CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2018

PPS NO.	PROJECT TITLE	OPERATIONAL FTES		TOTAL OPERATIONAL FTES
		DOMESTIC	FOREIGN	
	TOTAL	107.25	9.62	116.87
41	HUMAN CELLULAR, TISSUE, AND GENE THERAPIES	41.89	0.41	42.30
42	BLOOD AND BLOOD PRODUCTS	62.47	6.18	68.65
45	VACCINE AND ALLERGENIC PRODUCTS	2.89	3.03	5.92

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**41.89**	**0.41**	**42.30**	
1	Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps)	41002B,C,D	39.04		39.04	41-2
2	Inspection of Cell and Gene Therapy Products	41848A,F,G & B,C,D	1.85	0.41	2.26	41-3
3	Therapeutic Products - Short Term Assignments	41B800	1.00		1.00	41-4

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE

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
41002B,C,D	X ORA ☐ CENTER	39.04

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	CBER PRIORITY ESTABS (2)	DOMESTIC INVESTI-GATION (HOURS) (3)						
	TOTAL ORA	**689**	**55**	**9662**						
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		39.8								
TOTAL HOURS		27422		9662						
CONVERSION FACTOR		950		950						
TOTAL OPERATIONAL FTEs		28.87		10.17						

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 July 19, 2017. These inspections are included in the planned inspection numbers.
(3) Domestic Investigation hours includes time for foreign inspections.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41848A,F,G and 41848B,C,D	[X] ORA [ ] CENTER	2.26

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (2)							
	TOTAL ORA	**9**	**2**							
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		195.0	195.0							
TOTAL HOURS		1755	390							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.85	0.41							

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.

(2) - Module time for foreign inspections does not exist. Module provided based off of Domestic inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Therapeutic Products - Short Term Assignments	Human Cellular, Tissue, and Gene Therapeutics - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41B800	[X] ORA [ ] CENTER	1.00

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INVESTI-GATIONS (Hours) (1)								
	TOTAL ORA	**950**								
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E)								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		950								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.00								

9. REMARKS

(1) Domestic investigations includes resources for center initiated directed inspection assignments or other unplanned activities on an as needed basis.

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**62.47**	**6.18**	**68.65**	
1	Inspection of Licensed and Unlicensed Blood Banks	42001F,G,H	42.56	0.21	42.77	42-6
2	Inspection of Source Plasma Establishments	42002A,F,G	15.06		15.06	42-7
3	Inspection of Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER (Team Biologics)	42008A,F,G	1.38	1.65	3.03	42-8
4	Inspection of Medical Device Manufacturers (Biologics)	42845A,B,C	0.53		0.53	42-9
5	Inspection of Plasma Derivatives of Human Origin (Team Biologics)	42848A-D,F,G	1.71	4.32	6.03	42-10
6	Blood and Blood Products/Assignments	42B800	1.00		1.00	42-11
7	Zika Virus Activities	42R878	0.23		0.23	42-12

CENTER PROJECT MANAGER/TELEPHONE

ORA PLANNER/TELEPHONE

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
42001F,G,H	[X] ORA [ ] CENTER	42.77

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (2)	DOMESTIC INVESTI-GATIONS (Hours) (3)	DOMESTIC INVEST-GATIONS OEI CLEAN-UP (Hours) (4)					
	TOTAL ORA	**850**	**7**	**2950**	**2460**					
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		41.2	28.0							
TOTAL HOURS		35020	196	2950	2460					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		36.86	0.21	3.11	2.59					

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) Foreign Blood Bank Inspections spread by OGROP/ORA/OO/OMPTO/DMPTPO.
(3) Domestic Investigation Time is for National Expert Domestic Investigations and Follow-Up Inspections.
(4) Domestic Investigation Hours includes time for washout inspections.

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
42002A,F,G	[X] ORA [ ] CENTER	15.06

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1) 42002FG	DOMESTIC INSPEC-TIONS (2) 42002A							
	TOTAL ORA	**238**	**20**							
	OFFICE OF BIOLOGICAL PRODUCTS									
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I	(b) (5), (b) (7)(E) [redacted]								
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		50.10	119.30							
TOTAL HOURS		11924	2386							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		12.55	2.51							

9. REMARKS

(1) Includes resources for 42002F and 42002G. Resources are planned under PAC 42002F.
(2) Resources planned under PAC 42002A to capture time spent on the pre-approval inspections of new source plasma establishments. The planned number is subject to change.
Use resources as needed to accomplish operational activities under this compliance program.

Report time under appropriate PACS.
All AIDS related activities will be reported under the appropriate Compliance Program and PAC.

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
Inspection of Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER (Team Biologics)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42008A,F,G	[X] ORA [ ] CENTER	3.03

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours) (2)						
	TOTAL ORA	**8**	**8**	**456**						
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		106.8	196.0							
TOTAL HOURS		854	1568	456						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		0.90	1.65	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
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
42845A,B,C	[X] ORA [ ] CENTER	0.53

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)								
	TOTAL ORA	**11**								
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E)								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		45.5								
TOTAL HOURS		501								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.53								

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 7 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.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42848A-D,F,G	X ORA ☐ CENTER	6.03

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC LICENSED INSPEC-TIONS (1)	FOREIGN LICENSED INSPEC-TIONS (1)							
	TOTAL ORA	**11**	**16**							
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		147.3	256.4							
TOTAL HOURS		1620	4102							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.71	4.32							

9. REMARKS

(1) - No separate resources are planned for Pre-License Inspections, use above resources as needed.
All resources are planned under PAC 42848F.
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.
Report ALL Accomplishments under Appropriate PAC and Operation Code.

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
Blood and Blood Products/Assignments	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42B800	[X] ORA [ ] CENTER	1.00

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INVESTI-GATIONS (Hours) (1)								
	TOTAL ORA	**950**								
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E)								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		950								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.00								

9. REMARKS

(1) Domestic investigations includes resources for center initiated directed inspection assignments or other unplanned activities on an as needed basis.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Zika Virus Activities	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42R878	[X] ORA [ ] CENTER	0.23

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INVESTIGA-TIONS (Hours) (1)								
	TOTAL ORA	**223**								
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E)								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		223								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.23								

9. REMARKS

(1) Domestic Investigations includes resources for Zika related activities on an as needed basis.

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**2.89**	**3.03**	**5.92**	
1	Licensed Allergenic Products (Post-Market & Pre-License)	45848A,F,G	0.33	0.67	1.00	45-14
	(Team Biologics)					
2	Licensed Vaccine Products (Post-Market & Pre-License)	45848B,C,D	2.56	2.36	4.92	45-15
	(Team Biologics)					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE

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
45848A,F,G	X ORA ☐ CENTER	1.00

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (1)							
	TOTAL ORA	**3**	**5**							
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		105.7	126.7							
TOTAL HOURS		317	634							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.33	0.67							

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 (foreign inspections to be reported under operation code 11).

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
45848B,C,D	[X] ORA [ ] CENTER	4.92

	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (1)							
	TOTAL ORA	**11**	**10**							
	OFFICE OF BIOLOGICAL PRODUCTS	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
DIVISIONS	Division of Biological Products Operations I									
	Division of Biological Products Operations II									
ESTIMATED HOURS PER OPERATION		220.7	224.6							
TOTAL HOURS		2428	2246							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.56	2.36							

9. REMARKS

(1) - Resources are planned under PAC 45848C. Use resources as needed and report under appropriate PAC and Operation Code.
Report Foreign Inspections under Operation Code 11.

All Inspections will be performed by Team Biologics.

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