CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2017

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	131.0	4.3	7.7	143.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	44.7	0.3		45.0
42	BLOOD AND BLOOD PRODUCTS	74.5	4.0	3.9	82.4
45	VACCINE AND ALLERGENIC PRODUCTS	11.8		3.8	15.6

PROJECT SUMMARY SHEET

FY 2017

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

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**44.7**	**0.3**		**45.0**	
1	Inspection of Human Cells, Tissues and Cellular & Tissue-	41002 B,C,D, 41R824	38.7	0.3		39.0	41-2
	Based Products (HCT/Ps)						
2	Bioresearch Monitoring *	41808-41811	5.0			5.0	41-3
3	Inspection of Cell and Gene Therapy Products **	41848 A-D,FG	1.0			1.0	41-4
	* All resources are planned under PAC 41811.						
	* * All resources are planned under PAC 41848F.						

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps)	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41002 B,C,D, 41R824	[X] ORA [ ] CENTER	39.0

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	CBER PRIORITY ESTABS (2)	DOMESTIC INVESTI-GATION (HOURS) (3)	IMPORT INVESTI-GATION (HOURS) (4) 41R824					
	TOTAL ORA	**689**	**46**	**9378**	**285**					
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		39.8								
TOTAL HOURS		27422		9378	285					
CONVERSION FACTOR		950		950	950					
TOTAL OPERATIONAL FTEs		28.87		9.87	0.30					

9. REMARKS

(1) C.P. 7341.002 - Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
(covers HCT/Ps recovered on or after 5/25/2005)
C.P. 7341.002A - Inspection of Tissue Establishments (covers human tissue recovered before 5/25/2005)
(2) Refer to CBER's memo for inspectional priorities dated 7/20/16. These inspections are included in the total inspection numbers.
(3) Domestic Investigation Hours includes time for Follow-Up Inspections.
(4) Follow-Up to refused import entries - PAC 41R824.

* Domestic Investigation hours can be used for foreign inspections and for other CBER programs as needed.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Human Cellular, Tissue and Gene Therapies - 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 [ ] CENTER	5.0

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS (1)								
	TOTAL ORA	**48**								
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									
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								
TOTAL HOURS		4738								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.99								

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Cell and Gene Therapy Products (Domestic & Foreign)	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41848 A-D,F,G	[X] ORA [ ] CENTER	1.0

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)								
	TOTAL ORA	**5**								
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									
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		195.0								
TOTAL HOURS		975								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.03								

9. REMARKS

(1) Resources for all 41848 PACs are planned under PAC 41848F.
Report time under appropriate PAC and Operation Code.
All inspections will be performed by Team Biologics.

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	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	IMPORT	FOREIGN		
	TOTAL		**74.5**	**4.0**	**3.9**	**82.4**	
1	Inspection of Licensed & Unlicensed Blood Banks	42001 F,G,H	53.3		0.2	53.5	42-6
2	Inspection of Source Plasma Establishments	42002 A,F,G	12.9			12.9	42-7
3	Imported CBER - Regulated Products	42007,42R833, 42R824, 99R833		4.0		4.0	42-8
4	Inspection of Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER (Team Biologics)	42008 A,F,G	2.2		1.0	3.2	42-9
5	Bioresearch Monitoring *	42808-42811	4.4			4.4	42-10
6	Inspection of Medical Device Manufacturers	42845 A,B,C	0.5			0.5	42-11
7	Inspection of Plasma Derivatives of Human Origin (Team Biologics)	42848 A-D,F,G	1.2		2.7	3.9	42-12

* All domestic & foreign resources are planned under domestic PAC 42811.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed and Unlicensed Blood Banks (Domestic and Foreign)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42001 F,G,H	[X] ORA [ ] CENTER	53.5

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS	DOMESTIC INVESTI-GATION (HOURS) (2)	DOMESTIC INVESTI-GATION (HOURS) (3)					
	TOTAL ORA	**900**	**7**	**6755**	**6755**					
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*									
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	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		41.2	28.0							
TOTAL HOURS		37080	196	6755	6755					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		39.03	0.21	7.11	7.11					

9. REMARKS

(1) Domestic Blood Bank Inspections: All AIDS related activities should be reported under the appropriate compliance program and PAC. There will be no separate reporting of AIDS time.

(2) Domestic Investigation Time is for National Expert Domestic Investigations, Follow-Up Inspections, Resources for foreign inspections may be used as needed for other CBER programs.

(3) Domestic Investigation Hours includes time for washout inspections and OEI Clean-Up.

CBER will perform pre-license and pre-approval inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Source Plasma Establishments	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42002 A,F,G	[X] ORA [ ] CENTER	12.9

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1) 42002 FG	DOMESTIC INSPEC-TIONS (2) 42002A							
	TOTAL ORA	**197**	**20**							
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)								
	TOTAL FIELD									
NE	*REGIONAL STAFF*									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
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	MINNEAPOLIS									
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	PHILADELPHIA									
SE	*REGIONAL STAFF*									
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	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		50.1	119.3							
TOTAL HOURS		9870	2386							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		10.39	2.51							

9. REMARKS

(1) Includes resources for 42002F and 42002G. Resources are planned under PAC 42002F.
(2) Resources planned under PAC 42002A.
Use resources as needed to accomplish this compliance program.

Report time under appropriate PACS.
All AIDS related activities will be reported under the appropriate Compliance Program and PAC.
CBER will perform pre-license and pre-approval inspections.

Source Plasma PACs:
42002A Pre-License Inspection,
42002F Level 1 CGMP Inspection,
42002G Level 2 CGMP Inspection.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported CBER-Regulated Blood Products	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42007, 42R833, 42R824, 99R833	[X] ORA [ ] CENTER	4.0

REGION	6. ORGANIZATION	IMPORT INVESTI-GATION (HOURS) (1)								
	TOTAL ORA	**3800**								
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									
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										
TOTAL HOURS		3800								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.00								

9. REMARKS

(1) All resources are planned under PAC 42007 as Import Investigation Hours.
Planned Resources are to cover ALL Import Operations: Entry Review 42R833; Follow-Up to Refusals 42R824, 45R824; Filer Evaluations (Operation Code 95, 99R833), Resources include time for Mail Courier and International Mail Facilities reviews.

Report accomplishments under appropriate PAC and Operation Code.

Note: C.P. 7342.007 "Imported CBER-Regulated Products," and Addendum "Imported Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" provides product specific guidance.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed In Vitro Diagnostic (IVD) Devices Regulated by CBER	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42008 A,F,G	[X] ORA [ ] CENTER	3.2

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (HOURS) (2)						
	TOTAL ORA	**15**	**5**	**456**						
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
	TOTAL FIELD									
NE	*REGIONAL STAFF*									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
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	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
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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		106.8	196.0							
TOTAL HOURS		1602	980	456						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.69	1.03	0.48						

9. REMARKS

(1) No separate resources are planned for Pre-License Inspections, use above resources as needed.
PACs include:
42008A Pre-License Inspection - IVDs;
42008F - Level 1 Inspection - Licensed IVDs;
42008G - Level 2 Inspection - Licensed IVDs.
(2) Domestic investigation hours may be used for any Team Biologics program and by any district to support Team Biologics.

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring (PDUFA Domestic & Foreign)	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 [ ] CENTER	4.4

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS (1)								
	TOTAL ORA	**55**								
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									
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		76.0								
TOTAL HOURS		4180								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.40								

9. REMARKS

(1) Resources for PACs 42808, 42809, 42810, and 42811 are planned under PAC 42811 Clinical Investigators.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers (Biologics)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42845 A,B,C	[X] ORA [ ] CENTER	0.5

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)								
	TOTAL ORA	**12**								
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*									
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	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		45.5								
TOTAL HOURS		546								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.50								

9. REMARKS

(1) All Resources are planned under PAC 42845.
Report all operations under appropriate PAC and Operation Code. Number of domestic inspections includes resources for a maximum of 6 foreign inspections, if needed.
Work plan will be updated to reflect foreign inspections, if and when planned.

PACs include:
42845A Level 1 Inspection;
42845B Level 2 Inspection;
42845C Level 3 Inspection or follow-up inspection, as needed.

Note: Inspections of Manufacturers of Blood Bank Software should be reported under this program. Inventory provided by CBER.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Plasma Derivatives of Human Origin	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42848 A-D,F,G	[X] ORA [ ] CENTER	3.9

REGION	6. ORGANIZATION	DOMESTIC LICENSED INSPEC-TIONS (1)	FOREIGN LICENSED INSPEC-TIONS (1)							
	TOTAL ORA	**8**	**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									
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		147.3	256.4							
TOTAL HOURS		1178	2564							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.24	2.70							

9. REMARKS

(1) No separate resources are planned for Pre-License Inspections, use above resources as needed.
All resources are planned under PAC 42848F.
Report all Accomplishments under appropriate PAC and Operation Code.
42848A Pre-Licensed Inspection - Plasma Derivatives;
42848F Level 1 CGMP Inspection - Plasma Derivative;
42848G Level 2 CGMP Inspection - Plasma Derivatives.
42848B Pre-Licensed Inspection - Recombinant Analogues;
42848C Level 1 CGMP Inspection - Recombinant Analogues;
42848D Level 2 CGMP Inspection - Recombinant Analogues.

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	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	IMPORT	FOREIGN		
	TOTAL		**11.8**		**3.8**	**15.6**	
1	Bioresearch Monitoring *	45808-45811	8.0			8.0	45-14
2	Licensed Allergenic Products	45848 A,F,G	1.0		0.5	1.5	45-15
	(Team Biologics)						
3	Licensed Vaccine Products	45848 B,C,D	2.8		3.3	6.1	45-16
	(Team Biologics)						
	* All resources are planned under PAC 45811.						

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring (PDUFA Domestic & Foreign)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45808, 45809-IRBs, 45810-Spon/Mon/CROs, 45811 Clinical Investigators	X ORA ☐ CENTER	8.0

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)								
	TOTAL ORA	**86**								
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									
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		88.4								
TOTAL HOURS		7602								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		8.00								

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.
Inspections are to be conducted only when assignments are received from CBER.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Licensed Allergenic Products (Post-Market & Pre-License)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45848 A,F,G	[X] ORA [ ] CENTER	1.5

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (1)							
	TOTAL ORA	**9**	**4**							
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									
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		105.7	126.7							
TOTAL HOURS		951	507							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.00	0.53							

9. REMARKS

(1) Resources are planned under PAC 45848F. Use resources as needed for Domestic or Foreign inspections, and report under appropriate PAC and Operation code.

45848A Pre-License Inspection - Allergenics;
45848F Level 1 CGMP Inspection - Allergenics;
45848G Level 2 CGMP Inspection - Allergenics.

All inspections performed by Team Biologics.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Licensed Vaccine Products (Post-Market & Pre-License)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45848 B,C,D	[X] ORA [ ] CENTER	6.1

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (1)							
	TOTAL ORA	**12**	**14**							
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									
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		220.7	224.6							
TOTAL HOURS		2648	3144							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.79	3.31							

9. REMARKS

(1) Resources are planned under PAC 45848C. Use resources as needed and report under appropriate PAC.

45848B Pre-License Inspection - Vaccines;
45848C Level 1 CGMP Inspection - Vaccines;
45848D Level 2 CGMP Inspection - Vaccines.

All Inspections will be performed by Team Biologics.