Prescription Drug User Fee Act (PDUFA IV) Information Technology

Department of Health and Human Services
Food and Drug Administration

October 19, 2007

Moderator

Margo Burnette

Executive Director,
FDA Bioinformatics Board

Overview

- FDA's strategic vision for transforming regulatory operations
  - The importance of electronic submissions
- FDA's new approach for Information Technology (IT) development
- IT enhancements proposed under the Prescription Drug User Fee Act reauthorization (PDUFA IV)

Strategic Context for PDUFA Information Management

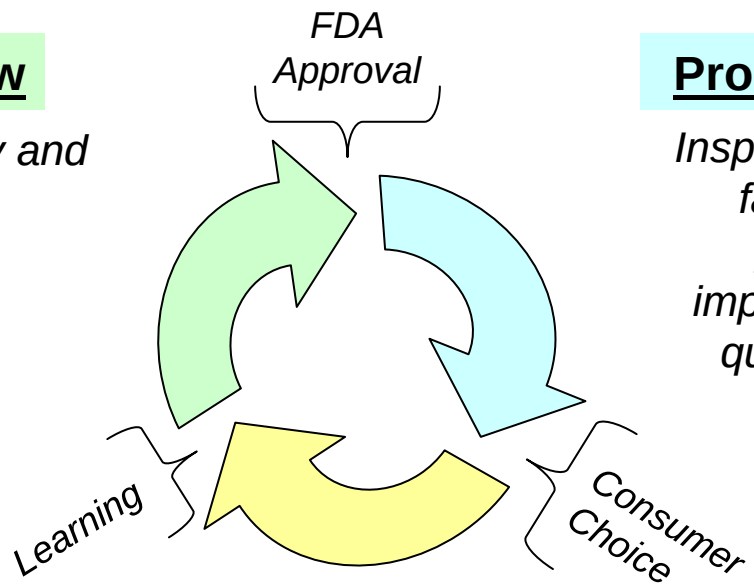
Malcolm Bertoni

Acting Assistant Commissioner for Planning

FDA's core business functions cover the life cycle of regulated products

Pre-Market Review

Assessment of safety and effectiveness of new medical products & safety of new food ingredients



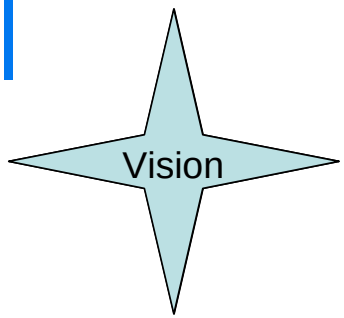
Product Quality/Safety

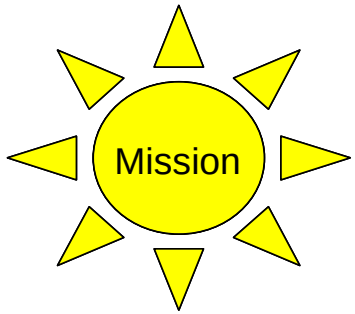
Inspection of manufacturing facilities, producers, and products (domestic and imported) to assure safety, quality & compliance with FDA regulations

Post-Market Consumer & Patient Safety

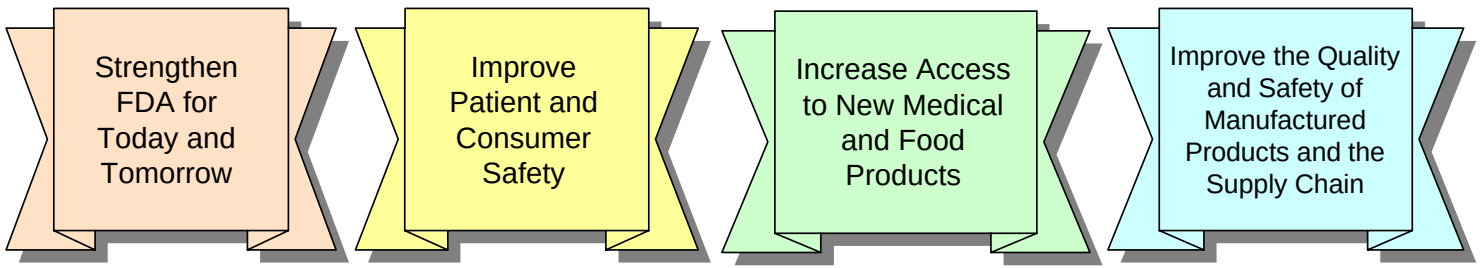
Post-marketing surveillance to evaluate product risks and benefits; risk management and communications to ensure the safety of consumers & patients who use FDA-regulated products

FDA's core business functions are reflected in our strategic goal framework





Strategic Goals



Objectives, Long-Term Outcome Goals & Mid-Range Strategies

Short-Term Action Items

Annual Performance Goals

FDA Modernized Application Review and Consultation During Development

Goal	PDUFA I	PDUFA II	PDUFA III
Complete review of priority original new drug and biologic applications and efficacy supplements	90% in 6 months		
Complete review of standard original new drug and biologic applications and efficacy supplements	90% in 12 months	90% in 10 months	
Complete review of manufacturing supplements	90% in 6 months	90% in 4 months if prior approval needed, 6 months otherwise	
Complete review of resubmitted new drug and biologic applications	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months	
Complete review of resubmitted efficacy supplements	No Goal	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months *
Discipline review letters for pre-submitted "Reviewable Units" of new drug and biologic applications	No Goal		90% in 6 months *
Report of substantive deficiencies (or lack thereof)	No Goal		90% within 14 days of filing date *
Respond to industry requests for meetings	No Goal	90% within 14 days	
Meet with industry within set times	No Goal	90% within 30, 60, or 75 days, depending on type of meeting	
Provide industry with meeting minutes	No Goal	90% within 30 days	
Communicate results of review of complete industry responses to FDA clinical holds	No Goal	90% within 30 days	
Resolve major disputes appealed by industry	No Goal	90% within 30 days	
Complete review of special protocols	No Goal	90% within 45 days	
Electronic application receipt and review	No Goal	In place by the end of FY 2002	Enhanced by the end of FY 2007

FDA uses vast volumes of information

Evaluation of new product applications

- 240 new drug applications (NDAs) and biological licensing applications (BLAs) reviewed; over 5,550 NDA/BLA supplements reviewed
- 13,000 active investigational new drugs (INDs) monitored
- 50 device PMAs, 3,600 510Ks, 230 active IDEs, 25 food additive petitions

Oversight of quality of manufacturing and production

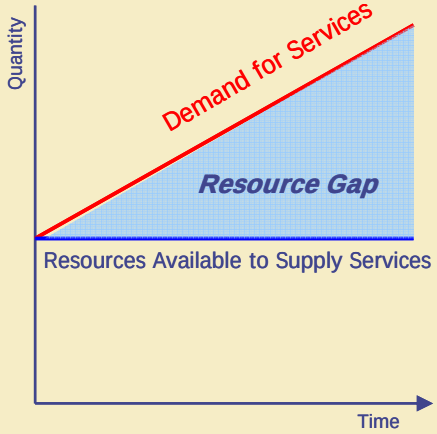
- 140,000 establishments in inventory (drugs, biologics, devices, food, etc.); 45,000 inspections annually
- 20 million total annual imports (12 million in Foods; 5.7 million in Medical Devices; 1.7 million Cosmetics; 380,000 Human Drugs; 260,000 Animal Drugs and Feeds)

Monitoring of product safety

- 200,000 serious/unexpected (15-day) drug adverse event reports (AERs)
- 150,000 medical device AERs
- 15,000 vaccine AERs
- 5,000 consumer complaints (9% involving death, illness, injury)

FDA recognizes the need to transform our operations to enable us to do more with what we have

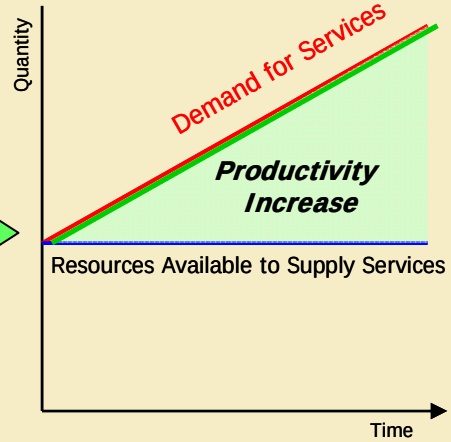
If we keep at it the way we're doing it now, the gap widens…



If, instead, we embrace a new vision…

Strategic redirection

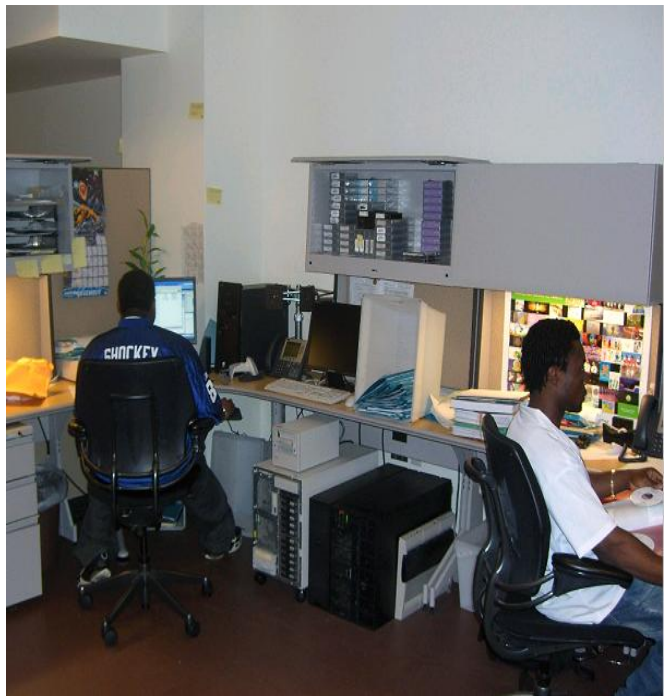
…and execute sound plans effectively…



"Science-Led Modernization"

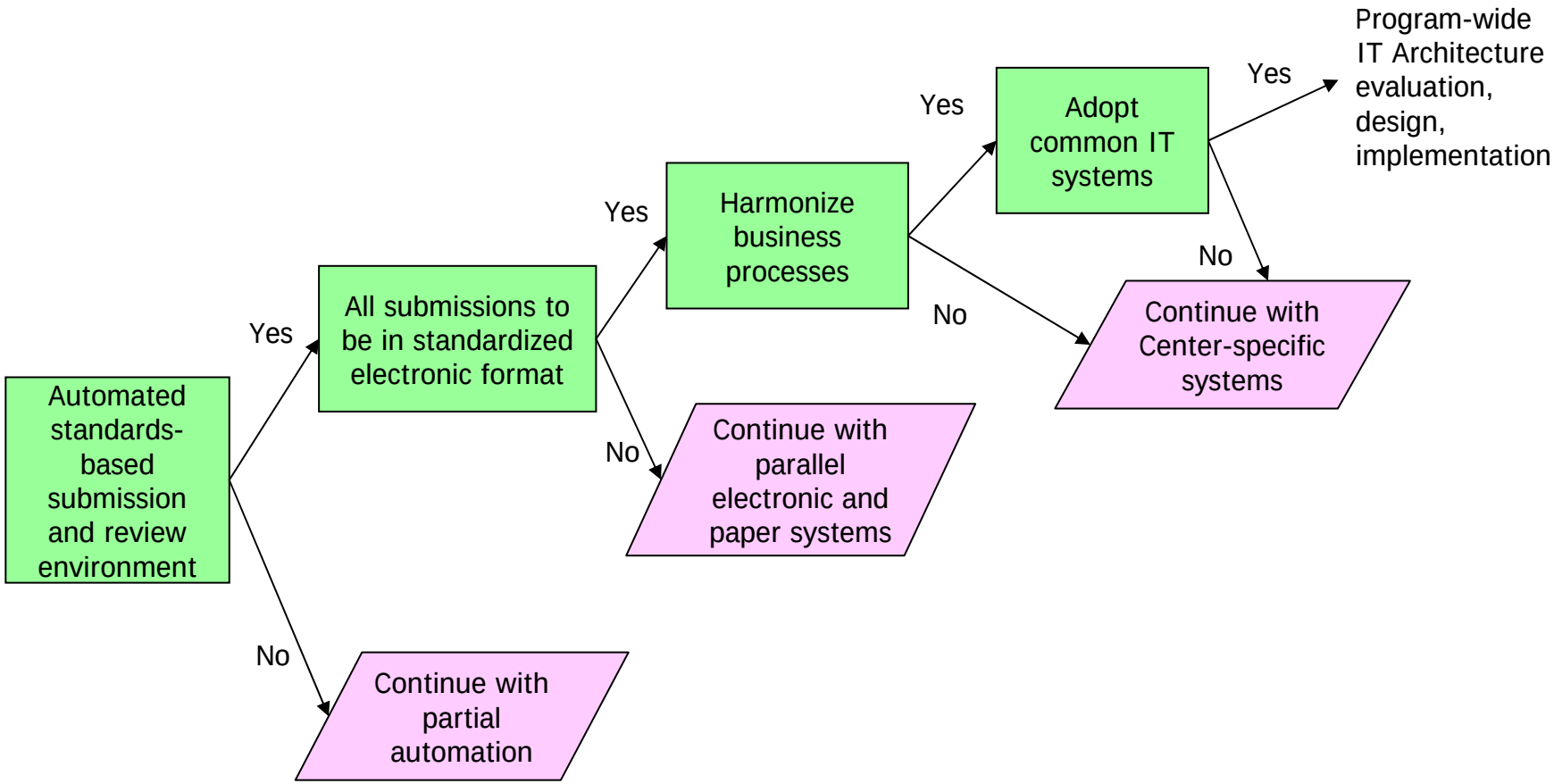
A key transformation involves eliminating paper!

Current Paper Document Room



Electronic Document Room

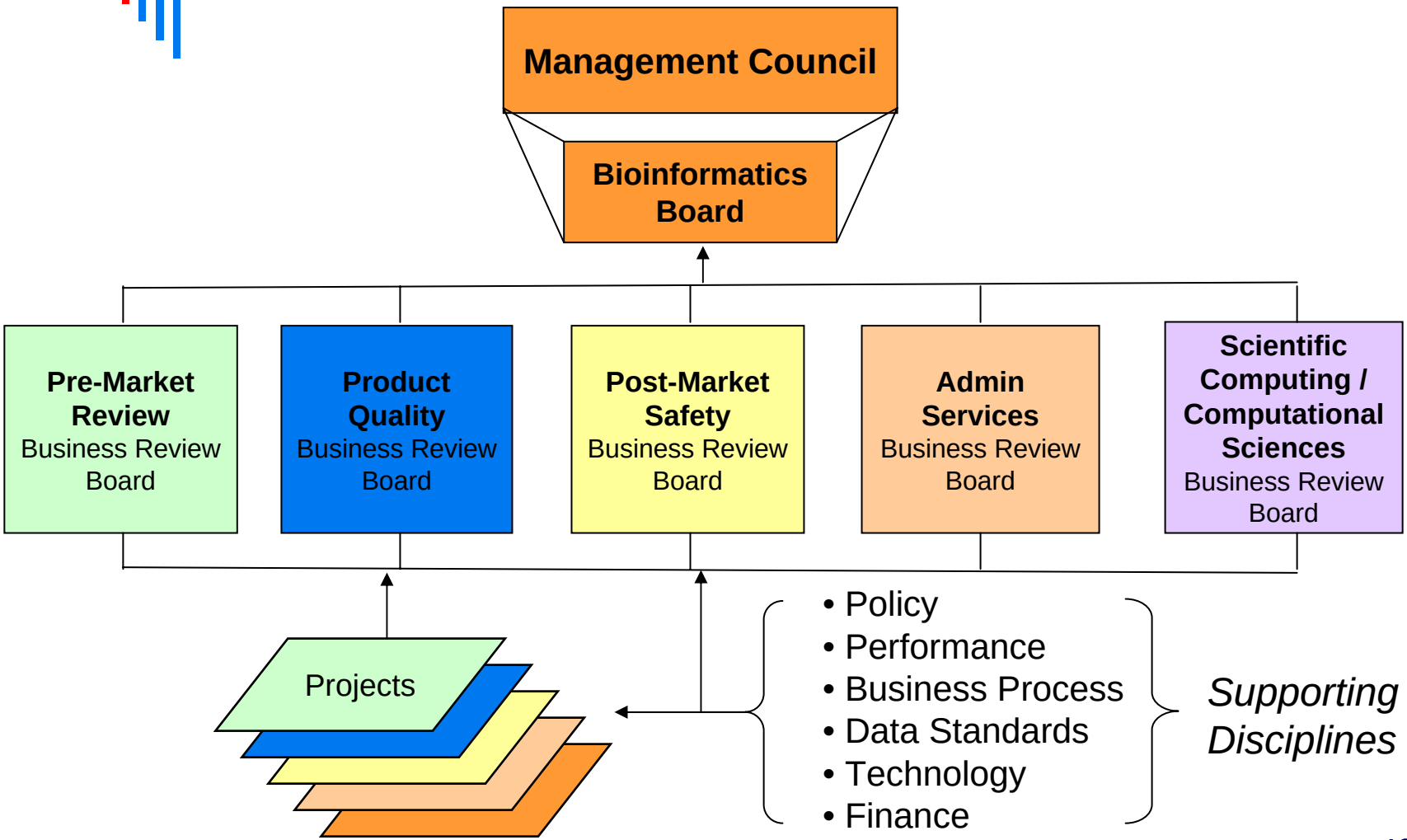
Strategic Driver: Long-term goal of an automated standards-based IT environment



We are working to improve the quality and usability of our data

- **Currently:**
  - No standardized format; varied systems reliability
  - Various media and mostly paper
  - Product data: more data landfill than database
  - Facility data: gaps & duplication in inventory
  - Public access to information: spotty
- **Plan for Future:**
  - Standardized format and terminology
  - All-electronic, reliable and secure
  - Products: can be analyzed across lifecycle, therapeutic class, patient subpopulation, etc.
  - Facility inventory: accurate & complete
  - Public access to information: timely & easy

FDA Bioinformatics Board Organization



FDA's New Approach to IT Development

Timothy Stitely

Chief Information Officer

Examples of areas being assessed for cross-Agency initiatives

- Technology infrastructure modernization to better support scientific computing
- Adverse event reporting and analysis
- Facility registration and product listing
- Electronic document storage
- Regulatory submission and review tracking

Information Technology Performance Commitments

Mark Gray

PDUFA IT Program Manager

Goal: Speed Progress Toward Fully Automated Standards-Based Human Drug Review

- Build on Information Technology (IT) accomplishments of PDUFA III
  - Electronic Common Technical Document (eCTD) standard for submitting INDs, NDAs, and BLAs electronically
  - FDA Electronic Gateway – single portal for electronic submissions to FDA via the Internet
  - Progress toward consolidated IT infrastructure
  - Improved communications and technical interactions
- Build toward FDA's vision for operations in the 21st Century

PDUFA IV IT: Objectives

- By the end of PDUFA IV:
  - Industry will be able to send in their electronic applications with automated cross-links to previously submitted data and information, so that they only have to submit information once
  - FDA reviewers will be able to retrieve all relevant submissions and related data electronically from their work station, and have efficient tools for searching and analyzing data to support their review
  - FDA will be able to manage drug labeling submittals and labeling discussions with sponsors in a modular manner using Structured Product Labeling electronic format, assuring integrity and configuration of the product labeling information
  - FDA will have capability to handle two-way regulatory correspondence with industry, accelerating movement toward all-electronic submission and review environment, and reducing paper submission management systems
  - FDA will have access to important external population databases for both additional epidemiologic research and targeted safety surveillance
  - FDA will have standards-based post-market drug safety information systems to support drug safety adverse event reporting activities and surveillance

PDUFA IV IT: Process and Measures

- Rolling five-year IT Plan for technical approach to a more integrated, standards-based automated regulatory electronic submission and review environment
- Quarterly meetings with industry to discuss implementation of the IT Plan and potential impacts of current and future activities on stakeholders
- Measures of progress toward achievement of objectives
  - Metrics on how often industry is submitting material electronically and how well they are complying with electronic submission standards
  - Metrics on how well FDA is transitioning from legacy IT systems to new-generation common systems

PDUFA IV IT: Five-year Plan

- Process
  - IT Plan will be reviewed and approved through appropriate FDA governance process
  - Draft IT Plan will be published for public comment by December 31, 2007
  - Publish final version no later than May 30, 2008
  - Conduct an annual assessment of progress
  - Periodically update the plan

- Content – provide a vision for FDA standards and technical infrastructure supporting the process for the review of human drug applications
  - business processes targeted for automation
  - electronic data standards being considered for adoption or development
  - implementation of information systems that are based on the electronic data standards
  - Description of the process for evaluating, adopting/developing, piloting, and deploying electronic data standards information systems for information exchange between FDA and regulated parties or external stakeholders

Benefits to patients, industry, and FDA from IT investments

- Improved public health through better information and analysis
- Improved productivity and efficiency
- Greater consistency across FDA
- More predictable technology improvement path
- Improved harmonization with international standards