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Business Case

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Section A: Investment Summary Information

Investment Name	Unique Investment Identifier
FDA ORA Imports	009-000353235

Investment Description

Imports enables the ORA staff to predict risk and screen import of FDA-regulated products and conduct sampling and examination of products offered for import. Imports include both 801a and 801m responsibilities, to ensure imports that do not meet regulations are not admitted into commerce and to protect against possible bioterrorism threats. The work includes all the stages of import review, including the steps needed to review PN's, make admissibility decisions, and address imports that are detained or refused entry.

Agency		Point of Contact	
Department of Health and Human Services		Karl Mathias - CIO	
		email	Not Provided

Investment Type	Bureau
Major IT Investments	Food and Drug Administration

Mission Support	Shared Service Category
Not Applicable	Not Applicable

Shared Service Identifier
Not Applicable

Date Investment First Submitted	Date of Last Investment Detail Update
09/19/2021	05/25/2022

Section B: Investment Detail

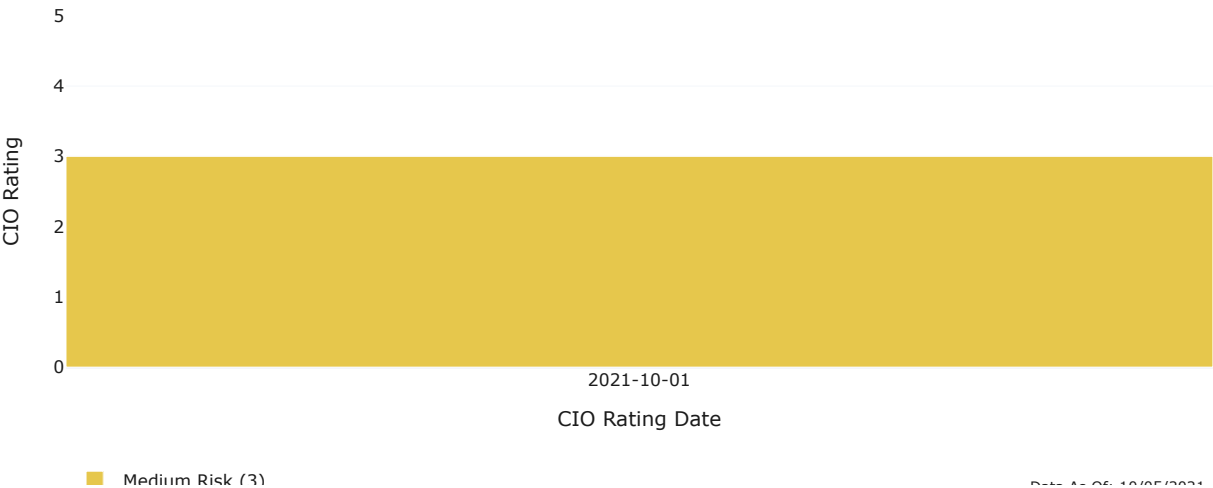
1. Briefly describe the investment's return on investment, including benefits internal and external to the government and outcomes achieved or planned.
- IMPORTS benefits the public by enabling import functions that ensure product safety in the supply chain. IMPORTS expands ORA's ability to share data with other public health organizations improving the nation's ability to detect, identify, and respond to health emergencies. IMPORTS' internal benefits include improved user interface, data management, and communication systems that increase productivity. The benefits for enhanced Imports set of applications are the resulting cost avoidance by the ORA staff being more efficient in executing their tasks. This results in each employee able to carry out more inspections, import entry review of exceptions, etc. Examples of this are: 1. Reduced time spent on tracking compliance actions & holds. 2. The system targeting shipments to inspect. 3. Reduced time spent on filed inspection/investigation and label exams, and sample collection administrative tasks. 4. Industry Help Desk efficiency. 5. Entry review integration to the Compliance Management System. 6. The expansion of self-service by the imports industry to check information on inspection status. These six benefits are estimated to exceed \$35M per year in cost avoidance to ORA staff and Industry/Trade participants.

Section C: Investment and Contracts

Contracts

- [HHSF223201610015G](#)
- [HHSF22301001T](#)
- [HHSF22301036T](#)
- [HHSF223201510173C](#)
- [HHSF223201710022G](#)
- [HHSF223201810010W](#)
- [HHSF22301001T](#)
- [HHSF22301001](#)
- [HHSN316201200034W](#)
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- [75F40120C00161-9999](#)
- [HHSF22301001T](#)
- [75F40120F80019](#)
- [75F40120F80019](#)
- [75F40119C10109-9999](#)
- [HHSF22301036T](#)

Section D: Historic CIO Rating



CIO Rating	Date	Comments
3	Oct 01, 2021	HHS's CIO evaluation is based on the risk evaluation framework provided by OMB's Capital Planning and Investment Control (CPIC) Guidance. As part of HHS's efforts to strengthen implementation of FITARA principles, in August 2017, HHS supplemented its existing CIO evaluation framework to consider the confidentiality and availability of department IT assets as they support public health, confidence and safety of the American people. Application of this additional evaluative factor, and subsequent scoring adjustments, reflects HHS's increased awareness and acknowledgement of risk inherent to investments. As demonstrated by data related to investments' cost, schedule and operations, HHS remains vigilant about establishing internal controls and ensuring strong program/project management to manage and mitigate risk across its IT portfolio.

Data Last Updated On: 10/05/2021

Section E: Investment Spending

Table 1: Distribution by Spending Type			
Spending Type	PY 2021	CY 2022	BY 2023
DME Costs	20.280209	11.21701	11.21701
O&M Costs	9.826222	10.88855	10.88855
Total	30.106431	22.10556	22.10556

Table 2: Distribution by Cost Pools			
Cost Pools	PY 2021	CY 2022	BY 2023
Internal Labor	0.676	0.676	0.676
External Labor	29.02811	20.56862	20.56862
Outside Services	0.215881	0.375	0.375
Hardware	0.010534	0.053	0.053
Software	0.175906	0.43294	0.43294
Facilities & Power	0	0	0
Telecom	0	0	0
Other	0	0	0
Internal Services	0	0	0
Totals	30.106431	22.10556	22.10556

Cost in millions (M)

Table 3: Distribution by IT Towers			
IT Tower	PY 2021	CY 2022	BY 2023
Security & Compliance	0	0	0
IT Management	0	0	0
Network	0	0	0
Data	0	0	0
Compute	0	0	0
Storage	0	0.028	0.028
End User	0	0	0
Output	0	0	0
Application	30.106431	22.07756	22.07756
Delivery	0	0	0
Platform	0	0	0
Data Center	0	0	0
Totals	30.106431	22.10556	22.10556

Cost in millions (M)

Data Last Updated On: 05/25/2022

Section F: Project and Activities Detail

Table 1: Project Details								
Project Name	Project UID	Status	Project Life Cycle Cost (\$M)	Cost Variance (%)	Start Date	End Date	Schedule Variance (%)	Schedule Variance (Days)
FDA ORA Imports SERIO FY22	000463899	In Progress	7.26	0	2021-09-20	2022-09-16	0	0
FDA ORA Imports Enhancements FY22	000463898	In Progress	7.26	0	2021-09-20	2022-09-16	0	0
FDA ORA Imports CBP-IWS Enhancements CY22	000463891	In Progress	10	0	2022-01-01	2023-12-31	0	0

Low

Medium

High

Table 2: Activity Details											
Unique Project ID	Activity Name	Activity Description	Planned Start Date	Projected Start Date	Actual Start Date	Planned Completion Date	Projected Completion Date	Actual Completion Date	Planned Total Cost (\$M)	Projected Total Cost (\$M)	Actual Total Cost (\$M)
000463899	FY22 DME	FY22 DME	2021-09-20	2021-09-20	2021-09-20	2022-09-16	2022-09-16		7.26	7.259	3.39
000463899	DME	DME	2021-09-20	2021-09-20	2021-09-20	2022-09-16	2022-09-16		7.26	7.259	3.39
000463898	FY22 DME	FY22 DME	2021-09-20	2021-09-20	2021-09-20	2022-09-16	2022-09-16		7.26	7.256	4.05
000463898	DME	DME	2021-09-20	2021-09-20	2021-09-20	2022-09-16	2022-09-16		7.26	7.256	4.05
000463891	CY22 Enhs	CY22 Enhs	2022-01-01	2022-01-01	2022-01-01	2022-03-31	2022-03-31		0.54	0.54	0.5
000463891	Increment 1.0 - IWS/ACE Priority 1 Enhancements	Increment 1.0 - IWS/ACE Priority 1 Enhancements	2022-01-01	2022-01-01	2022-01-01	2022-03-31	2022-03-31		0.54	0.54	0.5

Table 3: Project Related Details	
<div>FDA ORA Imports SERIO FY22</div> <div><div>1. Are information technology investments adequately implementing incremental development methodology? (Y/N)</div><div>Yes</div><div>2. What is the frequency of incremental development iterations? (ex. 1 month, 3 months, 6 months, 12 months or greater)</div><div>Months</div><div>3. Please describe the iterative development methodology being employed. (500 characters or less)</div><div>agile</div></div> <div>FDA ORA Imports Enhancements FY22</div> <div><div>1. Are information technology investments adequately implementing incremental development methodology? (Y/N)</div></div>	

Yes

2. What is the frequency of incremental development iterations? (ex. 1 month, 3 months, 6 months, 12 months or greater)

Months

3. Please describe the iterative development methodology being employed. (500 characters or less)

agile

FDA ORA Imports CBP-IWS Enhancements CY22

1. Are information technology investments adequately implementing incremental development methodology? (Y/N)

Yes

2. What is the frequency of incremental development iterations? (ex. 1 month, 3 months, 6 months, 12 months or greater)

Weeks

3. Please describe the iterative development methodology being employed. (500 characters or less)

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