, and medical devices

- *Goal 4: Enhance the Capacity and Productivity of the Nation's Health Science Research Enterprise.* To achieve this goal, DHHS will concentrate on:
    - ♦ Making investments that advance the understanding of basic biomedical and behavioral science and how to prevent, diagnose, and treat disease and disability; and
    - ♦ Accelerating the development of new drugs, medical technology, and biologic therapies.

- *Goal 5: Improve the Quality of Health Care Services*. DHHS will especially focus on:
    - ♦ Steps to reduce medical errors and improve consumer and patient protections; and
    - ♦ Accelerating the development and use of an electronic health information infrastructure.

- *Goal 8: Achieve Excellence in Management Practices.* To help us achieve the other goals and program objectives, DHHS will institute a multi-pronged approach to improve management practices and achieve excellence by focusing on key areas in the President's Management Agenda. For example, management reforms will center on:

    - ♦ Creating a unified "One HHS"
    - ♦ Improving workforce planning and financial management
    - ♦ Enhancing the efficiency and effectiveness of competitive sourcing; and
    - ♦ Enhancing the use of electronic commerce.

In addition, the DHHS Assistant Secretary for Budget, Technology, and Finance (ASBTF), Office of Information Resources Management (OIRM) is in the process of developing a Department-wide information technology strategic plan with the following goals:

- Provide a secure and trusted information technology environment
- Enable and improve the integration of health and human services information
- Enhance the quality, availability, and delivery of HHS information and services to citizens, employees, business, and governments
- Implement enterprise approach to IT infrastructure and common administrative systems that will foster innovation and collaboration
- Achieve excellence in IT management practices

6.2 FDA Goals

6.2.1 Agency Strategic Plan

FDA's Strategic Plan highlights the following five strategic priorities. There are significant information management and information technology components involved in the activities associated with these five strategic priorities:

Strong FDA – FDA will maintain a strong science-based organization to support its risk management responsibilities by: attracting and retaining the most talented scientists; operating a streamlined and cost-effective agency that is optimally organized to support mission-critical activities; and implementing the President's Management Agenda to deliver value to our constituents.

Risk Management – FDA will continue to effectively manage product risks throughout their life cycle– from research and development through consumption. Risk management decisions will be supported by rigorous scientific analysis that weighs the risk versus risk and risk-benefit associated with Agency actions.

BioDefense – FDA will assist in countering the terrorist threat by: 1) preparing for the possibility of attacks on the U.S. population through a strengthened product monitoring infrastructure and emergency preparedness plans; and 2) responding rapidly and appropriately in the event of an actual attack with effective medical countermeasures.

Consumer Information – FDA will provide information to consumers, health professionals, and other constituencies that will enable them to make prudent decisions regarding the use of FDA-regulated products. A well-informed constituency will raise the likelihood that product risks will be reduced and improved health outcomes will be realized.

Adverse Events and Medical Errors – FDA will contribute to the reduction of adverse events and medical errors through enhanced reporting capability, strengthened problem analysis, and appropriate risk management strategies to address the problems.

6.2.2 Information Management/Information Technology Goals and Objectives

6.2.2.1 Agency PDUFA IT Objectives

The Office of the CIO has identified three major objectives or courses of action to guide Agency PDUFA IT initiatives and efforts.

- *Provide a strong governance framework, management, and oversight of IT decision-making*

The CIO is responsible for the overall coordination and success of the PDUFA IT Program and will conduct quarterly reviews on the progress of projects and initiatives and take corrective action as appropriate. As outlined in the PDUFA IT goals, an annual assessment of the program's progress will be developed for the Commissioner of the FDA, with allowable information shared with the public.

- *Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward.*

  The ERSR program is comprised of many projects and activities. ERSR covers projects involved in applying IT solutions for the electronic receipt of submissions and for how data is submitted, tracked, managed and responded to throughout the review and approval processes for new drugs and biologic products. The ERSR program will be reevaluated to determine the best course to build upon its successful initiation in PDUFA II and continue advancing projects to fully achieve PDUFA III goals. Study results will influence future plans and the priority of resource allocation.

- *Increase the efficiency of IT programs and services to better support all of its customers*

  There are many initiatives that will be led and directed by the Office of the CIO in collaboration with the FDA Centers and Offices. The FDA CIO's office has embarked on a number of crosscutting initiatives designed to increase the efficiency of IT programs and services to better support all of its customers. PDUFA efforts will be enhanced by these initiatives. The initiatives include consolidation planning and implementation (closely coordinated with the Agency's Shared Services initiative), the development of an Agency-wide enterprise architecture that includes PDUFA program needs, increased attention to IT portfolio management, and assessment, training and mentoring in the application of CMM best management practices for project managers.

6.2.2.2 CBER and CDER IM/IT Goals and Objectives

The PDUFA Centers are in the process of developing comprehensive information management/information technology strategic plans that will lay out the goals and objectives over the next five years. In addition, it will tie the work to be done to the overall Agency strategic plan. ORA requirements for communication with and access to Center information systems will be identified and incorporated within the strategies for accomplishing the Center goals.

Specific information management objectives that require IT solutions are being identified for the IM/IT goals that have been identified as follows:

- *Disseminate real-time drug information to healthcare providers, patients, and consumers in an easily usable and widely accessible format*

  Directly supporting the FDA goal for providing information to consumers, health professionals, and other constituents, objectives for this goal include developing a structured format, repository, and review tools for the drug label and revitalizing the internet and intranet sites by expanding the comprehensiveness, quality, effectiveness, and delivery of information posted.

- *Identify or develop and maintain data standards and data transport standards for the drug development and clinical trials processes and for drug safety surveillance*

  Underlying all the information management and information technology goals and objectives is the critical need for standard terminologies, formats, and other data. This goal encompasses efforts to define those standards, maintain them, and publish detailed guidance for using them.

- *Apply modern technology to enhance scientific decision-making and productivity during drug regulatory responsibilities prior to drugs reaching the market*

  Significant time and resources will be devoted to providing better tools and systems to drug and biologic product reviewers. With powerful processing, storage, and analytical capability, reviewers will be able to leverage more existing information and make more-informed decisions. Objectives within this goal include provisions for addressing requirements for field investigator access of these tools and systems.

- *Apply modern technologies to enhance scientific decision-making and productivity during regulatory responsibilities after drugs reach the market*

  Objectives for accomplishing this goal include increasing FDA's technological capability to perform drug safety surveillance, leveraging existing and potential Center and Agency information to support drug product compliance activities, and improving drug product quality monitoring. Other objectives involve updating and modernizing the Agency's capability to receive, process and query information about all manufacturers, repackers, and distributors and developing new tools to enhance evidence-based decision-making during drug surveillance activities.

- *Improve cost-effectiveness, efficiency, and security measures across the Center*.

  To accomplish their goals and objectives, the Centers must create a solid foundation of management practices and infrastructure. The Centers will play active roles in supporting Agency initiatives such as establishing an Enterprise Architecture, improving project management tools, techniques, and skills, and establishing IT governance processes. Further, the Centers will work to enhance and maintain a reliable, robust, and secure computing infrastructure. With a firm foundation, the Centers hope to be able to provide their reviewers with high quality, cost-efficient, timely, and secure systems development and maintenance services.

6.3 PDUFA III Goals

6.3.1 Business Goals

Over the past 10 years, PDUFA has provided FDA with revenues essential for speeding up the application review process for new drugs and biological products. Hiring more professional staff and upgrading information technologies resulted from this influx of resources. FDA's performance met or exceeded expectations, and the benefits to consumers can be seen in the faster arrival of important new products to the market.

Generally regarded as an unqualified success, PDUFA I (FY 1992-97) sought and achieved quicker review of drug and biological product applications, and the elimination of backlogs at FDA. During PDUFA I, for example, FDA implemented performance tracking, project management methods, and standards for computer-assisted applications.

PDUFA II (FY 1998-2002) called upon FDA to shorten review times further, but more importantly, to speed up the entire drug development process. New performance goals were added that specified timeframes for activities such as scheduling meetings with product sponsors and responding to various sponsor submissions. Even though approval times for some applications began to increase toward the end of PDUFA II, FDA met the increasingly stringent performance goals.

In PDUFA III (FY 2003-2007), Congress authorized higher fees for product sponsors and some new goals and approaches for FDA. PDUFA III retains the performance goals of PDUFA II, and it adds some new goals dealing with the exchange of information between FDA and product sponsors. Application submission processes, risk management practices, and information technology enhancements are examples of new goal areas.

PDUFA has seen a progression of performance commitments designed to speed drug development and approval while preserving and even raising FDA's high standards for safety, effectiveness, and product quality. The role of information technologies over the course of PDUFA is the topic of the next section.

6.3.2 PDUFA III IT Goals

As a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, in Section XII of a transmittal letter from the Department Secretary to Congress, goals for PDUFA III IT activities were presented. The text for these goals is presented in its entirety in Attachment A, but is summarized here:

a) Centralize accountability of funds under the Agency Chief Information Officer (CIO);
b) Hold quarterly briefings with Industry and provide annual progress reports to FDA Commissioner;
c) Ensure common solutions for secure exchange and submission of application components;
d) Provide a single point of entry for all electronic submissions within a highly secure environment;
e) Implement the eCTD and provide format specification for electronic submissions of eCTDs;

f) Conduct an objective analysis for consolidation of PDUFA III IT infrastructure and desktop management services;
g) Implement a software development process improvement initiative consistent with the concepts and requirements for provided by the Capability Maturity Model (CMM) framework;
h) Ensure that PDUFA organizations use the same software applications (e-CTD, COTS) for common business needs where appropriate; and
i) Publish a PDUFA III 5-year Plan within 6 months of authorization.

These PDUFA III goals constitute an important subset of FDA's overall IT goals and objectives. FDA will address each and every PDUFA III IT goal in action and principle, reporting annually on progress made. To improve communications with our external partners, we have provided a broader picture of FDA's IT future in this IT 5-year plan, a view that goes beyond PDUFA.

7.0 PDUFA III IT STRATEGY

This section provides a summary of the programs, projects, and efforts FDA will pursue within the scope of "PDUFA III IT". In addition to providing the Agency strategy for accomplishing the PDUFA III IT goals (included in Attachment A), this section highlights how these activities will support Center/Office, Agency, and Departmental business goals.

The PDUFA III IT activities will be presented within the framework provided by the CIO's major goals:

- Provide a governance framework, management, and oversight of IT decision-making;
- Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward; and
- Increase the efficiency of IT programs and services to better support all of its customers.

7.1 IT Governance

FDA will centralize accountability and funding for all PDUFA IT initiatives/activities for CBER, CDER, ORA and OC under the leadership of the CIO. The FDA CIO is responsible for ensuring IT investments support the Agency's common IT goals, fit into a common computing environment, and follow IT industry standard management practices and CMM principles.

STRATEGY
Establish an IT Governance Process

FY 2003-2004 Targets

- Publish standard operating procedures for governance process
- Hold quarterly reviews and meetings
- Formally assess all new projects
- Develop annual report
- Acquisition and implementation of an IT Portfolio Management tool

FDA leadership will require IT projects or initiatives to have made a clear and compelling business case prior to committing resources. The governance process will include steps for monitoring and evaluating progress of IT projects by requiring in-process reviews of project schedule, cost, risk, and performance information.

The governance process objectives are to:

- Review, prioritize and fund new PDUFA investments
- Review and authorize adjustment to existing PDUFA investments
- Review and authorize PDUFA maintenance and operations funding, and
- Maintain and update the PDUFA III IT 5-Year Plan to ensure linkage to Agency strategic goals.

FDA is in the process of acquiring and setting up an IT Portfolio Management process and repository. This Portfolio Management tool will help simplify the budget process and will facilitate prioritizing, approving, and monitoring IT investments.

7.2 ERSR Program

The ERSR initiative began under PDUFA II, and both CBER and CDER have made significant progress in establishing an electronic submission and review environment. The Agency has gained experience in receiving marketing applications in CBER and CDER and Investigational New Drug (IND) applications in CBER. In addition, FDA has gained experience in receiving files electronically using a central gateway and secure email. Currently, FDA also receives abbreviated new drug applications (ANDAs), Biologics Licensing Applications (BLAs), NDAs,

Investigational New Drugs (INDs) advertising material and post-marketing safety report submissions in electronic format.

The ERSR program objectives are to:

- Establish ***standards*** for the format, content, and technical specifications for electronic submissions;
- Provide ***guidance*** for industry to follow in preparing electronic submissions;
- Design and implement ***systems*** to provide the capability and capacity for the receipt, review, and tracking of electronic submissions; and
- Update and maintain the technical and non-technical ***infrastructure*** to support the electronic review environment

FDA management now believes that the ERSR program needs to be reviewed in its entirety to use its recently-gained experience and ensure that its direction and outcomes use the best and most cost effective technology over the next 5 to 10 years.

Further, with the many fundamental management and organizational changes taking place in FDA, the Agency considers this an opportune time to assess the ERSR Program both in the context of PDUFA III IT goals and overall business goals. FDA already has made significant progress toward accomplishing the PDUFA III IT goals by making the decision to transfer the review of biologic therapeutic products from CBER to CDER (discussed further in section 7.3.2). FDA must re-assess its ERSR project plans to determine the best path for system development in light of this decision.

The goal is to enhance the electronic submission and review environment by identifying opportunities to standardize the receipt and processing of electronic submissions, and to develop review tools with the objective of integration and collaboration.

Specific strategies for accomplishing ERSR program objectives are highlighted in the following paragraphs.

7.2.1 Standards

STRATEGY
Collaborate with standards organizations to define document and data standards

FY 2003-2004 Targets
- Complete ICH eCTD specifications
- Develop standards for clinical and non-clinical study data

The Agency plans on developing and implementing an overall electronic submission strategy based on standards for document information developed by the International Conference on Harmonisation (ICH) for the electronic common technical document (eCTD) and working with other standards organizations, such as HL7 and CDISC, for establishing data submission standards. This strategy will also include a consolidated guidance process for providing human pharmaceutical applications and related submissions in electronic format including New Drug Applications (NDA), Biologics Licensing Applications (BLAs), Abbreviated NDAs (ANDAs), Investigational New Drugs (INDs), Drug Master Files (DMFs), annual report and advertising material.

7.2.2 Guidance

FDA has found that reviewing applications provided in electronic format is more efficient than reviewing applications provided in paper. However, we have also discovered problems with electronic submissions that interfere with the review efficiency. For example, electronic submissions that do not follow our guidance can be worse than paper. In addition, lack of consistency with the organization of data delays the processing and evaluation of submissions.

STRATEGY
Develop and publish guidance to Industry

FY 2003-2004 Targets

- Publish consolidated electronic submissions guidance document
- Continue external training sessions
- Develop review technology staff
- Publish guidance and develop regulations to improve consistency with submission data

FDA believes that improving the quality and quantity of electronic submissions will increase our review efficiency. To assist industry in providing quality submissions, we are working to improve our guidance to industry by consolidating the existing multiple electronic submissions guidance documents into a single guidance document.

Improved consistency in guidance should be helpful to industry in preparing submissions. In addition, we are considering various methods to assist companies in answering questions on preparing electronic submissions, including the concept of review technologist co-located in each review division. We feel that this will also improve consistency between review divisions on electronic submission advice.

We will continue to provide external training and tutorial sessions on preparing and using electronic submissions. We will work with vendors who are developing tools for preparing and reviewing electronic submissions.

We will work with Industry to increase the number of submissions sent to the Agency electronically. We will develop guidance and regulations to improve the consistency of data organization to improve submission processing, access to documents and data, and evaluation of submission information.

In FY2003, we will publish a draft consolidated guidance document and continue external training sessions. We will begin establishing the review technology staff.

In FY2004, we will publish final consolidated guidance document and have review technologists in each review unit. We will publish guidance and develop regulations to improve consistency with submission data.

7.2.3. Systems

The objective within the ERSR Program that requires the most resources is the objective to design, develop, and implement information systems. Various systems are required to perform end-to-end processing of an electronic submission. More are required to develop, manage, approve, and store internally developed documents. Where business requirements dictate, these systems must be integrated.

STRATEGY
Evaluate the ERSR Program and Develop a Target Architecture

FY 2003-2004 Targets
- Define Target ERSR Architecture
- Conduct Gap Analysis from existing to target
- Develop migration strategy for achieving target architecture

Design and development of many of these systems began during the PDUFA II timeframe. Some were implemented and are in production now. As mentioned earlier, FDA considers now the time to assess its plans for developing new and enhancing existing systems within the ERSR Program. To that end, FDA plans to develop and document the following:

- A target architecture for systems within the ERSR Program that will maximize use of existing ERSR systems, but will provide for a future homogeneous review environment, where feasible and appropriate;
- A gap analysis between existing systems and the target architecture; and
- A development and/or migration strategy for achieving the target architecture.

The following paragraphs describe the functional areas within the ERSR program that would be considered within the scope of this assessment.

A. Electronic Submissions

The scope of "electronic submissions" includes all systems necessary to receive and view information and applications submitted to FDA. It also includes any IT solutions necessary to ensure the security and validity of electronic submissions.

The FDA intends to review the electronic submission process within FDA and industry. As a part of this review, FDA will assess the implications of existing FDA and industry electronic submissions initiatives such as the concept of a trusted third party proposed by the Pharmaceutical Research and Manufacturers of America (PhRMA).

STRATEGY
Define a path forward to meet electronic submissions requirements

A gap analysis will be performed between the target business needs in this area and the available and planned technology. This will serve as input to define the e-submission component of the FDA target architecture described further in section 7.3.4, "Enterprise Architecture". The target architecture will provide the foundation to develop a transition strategy from the current architecture to the target architecture meeting all PDUFA III business requirements.

FY 2003-2004 Targets
- Define Target E-Submissions Architecture
- Develop plan to achieve target architecture

FDA will continue its progress with developing an eCTD Viewer System, a system already developed as a collaborative effort between CBER and CDER. FDA has worked diligently with their partners in the International Conference on Harmonisation (ICH) on the Common Technical Document (CTD). The CTD provides the harmonized format and content for new product applications in the US, the European Union (EU), and Japan. While the CTD is based on a paper paradigm, the FDA has also worked with their partners in ICH to develop the Electronic Common Technical Document (eCTD) to provide the electronic transmission of CTD applications from

applicant to regulator. The eCTD specification is ready for implementation, as it has reached Step 4 in the ICH process. For FDA, the eCTD format will replace many of the current electronic submission formats and will allow the electronic transmission of applications that currently do not have an electronic solution. Leveraging a common technology across submission types will enhance the review process by allowing the FDA to build a common infrastructure and user interfaces for multiple submission types.

STRATEGY
Comply with ICH eCTD submission standards

To start receiving new product applications in the eCTD format, FDA has developed an internal prototype of the eCTD Viewer System (EVS). Version 1.0 of the software is scheduled for release to the review communities in CDER and CBER in the third quarter of FY03. This version will allow the reviewers to view, navigate, and download eCTDs that are submitted to the Agency. The EVS interface is built to reviewer requirements by utilizing the XML data associated with the content files and defined in the ICH Step 4 eCTD and Study Report proposal specifications.

FY 2003-2004 Targets
- Release eCTD viewer System v1.0 to production to CBER/CDER review community
- Integrate EVS into Agency architecture for e-submissions

B. Electronic Document Storage

The Electronic Document Room (EDR) functions as an electronic library for storing electronic submissions and regulatory correspondence. The EDR provides FDA a capability to receive, view, and store electronic submissions, allowing access to information from any desktop, automating analytical and administrative processes.

The EDR is integrated with the FDA regulatory databases to allow for advanced searches based on data in the FDA databases. The EDR automates processing of submissions and automatically sends notifications to reviewers. The EDR also serves as a repository for FDA generated final documents. FDA is planning enhancements to its EDR to create an automated document management system improving the efficiency of processing and accessing information.

C. Regulatory Project Management and Submission Tracking Systems

FDA is working on improving current project management tools and submission tracking systems. These systems facilitate management of applications and reporting of regulatory progress. The design includes an interface with several other systems to improve the efficiency of processing and accessing information. Submission tracking systems will improve the receipt, processing and routing of submissions and improve the ability of reviewers to retrieve documents.

D. Internal document Generation and Storage

Systems are being developed or improved to better manage the creation, storage and access to internal documents. Templates are used to assist reviewers in generating letters, memos and other types of review documents in a standardized electronic format. Functions such as automated routing, electronic signatures and integration with external document management systems improve the agency's ability for knowledge management

E. Improved, integrated user interface

Improvements to the interface to systems will improve user acceptance and their ability to work effectively. Development of Graphical User Interface (GUI) or IT Portal applications will provide the review community easy to use access to IT services and an organized structured approach for information display, retrieval, and manipulation of information while presenting the information in a clear, concise fashion.

F. Medical Information Dissemination

This significant area within ERSR is in a stage of conceptual discussion and proof of concept and involves the processing and dissemination of medical information contained in a drug label. CDER receives thousands of submissions for changes in labeling for drug products annually. These "Labeling submissions" are in addition to the tens of thousands of other application submissions (e.g., IND and NDAs) which CDER receives on an annual basis. Facilitating the processing, review and update of labeling, should improve the timeliness of disseminating medication information to the public.

The "DailyMed" initiative -- a collaborative effort between manufacturers, FDA, the National Library of Medicine (NLM), and healthcare information suppliers -- is an initiative that will improve the access to up-to-date medication information from the product labeling which is jointly created by manufacturers and FDA. Up-to-date labeling would be sent to NLM for dissemination to the healthcare information suppliers who would then make it available to the public. For the DailyMed to function properly, FDA needs to receive, process, and review labeling and then export it to the NLM in a timely fashion.

To help in the process, FDA is working on a proof of concept for an Electronic Labeling Information Processing System (ELIPs). This system will automate the receipt, validation and routing of labeling changes. It will also encompass the review, and approval process including editing, versioning, and sign-off. Finally, the system will export the up to date labeling for transmission to NLM for dissemination.

7.2.4 Technical and Non-technical Infrastructure

This objective within the ERSR program includes all support functions, including reviewer training and maintenance activities required to keep systems operating.

Training

As we strive to improve our efficiency using technology, reviewers are challenged to keep up with the skills necessary to do their work. From using email software to using sophisticated statistical software, reviewers must have the necessary proficiency to use these tools to do their job. We have found that training classes are not sufficient to maintain the high level of expertise needed. For some reviewers, it may be weeks or even months before they are required to use the skills taught in the sessions. For other reviewers, training classes are not the best environment for learning.

STRATEGY

Provide Training for Reviewers on using Electronic Submissions and new tools

FY 2003-2004 Targets

- Update training manuals to include new technologies
- Begin to develop review technology staff
- Implement "core competencies" and learning pathways

We are developing new training methods to improve reviewer efficiency in using technology tools. We are developing "core competencies" that detail what skills reviewers should have and "learning pathways" that list classes that should be taken for each discipline. In addition to existing training programs, we are considering developing a support staff of review technologists to personally assist reviewers in using software tools. The review technologists will be co located with the reviewers and provide "over the shoulder" training and assistance. The review technologists also provide "just in time" training so that new FDA reviewers and reviewers new to the electronic submission process have lessons right before they begin working on electronic submissions. We are also planning on providing training sessions on tape or online for easier access.

In FY 2003, we will update our training manuals to include new technologies and begin to develop the review technology staff. We also plan to implement the "core competencies and learning pathways. In FY 2004, we are targeting to have review technologist in each review unit.

Operations and Maintenance

Most infrastructure systems, applications, and services support a large number if not all of the FDA end users. Therefore, with such a broad dependency on these systems and services, it is critical to ensure reliable and thorough operations and maintenance resources are committed.

Operations and maintenance activities and costs include:

- FDA IT Security Program -- includes planning and execution for the Federal Information Security Management Act and Critical Infrastructure Protection activities. These activities also include security audits and remediation and any other expenses related to IT Security such as antivirus software licensing, disaster recovery, and off-site storage;
- FDA Internet/ Intranet/Web Services – includes Agency Internet/Intranet services involving development, operations, and support;
- FDA Customer Service - includes customer service Support for personal computers (PCs) and software on the desktop;
- Desktop Management -- includes desktop and laptop receiving and distribution, purchases of desktop PCs and peripherals, software such as Enterprise Policy Orchestrator and desktop test equipment;
- Network Support – includes leases for dark fiber, network storage, connections between the Center buildings and the Agency Network Control Center (NCC). Also includes building cabling, routers, switches, remote access server (RAS) software, hardware, and other set-up costs.
- Applications Software Licensing - includes applications software licensing for e-mail, desktop operating systems, standard desktop software, external computing services, Oracle, Documentum, SAS, and other licensing agreements;
- Server Support (VMS/UNIX/NT) – includes network and application server support, network operating systems, service and equipment for file and print servers, and equipment and supplies for server support; and
- Existing Application Operations and Maintenance – includes activities required to keep existing applications operating. Also includes query and reporting support for end users.

STRATEGY

Continue the operation and maintenance of existing systems and services

FY 2003-2004 Targets

- Maintain technical infrastructure and applications
- Seek opportunities to reduce O&M costs

The FDA CIO's office is committed to ensuring high quality operations and maintenance resources to ensure superior reliability and availability of these services. With that in mind, the CIO will also be seeking opportunities to reduce the current high costs of system maintenance – costs that seem to grow higher each year.

7.3 Efficiency

This section highlights major efforts that will increase the efficiency of IT programs and services to better support all IT customers.

Several of the strategies within this section must be accomplished not only to meet PDUFA III IT goals, but also Agency and DHHS goals. Therefore, the strategies presented here must be applied consistently across the Agency to achieve the maximum benefit of the efforts. PDUFA funding for these strategies, however, will be applied only in a manner that is commensurate to the proportion of PDUFA organizations to Agency-wide organizations.

7.3.1 IT Consolidation

FDA will implement an IT consolidation strategy that focuses on outcomes in three areas: organization, infrastructure services and processes.

IT Organization

The first priority of the consolidation effort is to build an IT organization that will ensure the right services are consolidated and that the requisite personnel are available at the right organizational level to manage and provide the services.

FDA will consolidate certain IT services following a "Shared Services" concept. IT services that will be in the IT Shared Services portfolio include functions such as customer service call center and e-mail administration. These services will be consolidated and managed at the Agency-level, and services will be provided to Agency sub-organizations following the requirements of the customers as stipulated in service level agreements.

Success of this shared service model will be measured by attainment of certain service performance targets and agreed-upon levels of customer satisfaction, also stipulated in service level agreements.

Infrastructure Services

Within the framework of Shared Services, the Agency will meet the Department's goal of "Consolidation of the infrastructure organization to a single organization that administers and operates servers and supporting functions such as web, database, file, print, application, e-mail, network authentication, and remote access servers". This will be accomplished by first establishing a precise definition of the services, followed by the development and phased implementation of migration plans that minimize disruption to current services and ensure "manageable and achievable milestones". Eventually, consolidation will facilitate the Agency's ability to analyze and refine its infrastructure services for greater efficiencies, as well as provide smoother adoption of new technologies.

STRATEGY
Implement IT Consolidation

FY 2003-2004 Targets
- Establish IT Shared Services Organization
- Develop Service Level Agreements
- Implement consolidated call center

Supporting Processes

FDA must establish processes for introducing and managing the application of new technologies into the Agency. While FDA has some of those processes currently, they were configured for a decentralized IT organization and technology infrastructure. As a result, FDA will now create processes to ensure:

- The right projects are selected that most effectively support the Agency's mission and business needs;
- Technologies will be deployed that are consistent with the business needs of the Agency; and are managed to ensure standardization and technical success;
- Projects will be managed in a consistent, measurable manner that will increase the chance for successful implementation of IT projects, provide management with reliable progress reports, and enable more accurate cost estimates;
- Existing processes, where necessary and feasible, will be used in order to reduce costs and time; and
- Integration with the FDA Continuity of Operations Plan (COOP) will be a normal requirement of the planning process, with special emphasis on Data Backup and Recovery.

Infrastructure/organizational consolidation efforts are underway, most notably the consolidation of the FDA call center for CDER, CBER, OC and ORA/HQ, which is anticipated to be activated by the 4th quarter of FY 2003.

7.3.2 Transfer of CBER/OTRR to CDER

A major element of the FDA's consolidation efforts is organizational alignment to improve efficiency. The Agency plans to transfer the therapeutic biologic review functions from CBER to CDER. This decision was made after a lengthy process of fact finding and deliberation.

The transfer of these therapeutic review functions to CDER is a major undertaking that will take careful planning to implement. Slightly more than 200 positions will be moving from the CBER organization to CDER. This number equates to approximately one third of the PDUFA supported staffing and resources under CBER. The challenge is to make this transition as smooth as possible as these business functions and processes are integrated.

From an IT perspective, a smooth transition is best implemented gradually. Within the first year, the transition plan includes placing staff physically and organizationally. Network and email accounts will be set up within CDER, but review staff will still use CBER software applications and data for the review process. Access to CDER software applications and data will be set up for each person, as well as access to CBER/OTRR systems for CDER personnel. FY04 targets and beyond include the analysis and eventual migration of data into CDER's central database and the elimination of duplicate tracking systems and applications. Additional resources needed to support these additional systems, whether personnel or hardware, need to be established within the guidelines of the CIO's Shared Services model.

STRATEGY

Transfer Therapeutics Review from CBER to CDER

FY 2003-2004 Targets

- Place staff physically and organizationally
- Ensure access to servers, systems, and applications
- Analyze data migration requirements
- Perform requisite data migration

The efficiency of reporting and the dissemination of information across the two databases will rely not only on the success of IT and data integration, but on the development of common reporting standards, common business practices, and common definitions of terms and codes. The initial target is for annual compilation of reports across the databases. Subsequent analysis and development of these common standards, practices, and definitions will help facilitate the migration of data into CDER's database.

The creation of an entire new Office of Drug Evaluation for the additional reviewers presents an obvious need for additional document room services. While a new document room is an obvious but expensive solution, it undermines the initiative of a central point of entry for all submissions. The targeted interim solution is to use an existing document room and establish courier service between the buildings. Analysis on the efficiency of this solution, whether it can work in other areas, and other alternative solutions will then be performed.

The difference in business practices between the two groups is the final hurdle in this transfer and affects each of the other areas above. Though parallel in the paths taken, adjustments are necessary in processes such as the tracking applications and submission status, calculating goal dates, time reporting, and user fees billing. These practices, in some cases, will require social change among the review community as much as process change will need to happen over time. The success of this consolidation, by all accounts, will make great strides toward an efficient and unified Center.

7.3.3 Project Management/Capability Maturity Model (CMM)

The FDA is pursuing a standardized approach to its IT project management to achieve full compliance with government capital planning investment control requirements and to expand sound project management (PM) practices within the Agency. At the current time, Centers and Offices are using a wide variety of project management techniques. CDER has had success in instituting a CMM program over the last two years, achieving near CMM Level II results. The Agency-wide effort will build on CDER's success and expand the application of best management practices to projects in CBER, ORA, OC and other FDA Centers. As part of the re-structuring of the CIO's office, a Project Management Office will be formed to serve as a center of excellence for the Agency.

STRATEGY

Standardize and improve project management techniques; advance software development maturity

FY 2003-2004 Targets

- Establish an Agency-level Project Management Office
- Complete Assessment
- Develop Action Plan
- Begin training and mentoring
- Adjust training and mentoring as needs define

At the beginning of FY2003, FDA acquired expert training and consulting services to assess FDA progress and train and mentor FDA IT staff. The consultant and FDA staff have performed an assessment of current Agency project management practices across centers and offices which concluded in the second quarter of FY 2003. This assessment examined two projects each from the eight Centers and Offices to form an Agency baseline of practices. From this, best management practices recommendations are expected to be developed in the late March/April time period. By the summer of 2003, training of staff will be underway. Training and mentoring of best management practices will be ongoing for the next 12 to 18 months as needed. At the same time, periodic measurement of results will be taken to assess Agency progress toward more standardized, repeatable project management results.

7.3.4 FDA Enterprise Architecture (EA)

Over the last few years, the Agency has proceeded aggressively with its Information Systems Architecture (ISA) initiative to standardize its infrastructure. FDA has established a common computing environment through the implementation of ISA by standardizing desktop and

network operating systems, desktop "office" processing software, and e-mail and calendar systems across the Agency.

FDA plans to progress further by building a common architecture for all of FDA that addresses mission/business needs. This Enterprise Architecture (EA) initiative is a collaborative effort that will include participation and cooperation of the FDA centers and the guidance of DHHS.

The architecture initiative will evaluate the business needs of the Agency, define a baseline, map a path to the desired target architecture, and provide guidance for capital expenditures. This project aligns with the Federal Enterprise Architecture published by the Office of Management and Budget (OMB) in that FDA will use the business reference model of the Federal Enterprise Architecture to identify and address areas of service to its customers.

STRATEGY
Develop an Enterprise Architecture

The EA study is underway at the writing of this Plan. In FY 2003, FDA will establish the baseline architecture. The first assessment of the "As Is" environment has been developed and will be reviewed in the spring of 2003. The first version of the "Target" architecture is expected in the summer of 2003.

FY 2003-2004 Targets

- Complete first "As-Is" Assessment
- Conduct first "Target" Assessment
- Complete second "Target" Assessment
- Implement CM practices

In FY 2004, FDA will establish Agency architecture configuration management (CM) procedures. The second versions of the "As Is" and "Target" architectures will be completed in early 2004. Establishment of the configuration management repository is expected in mid 2004. Full implementation of the "Target" architecture is anticipated in FY 2005.

7.4 Summary

The following table summarizes the strategies the FDA will pursue in FY 2003-2004 and shows a mapping of those strategies to PDUFA III, Center/Office, Agency, and Departmental goals.

	PDUFA III IT	Center/Office					Agency					DHHS			
FDA IT STRATEGIES	PDUFA III IT Goals A-I (See Appendix A for Mapping)	Information Dissemination	Standards Development	Pre-Market Decision-Making	Post-Market Surveillance	Field Processes	Strong FDA	Risk Management	BioDefense	Consumer Information	Adverse Events and	BioTerrorism	Nation's Health Science Research	Quality of Health Care	Achieve Excellence in Management Practices
Provide a governance framework, management, and oversight of IT decision-making															
Establish an IT Governance Process	**A, B, I**	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Review the efforts within the ERSR Program and move the Program forward															
Collaborate with standards organizations to define document and data standards	**C, D, E, F, I**	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Develop and publish guidance to Industry	**E, I**		✔	✔				✔						✔	
Evaluate ERSR Program and develop a target ERSR Architecture	**C, D, E, F, H, I**		✔	✔		✔	✔	✔						✔	
Define a path forward to meet electronic submissions requirements	**C, D, E, H, I**	✔		✔		✔	✔	✔					✔	✔	
Comply with ICH eCTD submission standards	**E, I**			✔			✔	✔						✔	
Provide Training for Reviewers on using Electronic Submissions and new tools	**E, I**			✔		✔	✔	✔						✔	
Continue the operation and maintenance of existing systems and services	**A, I**	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Increase the efficiency of IT programs and services															
Implement IT Consolidation	**A, C, F, I**			✔		✔	✔	✔					✔	✔	
Transfer Therapeutics Review from CBER to CDER	**A, F, I**			✔			✔	✔					✔	✔	
Standardize and improve project management techniques; advance software development maturity	**A, F, G, I**		✔			✔	✔	✔					✔	✔	✔
Develop an Enterprise Architecture	**A, C, F, H, I**	✔	✔			✔	✔	✔			✔		✔	✔	

ATTACHMENT A: PDUFA III ELECTRONIC APPLICATIONS AND SUBMISSION – GOALS

A. The Agency will centralize the accountability and funding for all PDUFA Information Technology initiatives/activities for CBER, CDER, ORA and OC under the leadership of the FDA CIO. The July 2001 HHS IT 5-year plan states that infrastructure consolidation across the department should be achieved, including standardization. The Agency CIO will be responsible for ensuring that all PDUFA III IT infrastructure and IT investments support the Agency's common IT goals, fit into a common computing environment, and follow good IT management practices.

B. The Agency CIO will chair quarterly briefings on PDUFA IT issues to periodically review and evaluate the progress of IT initiatives against project milestones, discuss alternatives when projects are not progressing, and review proposals for new initiatives. On an annual basis, an assessment will be conducted of progress against PDUFA III IT goals and, established program milestones, including appropriate changes to plans. A documented summary of the assessment will be drafted and forwarded to the Commissioner. A version of the study report redacted to remove confidential commercial or security information, or other information exempt from disclosure, will be made available to the public. The project milestones, assessment and changes will be part of the annual PDUFA III report.

C. FDA will implement a common solution in CBER, CDER, ORA and OC for the secure exchange of content including secure e-mail, electronic signatures, and secure submission of, and access to application components.

D. FDA will deliver a single point of entry for the receipt and processing of all electronic submissions in a highly secure environment. This will support CBER, CDER, OC and ORA. The system should automate the current electronic submission processes such as checking the content of electronic submissions for completeness and electronically acknowledging submissions.

E. FDA will provide a specification format for the electronic submission of the Common Technical Document (e-CTD), and provide an electronic review system for this new format that will be used by CBER, CDER and ORA reviewers. Implementation should include training to ensure successful deployment. This project will serve as the foundation for automation of other types of electronic submissions. The review software will be made available to the public.

F. Within the first 12 months, FDA will conduct an objective analysis and develop a plan for consolidation of PDUFA III IT infrastructure and desktop management services activities that will access and prioritize the consolidation possibilities among CBER, CDER, ORA and OC to achieve technical efficiencies, target potential savings and realize cost efficiencies. Based upon the results of this analysis, to the extent appropriate, establish common IT infrastructure and architecture components according to specific milestones and dates. A documented summary of analysis will be forwarded to the Commissioner. A version of the study report redacted to remove confidential commercial or security information, or other information exempt from disclosure, will be made available to the public.

G. FDA will implement Capability Maturity Model (CMM) in CBER, CDER, ORA and OC for PDUFA IT infrastructure and investments, and include other industry best practices to ensure that PDUFA III IT products and projects are of high quality and produced with optimal efficiency and cost effectiveness. This includes the development of project plans and schedules, goals, estimates of required resources, issues and risks/mitigation plans for each PDUFA III IT initiative.

H. Where common business needs exist, CBER, CDER, ORA and OC will use the same software applications, such as eCTD software, and COTS solutions.

I. Within six months of authorization, a PDUFA III IT 5-year plan will be developed. Progress will be measured against the milestones described in the plan.