BIORESEARCH MONITORING PROGRAM
RESOURCE SUMMARY
FY 2018

PPS NO.	PROJECT TITLE	OPERATIONAL FTES		TOTAL OPERATIONAL FTEs
		DOMESTIC	FOREIGN	
	TOTAL	83.20	24.80	108.00
09	RESPONSIVE INVESTIGATIVE/LABORATORY OPERATIONS (BIMO INSPECTIONS)	0.25		0.25
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	4.94		4.94
42	BLOOD AND BLOOD PRODUCTS	3.28		3.28
45	VACCINE AND ALLERGENIC PRODUCTS	6.02		6.02
48	BIORESEARCH MONITORING HUMAN DRUGS	49.69	23.18	72.87
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	1.64	0.14	1.78
83	PRODUCT EVALUATION: DEVICES	17.04	0.99	18.03
98	REGULATED TOBACCO PRODUCTS: BIORESEARCH MONITORING / CLINICAL INVESTIGATORS	0.34	0.49	0.83

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Foodborne Biological Hazards- 09

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**0.25**		**0.25**	
1	Responsive Investigative/Laboratory Operations (10 BIMO Inspections)	(b) (5), (b) (7)(E) [redacted]				
	Good Laboratory Practices (Nonclinical Labs)					
	Institutional Review Boards					
	Sponsors, Monitors, and Contract Research Organizations					
	Clinical Investigators *	0				
	* This PAC is for planning purposes only.					
	Accomplished work must be reported against the					
	appropriate program or assignment PAC.					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Travis Parsley 301-796-4630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring Responsive Investigative/Laboratory Operations	Foodborne Biological Hazards - 09

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
09808: GLPs, 09809: IRBs, 09810: Spon/Mon/CROs, 09811:Clinical Investigators	[ ] ORA [x] CENTER	0.25

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (HOURS) (1)								
	TOTAL ORA	**290**								
	OFFICE OF BIORESEARCH MONITORING OPERATIONS									
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION										
TOTAL HOURS		290								
CONVERSION FACTOR		1160								
TOTAL OPERATIONAL FTEs		0.25								

(b) (5), (b) (7)(E)

[redacted]

9. REMARKS

(1) Plan resources under PAC 09811 Clinical Investigators. Resources may be used for foreign inspections as needed. Resources for domestic and foreigninspections planned under PAC 09811, but may be reported under appropriate PACs as needed.

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Human Cellular, Tissue and Gene Therapeutics - 41 Blood and Blood Products - 42 Vaccines and Allergenic Products - 45

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**14.24**		**14.24**	
1	Bioresearch Monitoring Programs *	(b) (5), (b) (7)(E) [redacted]				
	Good Laboratory Practices (Nonclinical Labs)					
	Institutional Review Boards					
	Sponsors, Monitors, and Contract Research Organizations					
	Clinical Investigators *					
	* All resources are planned under PAC 41811.					
2	Bioresearch Monitoring Programs *					
	Good Laboratory Practices (Nonclinical Labs)					
	Institutional Review Boards					
	Sponsors, Monitors, and Contract Research Organizations					
	Clinical Investigators *					
	* All domestic & foreign resources are planned under domestic PAC 42811.					
3	Bioresearch Monitoring Programs *					
	Good Laboratory Practices (Nonclinical Labs)					
	Institutional Review Boards					
	Sponsors, Monitors, and Contract Research Organizations					
	Clinical Investigators *					
	* 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

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators	Human Cellular, Tissue and Gene Therapeutics - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41808: GLPs, 41809: IRBs, 41810: Spon/Mon/CROs 41811: Clinical Investigators	[X] ORA [X] CENTER	4.94

	6. ACCOMPLISHING ORGANIZATION	INSPEC-TIONS 41808-811 (1)								
	TOTAL ORA	**58**								
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		98.70								
TOTAL HOURS		5725								
CONVERSION FACTOR		1160								
TOTAL OPERATIONAL FTEs		4.94								

9. REMARKS

(1) - Resources for PACs 41808, 41809, 41810, and 41811 are planned under PAC 41811 Clinical Investigators.

Report accomplishment hours under appropriate PAC.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42808: GLPs, 42809: IRBs, 42810: Spon/Mon/CROs 42811: Clinical Investigators	X ORA X CENTER	3.28

	6. ACCOMPLISHING ORGANIZATION	INSPEC-TIONS 42808-811 (1)								
	TOTAL ORA	**50**								
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		76.00								
TOTAL HOURS		3800								
CONVERSION FACTOR		1160								
TOTAL OPERATIONAL FTEs		3.28								

9. REMARKS

(1) - Use above resources for Foreign Inspections as needed. Resources for PACs 42808, 42809, 42810, and 42811 are planned under PAC 42811 Clinical Investigators.

Report accomplishment hours under appropriate PAC.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45808: GLPs, 45809: IRBs, 45810: Spon/Mon/CROs 45811: Clinical Investigators	[X] ORA [X] CENTER	6.02

	6. ACCOMPLISHING ORGANIZATION	INSPEC-TIONS 45808-811 (1)								
	TOTAL ORA	**79**								
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		88.40								
TOTAL HOURS		6984								
CONVERSION FACTOR		1160								
TOTAL OPERATIONAL FTEs		6.02								

9. REMARKS

(1) - Use above resources for Foreign Inspections as needed. Resources for PACs 45808, 45809, 45810, and 45811 are planned under PAC 45811 Clinical Investigators.

Report accomplishment hours under appropriate PAC.

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	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		**49.69**	**23.18**	**72.87**	
1	In Vivo Bioequivalence Pre-Approval (NDA - PDUFA; ANDA - Non PDUFA)					48-8
	In Vivo Bioequivalence Pre-Approval (ANDA/ Pre-Approval) retiring	48001				
	In Vivo Bioequivalence Pre-Approval (NDA- PDUFA) retiring	48001A				
	CLINICAL IN-VIVO BA/BE (ANDAs)- New PAC Code	48001F	3.62	4.40	8.02	
	CLINICAL IN-VIVO BA/BE (NDAs AND BLAs)-New PAC Code	48001G	1.24	1.36	2.60	
	BIOANALYTICAL IN-VIVO BA/BE (ANDAs)-New PAC Code	48001L	1.81	1.91	3.72	
	BIOANALYTICAL IN-VIVO BA/BE (NDAs AND BLAs)- New PAC Code	48001M	0.69	0.75	1.44	
2	Enforcement of the Adverse Drug Experience Reporting Regulation					48-9
	Good Laboratory Practices (Non-Clinical Lab)	48808	2.13		2.13	
	Institutional Review Board	48809, 48809A	4.61		4.61	
	Sponsors, Contract Research Organizations, and Monitors	48810	5.26	0.59	5.85	
	Clinical Investigators	48811	16.41	13.67	30.08	
	Clinical Investigators & Follow Up & Complaints	48811, D, F	8.61		8.61	
3	ADV DRUG EXPERIENCE RPTG REGS-CNTR INIT (PADE) - NEW	53001A	4.59	0.50	5.09	48-10
4	Risk Evaluation and Mitigation System (REMS) - NEW	53001C	0.72		0.72	48-11

CENTER PROJECT MANAGER/TELEPHONE	**ORA PLANNER/TELEPHONE**
Sharon Turner-Rinehardt (301)796-2254; Nicola Fenty-Stewart (301)796-3394; Allen Lou (301) 796-5652	Travis Parsley 301-796-4630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring 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: IN-VIVO BIOEQUIVALENCE (ANDAs) (retiring) 48001A: IN-VIVO BIOEQUIVALENCE (NDAs) (retiring) 48001F - CLINICAL IN-VIVO BA/BE (ANDAs) 48001G - CLINICAL IN-VIVO BA/BE (NDAs AND BLAs) 48001L - BIOANALYTICAL IN-VIVO BA/BE (ANDAs) 48001M - BIOANALYTICAL IN-VIVO BA/BE (NDAs AND BLAs)	[X] ORA [X] CENTER	15.78

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC CLINICAL INSPEC-TIONS ANDA 48001F (1)	DOMESTIC CLINICAL INSPEC-TIONS NDA 48001G (2)	FOREIGN CLINICAL INSPEC-TIONS ANDA 48001F (1)	FOREIGN CLINICAL INSPEC-TIONS NDA 48001G (2)	DOMESTIC BIOANALYTICAL INSPEC-TIONS ANDA 48001L (1)	DOMESTIC BIOANALYTICAL INSPEC-TIONS NDA 48001M (2)	FOREIGN BIOANALYTICAL INSPEC-TIONS ANDA 48001L (1)	FOREIGN BIOANALYTICAL INSPEC-TIONS NDA 48001M (2)	
	TOTAL ORA	**60**	**18**	**60**	**18**	**30**	**10**	**26**	**10**	
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		70.00	80.00	85.00	87.50	70.00	80.00	85.00	87.50	
TOTAL HOURS		4200	1440	5100	1575	2100	800	2210	875	
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	
TOTAL OPERATIONAL FTEs		3.62	1.24	4.40	1.36	1.81	0.69	1.91	0.75	

9. REMARKS

(1) ANDA PEPFAR Resources are planned under 48001F and L and should be reported under 48001J and R.

(2) NDA PEPFAR Resources are planned under 48001G and M and should be reported under 48001H and N. Biosimilar Resources are planned under 48001G and M and should be reported under 48001K and T.

Note: Foreign inspections are planned at the National level and include resources for Cadre, National Experts, Districts and OIP staff.
Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification.
District allocations may change based on assignments issued.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring Enforcement of the Adverse Drug Experience Reporting Regulation	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48808: GLPs 48809, 48809A: IRBs, Radioactive Drug Research Committee 48810: Spon/Mon/CROs 48811, D, F: Clinical Investigators,	[X] ORA [X] CENTER	51.28

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS 48808	DOMESTIC INSPEC-TIONS 48809, 48809A (1)	DOMESTIC INSPEC-TIONS 48810 (2)	DOMESTIC INSPEC-TIONS 48811	FOREIGN INSPECT-IONS 48811	DOMESTIC INSPEC-TIONS Follow-Up & Complaints 48811F	FOREIGN INSPEC-TIONS 48810 (2)			
	TOTAL ORA	**26**	**88**	**61**	**244**	**167**	**90**	**7**			
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]									
DIVISIONS	**DIVISON TOTAL**										
	Division of Bioresearch Monitoring Operations I										
	Division of Bioresearch Monitoring Operations II										
HOURS PER OPERATION		95.00	60.81	100.00	78.00	95.00	111.00	97.00			
TOTAL HOURS		2470	5351	6100	19032	16150	9990	679			
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160			
TOTAL OPERATIONAL FTEs		2.13	4.61	5.26	16.41	13.67	8.61	0.59			

9. REMARKS

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

(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

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001A: ADV DRUG EXPERIENCE RPTG REGS-CNTR INIT (PADE)	[X] ORA [X] CENTER	5.09

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS (1)							
	TOTAL ORA	**70**	**10**							
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		76.00	58.00							
TOTAL HOURS		5320	580							
CONVERSION FACTOR		1160	1160							
TOTAL OPERATIONAL FTEs		4.59	0.50							

9. REMARKS

(1) Foreign inspections include planned resources for Cadre, National Experts, Districts, and OIP staff.

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

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001C: Risk Evaluation and Mitigation System (REMS)	[X] ORA [X] CENTER	0.72

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS								
	TOTAL ORA	**15**								
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7) (E)								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		55.50								
TOTAL HOURS		833								
CONVERSION FACTOR		1160								
TOTAL OPERATIONAL FTEs		0.72								

9. REMARKS

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

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	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		**1.64**	**0.14**	**1.78**	
1	Bioresearch Monitoring					68-13
	(Pre-Market) GLP	68808	0.99		0.99	
	(Pre-Market) Spon/Mon/Con	68810		0.08	0.08	
	(Pre-Market) Clinical Investigators	68811	0.65	0.06	0.71	

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Jeremy Robbi 240-276-9227	Travis Parsley 301-796-4630

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring GLPs Sponsor-Monitors-CROs, Clinical Investigators (Pre-Market)	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: GLPs 68810: Spon/Mon/CROs 68811: Clinical Investigators	[X] ORA [X] CENTER	1.78

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS 68808 (1)	DOMESTIC INSPEC-TIONS 68811 (1)	FOREIGN INSPEC-TIONS 68810 (2)	FOREIGN INSPEC-TIONS 68811 (2)					
	TOTAL ORA	**9**	**15**	**1**	**1**					
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		128.00	50.00	90.00	74.00					
TOTAL HOURS		1152	750	90	74					
CONVERSION FACTOR		1160	1160	1160	1160					
TOTAL OPERATIONAL FTEs		0.99	0.65	0.08	0.06					

9. REMARKS

(1) PAC 68808 includes resources for PAC 68810 Sponsors, Monitors, & Contract Research Organizations

(2) Inspections are to be conducted based on CVM issued assignments. District allocations may change based on assignments.

PROJECT SUMMARY SHEET

FY 2018

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

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE		TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	FOREIGN		
	TOTAL		**17.04**	**0.99**	**18.03**	
1	Bioresearch Monitoring (Pre-Market)					83-15
	Good Lab Practice Prgm (Nonclinical Labs)	83808	0.29	0.06	0.35	
	Institutional Review Board (IRB/ IRC) Prgm	83809	1.99		1.99	
	Sponsor,Monitor, Contract Research Org.Prgm	83810	2.99	0.13	3.12	
	Clinical Investigators	83811	11.77	0.80	12.57	

CENTER PROJECT MANAGER/TELEPHONE	**ORA PLANNER/TELEPHONE**
Zack Showman 301-796-5818	Travis Parsley 301-796-4630

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83808: GLPs 83809: IRBs, 83810: Spon/Mon/CROs 83811: Clinical Investigators	[X] ORA [X] CENTER	18.02

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS 83808	DOMESTIC INSPEC-TIONS 83809	DOMESTIC INSPEC-TIONS 83810	DOMESTIC INSPEC-TIONS 83811	FOREIGN INSPEC-TIONS 83808	FOREIGN INSPEC-TIONS 83810	FOREIGN INSPEC-TIONS 83811			
	TOTAL ORA	**5**	**42**	**45**	**195**	**1**	**2**	**11**			
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]									
DIVISIONS	**DIVISON TOTAL**										
	Division of Bioresearch Monitoring Operations I										
	Division of Bioresearch Monitoring Operations II										
HOURS PER OPERATION		68.00	55.00	77.00	70.00	68.00	74.00	84.00			
TOTAL HOURS		340	2310	3465	13650	68	148	924			
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160			
TOTAL OPERATIONAL FTEs		0.29	1.99	2.99	11.77	0.06	0.13	0.80			

9. REMARKS

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Bioresearch Monitoring: Tobacco 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		**0.34**	**0.49**	**0.83**	
1	Bioresearch Monitoring: Regulated Tobacco Products Clinical Investigator (PMTA; MRTPA)					98-17
	Good Lab Practice Prgm					
	Institutional Review Board (IRB/ IRC) Prgm					
	Sponsor,Monitor, Contract Research Org.Prgm					
	Clinical Investigators	98811	0.34	0.49	0.83	

CENTER PROJECT MANAGER/TELEPHONE	**ORA PLANNER/TELEPHONE**
Lillian Ortega 240-402-9041	Travis Parsley 301-796-4630

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
98808: GLPs 98809: IRBs, 98810: Spon/Mon/CROs 98811: Clinical Investigators	[ ] ORA [X] CENTER	0.83

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC PRE-MARKET INSPEC-TIONS 98811 (1)	FOREIGN PRE-MARKET INSPEC-TIONS 98811 (1)							
	TOTAL ORA	**5**	**6**							
	OFFICE OF BIORESEARCH MONITORING OPERATIONS	(b) (5), (b) (7)(E) [redacted]								
DIVISIONS	**DIVISON TOTAL**									
	Division of Bioresearch Monitoring Operations I									
	Division of Bioresearch Monitoring Operations II									
HOURS PER OPERATION		80.00	95.00							
TOTAL HOURS		400	570							
CONVERSION FACTOR		1160	1160							
TOTAL OPERATIONAL FTEs		0.34	0.49							

9. REMARKS

(1) Domestic/Foreign Pre-Market Authorization Inspections represent the Center's potential need for Inspections.