Bioresearch Monitoring Programs
RESOURCE SUMMARY
FY 2017

PPS NO.	PROJECT TITLE	OPERATIONAL FTES		TOTAL OPERATIONAL FTEs
		DOMESTIC	FOREIGN	
	TOTAL	109.5	30.8	140.3
	CBER			
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	5.0		5.0
42	BLOOD AND BLOOD PRODUCTS	4.4		4.4
45	VACCINE AND ALLERGENIC PRODUCTS	8.0		8.0
	CVM			
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	6.8	0.4	7.2
	CDRH			
83	PRODUCT EVALUATION: DEVICES	23.5	1.2	24.7
	CDER			
48	BIORESEARCH MONITORING HUMAN DRUGS	61.2	29.2	90.4
	CTP			
98	REGULATED TOBACCO PRODUCTS: BIORESEARCH MONITORING / CLINICAL INVESTIGATORS	0.6		0.6
	CFSAN			
03	RESPONSIVE INVESTIGATIVE/LABORATORY OPERATIONS (BIMO INSPECTIONS)	N/A	N/A	N/A

PROJECT SUMMARY SHEET - CBER BIMO

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Human Cellular, Tissue and Gene Therapeutics - 41 Blood and Blood Products - 42

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**17.4**		**17.4**	
1	Bioresearch Monitoring Programs *		5.0		5.0	41-3
	Good Laboratory Practices (Nonclinical Labs)	41808	*			
	Institutional Review Boards	41809	*			
	Sponsors, Monitors, and Contract Research Organizations	41810	*			
	Clinical Investigators *	41811	[5.0]			
	* All resources are planned under PAC 41811.					
2	Bioresearch Monitoring Programs *		4.4		4.4	42-10
	Good Laboratory Practices (Nonclinical Labs)	42808	*			
	Institutional Review Boards	42809	*			
	Sponsors, Monitors, and Contract Research Organizations	42810	*			
	Clinical Investigators *	42811	[4.0]			
	National Experts	42808, 42811	[0.4]			
		45808, 45811				
	* All domestic & foreign resources are planned under domestic PAC 42811.					
	Foreign resources to cover PPS 41, 42, 45.					
3	Bioresearch Monitoring Programs *		8.0		8.0	45-14
	Good Laboratory Practices (Nonclinical Labs)	45808	*			
	Institutional Review Boards	45809	*			
	Sponsors, Monitors, and Contract Research Organizations	45810	*			
	Clinical Investigators *	45811	[8.0]			
	* All domestic & foreign resources are planned under domestic PAC 45811.					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Carrie Mampilly 240-402-2973	Travis Parsley 301-796-4630

FORM FDA 2622 (02/16)

PAGE NOs. 41-1, 42-5, 45-13

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators	**CBER** Human Cellular, Tissue and Gene Therapeutics - 41 Blood and Blood Products - 42 Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41808, 42808, 45808:-GLPs, 41809, 42809, 45809:-IRBs, 41810, 42810, 45810:-Spon/Mon/CROs 41811, 42811, 45811:-Clinical Investigators	[X] ORA [ ] CENTER	17.4

REGION	6. ORGANIZATION	INSPEC-TIONS 41808-811 (1)	INSPEC-TIONS 42808-811 (2)	INSPEC-TIONS 45808-811 (3)						
	TOTAL ORA	**48**	**55**	**86**						
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
	TOTAL FIELD									
NE	*REGIONAL STAFF*									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	TOTAL LABORATORY									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		98.7	76.0	88.4						
TOTAL HOURS		4738	4180	7602						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		4.99	4.40	8.00						

9. REMARKS

(1) - Resources for PACs 41808, 41809, 41810, and 41811 are planned under PAC 41811 Clinical Investigators.
(2) - Use above resources for Foreign Inspections as needed. Resources for PACs 42808, 42809, 42810, and 42811 are planned under PAC 42811 Clinical Investigators.
(3) - Use above resources for Foreign Inspections as needed. Report Foreign Inspections under Operation Code 11.
Resources for PACs 45808, 45809, 45810, and 45811 are planned under PAC 45811 Clinical Investigators.

Inspections are to be conducted only when assignments are received from CBER.
Report accomplishment hours under appropriate PAC.

PROJECT SUMMARY SHEET - CVM BIMO

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Animal Drugs and Feeds	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**6.8**	**0.4**	**7.2**	
1	Bioresearch Monitoring		6.8	0.4	7.2	68-3
	* (Pre-Market) GLP	68808	[4.3]		[4.3]	
	* (Pre-Market) Spon/Mon/Con	68810		[0.2]	[0.2]	
	(Pre-Market) Clinical Investigators	68811	[2.5]	[0.2]	[2.7]	
	* PAC 68808 includes resources for domestic PAC 68810.					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Jeremy Robbi 240-276-9227	Sudha Komaragiri 240-402-6493

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs Sponsor-Monitors-CROs, Clinical Investigators (Pre-Market)	CVM Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68808; 68810; 68811	[X] ORA [ ] CENTER	7.2

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS 68808	DOMESTIC INSPEC-TIONS 68811	FOREIGN INSPEC-TIONS 68810	FOREIGN INSPEC-TIONS 68811					
	TOTAL ORA	**30**	**44**	**2**	**3**					
HQ	HEADQUARTERS	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		137.0	54.0	90.0	74.0					
TOTAL HOURS		4110	2376	180	222					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		4.33	2.50	0.19	0.23					

7. REMARKS

Inspections are to be conducted based on CVM issued assignments. District allocations may change based on assignments.
PAC 68808 includes resources for PAC 68810 Sponsors, Monitors, & Contract Research Organizations

PROJECT SUMMARY SHEET - CDRH BIMO
FY 2017

1. PROGRAM CATEGORY	**2. PPS PROJECT NAME/NUMBER**
Medical Devices and Radiological Health	Product Evaluation: Devices - 83

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE DOMESTIC	6. OPERATIONAL FTE FOREIGN	TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL		**23.5**	**1.2**	**24.7**	
1	Bioresearch Monitoring (Pre-Market)		23.5	1.2	24.7	83-12
	Good Lab Practice Prgm (Nonclinical Labs)	83808	0.3		0.3	
	Institutional Review Board (IRB/ IRC) Prgm	83809	3.4		3.4	
	Sponsor,Monitor, Contract Research Org.Prgm	83810	4.2	0.2	4.5	
	Clinical Investigators	83811	15.6	1.0	16.6	

CENTER PROJECT MANAGER/TELEPHONE	**ORA PLANNER/TELEPHONE**
Zack Showman 301-796-5818	Archana Mathur 301-796-4393

FORM FDA 2622 (2/16)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83808, 83809, 83810, 83811	[X] ORA [ ] CENTER	24.7

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS 83808	DOMESTIC INSPECTIONS 83809	DOMESTIC INSPECTIONS 83810	DOMESTIC INSPECTIONS 83811	FOREIGN INSPECTIONS 83810	FOREIGN INSPECTIONS 83811			
	TOTAL ORA	**5**	**58**	**51**	**200**	**3**	**11**			
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		60.00	55.00	78.54	74.24	72.00	84.00			
TOTAL HOURS		300	3190	4006	14848	216	924			
CONVERSION FACTOR		950	950	950	950	950	950			
TOTAL OPERATIONAL FTEs		0.32	3.36	4.22	15.63	0.23	0.97			

7. REMARKS

PROJECT SUMMARY SHEET
FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Bioresearch Monitoring: Human Drugs - 48

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**61.2**	**29.2**	**90.4**	
1	In Vivo Bioequivalence Pre-Approval (ANDA/ Pre-Approval)	48001	7.4	7.6	15.0	48-04
	In Vivo Bioequivalence Pre-Approval (NDA- PDUFA)	48001A	2.3	3.2	5.5	
2	Bioresearch Monitoring		51.5	18.4	69.9	48-05
	Good Laboratory Practices (Non-Clinical Lab)	48808	[3.6]		[3.6]	
	Institutional Review Board	48809, 48809A	[7.3]		[7.3]	
	Sponsors, Contract Research Organizations, and Monitors	48810	[6]	[0.7]	[6.7]	
	Clinical Investigators	48811	[22.4]		[22.4]	
	Clinical Investigators & Follow Up & Complaints	48811, D, F	[12.2]	[17.7]	[29.9]	

CENTER PROJECT MANAGER/TELEPHONE
Sharon Turner-Rinehardt (301)796-2254; Nicola Fenty-Stewart (301)796-3394; Allen Lou (301) 796-5652

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence Pre-Approval (NDA - PDUFA; ANDA - Non PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48001, 48001A	X ORA X CENTER	20.5

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS ANDA 48001	DOMESTIC INSPECTIONS NDA 48001A	FOREIGN INSPECTIONS ANDA 48001	FOREIGN INSPECTIONS NDA 48001A					
	TOTAL ORA	**100**	**29**	**100**	**32**					
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		70.3	75.0	72.0	95.4					
TOTAL HOURS		7030	2175	7200	3053					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		7.40	2.29	7.58	3.21					

9. REMARKS

Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification.

Planned Resources and Reporting Guidance:
NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001 and should be reported under 48001D and 48001E, respectively.

Note: Foreign inspections are planned at the National level and include resources for Cadre, National Experts, Districts and OIP staff.

Note: District allocations may change based on assignments issued by the Center.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors (PDUFA). Clinical Investigators (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48808, 48809, 48809A, 48810 48811, D, F	[X] ORA [X] CENTER	69.9

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS 48808	DOMESTIC INSPEC-TIONS 48809, 48809A (1)	DOMESTIC INSPEC-TIONS 48810 (2)	DOMESTIC INSPEC-TIONS 48811	DOMESTIC INSPECT-IONS Follow-Up & Complaints 48811F	FOREIGN INSPEC-TIONS 48810 (2)	FOREIGN INSPECT-IONS Follow-Up & Complaints 48811D	DOMESTIC INVESTI-GATIONS (Hours) 48808	DOMESTIC INVESTI-GATIONS (Hours) 48811 (3)
	TOTAL ORA	**31**	**116**	**57**	**244**	**100**	**6**	**125**	**361**	**532**
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		100.0	60.0	100.0	85.2	115.8	104.0	134.4		
TOTAL HOURS		3100	6960	5700	20789	11580	624	16800	361	532
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		3.26	7.33	6.00	21.88	12.19	0.66	17.68	0.38	0.56

9. REMARKS

Planned inspections include Center-initiated and directed assignments that will cover surveillance inspections and studies associated with IND's and NDA's.

Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A.
(1) 48809A: Resource (1 FTE) for the Radioactive Drug Research Committee (RDRC) is not planned separately. However, please use above resources as needed and report RDRC work under PAC 48809A.

(2) 48810: Sponsors, Contract Research Organizations, and Monitors
48808: Resources planned for Inspections may also be used for DSCs

(3) Domestic Investigation hours are planned for National Experts

Note: District allocations may change based on assignments issued by the Center.

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Regulated Tobacco Products:Bioresearch Monitoring / Clinical Investigators	Tobaccor Pre-Market Activities - 98

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**0.6**		**0.6**	
1	Regulated Tobacco Products: Bioresearch Monitoring / Clinical Investigators	98T800, 98811	0.6		0.6	98-4

CENTER PROJECT MANAGER/TELEPHONE
Lillian Ortega 240-402-9041

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Regulated Tobacco Products: Bioresearch Monitoring/Clinical Investigator	Tobacco Pre-Market Activities - 98

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
98T800, 98811	[X] ORA [ ] CENTER	0.6

REGION	6. DISTRICT/SPECIALIZED LABORATORY	DOMESTIC PRE-APPROVAL INSPEC-TIONS (1)							
	TOTAL ORA	**10**							
HQ	*HEADQUARTERS*	(b) (5),							
	TOTAL FIELD	(b) (7)(E)							
NE	*REGIONAL STAFF*								
	NEW ENGLAND								
	NEW YORK								
CE	*REGIONAL STAFF*								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	*REGIONAL STAFF*								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	*REGIONAL STAFF*								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	*REGIONAL STAFF*								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
LABS	**TOTAL LABORATORY**								
	ARKANSAS REGIONAL LAB								
	DENVER LAB								
	DETROIT LAB								
	FORENSIC CHEM. CTR								
	KANSAS LAB								
	NORTHEAST REGIONAL LAB								
	PACIFIC REGIONAL LAB-NW								
	PACIFIC REGIONAL LAB-SW								
	PHILADELPHIA LAB								
	SAN FRANCISCO LAB								
	SOUTHEAST REGIONAL LAB								
	SAN JUAN LAB								
	WEAC								
ESTIMATED HOURS PER OPERATION		60.0							
TOTAL HOURS		600							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		0.63							

9. REMARKS

(1) Domestic Pre-Market Authorization Inspections represent the Center's potential need for Inspections. There may not be any Pre-Market Authorization Inspections conducted in the FY.

PROJECT SUMMARY SHEET - CFSAN BIMO

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Foodborne Biological Hazards- 03

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL					
1	Responsive Investigative/Laboratory Operations	03F813 *	N/A	N/A	N/A	03-10
	(10 BIMO Inspections)					
	* This PAC is for planning purposes only.					
	Accomplished work must be reported against the					
	appropriate program or assignment PAC.					

CENTER PROJECT MANAGER/TELEPHONE
Mallory Kelly 240-402-2401

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Responsive Investigative/Laboratory Operations	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F813	X ORA X CENTER	179.5 (N/A)

REGION	6. ORGANIZATION	BIMO INSPECTIONS (1) (2) (3)								
	TOTAL ORA	**10**								
HQ	HEADQUARTERS	(b) (5), (b) (7)(E)								
	TOTAL FIELD									
NE	*REGIONAL STAFF*									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	TOTAL LABORATORY									
LABS	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANSISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS										
CONVERSION FACTOR										
TOTAL OPERATIONAL FTEs										

7. REMARKS

NOTE: 03F813 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see BIMO PAC list for a listing of compliance programs and corresponding reporting PACS.

(1) - Includes resources for 10 BIMO Inspections (3 GLP, 3 Human Subjects Protection, 3 IRB, and 1 additional of the above categories).
(2) - 8275 Hours are planned under 'Emerging Issues Inspections'. Includes resources for Registration Verification, Emerging Issues, and 10 BIMO inspections.
(3) - Include both foreign and domestic inspections