PRESIDENT'S MANAGEMENT AGENDA

The President's Management Agenda (PMA), announced in the summer of 2001, is an aggressive strategy for improving the management of the Federal government. It focuses on five areas of management across the government where improvements and progress can be made to deliver results to the American people. It reflects the Administration's commitment to achieve immediate, concrete, and measurable results in the near term, while focusing on remedies to serious problems, and commits to implement them fully.

The five government-wide goals are Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Performance, Expanded E-government, and Budget and Performance Integration. These goals are mutually reinforcing. For example, workforce planning and restructuring undertaken as part of Strategic Management of Human Capital will be defined in terms of each agency's mission, goals, and objectives--a key element of Budget and Performance Integration. Agency restructuring is expected to incorporate organizational and staffing changes resulting from Competitive Sourcing and Expanded E-government. Likewise, efforts toward Budget and Performance Integration will reflect improved program performance and savings achieved from Competitive Sourcing and will benefit from financial and cost accounting and information systems which are part of efforts in Improved Financial Management. This review will give an update of the Agency's progress and achievements made during the past year.

Strategic Management of Human Capital

FDA is moving assertively to meet the goals of the PMA and is firmly committed to the DHHS goals to significantly improving efficiency and controlling FTE growth. The Agency has already taken a series of important steps towards achieving these goals and will continue to do so to meet the PMA and the DHHS initiatives.

Workforce Development Programs -- The FDA has expanded its FAME [Formula for Achieving Managerial Excellence] leadership training created to assist supervisors, managers and team leaders in identifying and developing the critical management and leadership skills necessary to communicate effectively, manage successfully, and create and contribute to motivated high-performance teams. FAME has also been expanded to include a fourth course, Supervisory Potential Program, which was designed to address FDA's succession planning needs and supports the FDA's strategic workforce plan to build a strong FDA by identifying future supervisors early in their careers. FDA widened its audience to include non-supervisory employees seeking the opportunity to explore supervision as a career. A leadership development program was redesigned to internally groom the future leaders of the agency.

Workforce Analysis and Workforce Planning -- A strategic workforce restructuring plan was submitted during the FY 2005 budget process outlining FDA's on-going restructuring initiatives to right-size FDA's workforce

transitioning from a large administrative support staff within each of FDA's components to a smaller, centralized unit providing administrative and support services customized according to component's needs and funded on a reimbursable basis.

FDA is moving toward competency-based business processes that depend on the correct mix of skills and abilities. With improved business processes and realigned support services, FDA should be able to redirect its resources into more mission critical positions whose skills and abilities would enable the Agency to meet its performance commitments.

Workforce Restructuring -- In an effort to improve upon our Human Capital Management Initiative, FDA offered Voluntary Separation Incentives (VSIP) to an estimated 900 employees in various administrative series. The incentives were offered in an effort to reduce administrative FTE and to assist those employees affected by the current competitive sourcing studies. A total of 320 employees accepted this incentive in FY 2004.

In January 2004, FDA began to receive its human resource (HR) services from the Department's Rockville HR Center. FDA retained the strategic workforce planning and several customized programs tailored to Agency operations. These include the administration of the Peer Review System, Commissioned Corp HR liaison, performance management, and award ceremonies.

In early FY 2004, the Office of Shared Services (OSS) was launched to provide administrative services from a single organization. By the end of FY 2004, all of FDA components including the ORA and NCTR were integrated into the OSS framework. The promise of OSS, combined with improved business processes, will allow FDA to maintain administrative service levels with substantially fewer staff.

Special Recruiting -- The Agency has embarked on a strategic recruitment outreach initiative designed to ameliorate the most significant area of under representation in the FDA workforce, namely the Hispanic community. FDA has also participated in the implementation of the Department's Hispanic Outreach Initiative.

Accountability -- In FY 2004, all of FDA's employee performance contracts and plans were linked to Agency and Departmental program goals and management objectives. This requirement will continue in FY 2005.

Improved Financial Performance

Erroneous Payments
FDA participated in the DHHS' Recovery Auditing Work Group, to develop uniform policies and procedures to be used across the Department in complying with the Improper Payment Improvement Act. The final Statement of Work has been submitted for review. FDA also conducted improper payments risk assessments for its Foods, Human Drugs, and Medical Devices programs.

Financial Management Improvement --
At the beginning of FY 2004, FDA transferred its processing of financial transactions (commercial payments,

travel, payroll, etc.) from the Office of Financial Management (OFM) to the OSS, which was created to provide administrative services for all FDA staff in the centers, field, and headquarters using the "shared services" model to achieve savings through management efficiencies and cost effective service delivery. OFM retained the functions related to policy, reporting, systems, application management, budget formulation, and budget execution.

FDA created the User Fees Team to better manage the execution, reporting and accountability of the FDA's user fee programs, in addition to the information provided for the budget formulation process. These programs include the Prescription Drug User Fee Act (PDUFA), Medical Device User Fee and Modernization Act (MDUFMA), Animal Drug User Fee Act (ADUFA), Mammography Quality and Standards Act (MQSA), and Export Certification user fees. The User Fees Team is also responsible for implementing the new user fee system to administer user fee transactions and assist in the development of the financial reports required by Congress for PDUFA, MDUFA, and ADUFA.

FDA received its seventh consecutive unqualified, or clean, audit opinion on its financial statements from the DHHS Office of Inspector General in December 2004.

FDA jointly lead a financial shared services center study for HHS which will be used along with the information obtained from other OPDIVs to formulate DHHS policy on financial services.

Data clean-up and process improvement activities continued in multiple areas, including Open Documents, fund Balance with Treasury, SF-224, Accounts Receivable, Travel Advances, and Grants Reconciliation.

Financial Systems -- In FY 2004, FDA entered the development phase of UFMS. This involves evaluating the software to see if it meets FDA-specific needs, testing the new system and determining training requirements for users. The Agency will also continue data clean-up, collect management reporting requirements, and support the upgrade of the legacy systems.

In FY 2005, FDA will complete implementation of UFMS, replacing its old general ledger accounting system and continue planning for additional modules while continuing to support its current systems. FDA-specific projects are known as the Financial Enterprise Solutions (FES) that is comprised of a set of distinct and separate FDA financial systems that are integrated with HHS' UFMS. The following is a description of the UFMS and FES project activities:

UFMS

- Completed the business process flows that document the FDA approach to processing financial transactions through the system;
- Began the Data Conversion strategy discussions for FDA in preparation for the cutover on October 1, 2004 and April 2005;
- Began validating the FDA accounting transaction codes and associated pairs against the Treasury Standards to identify the gaps;
- Began participation in global interface teams for both global and FDA specific interfaces including: payroll, grants, procurement, travel and property;
- Worked on refining the plan for incorporation of Business Transformation Activities;
- Conducted the FDA Conference Room Pilot with FDA components to demonstrate that Oracle Financial software could meet FDA business needs and that FDA's implementation strategy will meet the UFMS global needs; and,
- Drafted plans for communication, and began reviewing strategies for organizational assessments and Agency-wide end user training.

FDA's share of the FY 2006 UFMS costs is $ 11.595 million, which excludes operations and maintenance costs.

FES

- Modernized financial management infrastructure for the remaining user fee programs (PDUFA, MDUFMA, MQSA, and export certification) based on the successful implementation of the Animal Drug User Fee Act. Accomplishments include:
    - Interfaced to obtain applicant data, track user fee billing and collection, and provide financial reports of user fee activities; and,
    - Modified the Accounts Receivable System by capturing initial user fee program receipts and transitioning these receipts to the Accounts Receivable module of the new financial system.
- Continued the implementation of the Purchase Request Information System (PRISM) by:
    - Working with FDA contracting staff to develop requirements for the contracts implementation of PRISM; and,
    - Begining planning the implementation of i-Procurement software that will automate the process of requisitions and interface with PRISM and UFMS. I-Procurement will begin implementation in April 2005 and continue through FY 2006.

- Travel Manager and 348 Sponsored Travel Module
    - Completed implementation of FDA Travel Manager for the entire Agency;
    - Completed (HHS-348) Sponsored Travel module roll-out;
    - Provided safeguards to insure complete review of documents, compliance with travel regulations and official approvals, including on-line signature capabilities; and,
    - Allowed users to assign and allocate cost differentials among sponsors, handle diverse travel reimbursement categories, certify and print associated documents, and electronically route documents and forms to correct destinations.

Accountability -- FDA has strong internal controls over financial reporting and management practices. Some examples include the following:

- Prepared monthly and quarterly reconciliations as required by the Department to ensure the balances reported in financial reports are accurate;
- Ensured that training, communications, completing critical reconciliations, and holding managers accountable for their assigned areas of responsibility.
- Included financial performance measures in the performance plans of all senior executives at FDA;
- Prepared and submitted FY 2004 Corrective Action Plan to DHHS; and,
- Prepared and released the MDUFMA and PDUFA reports on the management of both user fee funds.

The FY 2004 Conformance Statement determined that FDA's financial management systems were in general conformance to financial system requirements found in OMB Circular A-127. This determination was based on a review of previous audit findings, completed corrective actions, and the design and implementation of new financial management system that is intended to bring all of the Agency's financial systems into substantial compliance to Section 803(a) of the Federal Financial Management Improvement Act (FFMIA).

While the OIG determined in the financial statement audit that FDA's financial management systems do not substantially comply with FFMIA, this noncompliance should be removed once UFMS is fully operational. No instances exist in which FDA's financial management systems do not substantially comply with Federal accounting standards and the U.S Standard General Ledger at the transaction level.

Integrate Financial and Performance Management Systems -- The requirement to support the integration of performance and financial reporting that meet the specifications in OMB Circular A-11, Part 6 has been identified within UFMS. Currently, no method exists for reporting. A custom reporting solution in the Oracle Federal Financial software will be created to comply with this requirement.

In addition, the FDA's Annual Financial Report includes both cost information and performance results. Performance results come from select performance goals and measures chosen by FDA programs, while cost information is derived from the Statement of Net Costs. Combining these elements provides a picture of the program, its accomplishments and costs.

Expanded E-Government

IT Consolidation - FDA continued its progress towards the consolidation of its IT infrastructure by collaborating with DHHS towards achieving its "One HHS" goals and objectives; initiating efforts to accomplish the IT consolidation goals mandated by the reauthorization of PDUFA, and establishing an IT Shared Services organization to manage the FDA's consolidated IT infrastructure. To this end, FDA has:

- Launched the Office of Information Technology Shared Services (OITSS) – The goal of the FDA was to facilitate the goal of IT consolidation, enabling the Agency to deploy IT effectively and efficiently. This was achieved on October 1, 2003. The support of the ORA and NCTR completed by the end of FY 2004. This organization will facilitate management of FDA's IT resources, enabling the Agency to devote more time and effort to its E-Gov. efforts;

- Reorganized the Office of the Chief Information Officer (CIO) to ensure key strategic leadership in IT and improved capability for ensuring that IT strongly supports FDA mission goals and objectives;

- Transitioned all Center, OC and ORA formal IT organizations to directly report to the CIO;

- Awarded the Single Source Infrastructure Service Support Contract in August 2004 that will provide efficiencies and savings through consolidation of services and management of contractors;

- Completed its PDUFA III IT Strategic Plan which outlines long term strategies for meeting PDUFA goals and effecting consolidation;

- Instituted the PDUFA IT Governance process to more closely link PDUFA IT initiatives to satisfying PDUFA III IT goals;

- Made substantial progress in the area of standardization by implementing the Electronic Common Technical Document (eCTD) specification, releasing draft guidance, and deploying the eCTD Viewer system as a tool in reviewing the new application submitted in the eCTD format.

Enterprise Architecture – IT Projects –

- Developed "As Is" baseline architecture and initiated the Agency e-submission strategy by developing requirements and the appropriate target architecture;

- Produced, and initiated implementation of a Corrective Action Plan to effect mature project management practices throughout the Agency including establishment of a project management (PM) training program;

- Developed and implemented the FDA Unified Registration and Listing; in the short term, produced a Food Registration and Account Management Module that met the mandatory requirement for Food Facilities to begin registration on October 12, 2003 and; in the long term, will consolidate other FDA registration systems; and,

- Advanced the Capital Planning and Investment Control process as a result of the establishment of the Project Management Office, which has fostered project management training, and development of policies relating to the systems development life cycle and governance process; and the acquisition and institutionalization of a portfolio investment management tool.

Government E-Projects – FDA has made significant contributions to this effort by providing key IT and technical personnel to actively participate on each DHHS project team. This collaborative effort also extends to the Enterprise Human Resource Planning project and HHS Corporate University. Agency IT staff has also made contributions as part of the development of the HHS 5-Year IT Strategic Plan. The FDA has begun the development of an Enterprise Architecture (EA), having completed an "As Is" baseline. The EA efforts continue to be closely aligned with the DHHS EA Program.

FDA is continuing to contribute key IT and financial technical personnel in support of various Departmental projects. For example, FDA is participating with the Department, who is a managing partner, in the Federal Health Architecture initiative, which is a set of guiding technology and management principles that will impact the health industry by enabling innovation in care, reduced cost, and improved access and enhanced public health threat preparedness.

The Agency is involved in the Business Gateway E-Gov initiative by participating in design and implementation meetings and using the E-Forms Catalog to register FDA forms.

FDA assumed a leadership role in the Department for the Online Rulemaking Initiative – the formal launch of Phase I of www.regulations.gov was successfully held on January 23, 2003. Work has begun on structuring Module 2, and a team has been set up to provide continuing maintenance and web site change control.

The team is now involved in the Phase II requirements process. The team has a representative on the technical and the legal workgroups. The legal workgroup is currently identifying legal issues that will have to be resolved before moving to a central system. The technical

workgroup is working to define the technical blueprint/road map for the construction of the eRulemaking system.

In addition to these activities, FDA supported various Departmental initiatives such as:

Secure One HHS – The goal of Secure One is "to create an enterprise-wide secure and trusted IT environment in support of the overall HHS mission". FDA has supported this goal by establishing a comprehensive security program that:

- Contains security performance measures and metrics, regularly monitored by the FDA Chief Information Systems Security Officer;

- Characterizes and categorizes systems and resources to identify what is most critical and vulnerable, in order to develop reliable and appropriate security plans;

- Institutionalizes an Agency-wide training program impacting both system managers and the general user; and,

- Makes use of a well-coordinated communications effort to highlight security as the highest priority of the FDA CIO and inform all levels of the FDA workforce.

In FY 2004, FDA documented in formal reports (Privacy Impact Assessments, Plan of Actions and Milestones, and Certification and Accreditation) outcomes demonstrating FDA successfully and fully met the goals of the Secure One HHS Program.

Grants Consolidation – FDA is working with NIH staff regarding details of the migration to the eRA/IMPAC II Grants Management System. FDA has also participated in two DHHS subcommittees established to achieve efficiencies and uniform processes across the Department.

HHS enterprise-wide initiatives – Consolidation of like-services has been a linchpin of the "One HHS" strategy. FDA has provided expertise and resources, with special emphasis on the following projects:

- HHSnet – HHSnet is a department wide initiative to architect a comprehensive network design that encompasses all aspects of the HHS Enterprise Network including the build-out of the HHSnet Network Operation Center (HHS/NOC), while maintaining a strong security posture. The goals of the network redesign are to support intra-operational division communications, to ensure high performance and reliability of strategic systems. FDA assumed a leadership role in the effort, working closely with OPDIV and HHS counterparts, and meeting regularly with senior HHS leadership to discuss progress. FDA was the first OPDIV to transition to the new network, and then coordinated the deployment of other segments throughout HHS. FDA will relinquish control in October when the network is operational; and,

- Unified E-mail – Another consolidation strategy has been unifying e-mail systems across HHS

in order to take advantage of economies of scale and common standards. FDA has been a strong participant, having appointed a team responsible for managing FDA's responsibilities from design to rollout. The team is currently working to define FDA requirements and incorporating them into the final design.

Competitive Sourcing

FAIR Act Inventory --
In accordance with the Federal Activities Inventory Reform (FAIR) Act of 1998, FDA submitted its 2004 FAIR Act inventory, which identified 1,516 FTE as commercial and 9,044 FTE as inherently governmental. The development of the FY 2004 FAIR Act inventory began in March 2004.

Competition Schedule – In FY 2003, FDA completed all six scheduled studies involving 230 FTE in an average of 12 months or less meeting both the competitive sourcing standards for success.

Full cost comparison studies of graphic arts/visual information services, medical/scientific library services, and a television studio were done in FY 2003. The decision was to retain the functions in-house, with Most Efficient Organizations (MEOs) implemented in December 2003. Full cost comparison studies on General Accounting, Facilities, and Biological Physical Science Technicians were completed in FY 2003. These MEOs were implemented in March 2004.

FDA estimated total expected savings over a five year performance period for the six MEOs at $16.4 million with no involuntary separations. Coupled with the other administrative restructuring taken in FY 2003 and FY 2004, FDA met the Secretary's goal of administrative staff reduction set in FY 2005 and achieved significant savings that were redirected into mission critical activities. FDA formally began its study for clerical support services on February 26, 2004. This study encompasses 350 FTE and is currently in the source selection phase of the competition with a target completion date of February 25, 2005.

Participates in Department-wide Initiatives -- FDA is also renegotiating its Memorandum of Agreement with the National Treasury Employee's Union to reflect changes to OMB Circular A-76. FDA has also been instrumental in helping HHS formulate its competitive sourcing and green plans. In addition, FDA is working with HHS to develop criteria to define a high performing organization**.**

Budget and Performance Integration

The Office of Management and Budget specified criteria that DHHS had to show progress in order to achieve a passing score. Progress is shown in four areas: performance information in the DHHS FY 2006 budget request, development of the FY 2006 HHS Annual Performance Plan, use of PART information in Agency decision-making, and using reports integrating financial and performance information for agency deliberations.

FDA's FY 2005 Congressional Justification (CJ) integrated performance information throughout the budget

narrative and aligns program sections by FDA strategic goals. The CJ contained an efficiency goal and several outcome performance goals that were recommended in the first PART assessment, and explained how OMB's PART evaluation was used to guide resource and performance decision-making in creating the FY 2005 budget and performance request. The CJ also included full cost information for each performance goal.

Development of Annual Performance Plan / Report -- FDA has worked with the HHS Office of Budget staff to complete the final FY 2006 HHS Annual Performance Plan. Two of the 19 representative programs are from FDA. FDA provided accurate and timely performance and budget information on both of its represented programs. FDA has decreased the overall number of goals in the performance plan from 71 to 44 and also included new long-term outcome goals. In addition, the mix of goals has been refocused toward high-risk goals, particularly to guard against the terrorist threat.

In the FY 2006 budget period, the FDA budget request and performance plan are combined into one performance budget document. This document adds performance plan information along with the FY 2006 performance goals and its full cost information to the traditional budget program chapter. The remaining items contained in the former plan are part of the performance budget's appendices.

Use of Information From PART in the Integration Process -- Since FDA was fully assessed in FY 2005, the Agency did not have any programs to propose for FY 2006-2008.

FDA has responded to the OMB PART with a concerted effort led by our Commissioner and his leadership team. The result of that effort yielded FDA a moderately effective rating. OMB requested FDA to provide yearly updates to show progress on the development of new long-term outcome goals.

Accordingly, FDA developed eight new long-term outcome goals for the FY 2005 PART. In order to meet the strategic goals' performance commitments specified by the annual performance and outcome goals, Agency leadership also developed a Strategic Action Plan (issued in August 2003) which provided the framework for building the capacity and capability for meeting these commitments.

To monitor the Strategic Action Plan's objectives and GPRA performance commitments, FDA leadership established the Strategic Planning Council to ensure timely progress.

In January 2004, this council agreed to establish a performance framework that systematically linked an array of program activities, outputs, and outcomes to support and demonstrate progress in meeting the long-term outcome goals. This council has also charged that the Agency should prepare for the FY 2006 PART process with DHHS and OMB in order to improve the Agency's PART score and make performance and resource decisions for the upcoming budget cycle.

In addition, the budget and performance integration efforts of the past several years have more consciously linked resources with results. Under this new methodology, the traditional budget presentation is now coupled with performance information presenting a complete resource and performance picture. The presentation order in the FY 2006 performance budget is: base activities (justification), program activity data (PAD), and performance targets. The resource request funds base activities that in turn support the accomplishment of discrete workload outputs, PAD and performance goal targets, which contribute to the achievement of long-term public health outcomes and strategic goals.

Examination of Reports Integrating Financial and Performance Information - Through two of its senior Agency level decision-making bodies, the bi-weekly Strategic Planning Council and the Management Council, FDA uses integrated performance and resource information to review the progress of implementing long-term outcome performance goals, to prepare for the PART meetings with DHHS and OMB, and to make performance and resource decisions for the upcoming budget cycle.

FDA also developed a marginal cost methodology that will enable program managers to determine performance and cost impacts on various budget scenarios. This methodology was presented at the Strategic Planning Council for review and concurrence. The Animal, Drugs and Feeds Program is being used as the pilot to test this methodology.

Program Assessment Rating Tool (PART) Summary

Food and Drug Administration

FY 2004–2006

(Dollars in Millions)

FY 2004 PARTs**	FY 2004 Enacted	FY 2005 Appropriation	FY 2006 Request	Narrative Rating
FDA's Five Centers were evaluated: -- Center for Biologic Evaluation & Research -- Center for Devices & Radiological Health -- Center for Drug Evaluation & Research -- Center for Food Safety & Applied Nutrition -- Center for Veterinary Medicine				All received Results not Demonstrated

**No resources are shown because OMB decided in the FY 2005 PART process to evaluate FDA as a whole entity and not as separate components as in the FY 2004 PART.

FY 2005 PARTs	FY 2004 Enacted	FY 2005 Appropriation	FY 2006 Request	Narrative Rating
Food and Drug Administration	$1,800,541,000	$1,881,489,000	+$80,948,000	moderately effective
FY 2006 PARTs				
No PART was performed in FDA during the FY 2006 budget cycle.				

Narrative

For the FY 2005 PART, OMB decided to evaluate FDA as a single entity and not five programs. FDA senior leadership made a concerted effort to improve the PART score by developing outcome and efficiency goals, reducing the number of performance goals, and implementing management improvements. Based on these actions, OMB gave FDA a rating of moderately effective. Specifically, the FY 2005 PART assessment found:

- FDA has a clear mission and a unique Federal role in protecting public health;
- FDA is well managed, and a has strong and comprehensive strategic planning process;
- FDA's annual performance goals allow for measurement of performance results;
- FDA generally meets most annual performance goals;
- Financial management at FDA is sound; FDA has received a clean audit free of internal material control weaknesses for five consecutive years; and
- FDA is improving collaborative efforts with stakeholders and other Federal agencies.

FDA's senior leadership used integrated performance and financial reports to deliberate and decide on the Agency's approach to preparing FDA's Performance Budget submission. These reports enabled senior managers to understand the FY 2004 funding environment, the projected budget environment in FY 2005, and the cumulative impact of these conditions on the FY 2006 performance budget submission. This information also enabled FDA senior leadership to examine the performance impact under various budget scenarios. The FY 2006 Performance Budget reflects the deliberations of this group, based in large part on the information contained in integrated financial and performance reports.

NOTE: The OMB PART Summary Rating, which follows this summary narrative, contains a correction in the "Actual" column of the Long-term efficiency measure. This number, 2,766, is the correct number. In the FY 2006 President's Budget, this document contains the error.

Program: *Food and Drug Administration*

Agency: *Department of Health and Human Services*

Bureau: *Food and Drug Administration*

Rating: *Moderately Effective*

Program Type: *Regulatory Based*

Last Assessed: *1 year ago*

Key Performance Measures from Latest PART	*Year*	*Target*	*Actual*
Long-term Efficiency Measure: Reduce administrative staff	2004	2,855	2,766
	2005	2,623	
	2008	2,623	
Annual Measure: Percentage of new drugs and biologic product reviews completed within 10 months.	2004	90%	
	2005	90%	
	2006	90%	
Long-term Measure: Percentage of medical device submissions that will receive final decisions within 320 review days.	2001		72%
	2005	70%	
	2006	80%	
	2007	90%	

Recommended Follow-up Actions	*Status*
Is requesting additional food defense resources to support the achievement of FDA's lab surge capacity targets.	Action taken, but not completed
Will track FDA performance on new long-term outcome goals.	Action taken, but not completed

Update on Follow-up Actions:

FDA has started efforts to measure performance on long-term outcome goals developed for the FY 2005 PART. For some of these long-term outcome goals, the agency is developing baseline data needed to measure performance improvements. For others, the agency is focusing efforts on improvements in performance and management practices.

Program Funding Level (in millions of dollars)

2004 Actual	2005 Estimate	2006 Estimate
1,695	1,801	1,881

APPROPRIATIONS LANGUAGE

TITLE VI
RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; and notwithstanding section 521 of Public Law 107–188; [$1,820,849,000] *$1,881,489,000, of which $7,000,000 shall remain available until expended for plans, construction, extension, alteration, and purchase of fixed equipment or facilities*: Provided, That of the amount provided under this heading, [$284,394,000] *$305,332,000* shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, [and] shall be credited to this account and remain available until expended, Provided, That this amount shall not include any fees pursuant to 21 U.S.C. 379h(a)(2) and (a)(3) assessed for fiscal year [2006] *2007* but collected in fiscal year [2005] *2006*; [$33,938,000] *$40,300,000* shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; and [$8,000,000] *$11,318,000* shall be derived from animal drug user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, and animal drug assessments received during fiscal year [2005] *2006*, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year [2005] *2006* limitation: Provided further, That none of these shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701 [*Provided further,* That of the total amount appropriated: (1) $439,038,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $498,647,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $172,714,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $98,964,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $235,078,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $40,530,000 shall be for the National Center for Toxicological Research; (7) $57,722,000 shall be for Rent and Related activities, other than the amounts paid to the General Services Administration for rent; (8) $129,815,000 shall be for payments to the General Services Administration for rent; and (9) $115,970,000 shall be for other activities, including the Office of the Commissioner; the Office of Management; the Office of External Relations; the Office of Policy and Planning; and central services for these offices:]

In addition, mammography user fees authorized by 42 U.S.C. 263b may be credited to this account, to remain available until expended.

In addition, export certification user fees authorized by 21 U.S.C. 381 may be credited to this account, to remain available until expended.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The budget provides a [$108.78] *$49,628,000* increase in budget authority over the FY [2004 Omnibus Appropriation Act] *2005 Enacted Budget*. In addition, the Budget includes an increase of [$39.85] *$31,320,000* in current law user fees over FY [2004] *2005*, which will be used to cover *non pay related* inflationary increases [as well as increases in workload for the PDUFA, MDUFMA, and ADUFA programs]. In total, the budget includes [$1.821] *$1,881,489,000* at the program level, which includes funding for counter terrorism activities that specifically relate to the protection of products or therapies regulated by the FDA (such as drugs, vaccines, foods, and animal feed), and the availability of medical products for public health preparedness in the event of an attack. Specifically, the budget requests increased funding for food defense, *medical device review, the Office of Drug Safety, GSA Rent payments, moving expenses the CDRH Engineering and Physics lab and the shared data facility at the White Oak campus, and maintenance of building and facilities.*[medical counter measures related to terrorism or other related threats to pubic health, medical device reviews, protecting the safety of the U.S. food and feed supply from Bovine Spongiform Encephalopathy (BSE), inflationary pay increases], and moving expenses for a new Human Drugs facility in White Oak, Maryland].

Salaries and Expenses - Explanatory Notes

1/ Language is retained which provides FDA with the authority to credit to this account fees that may have been collected in excess of amounts appropriated in a previous year, if any such excess collections occurred. This is the intent of section 736(g)(4) of the Food Drug and Cosmetic Act, and it exempts FDA from making small individual refunds of unanticipated excess collections. Excess fees from previous years, if any, would be used to reduce the amount of fees FDA would collect in a subsequent year--in effect lowering the fees that FDA would otherwise assess and collect. This is intended to make appropriation language consistent with authorizing language.
2/ Important language is added that enables FDA to collect user fees for drug establishments and products, as set forth in the Prescription Drug User Fee Act (PDUFA), but that such fees collected during fiscal year [2005] *2006* year and assessed for fiscal year [2006] *2007*, not count against the FY [2005] 2006 collection ceiling established in the FY [2005] *2006* appropriation law.