Exhibit 300 (BY2008)

PART ONE	
OVERVIEW	
1. Date of Submission:	2007-02-05
2. Agency:	009
3. Bureau:	10
4. Investment Name:	FDA Mission Accomplishments and Regulatory Compliance Services (MARCS) (FY08)
5. UPI:	009-10-01-02-01-0206-00
6. What kind of investment will this be in FY2008?	
Mixed Life Cycle	
7. What was the first budget year this investment was submitted to OMB?	
FY2004	
8. 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.	
The MARCS program manages the integration and reengineering of eight legacy systems into a comprehensive IT infrastructure to support ORA's mission. FDA uses MARCS' applications to: * Plan FDA field activities and assign staff to inspections, investigations, recalls and other compliance activities * Track and control samples and the results of laboratory analysis * Collect and maintain information resulting from field activities * Collect performance data, particularly that related to PDUFA and MDUFMA * Sends Prior Notice for food imports to Customs and accepts import product information from Customs for screening * Screen 18 million import lines a year based on calculated risk * Collect information about the facilities FDA regulates and those in the import supply chain for risk-based targeting * Provide FDA Centers with information on inspections, compliance actions, recalls, laboratory analysis and facilities. Although ORA was meeting its performance goals with its legacy systems, their weaknesses pose increasing risk. HW and SW platforms were aging and inconsistent with FDA and HHS architecture resulting in degraded performance, risk of failure and a projected lack of vendor support. Import functionality had outgrown its platforms, degrading performance; as imports increased, this gap widened. Platforms did not support true 24/7 operation--a Bioterrorism Act requirement. The paradigm on which import screening was based was changing and new technologies made a better approach possible. Interfaces with FDA labs were inadequate, and lab use for investigations inefficient. Stove-piped systems supported functions (investigations, recalls, compliance, etc.) which should be interdependent and better integration would improve staff. And enhancements were "backed" up behind the high cost of maintaining the legacy framework. MARCS is addressing these problems through a combination of technical upgrades, redesign or core components, and enhancements to existing functionality. Migration of MARCS' legacy	

systems to the Web is complete and migration to Sun/Solaris platforms is targeted for 2008. New database structures have been proposed and will be implemented through an SOA architecture approach, component by component, along with new functionality defined by the user community though a user-driven requirements process.
9. Did the Agency's Executive/Investment Committee approve this request?
yes
9.a. If "yes," what was the date of this approval?
2006-06-23
10. Did the Project Manager review this Exhibit?
yes
12. Has the agency developed and/or promoted cost effective, energy-efficient and environmentally sustainable techniques or practices for this project.
yes
12.a. Will this investment include electronic assets (including computers)?
yes
12.b. Is this investment for new construction or major retrofit of a Federal building or facility? (answer applicable to non-IT assets only)
no
13. Does this investment support one of the PMA initiatives?
yes
If yes, select the initiatives that apply:
Competitive Sourcing
Expanded E-Government
Human Capital
13.a. Briefly describe how this asset directly supports the identified initiative(s)?
Manage Human Capital: Automates scheduling & assignment of investigators, reviewers, and compliance officers. Captures time spent on activities. Relates activities to ORA PART, PDUFA and other performance goals. Expand EGov: 1. Allows FDA to use state inspectors by providing an interface that gives them electronic access to MARCS to input inspection results 2. Gives the public an interface to input Prior Notice on food imports directly to FDA when not required to file with Customs
14. Does this investment support a program assessed using OMB's Program Assessment Rating Tool (PART)?
yes
14.a. If yes, does this investment address a weakness found during the PART review?

no	
14.b. If yes, what is the name of the PART program assessed by OMB's Program Assessment Rating Tool?	
2005: FDA - Overall FDA	
14.c. If yes, what PART rating did it receive?	
Moderately Effective	
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 3	
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 FFMIA compliance area?	
no	
19.a.2. If no, what does it address?	
Mission Accomplishments Regulatory Compliance Services	
20. What is the percentage breakout for the total FY2008 funding request for the following? (This should total 100%)	
Hardware	0
Software	0
Services	87
Other	13
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

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Title

FDA Privacy Act Officer

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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
Planning Budgetary Resources	3.309	1.261	0.750	0.700
Acquisition Budgetary Resources	5.500	6.887	9.250	9.300
Maintenance Budgetary Resources	0.210	0.995	5.500	5.500
Government FTE Cost	0.266	0.600	0.960	0.960
# of FTEs	2	5	8	8

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.

MARCS requested, and received HHS approval for, a new baseline in April 2006. The cost of DME in the approved baseline is $113.873M in combined FTE and contractor costs with a completion date of 8/31/19. The costs of DME in the prior baseline were $38.022M with 12/30/08 through FY10. The increase in both time and schedule is fully explained in the April 2006 request, the result of a budget reduction of 16% for FY 2006, the realignment of some ORA IT funding to better support EVM reporting, and the HHS request to plan for an extended lifecycle (2019 instead of 2010)--which expanded both DME and SS. Planned costs for near-term budget years are consistent with those in the FY07 submission. The April 2006 request for rebaseline details the relationship of the FY07 Summary and FY07 1.H table to those of this submission.

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	2006	FY06 FDA Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve	FDA-wide PART Goal 4. "Increase percentage of contract dollars allocated to	FACTS, OASIS, Turbo, RES, Portal were all CPFF contracts with no clear	100% of new MARCS development contracts will be performance	100% of new MARCS SOW's are performance based.

		excellence in management practices." FDA-wide PART Goal 4. "Increase percentage of contract dollars allocated to performance based contracts."	performance based contracts."	performance measures	based, and clearly tied to the business models already completed and the strategic planning documents currently underway.	
2	2006	FY06 FDA Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve excellence in management practices."	Reduce number of review levels in the Agency to help streamline operations	though MARCS work flow mgmt.	Reduce by 20% the automated portion of the time it takes for Compliance officers to approve the results of an investigation.	TBD
3	2006	FY06 Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve excellence in management practices."	Standardization of staff allocation and reduction in time spent on this activity.	Assignment of staff in the districts is still largely a manual process because automated work planning tools only exist at the HQ level.	Increase efficiency of staff assignment by >10% by automating the allocation of field staff through MARCS tactical work planner.	For those PAC codes implemented in first release, efficiency increased but full benefit cannot be measured until Work Planning is fully integrated in MARCS.
4	2006	FY06 FDA Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve	FDA-wide PART Goal 7. Establish an Agency-wide Enterprise Architecture	Legacy systems were not accurately documented in FDA's EA documentation	MARCS target architecture will be 100% compliant with FDA's	MARCS is fully documented in METIS and legacy systems are

		excellence in management practices."		and were not compliant with it.	EA and TRM and fully documented in METIS	being migrated to compliant architecture
5	2006	FY06 FDA Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve excellence in management practices."	FDA-wide PART Goal 7. "Establish an Agency-wide Enterprise Architecture."	Prior to FY05, FACTS and OASIS were client/server applications based on Compaq GS80's. SW was Oracle Forms in a version which will no longer be supported by ORACLE	FACTS and OASIS operate in a 100% web environment in FY06.	FACTS and OASIS began operating in a 100% web environment in June 2006.
6	2006	FY06 FDA Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve excellence in management practices."	FDA-wide PART Goal 7. "Establish an Agency-wide Enterprise Architecture."	Prior to FY05, the FACTS and OASIS SW was Oracle Forms which will no longer be supported by ORACLE.	System performance after migration to the Target Architecture must equal to or faster than (= or >) that under c/s and Citrix.	With 25% of users on the web, for most, performance is faster than C/S for most users.
7	2006	FY06 FDA Strategic Goal 5: A Strong FDA; HHS Goal 8: "Achieve excellence in management	FDA-wide PART Goal 7. "Establish an Agency-wide Enterprise Architecture."	Prior to FY05, the FACTS and OASIS databases were on VMS platforms (Compaq GS80s) which were "maxed-out" in performance. SW was Oracle Forms which will no longer be supported by ORACLE.	100% of MARCS' databases must be off VMS by 2008 and executing successfully in a Unix environment with accessibility and reliability equal to or better than	Migration to Unix is on schedule for completion in 2007.

					that on the VMS platforms.	
8	2006	FY06 FDA Strategic Goals 1 (Efficient Risk Management) 3 (Consumer Safety) and 4 (Counter-terrorism); HHS Goal 2: " "Enhance the ability of the Nations' health care system to respond to bioterrorism and other public health challenges	A reduction in downtime as a result of new HW/SW infrastructure architecture implemented for Web conversion and Unix migration			
9	2007	FY06 FDA Strategic Goals 1 (Efficient Risk Management) 3 (Consumer Safety) and 4 (Counter-terrorism); HHS Goal 2: " "Enhance the ability of the Nations' health care system to respond to bioterrorism and other public health challenges".				

10	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS Goal 4: "Enhance the capacity and productivity of the Nations' health science research enterprise"	The number of inspections of foreign and domestic establishments identified as high -risk human drug manufacturers.		500	TBD
11	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS Goal 4 and 8: "Enhance the capacity and productivity of the Nations' health science research enterprise" and "Management	Maintain interfaces with Center Systems to ensure 100% data compatibility.	New Drug Applications are rapidly becoming paperless. As CDER moves toward more electronic processing and review, interfacing MARCS systems will have reengineer its interfaces to support these changes.	Metrics on the specific interactions of FACTS and the approval process will be captured to become a baseline for comparison with both CDER MARCS performance as MARCS begins to enhance functionality	TBD
12	2007	FY06 FDA Strategic Goals 1 (Efficient Risk Management) 3 (Consumer Safety) and 4 (Counter-terrorism);	Perform sufficient number of risk-based inspections to maintain the security of the food supply			TBD

		HHS Goal 2, and 4: " "Enhance the ability of the Nations' health care system to respond to bioterrorism and other public health challenges".				
13	2007	FY06 FDA Strategic Goals 1 (Efficient Risk Management) 3 (Consumer Safety) and 4 (Counter-terrorism); HHS Goal 2, Enhance the capacity and productivity of the Nations' health science research enterprise.				TBD
14	2007	FY06 FDA Strategic Goals 1 (Efficient Risk Management) 3 (Consumer Safety) and 4 (Counter-terrori sm); HHS Goal 2, and 4: " "Enhance the	Increase linkage between states' systems and consumers to ensure the safety of the food supply.	Linkage between FDA systems and other agencies, states, and citizens, does not support the PMA, and inhibits FDA's ability to share information with collaborating	Provide at least ten more States access to data related to food inspections	TBD

		ability of the Nations' health care system to respond to bioterrorism and other public health challenges"		agencies.		
15	2007	FY06 FDA Strategic Goals 1 (Efficient Risk Management) 3 (Consumer Safety); HHS 4: " Enhance the capacity and productivity of the Nations' health science research enterprise.	Conduct postmarketing monitoring food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements.	FDA staff is decreasing while foods requiring oversight are increasing. Staff needs to be allocated based on risk based patterns, instead of the historical rotational approach.	.	TBD
16	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS Goal 4 and 8: "Enhance the capacity and productivity of the Nations' health science research enterprise" and "Management	Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported	Reduce the time spent reviewing drugs. MARCS maintains information on facility inspections and processes, this interface provides some of the information needed to track and manage the evaluation of new drug applications.		

		Practices."				
17	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS Goal 4 and 8: "Enhance the capacity and productivity of the Nations' health science research enterprise" and Management Practices."	Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination			
18	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS Goal 4 and 8: "Enhance the capacity and productivity of the Nations' health science research enterprise" and "Management Practices."	Increase risk-based compliance and enforcement activities by conducting tissue inspections to enforce the new regulations.			.
19	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS	Increase risk-based compliance and enforcement activities by			

		Goal 4 and 8: "Enhance the capacity and productivity of the Nations' health science research enterprise" and "Management Practices."	targeting inspections coverage for Class II and Class III medical device manufacturers			
20	2007	FY06 FDA Strategic Goals 1 (Risk Management) and 5 (Strong FDA); HHS Goal 4 and 8: "Enhance the capacity and productivity of the Nations' health science research enterprise" and "Management Practices."	Improve the efficiency and effectiveness of the drug review programs to ensure a safe and effective drug supply is available.	Increase risk-based compliance and enforcement activities to ensure drug product quality.	.	

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.

Table 2

	Fiscal	Measurement	Measurement	Measurement	Baseline	Planned	Actual

	Year	Area	Grouping	Indicator		Improvement to the Baseline	Results
1	2006	Mission and Business Results	Workforce Planning	Improve the ability to schedule inspections	Performed manually w/ Excel	50% of PAC codes automated	50% of PAC codes automated
2	2006	Mission and Business Results	Population Health Management and Consumer Safety	Reduced Prior Notice Downtime	Avg 8 hours a month	50% reduction	50% for 45 days since release
4	2006	Processes and Activities	Privacy	Privacy control	New data class	0 POAM on data handling	Security planning documents are included in the SDLC reviews for MARCS and its programs.
5	2007	Technology	Availability				TBD
6	2007	Mission and Business Results	Emergency Response	Increased ability to identify facilities based on geographic position	Limited # can now be identified	50% of facilities can be identified by a GPS tool	TBD
7	2007	Processes and Activities	Risk	Improved scheduling of Lab processes	No automated support for Lab scheduling	Automated support for Lab scheduling	TBD
9	2007	Customer Results	Service Efficiency	More off-line capability for investigators	5% of Inspection functions off line	20% increase	TBD
10	2006	Customer Results	Access	Access to required functionality unreliable through Citrix	One Citrix-related incident per month	< 1 per month on Web	100%

12	2006	Technology	Response Time	Improved response time for users in the field	Variable depending on location	= or < response time on Web	< in most locations; = in others
13	2007	Technology	Improvement	Time required for Business managers to track change requests	2-5 days after request to contractor	15 minutes	TBD
14	2007	Processes and Activities	Cycle Time	Time required for automated screening	Variable depending on volume.	10% reduction	TBD
15	2006	Processes and Activities	Productivity	Improved productivity of Import Reviewers from single entry at review site	Eliminate entry from written source	50%	50% Improvement with prototype alone

EA
In order to successfully address this area of the business case and capital asset plan you must ensure the inv included in the agency's EA and Capital Planning and Investment Control (CPIC) process, and is mapped to supports the FEA. You must also ensure the business case demonstrates the relationship between the investm 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
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 mos annual EA Assessment.
Mission Accomplishment and Regulatory Compliance Services (MARCS) (FY07)
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 followi 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 identi service component in the FEA SRM.
Reused Name and UPI: A reused component is one being funded by another investment, but being used by th investment. Rather than answer yes or no, identify the reused service component funded by the other investm

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 departme reusing a service component provided by another agency within the same department. External reuse is one within a department reusing a service component provided by another agency in another department. A good 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 servic component listed in the table. If external, provide the funding level transferred to another agency to pay for t service.

	Agency Component Name	Agency Component Description	Service Type	Component	Reused Component Name	Reused UPI	Internal or External Reuse?
1	MARCS Broker Management Service	MARCS will replace and enhance the existing OASIS capability to evaluate the performance of broker/filers who submit entries to FDA, and will provide the ability to take action against them when their performance is inadequate.	Customer Relationship Management	Partner Relationship Management	Partner Relationship Management	009-10-01-02-02-1020-00	Internal
2	Prior Notice System Interface	MARCS will provide an electronic interface to customer assistance for its users, as well as on-line tutorials.	Customer Initiated Assistance	Online Help	Online Help	009-10-01-02-02-1020-00	Internal
3	Prior Notice System Interface	Prior Notice will continue to have an electronic	Customer Initiated Assistance	Online Tutorials	Online Tutorials	009-10-01-02-02-	Internal

		interface to educate and assist the public in submitting prior notice for food products entering the US				1020-00	
4	Activity Tracking	MARCS will replace and enhance the existing core capabilities in FACTS to track/manage inspections, investigations, and legal actions including related correspondence, and assembled evidence.	Tracking and Workflow	Process Tracking	Process Tracking	009-10-01-02-02-4040-00	Internal
5	Compliance Case Management	MARCS will replace the	Tracking and Workflow	Case Management	Case Management	009-10-01-02-02-4040-00	Internal
6	Document Management	MARCS will include a document management service that will support the capture, linkage, and retrieval of evidence captured during an inspections or investigation that can be used to support regulatory actions taken to ensure compliance and	Tracking and Workflow	Conflict Resolution	Conflict Resolution		No Reuse

		support the FDA's position during a confict over evidence both before or during legal actions.					
7	Activity Tracking	This service will maintain, track, and manage internally initiated communication between FDA and the pubic or other agencies related to an investigation, inspection, recall, or compliance action. It will incorporate ORA regulatory policy and processes into its logic.	Routing and Scheduling	Outbound Correspondence Management	Process Tracking	009-10-01-02-02-4040-00	Internal
8	Import Screening	MARCS current import processing will be modified to incorporate a new service component being developed under separate funding.	Knowledge Discovery	Modeling	Modeling	009-10-01-02-02-1020-00	No Reuse
9	Various functional components	MARCS captures the data to establish trends, predict future needs, and define risks that is input into	Analysis and Statistics	Mathematical	Mathematical	009-10-01-02-02-4040-00	Internal

		ORA's decision support system. Capability to capture and maintain that data, and to use it for ad hoc reporting exists in all the legacy systems and will be enhanced in MARCS					
10	MARCS Database	MARCS will support some ad hoc reporting,. However, but most of ORA's ad hoc reporting needs will be met by ORADSS using data obtained through the MARCS-ORADSS interface.	Reporting	Ad Hoc	Ad Hoc	009-10-01-02-02-4040-00	Internal
11	Import Screening	A major component of OASIS is an automated screening module which screens 20,000-30,000 a day for threats to health and makes automated decisions based on risk factors. Based on the results of this screening, ORA staff review questionable products based	Business Intelligence	Decision Support and Planning	Decision Support and Planning	009-10-01-02-02-1020-00	No Reuse

		on the risk criteria OASIS presents. This functionality will be enhanced in MARCS.					
12	Configuration Managemenet	Configuration management is institutionalized in MARCS' legacy systems and will plan and enforced in by the MARCS Program office. And through the deliverables required by the FDA SDLC Stage Gates. Tools vary by contract and vendor.	Management of Processes	Configuration Management	Configuration Management	009-10-01-02-02-4040-00	Internal
13	Change Control	MARCS is instituting a comprehensive change management process at the program level that will be integrated with the change management processes for the various legacy systems and functional components. It is unclear at this time whether the current plan for a MARCS specific tool will be abandoned in	Management of Processes	Change Management	Change Management	009-10-01-02-02-4040-00	Internal

		favor of Dekker functionality.					
14	Requirements Management	MARCS legacy systems all have existing requirements management processes to validate the design and test the software. MARCS is developing a program level requirements management process to track high level business processes and priorities. This process will work in conjunction with the Program level Change Management process.	Management of Processes	Requirements Management	Requirements Management	009-10-01-02-02-4040-00	Internal
15	Historical Record Management	MARCS has to maintain years of information related to imports and inspection and the volume requires non-production storage.	Data Management	Loading and Archiving	Library / Storage	009-10-01-02-02-4040-00	No Reuse
16	Import applications, Fieldwork Operations, Compliance Applications,	MARCS software captures the data needed to perform and codifies the	Management of Processes	Governance / Policy Management	Governance / Policy Management	009-10-01-02-02-4040-00	Internal

	and Recalls	process of FDA's regulatory mission. Its modules support FDA's decisions, actions, business rules, and the processes and procedures of investigations, inspections, recalls and compliance activities.					
17	Quality Management	MARCS PMP address systems quality assurance and quality controls. With ORA's quality assurance team, it has fully implemented FDA's SDLC the program has passed the planning stage gate and all individual projects have held and passed stage gates appropriate to their phase of development.	Management of Processes	Quality Management	Quality Management	009-10-01-02-02-4040-00	Internal
18	Import applications, Fieldwork Operations, Compliance Applications, and Recalls	The core functionality of FACTS, OASIS, RES, and Turbo codifies ORA's investigations and operations manual,	Management of Processes	Business Rule Management	Business Rule Management	009-10-01-02-02-1020-00	Internal

		managing the processes that execute FDA policies and enable it to perform its legal responsibilities. This functionality will be reengineered and enhanced in MARCS.					
19	Import applications, Fieldwork Operations, Compliance Applications, and Recalls	The primary goal of FACTS, OASIS, RES, and Turbo is to manage the risk that an FDA regulated product would cause harm to American citizens. MARCS objective is to effectively manage risk.	Management of Processes	Risk Management	Risk Management	009-10-01-02-02-1020-00	Internal
20	Fieldwork Management	MARCS intends to implement a groupware component to better enable staff in multiple locations who perform separate but related functions to communicate more effectively--particularly in times of emergency.	Organizational Management	Workgroup / Groupware	Workgroup / Groupware		No Reuse

21	Document Review Services	MARCS will provide the capability to approve work performed by other staff members through a hierarchically controlled process.	Content Management	Content Review and Approval	Content Review and Approval		No Reuse
22	Alerts	MARCS will support the ability of ORA staff to publish the results of investigatory work within the FDA	Content Management	Content Publishing and Delivery	Content Publishing and Delivery		No Reuse
23	Standard Evidence Archive and Retrieval Service	Planned document management capability will include.	Document Management	Document Referencing	Document Referencing		No Reuse
24	Standard Evidence Archive and Retrieval Service	A new document management service will enable staff in the field to revise and edit documents as part of the approval/review process that are standard procedures.	Document Management	Document Revisions	Document Revisions		No Reuse
25	Standard Evidence Archive and Retrieval Service	MARCS will provide a library 0f documents created by the system, scanned documents, graphics, pictures, etc.	Document Management	Library / Storage	Library / Storage		No Reuse

26	Standard Evidence Archive and Retrieval Service	MARCS will provide enhanced support the cycle of write/review/edit and multi-level (and multi-organization) approvals that are a standard part of the investigation process.	Document Management	Document Review and Approval	Document Review and Approval		No Reuse
27	Import applications, Fieldwork Operations, Compliance Applications, and Recalls	MARCS captures information from users as well as from the transactions a day from CBP.	Knowledge Management	Knowledge Capture	Knowledge Capture		No Reuse
28	External Data Access Services	MARCS provides a extract to ORADSS, ORA's corporate data warehouse and decision support system. Through ORADSS, information collected in MARCS will supply information to the many current users of FACTS and OASIS information.	Knowledge Management	Knowledge Distribution and Delivery	Knowledge Distribution and Delivery	009-10-01-02-02-4040-00	Internal
29	Customs System Interface	MARCS retrieves data about imports from CBP's	Knowledge Management	Information Retrieval	Information Retrieval	009-10-01-02-02-1020-	Internal

		Automated Commercial System (ACS) via a 24/7 link between the systems. It will also retrieve data from Center database for use in review of imported products.				00	
30	Import applications, Fieldwork Operations, Compliance Applications, and Recalls	MARCS will provide the existing FACTS, OASIS, RES, and Turbo user communities to better share information by enhancing support for the use of evidence resulting from inspections in a multi-user organizations.	Knowledge Management	Information Sharing	Information Sharing	009-10-01-02-02-1020-00	Internal
31	Import Applications	Marcs provides information on customer interactions including calls, email, correspondence, etc, and provides for the maintenance of facilities business information	Customer Relationship Management	Contact and Profile Management	Contact and Profile Management	009-10-01-02-02-1020-00	Internal
32	Import Application	Provide the ability to take action against customs brokers	Customer Relationship Management	Customer Analytics	Customer Analytics	009-10-01-02-02-1020-	Internal

		when their performance is inadequate.				00	
33	TWP	Tactical Work Planner provides the capability to schedule field investigations for specific PAC codes	Customer Initiated Assistance	Scheduling	Scheduling	009-10-01-02-02-4040-00	Internal
34	Import Screening	MARCS current import processing will be modified to incorporate a new service component being developed under separate funding.	Knowledge Discovery	Data Mining	Data Mining		No Reuse
35	Import Screening	MARCS current import processing will be modified to incorporate a new service component being developed under separate funding.	Knowledge Discovery	Simulation	Simulation		No Reuse
36	Import applications, Fieldwork Operations, Compliance Applications, and Recalls	A MARCS objective is to integrate new HW/SW applications with ORA's legacy systems	Development and Integration	Legacy Integration	Legacy Integration		No Reuse
37	Multiple	ORA's legacy systems are being redesigned into an integrated SOW architecture that	Development and Integration	Data Integration	Data Integration		No Reuse

		will use a common set of data structures and rules					
38	Multiple	MARCS validates performance and functionality with Mercury test tools	Development and Integration	Instrumentation and Testing	Instrumentation and Testing		No Reuse
39	Multiple	MARCS SOA architecture will eventually support easier generation and integration of new COTS and applications	Development and Integration	Software Development	Software Development		No Reuse
40	MARCS Interface	MARCS-MI identifies and authenticates users	Security Management	Identification and Authentication	Identification and Authentication	009-10-01-02-02-1060-00	Internal
41	MARCS Interface	MARCS-MI provides access control	Security Management	Access Control	Access Control	009-10-01-02-02-1060-00	Internal
42	MARS (Turbo)	MARCS-Turbo requires and supports digital signature on the EIR report	Security Management	Digital Signature Management	Digital Signature Management	009-10-01-02-02-1060-00	Internal
43	Multiple	Audit trails exist on legacy systems and will be incorporated into MARCS	Security Management	Audit Trail Capture and Analysis	Audit Trail Capture and Analysis	009-10-01-02-02-4040-00	Internal
44	SEARS (DMS)	The Standards Evidence Archive and Retrieval	Collaboration	Document Library	Document Library		No Reuse

		Service is a Doc Management service that supports the archiving of evidence collected from FDA regulatory actions					
45	Multiple	Like its legacy systems, MARC will support retrieval of records based on specific selection criteria	Search	Query	Query	009-10-01-02-02-4040-00	Internal
46	Multiple	Like its legacy systems, MARCS will be able to rank records retrieved through queries	Search	Precision / Recall Ranking	Precision / Recall Ranking	009-10-01-02-02-4040-00	Internal
47	Multiple	Like its legacy systems, MARCS retrieve records organized by shared characteristics in content or context	Search	Precision / Recall Ranking	Classification	009-10-01-02-02-4040-00	Internal
48	Multiple	Like its legacy systems, MARCS uses pattern matching to retrieve records based on imputed characteristics	Search	Pattern Matching	Pattern Matching	009-10-01-02-02-4040-00	Internal
49	MARS	Some MARCS systems capture and track user-reported issues	Systems Management	Issue Tracking	Issue Tracking	009-10-01-02-02-1060-	Internal

		and problems				00	

4. To demonstrate how this major IT investment aligns with the FEA Technical Reference Model (TRM), plea 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 colu 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 specifie 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 Specifica (i.e., vendor and name)
1	Information Retrieval	Service Access and Delivery	Access Channels	Web Browser	Internet Explorer
2	Digital Signature Management	Component Framework	Security	Certificates / Digital Signatures	Entrust
3	Identification and Authentication	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	Oracle
4	Process Tracking	Service Access and Delivery	Delivery Channels	Intranet	
5	Case Management	Service Access and Delivery	Service Requirements	Legislative / Compliance	508, Accessibility Security, Privacy
6	Process Tracking	Service Platform and Infrastructure	Support Platforms	Platform Independent	Solaris
7	Process Tracking	Service Platform and Infrastructure	Support Platforms	Wireless / Mobile	Dell Notebooks
8	Process Tracking	Service Platform and Infrastructure	Delivery Servers	Application Servers	Oracle
9	Quality Management	Component Framework	Business Logic	Platform Independent	Oracle
10	Instrumentation and Testing	Service Platform and Infrastructure	Software Engineering	Test Management	Mercury Interacti Runner
11	Configuration Management	Service Platform and Infrastructure	Software Engineering	Software Configuration Management	PVCS, Rational R Pro
12	Modeling	Service Platform	Software	Modeling	Rational

		and Infrastructure	Engineering		
13	Data Integration	Service Platform and Infrastructure	Database / Storage	Database	Oracle
14	Audit Trail Capture and Analysis	Service Platform and Infrastructure	Database / Storage	Storage	Storage Area Net
15	Loading and Archiving	Service Platform and Infrastructure	Hardware / Infrastructure	Servers / Computers	Sunfire 6800
16	Loading and Archiving	Service Platform and Infrastructure	Hardware / Infrastructure	Embedded Technology Devices	Various
17	Ad Hoc	Service Platform and Infrastructure	Hardware / Infrastructure	Peripherals	Various
18	Information Retrieval	Service Platform and Infrastructure	Hardware / Infrastructure	Local Area Network (LAN)	Virtual Lan
19	Information Retrieval	Service Platform and Infrastructure	Hardware / Infrastructure	Wide Area Network (WAN)	PPP and Dial Up
20	Information Sharing	Service Platform and Infrastructure	Hardware / Infrastructure	Network Devices / Standards	2Gb Fiber Chann connect
21	Access Control	Component Framework	Security	Certificates / Digital Signatures	Entrust
22	Information Retrieval	Component Framework	Presentation / Interface	Static Display	Hyper Text Mark Language (HTMI
23	Pattern Matching	Component Framework	Data Management	Reporting and Analysis	OLE/DB, JDBC
24	Issue Tracking	Component Framework	Business Logic	Platform Independent	Enterprise Java B
25	Query	Component Framework	Data Interchange	Data Exchange	MQ
26	Document Library	Service Platform and Infrastructure	Database / Storage	Database	Documentum
27	Information Retrieval	Component Framework	Data Management	Reporting and Analysis	Documentum, Bu Objects, Adobe
28	Information Retrieval	Service Interface and Integration	Integration	Middleware	PL/SQL
29	Precision / Recall Ranking	Service Interface and Integration	Interoperability	Data Format / Classification	XML, PDF
30	Knowledge Capture	Service Interface and Integration	Interoperability	Data Types / Validation	XLM Schema, D

31	Online Tutorials	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	Oracle, J2EE
32	Online Help	Service Access and Delivery	Access Channels	Web Browser	xml, pdf
33	Partner Relationship Management	Component Framework	Data Interchange	Data Exchange	Oracle, J2EE
34	Contact and Profile Management	Component Framework	Data Interchange	Data Exchange	Oracle, J2EE
35	Customer Analytics	Component Framework	Data Interchange	Data Exchange	Oracle, J2EE
36	Scheduling	Service Interface and Integration	Integration	Enterprise Application Integration	Oracle, J2EE
37	Conflict Resolution	Service Interface and Integration	Integration	Enterprise Application Integration	Oracle, J2EE
38	Outbound Correspondence Management	Service Interface and Integration	Integration	Enterprise Application Integration	Oracle
39	Mathematical	Component Framework	Data Management	Reporting and Analysis	ORACLE
40	Software Development	Service Platform and Infrastructure	Software Engineering	Integrated Development Environment	SOA
41	Change Management	Component Framework	Data Interchange	Data Exchange	Oracle, J2EE
42	Requirements Management	Component Framework	Data Interchange	Data Exchange	Oracle, J2EE
43	Quality Management	Service Platform and Infrastructure	Software Engineering	Test Management	Mercury Test Sui
44	Governance / Policy Management	Service Access and Delivery	Service Requirements	Legislative / Compliance	Oracle, J2EE
45	Business Rule Management	Component Framework	Business Logic	Platform Independent	Oracle, J2EE
46	Risk Management	Component Framework	Security	Supporting Security Services	PKI, Entrust
47	Content Review and Approval	Service Interface and Integration	Integration	Enterprise Application	Documentum, Or

				Integration	
48	Document Referencing	Service Interface and Integration	Interoperability	Data Format / Classification	Documentum
49	Document Revisions	Service Interface and Integration	Interoperability	Data Format / Classification	Documentum
50	Library / Storage	Service Interface and Integration	Interoperability	Data Format / Classification	Documentum
51	Document Review and Approval	Service Interface and Integration	Integration	Enterprise Application Integration	Documentum
52	Knowledge Distribution and Delivery	Service Platform and Infrastructure	Hardware / Infrastructure	Wide Area Network (WAN)	Frame Relay, AT
53	Information Retrieval	Service Platform and Infrastructure	Database / Storage	Database	Oracle
54	Case Management	Service Interface and Integration	Interoperability	Data Format / Classification	XML, XML Link EDI, DTD, SCL S
55	Workgroup / Groupware	Service Interface and Integration	Integration	Enterprise Application Integration	PBM, Transforma Formatting,
56	Decision Support and Planning	Component Framework	Data Management	Reporting and Analysis	OLAP, XBRL, Bu Objects
57	Content Publishing and Delivery	Service Access and Delivery	Delivery Channels	Internet	
58	Data Mining	Component Framework	Data Management	Reporting and Analysis	OLAP, XBRL, Bu Objects
59	Simulation	Component Framework	Data Management	Reporting and Analysis	OLAP, XBRL, Bu Objects
60	Legacy Integration	Service Interface and Integration	Integration	Enterprise Application Integration	XML, XML Link EDI, DTD, SCL S

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

yes

5.a. If yes, please describe.

Yes. Through its interfaces with CBP's systems, MARCS will continue to enable FDA staff to work collabor the U.S. borders with CBP to screen, review, hold, or seize FDA regulated products that might cause harm to

or other animals. Neither CBP nor FDA could accomplish the full mission by themselves, but the automated that are currently in place provide limited support to this function. As FDA evolves to MARCS and CBP imp ACE this interaction should be even tighter. In addition to providing more effective screening for safety, this collaboration reduces the impact on trade that would be the result of separate systems.
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 TWO
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?
2006-06-01
1.b. Has the Risk Management Plan been significantly changed since last year's submission to OMB?
no
3. Briefly describe how investment risks are reflected in the life cycle cost estimate and investment schedule: (O&M investments do NOT need to answer.)
Risk was one of the major factors in selecting the overall MARCS approach (the alternative to migrate to web and rebuild over time) because FDA's regulatory environment is dynamic and cannot be put in position where change cannot be accommodated quickly. Where possible, higher risk projects are scheduled without time critical dependencies so that a schedule delay will not impact other projects, e.g. the Project Manager risk-adjusted the project and contractor team's schedule and costs for the Web and Unix conversions - two projects considered high risk due to the potential adverse impact on the field by adding more testing and modification than originally planned. For the Document Management project, project management planned/spent extra time developing a concept of operations and documenting high level requirements to ensure that the project's scope and contract delivery estimates were realistic. The combination of these approaches--risk-adjusted costs and substantial planning - have been applied to contracts, in addition to project managers applying risk mitigation strategies to the individual projects.
COST & SCHEDULE

Does the earned value management system meet the criteria in ANSI/EIA Standard 748?
yes
2.a. What is the Planned Value (PV)?
19.019
2.b. What is the Earned Value (EV)?
18.652
2.c. What is the actual cost of work performed (AC)?
18.096
What costs are included in the reported Cost/Schedule Performance information?
Contractor and Government
2.e. As of date:
2006-12-31
3. What is the calculated Schedule Performance Index (SPI= EV/PV)?
0.98
4. What is the schedule variance (SV = EV-PV)?
-0.367
5. What is the calculated Cost Performance Index (CPI = EV/AC)?
1.03
6. What is the cost variance (CV = EV-AC)?
0.556
7. Is the CV or SV greater than 10%?
no
7.c. If yes, what corrective actions are being taken?
MARCS steady state variance of 11% was the result of 2 factors: 1) The implementation of Web Migration into production resulted in a smaller number of bugs than were anticipated so less O&M support was expended. 2) TWP is used to support work force planning during September 05 and January 06 . Bug fixes were made during that time period but planned changes were completed in April at slightly under $$ budgeted and no significant O&M charges were made this summer. Since SS is an LOE effort, and since all M&O objectives were met, the BCWP remained equal to the BCWS. However, level of effort decreased somewhat, largely because the "clean" release of Web migration meant that costs for support was lower than anticipated--resulting in a positive variance for ACWS. We do not anticipate that O&M costs will remain positive to the same degree in the future as more maintenance comes under MARCS control.
7.d. What is most current Estimate at Completion?

110.966
8. Have any significant changes been made to the baseline during the past fiscal year?
no