

**Exhibit 300 (BY2008)**

<b>PART ONE</b>	
<b>OVERVIEW</b>	
<b>1. Date of Submission:</b>	2006-09-11
<b>2. Agency:</b>	009
<b>3. Bureau:</b>	10
<b>4. Investment Name:</b>	FDA Consolidated Infrastructure (FY08)
<b>5. UPI:</b>	009-10-02-00-01-0301-00
6. <i>What kind of investment will this be in FY2008?</i>	
Operations and Maintenance	
7. <i>What was the first budget year this investment was submitted to OMB?</i>	
FY2004	
8. <i>Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap.</i>	
<p>Since 2003, FDA IT infrastructure has been managed in a centralized manner by the Office of Shared Services (OITSS). OITSS is guided by the following principles: Management from an FDA &amp; performance-based perspective; Controls in place to assure customer expectations would be met; Portfolio of services that mapped directly to support FDA's mission; &amp; Efficiencies gained without negatively impacting performance. There is a focus on creating standards and uniform processes and effectively leveraging enterprise wide solutions to more effectively manage our IT Infrastructure. Performance is monitored through a performance based Service Level Agreement. Services include server mgmt., telecommunications &amp; network; Customer Care, including a consolidated IT Helpdesk &amp; on-site support; Applied Engineering, which ensures successful systems integration &amp; security operations; Strategic Projects, including customer relationship mgmt., planning/project mgmt., &amp; training efforts; Internet/Intranet Infrastructure mgmt.; &amp; White Oak Data Center Consolidation. The services are provided to over 12,000 employees &amp; contractors disbursed across the country.</p>	
9. <i>Did the Agency's Executive/Investment Committee approve this request?</i>	
yes	
9.a. <i>If "yes," what was the date of this approval?</i>	
2006-06-23	
10. <i>Did the Project Manager review this Exhibit?</i>	
yes	
12. <i>Has the agency developed and/or promoted cost effective, energy-efficient and environmentally sustainable techniques or practices for this project.</i>	
yes	
12.a. <i>Will this investment include electronic assets (including computers)?</i>	
yes	
12.b. <i>Is this investment for new construction or major retrofit of a Federal building or facility? (answer applicable to non-IT assets only)</i>	
no	
13. <i>Does this investment support one of the PMA initiatives?</i>	
yes	
<i>If yes, select the initiatives that apply:</i>	
Budget Performance Integration	
Competitive Sourcing	
Expanded E-Government	
Human Capital	
13.a. <i>Briefly describe how this asset directly supports the identified initiative(s)?</i>	

FDA will use competitive blanket purchase agreements and award competitively procured contracts for infrastructure initiatives. The FDA will use the A-76 study of the IT Shared Services Operations to determine how to manage the IT infrastructure and how to operate as a Most Efficient Organization. FDA will keep abreast of technology, embrace new technologies that fit the FDA structure and business needs, and achieve greater use of shared resources.

14. Does this investment support a program assessed using OMB's Program Assessment Rating Tool (PART)?

no

15. Is this investment for information technology (See section 53 for definition)?

yes

16. What is the level of the IT Project (per CIO Council's PM Guidance)?

Level 2

17. What project management qualifications does the Project Manager have? (per CIO Council's PM Guidance)

(1) Project manager has been validated as qualified for this investment

18. Is this investment identified as high risk on the Q4 - FY 2006 agency high risk report (per OMB's high risk memo)?

no

19. Is this a financial management system?

no

19.a. If yes, does this investment address a FFIA compliance area?

no

19.a.1. If yes, which compliance area:

Not applicable

19.a.2. If no, what does it address?

Consolidated infrastructure

19.b. If yes, please identify the system name(s) and system acronym(s) as reported in the most recent financial systems inventory update required by Circular A11 section 52.

Not applicable

20. What is the percentage breakout for the total FY2008 funding request for the following? (This should total 100%)

<b>Hardware</b>	4
<b>Software</b>	12
<b>Services</b>	31
<b>Other</b>	53

21. If this project produces information dissemination products for the public, are these products published to the Internet in conformance with OMB Memorandum 05-04 and included in your agency inventory, schedules and priorities?

yes

22. Contact information of individual responsible for privacy related questions.

Name

Betty Dorsey

Phone Number

301-827-6500

Title

FDA Privacy Act Officer

Email

betty.dorsey@fda.hhs.gov

23. Are the records produced by this investment appropriately scheduled with the National Archives and Records Administration's approval?

yes

## SUMMARY OF SPEND

1. Provide the total estimated life-cycle cost for this investment by completing the following table. All amounts represent budget authority in millions, and are rounded to three decimal places. Federal personnel costs should be included only in the row designated Government FTE Cost, and should be excluded from the amounts shown for Planning, Full Acquisition, and Operation/Maintenance. The total estimated annual cost of the investment is the sum of costs for Planning, Full Acquisition, and Operation/Maintenance. For Federal buildings and facilities, life-cycle costs should include long term energy, environmental, decommissioning, and/or restoration costs. The costs associated with the entire life-cycle of the investment should be included in this report.

All amounts represent Budget Authority

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 & Earlier	PY	CY	BY
	-2005	2006	2007	2008
<b>Planning Budgetary Resources</b>	0.000	0.000	0.000	0.000
<b>Acquisition Budgetary Resources</b>	0.000	0.000	0.000	0.000
<b>Maintenance Budgetary Resources</b>	156.589	68.733	71.867	74.870
<b>Government FTE Cost</b>	27.568	26.090	26.352	26.742
<b># of FTEs</b>	31	225	220	223

Note: For the cross-agency investments, this table should include all funding (both managing partner and partner agencies).

Government FTE Costs should not be included as part of the TOTAL represented.

2. Will this project require the agency to hire additional FTE's?

no

3. If the summary of spending has changed from the FY2007 President's budget request, briefly explain those changes.

An increase of approximately \$3M per year for FY2006, 2007, and 2008 for the HHS Enterprise Email System (EES) that will provide a unified enterprise-wide email and calendaring system. The funds will cover implementation costs that include mailbox fees. Additionally, the results of FDA's A-76 competitive sourcing efforts to select the Most Efficient Organization (MEO) to support the IT infrastructure will be made by December 2007. Due to the sensitive nature of pre-decisional competitive procurement activities, the Consolidate Infrastructure Ex. 300 Summary of Spending will be updated for BY2010 to reflect the implementation of the new supporting infrastructure organization after the selection decision has been formally announced.

## PERFORMANCE

In order to successfully address this area of the exhibit 300, performance goals must be provided for the agency and be linked to the annual performance plan. The investment must discuss the agency's mission and strategic goals, and performance measures must be provided. These goals need to map to the gap in the agency's strategic goals and objectives this investment is designed to fill. They are the internal and external performance benefits this investment is expected to deliver to the agency (e.g., improve efficiency by 60 percent, increase citizen participation by 300 percent a year to achieve an overall citizen participation rate of 75 percent by FY 2xxx, etc.). The goals must be clearly measurable investment outcomes, and if applicable, investment outputs. They do not include the completion date of the module, milestones, or investment, or general goals, such as, significant, better, improved that do not have a quantitative or qualitative measure.

Agencies must use Table 1 below for reporting performance goals and measures for all non-IT investments and for existing IT investments that were initiated prior to FY 2005. The table can be extended to include measures for years beyond FY 2006.

Table 1

	Fiscal Year	Strategic Goal(s) Supported	Performance Measure	Actual/baseline (from Previous Year)	Planned Performance Metric (Target)	Performance Metric Results (Actual)
1	2003	Maintain a strong and effective FDA:	Improve the provision of IT services while	Decentralized Services, multiple service contracts,	A Service Level Agreement was ratified by all FDA	Perf. eval. for services occurs at times appropriate

		Improve the provision of IT services while reducing cost and raising accountability	reducing cost and raising accountability	redundant systems	components which contains a list of key services, measurements, target levels, & freq of performance evaluation. Measures are operational, & targets are closely aligned to industry best practices.	for the service ranging from hrly for WAN connectivity, to annually for overall customer satisfaction. Approx. 90% of key services are measured & metrics exceed industry standard target levels.
2	2003	Maintain a strong and effective FDA: Improve the provision of IT services while reducing cost and raising accountability	Consolidate all IT service contracts under one primary vendor	There are 5 major IT support contracts and multiple purchase orders currently in use at FDA	Number of Consolidated Contracts	RFP was released Jan. 2004. Award of single IT Infrastructure Support contract on August 6, 2004. Implementation October 1, 2004.
3	2004	Maintain a strong and effective FDA: Improve the provision of IT services while reducing cost and raising accountability	Consolidate all IT service contracts under one primary vendor	There are 5 major IT support contracts and multiple purchase orders currently in use at FDA.	Cost Savings Realized	True savings will be realized in the reduction of resources that are required to manage only one contract (1 FTE).
4	2004	Maintain a strong and effective FDA: Improve the provision of IT services while reducing cost and raising accountability	Improve time to answer calls and resolve Help Desk issues by 10%	70% of Help Desk calls answered within acceptable time as defined by SLA; 75% of issues resolved within timeframe as defined in SLA	80% of calls answered within timeframe defined in SLA; 85% of issues resolved within time frame defined in SLA	100% of calls answered within timeframe defined in SLA; 80% of issues resolved within time frame defined in SLA
5	2004	Maintain a strong and effective FDA: Improve the provision of IT services while reducing cost and raising accountability	Improve resolution of Remote Access availability problems by 5%	80% of calls answered within timeframe defined in SLA; 85% of issues resolved within time frame defined in SLA	Remote Access availability problems resolved within timeframe defined in SLA 90% of the time	Remote Access availability problems are now being resolved within timeframe defined in SLA 80% of the time
6	2005	Maintain a strong and effective FDA and create a unified HHS committed to functioning as one Department	Consolidating servers/systems	At the present time, FDA has a large inventory of servers	Redundant Servers/ Systems Eliminated	Consolidation project began spring 2005
7	2005	Maintain a strong and effective FDA and enhance the use of IT in	Customer service delivery satisfaction ratings based on SLA metric	Prior to the implementation of the FDA Office IT Shared Services, there was no formal	Customer Satisfaction	A short survey is sent to each internal customer upon ticket closing by the IT Help Desk.

		service delivery(HHS goal).		mechanism in place for gauging customer satisfaction		Monthly analysis of surveys shows that the SLA has been met or exceeded for satisfaction across 5 categories
8	2005	Maintain a strong and effective FDA and enhance the use of IT in service delivery(HHS goal).	Customer service delivery satisfaction ratings at 80%.	Client services are not uniform across Agency; customer satisfaction is around 70% range	Customer Satisfaction 80%	Monthly surveys average 80%.
9	2005	Maintain a strong and effective FDA and enhance the use of IT in service delivery(HHS goal).	Improve time to answer calls and resolve Help Desk issues by 10%	80% of Help Desk calls answered within acceptable time as defined by SLA; 85% of issues resolved within timeframe defined in SLA	90% of calls answered within timeframe defined in SLA; 95% of issues resolved within time frame defined in SLA.	100% of calls answered within timeframe defined in SLA; 80% of issues resolved within time frame defined in SLA
10	2006	Enhance performance by transforming the systems and infrastructure to support critical agency operations.	Reduce time in capturing monitoring, and reporting infrastructure costs.	Manual process to integrate, analyze and manage various sources of financial data.	Capture activity based costing data.	A cost model has been established based on service level agreement. Provided more effective reporting.
11	2006	Enhance performance by transforming the systems and infrastructure to support critical agency operations.	Reduce time spent in monitoring performance of servers.	Non-integrated monitoring	Integrate enterprise performance data	Initial implementation has begun. Metrics will be available after implementation.
12	2006	Enhance performance by transforming the systems and infrastructure to support critical agency operations.	Capture 100% of IT inventory	Decentralize asset tracking; duplication of hardware; no consistent refresh plan/cycle.	Capture asset information: '06, 80% servers; '07, 95% servers, 50% PCs;	Initial development has begun. Metrics will be available after implementation.

All new IT investments initiated for FY 2005 and beyond must use Table 2 and are required to use the FEA Performance Reference Model (PRM). Please use Table 2 and the PRM to identify the performance information pertaining to this major IT investment. Map all Measurement Indicators to the corresponding "Measurement Area" and "Measurement Grouping" identified in the PRM. There should be at least one Measurement Indicator for at least four different Measurement Areas (for each fiscal year). The PRM is available at [www.egov.gov](http://www.egov.gov).

Table 2

	Fiscal Year	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Planned Improvement to the	Actual Results
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						Baseline	
1	2005	Technology	Operations and Maintenance Costs	IT Infrastructure maintenance cost	Current cost of infrastructure maintenance	10% reduction in cost of infrastructure maintenance	5% cost reduction
2	2005	Processes and Activities	Efficiency	Hours per day that products and services are available	Most distributed support organizations provided service 12 hours/day, 5 days/week	Critical systems available 24 x 7	Critical systems available 24 X 7
3	2005	Customer Results	Access	Hours per day that products and services are available	Most distributed support organizations provided service 12 hours/day, 5 days/week	Tier 1 Help desk support available 24 x 7	Tier 1 Help desk support available 24 X 7
4	2005	Technology	Operations and Maintenance Costs	Number of servers	Current number of servers	10% reduction in servers (more efficient use of resources in addition to maintenance cost reduction)	2.5% reduction in servers
5	2006	Technology	Licensing Costs	Cost of enterprise-wide software licensing	Current cost of enterprise supported software licensing	10% reduction in licensing costs through economies of scale	10% reduction in licensing costs
6	2006	Customer Results	Response Time	Average time between request and fulfillment	Desktop support calls handled per SLA metric	Desktop support calls closed with first Help Desk contact, where possible	70% are closed with first Help Desk contact. For those requiring deskside support, 95% are closed per SLA metric
7	2006	Mission and Business Results	Higher Education	Number of professional development courses per year taken by technical staff	No current requirement for continuing professional development	One course per year for all technical staff	65% technical staff have attended training.
8	2006	Processes and Activities	Knowledge Management	Number of Documented Processes	Current Number of documented processes	100% of processes are documented as they are developed and standardized	90% of processes are documented as they are developed and standardized.
9	2007	Technology	Improvement	Efficiency	Current service plans for Blackberry.	Management of plans to reduce overall costs by 10%.	TBD

10	2007	Customer Results	Response Time	% wait time to talk to Tier 1 level support within two minutes	90% of calls within SLA metric	92% of calls within SLA metric	TBD
11	2007	Processes and Activities	Efficiency	% of time servers are available	Within SLA server availability metric	Exceed SLA server availability metric	TBD
12	2007	Mission and Business Results	Higher Education	Number of courses per year taken by technical staff	One course per year for all technical staff	90% of staff provided at a minimum one training course.	TBD

**EA**

*In order to successfully address this area of the business case and capital asset plan you must ensure the investment is included in the agency's EA and Capital Planning and Investment Control (CPIC) process, and is mapped to and supports the FEA. You must also ensure the business case demonstrates the relationship between the investment and the business, performance, data, services, application, and technology layers of the agency's EA.*

1. Is this investment included in your agency's target enterprise architecture?

yes

1.a. If no, please explain why?

All components of the IT infrastructure have been identified in the FDA enterprise architecture. All HHS major and tactical investments will be included in the enterprise architecture by September 20, 2006 per EA program requirements.

2. Is this investment included in the agency's EA Transition Strategy?

yes

2.a. If yes, provide the investment name as identified in the Transition Strategy provided in the agency's most recent annual EA Assessment.

FDA Consolidated Infrastructure

3. Identify the service components funded by this major IT investment (e.g., knowledge management, content management, customer relationship management, etc.). Provide this information in the format of the following table. For detailed guidance regarding components, please refer to <http://www.whitehouse.gov/omb/egov/>.

*Component: Use existing SRM Components or identify as NEW. A NEW component is one not already identified as a service component in the FEA SRM.*

*Reused Name and UPI: A reused component is one being funded by another investment, but being used by this investment. Rather than answer yes or no, identify the reused service component funded by the other investment and identify the other investment using the Unique Project Identifier (UPI) code from the OMB Ex 300 or Ex 53 submission.*

*Internal or External Reuse?: Internal reuse is within an agency. For example, one agency within a department is reusing a service component provided by another agency within the same department. External reuse is one agency within a department reusing a service component provided by another agency in another department. A good example of this is an E-Gov initiative service being reused by multiple organizations across the federal government.*

*Funding Percentage: Please provide the percentage of the BY requested funding amount used for each service component listed in the table. If external, provide the funding level transferred to another agency to pay for the service.*

	Agency Component Name	Agency Component Description	Service Type	Component	Reused Component Name	Reused UPI	Internal or External Reuse?	Funding %
1	Consolidated Infrastructure	Help Desk Services	Customer Relationship Management	Call Center Management	Call Center Management		No Reuse	0
2	Consolidated Infrastructure	Help Desk Services	Customer Relationship Management	Customer / Account Management	Customer / Account Management		No Reuse	0

3	Consolidated Infrastructure	Help Desk Services	Customer Relationship Management	Customer Feedback	Customer Feedback		No Reuse	0
4	Consolidated Infrastructure	Help Desk Services	Customer Relationship Management	Surveys	Surveys		No Reuse	0
5	Consolidated Infrastructure	On-Site PC Management Services	Management of Processes	Change Management	Change Management		No Reuse	0
6	Consolidated Infrastructure	On-Site PC Management Services	Management of Processes	Configuration Management	Configuration Management		No Reuse	0
7	Consolidated Infrastructure	On-Site PC Management Services	Supply Chain Management	Procurement	Procurement	009-00-01-01-01-0001-00	Internal	0
8	Consolidated Infrastructure	IT Training Services	Human Resources	Education / Training	Education / Training		Internal	0
9	Consolidated Infrastructure	On-Site PC Management Services	Supply Chain Management	Ordering / Purchasing	Procurement	009-00-01-01-01-0001-00	Internal	0
10	Consolidated Infrastructure	On-Site PC Management Services	Supply Chain Management	Invoice / Requisition Tracking and Approval	Procurement	009-00-01-01-01-0001-00	Internal	0
11	Consolidated Infrastructure	E-Mail Administration Services	Collaboration	Email	Email	009-00-02-10-01-0009-00	Internal	0
12	Consolidated Infrastructure	Server Management Services	Systems Management	License Management	License Management		No Reuse	0
13	Consolidated Infrastructure	Server Management Services	Systems Management	Remote Systems Control	Remote Systems Control		No Reuse	0
14	Consolidated Infrastructure	Server Management Services	Systems Management	System Resource Monitoring	System Resource Monitoring		No Reuse	0
15	Consolidated Infrastructure	Server Management Services	Systems Management	Software Distribution	Software Distribution		No Reuse	0
16	Consolidated Infrastructure	Blackberry Messaging Services, Remote Access Services, Voice Over IP.	Communication	Computer / Telephony Integration	Computer / Telephony Integration		No Reuse	0
17	Consolidated Infrastructure	IT Security Services	Security Management	Identification and Authentication	Identification and Authentication		No Reuse	0
18	Consolidated Infrastructure	IT Security Services	Security Management	Access Control	Access Control		No Reuse	0
19	Consolidated Infrastructure	IT Security Services	Security Management	Digital Signature Management	Digital Signature Management		No Reuse	0

20	Consolidated Infrastructure	IT Security Services	Security Management	Virus Protection	Virus Protection		No Reuse	0
21	Consolidated Infrastructure	IT Asset and Inventory Management Services	Supply Chain Management	Inventory management	Inventory management		No Reuse	0
22	Consolidated Infrastructure	IT Requirements Analysis Services	Management of Processes	Requirements Management	Requirements Management		No Reuse	0
23	Consolidated Infrastructure	IT Project Management Services (internal OITSS)	Management of Processes	Program / Project Management	Program / Project Management		No Reuse	0
24	Consolidated Infrastructure	Network Management Services	Organizational Management	Network Management	Network Management		No Reuse	0
25	Consolidated Infrastructure	IT Facilities Management Services	Asset / Materials Management	Facilities Management	Facilities Management		No Reuse	0
26	Consolidated Infrastructure	Telecommunication Services	Communication	Video Conferencing	Video Conferencing		No Reuse	0
27	Consolidated Infrastructure	Telecommunication Services	Communication	Voice Communications	Voice Communications		No Reuse	0
28	Consolidated Infrastructure	Telecommunication Services	Communication	Instant Messaging	Instant Messaging		No Reuse	0
29	Consolidated Infrastructure	Customer Relationship Management Services	Customer Relationship Management	Partner Relationship Management	Partner Relationship Management		No Reuse	0
30	Consolidated Infrastructure	IT Asset and inventory Management Services	Reporting	Ad Hoc	Inventory management	009-00-03-10-02-0001-00	Internal	0

4. To demonstrate how this major IT investment aligns with the FEA Technical Reference Model (TRM), please list the Service Areas, Categories, Standards, and Service Specifications supporting this IT investment.

FEA SRM Component: Service Components identified in the previous question should be entered in this column. Please enter multiple rows for FEA SRM Components supported by multiple TRM Service Specifications.

Service Specification: In the Service Specification field, Agencies should provide information on the specified technical standard or vendor product mapped to the FEA TRM Service Standard, including model or version numbers, as appropriate.

	SRM Component	Service Area	Service Category	Service Standard	Service Specification (i.e., vendor and product name)
1	Call Center Management	Service Access and Delivery	Access Channels	Web Browser	Peregrine
2	Customer / Account Management	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	Microsoft
3	Customer Feedback	Service Platform and Infrastructure	Delivery Servers	Web Servers	MicroSoft
4	Surveys	Service Platform and Infrastructure	Delivery Servers	Application Servers	MicroSoft

5	Change Management	Service Platform and Infrastructure	Delivery Servers	Web Servers	Team Track
6	Configuration Management	Service Platform and Infrastructure	Software Engineering	Software Configuration Management	Confignia
7	Procurement	Service Access and Delivery	Access Channels	Web Browser	ORACLE
8	Education / Training	Service Platform and Infrastructure	Support Platforms	Platform Dependent	UMT
9	Ordering / Purchasing	Service Access and Delivery	Service Requirements	Legislative / Compliance	PRISM
10	Invoice / Requisition Tracking and Approval	Service Access and Delivery	Delivery Channels	Peer to Peer (P2P)	ORACLE
11	Email	Service Platform and Infrastructure	Support Platforms	Platform Dependent	Microsoft
12	License Management	Service Access and Delivery	Service Requirements	Legislative / Compliance	Microsoft
13	Remote Systems Control	Service Platform and Infrastructure	Support Platforms	Platform Dependent	Microsoft
14	System Resource Monitoring	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	NetIQ
15	Software Distribution	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	Microsoft
16	Computer / Telephony Integration	Component Framework	Security	Supporting Security Services	VOIP
17	Identification and Authentication	Service Platform and Infrastructure	Database / Storage	Database	Microsoft AD
18	Access Control	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	Microsoft AD
19	Digital Signature Management	Component Framework	Security	Certificates / Digital Signatures	Verisign
20	Virus Protection	Component Framework	Security	Supporting Security Services	McAfee
21	Inventory management	Service Platform and Infrastructure	Delivery Servers	Application Servers	Peregrine
22	Requirements Management	Component Framework	Data Management	Reporting and Analysis	Microsoft
23	Program / Project Management	Component Framework	Data Management	Reporting and Analysis	Microsoft
24	Network Management	Service Platform and Infrastructure	Hardware / Infrastructure	Network Devices / Standards	CISCO
25	Facilities Management	Service Platform and Infrastructure	Hardware / Infrastructure	Servers / Computers	Microsoft
26	Video Conferencing	Service Platform and Infrastructure	Hardware / Infrastructure	Video Conferencing	Polycom
27	Voice Communications	Component Framework	Presentation / Interface	Wireless / Mobile / Voice	AT&T, Nextel
28	Instant Messaging	Service Platform and Infrastructure	Delivery Servers	Application Servers	Microsoft

29	Partner Relationship Management	Service Access and Delivery	Access Channels	Collaboration / Communications	Microsoft
30	Ad Hoc	Component Framework	Data Management	Reporting and Analysis	Metis

5. Will the application leverage existing components and/or applications across the Government (i.e., FirstGov, Pay.Gov, etc)?

yes

5.a. If yes, please describe.

The IT Infrastructure Consolidation Investment will be a transport vehicle for all FDA related e-gov activities that leverage components across the Government. For example: - Government to Business Portfolio: Business Gateway: Business.gov helps promote FDA's mission by increasing businesses' access to resources that help businesses understand how to produce safe food and medicines. This also houses 113 FDA forms and resources in its Forms Catalog. E-Rulemaking: FDA has established a web site containing information about implementing current rule making programs, as well as posting information on Federal Register notices and regulatory proposals. - Government to Government: Grants.gov: HHS has implemented the Grants.gov functionality in all 11 OPDIVs including FDA which provide a single location to publish grant (funding) opportunities, to apply for grants using common forms, processes and systems. - Lines of Business: Federal Health Architecture line of Business: provides common health related vocabularies and technology standards through increased information sharing amongst HHS OPDIVs (including FDA) which will assist in decision making and in the delivery of HHS services (i.e. health science research, disease prevention, food and drug safety, medical preparedness for bio-terrorism and other emergencies).

6. Does this investment provide the public with access to a government automated information system?

yes

6.a. If yes, does customer access require specific software (e.g., a specific web browser version)?

no

### PART THREE

#### RISK

You should perform a risk assessment during the early planning and initial concept phase of the investment's life-cycle, develop a risk-adjusted life-cycle cost estimate and a plan to eliminate, mitigate or manage risk, and be actively managing risk throughout the investment's life-cycle.

Answer the following questions to describe how you are managing investment risks.

1. Does the investment have a Risk Management Plan?

yes

1.a. If yes, what is the date of the plan?

2006-03-23

1.b. Has the Risk Management Plan been significantly changed since last year's submission to OMB?

yes

1.c. If yes, describe any significant changes:

Technology Obsolescence from an aging infrastructure has become a high risk that could potentially degrade infrastructure services and impact day-to-day operations. Mitigation efforts include virtualization wherever appropriate, as well as replacements and upgrades as funding permits.

#### COST & SCHEDULE

1. Was operational analysis conducted?

yes

1.a. If yes, provide the date the analysis was completed.

2006-12-31

What were the results of your operational analysis?

All service level agreements have been met and several exceeded. Technology refresh issues are being addressed through virtualization efforts, replacement and upgrade of devices when funding permits, and IT and business management discussions. Operational analysis is conducted weekly, summarized and distributed monthly to managers, Center IT Directors, Customer Council, and Management Council (Commissioner and Center Directors).

