CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2017

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	256.7	49.9	141.4	448.0
46	NEW DRUG EVALUATION	11.0		16.5	27.5
48	BIORESEARCH MONITORING HUMAN DRUGS	61.2		29.2	90.4
52	GENERIC DRUG EVALUATION	5.9	2.0	16.6	24.5
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	7.2		0.5	7.7
56	DRUG QUALITY ASSURANCE	150.5	46.3	78.6	275.4
63	UNAPPROVED AND MISBRANDED DRUGS	8.9	1.6		10.5
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0

PROJECT SUMMARY SHEET
FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	New Drug Evaluation - 46

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		**11.0**		**16.5**	**27.5**	
1	NDA Pre-Approval - (PDUFA)	46832, B, C	9.0		14	23.0	46-02
2	Pre-License Biotech (BLA) - (PDUFA)	46832M	1.5		2.5	4.0	46-02
3	Positron Emission Tomography (PET) Pre-Approval	46832P	0.5			0.5	46-02

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Russ Wesdyk (301) 796-1552; Beth Philpy (301) 796-3334	Andrew Slarve (510) 337-6777

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval- (PDUFA), Pre-Licensed Biotech (BLA) - (PDUFA), Positron Emission Tomography (PET) Pre- Approval	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832, B, C, M, P	[X] ORA [X] CENTER	27.5

REGION	6. ORGANIZATION	DOMESTIC INSP 46832	CHEMISTON DOMESTIC INSP (Hours) (1) 46832	FOREIGN INSP 46832	CHEMISTON FOREIGN INSP (Hours) (1) 46832	DOMESTIC SAMPLE COLL CHEM (2) 46832B,C	DOMESTIC SAMPLE ANALYSIS PROFILE CHEM 46832B,C	DOMESTIC SAMPLE ANALYSIS PROFILE CHEM 46832B,C	DOMESTIC INSP (BLA) 46832M	FOREIGN INSP (BLA) 46832M	DOMESTIC INSP (PET) (3) 46832P
	TOTAL ORA	**135**	**703**	**190**	**4500**	**4**	**2**	**2**	**12**	**13**	**13**
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		54.8		46.3		10.0	248.0	10.0	118.0	180.7	39.0
TOTAL HOURS		7398	703	8797	4500	40	496	20	1416	2349	507
CONVERSION FACTOR		950	950	950	950	950	1180	1180	950	950	950
TOTAL OPERATIONAL FTEs		7.79	0.74	9.26	4.74	0.04	0.42	0.02	1.49	2.47	0.53

9. REMARKS

Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

(1) Includes Microbiologists on Inspections.

(2) Resources available as needed for any district.

(3) Inspections are to verify that the NDA applicant has facilities, equipment, controls, etc. as specified in the application.

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
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	IMPORT	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	ORA PLANNER/TELEPHONE
Sharon Turner-Rinehardt (301)796-2254; Nicola Fenty-Stewart (301)796-3394; Allen Lou (301) 796-5652	Andrew Slarve (510) 337-6777

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, 48001S	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]								
	TOTAL FIELD									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	TOTAL LABORATORY									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
LABS	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, S	[X] ORA [X] CENTER	69.9

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS 48808	DOMESTIC INSPECTIONS 48809, 48809A (1)	DOMESTIC INSPECTIONS 48810 (2)	DOMESTIC INSPECTIONS 48811	DOMESTIC INSPECTIONS Follow-Up & Complaints 48811F	FOREIGN INSPECTIONS 48810 (2)	FOREIGN INSPECTIONS 48811	DOMESTIC INVESTIGATIONS (Hours) 48808	DOMESTIC INVESTIGATIONS (Hours) 48811 (3)
	TOTAL ORA	**31**	**116**	**57**	**244**	**100**	**6**	**173**	**361**	**532**
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		100.0	60.0	100.0	85.2	115.8	104.0	97.3		
TOTAL HOURS		3100	6960	5700	20789	11580	624	16833	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	17.72	0.38	0.56

Use PAC 48811D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).
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
Human Drugs	Generic Drug Evaluation - 52

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		**5.9**	**2.0**	**16.6**	**24.5**	
1	ANDA Pre-Approval	52832, B, C, E	5.4	2.0	16.6	24.0	52-07
	Positron Emission Tomography (PET) Pre-Approval	52832P	0.5			0.5	52-08

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Russ Wesdyk (301) 796-1552; Beth Philpy (301) 796-3334	Andrew Slarve (510) 337-6777

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre-Approval, Positron Emission Tomography (PET) Pre-Approval	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832, B, C, E, P, S	[X] ORA [X] CENTER	24.5 [24.0]

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS ANDA 52832	DOMESTIC CHEMIST ON INSPECTION (Hours) (1) 52832	FOREIGN INSPECT-IONS (2) 52832	FOREIGN CHEMIST ON INSPECT-IONS (Hours) 52832	DOMESTIC SAMPLE COLL 52832B,C	DOMESTIC SAMPLE ANALYSIS BIOTEST CHEM 52832C	IMPORT SAMPLE COLL 52832B,C	IMPORT SAMPLE ANALYSIS CHEM (3) 52832B,C	FOREIGN INVESTI-GATIONS (Hours) 52832
	TOTAL ORA	**79**	**475**	**220**	**2974**	**26**	**26**	**105**	**105**	**466**
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		54.7		56.0		5.6	9.4	3.0	18.8	
TOTAL HOURS		4321	475	12320	2974	146	244	315	1974	466
CONVERSION FACTOR		950	950	950	950	950	1180	950	1180	950
TOTAL OPERATIONAL FTEs		4.55	0.50	12.97	3.13	0.15	0.21	0.33	1.67	0.49

9. REMARKS

(1) Includes Microbiologists on Inspections.

(2) PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

(3) NRL analyzes all Profile/Biotest ISCs and methods development ISAs.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre-Approval, Positron Emission Tomography (PET) Pre-Approval	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832, B, C, E, P	X ORA X CENTER	24.5 [0.5]

REGION	6. ORGANIZATION	ANDA (PET) INSPEC-TIONS 52832P								
	TOTAL ORA	**10**								
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		50.0								
TOTAL HOURS		500								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.52								

9. REMARKS

PROJECT SUMMARY SHEET
FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

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		**7.2**		**0.5**	**7.7**	
1	Enforcement of the Adverse Drug Experience Reporting Regulation	53001A	6.3		0.5	6.8	53-10
2	Risk Evaluation and Mitigation System REMS (PDUFA)	53001C	0.9			0.9	53-11
			.				

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Allen Lou (301) 796-5652	Andrew Slarve (510) 337-6777

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Adverse Drug Experience Reporting Regulation	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001A	[X] ORA [X] CENTER	6.8

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS	FOREIGN INSPECTIONS						
	TOTAL ORA	**88**	**10**						
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		67.5	53.0						
TOTAL HOURS		5940	530						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		6.25	0.56						

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Risk Evaluation and Mitigation System (REMS)	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001C	[X] ORA [X] CENTER	0.9

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS							
	TOTAL ORA	**15**							
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		57.0							
TOTAL HOURS		855							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		0.90							

9. REMARKS

Because of the complexity and individuality of each REMS program, contact CDER at least 2 weeks before conducting inspection. Forward EIRs directly to CDER's Division of Safety Compliance (CDER/OC/OSI).

PROJECT SUMMARY SHEET
FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Drug Quality Assurance - 56

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		**150.5**	**46.3**	**78.6**	**275.4**	
1	Drug Process Inspections	56002, A-D, F-Q	76.4		76.6	153.0	56-13
2	Drug Process Inspections - Compressed Medical Gases	56002E	1.0			1.0	56-14
3	Drug Quality Sampling and Testing Program	56008A, L	25.0			25.0	56-15-16
4	Drug Product Surveillance - Imported Drugs	56008H		46.3		46.3	56-17
5	Drug Quality Reporting System - DQRS	56021A, B	8.0			8.0	56-18
6	Enforcement of the Prescription Drug Marketing Act (PDMA)	56022, A	0.9			0.9	56-19
7	Post-Approval Inspections/Investigations	56843	2.0		2.0	4.0	56-20
8	Pharmacy Compounding Assignments	56D015, 56D017	27.2			27.2	56-21
9	Forensic Evaluation and Sample Analysis	56R838	10.0			10.0	56-22

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Russ Wesdyk (301) 796-1552; Beth Philpy (301) 796-3334; Allen Lou (301) 796-5652	Andrew Slarve (510) 337-6777; Michael Chasey (301) 796-4516

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process Inspections	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002, A-D, F-Q, S	[X] ORA [X] CENTER	153.0

REGION	6. ORGANIZATION	INSPECT-IONS (1)	DOMESTIC INSPECT-IONS	FOREIGN INSPECT-IONS (2)	CHEMIST ON INSPECT-IONS (Hours) (3)	MICRO ON INSPECT-IONS (Hours)	DOMESTIC SAMPLE COLL (4)	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	DOMESTIC SAMPLE ANALYSIS CHEM	DOMESTIC SAMPLE ANALYSIS MICRO	METHOD DEV MICRO
	TOTAL ORA	**1654**	**653**	**1001**	**12996**	**1197**	**236**	**156**	**80**	**156**	**80**	**3540**
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											
HOURS PER OPERATION		72.7					5.5			40.7	25.9	
TOTAL HOURS		120246			12996	1197	1298			6349	2072	3540
CONVERSION FACTOR		950			950	950	950			1180	1180	1180
TOTAL OPERATIONAL FTEs		126.57			13.68	1.26	1.37			5.38	1.76	3.00

9. REMARKS

(1) District allocations may change as a result of CDER's final site selections. The Surveillance List is available with the FY17 Work Plan on the ORA Work Plan website.

(2) Foreign inspections will be completed by National Experts, Cadre, OIP and the districts.

(3) Includes Microbiologists on inspections.

(4) Resources may be used to collect DOC samples by districts as needed.

Note: Shaded columns are a subset of the total inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process Inspections - Compressed Medical Gases	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002E	X ORA X CENTER	1.0

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS MEDICAL GAS							
	TOTAL ORA	**30**							
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		32.1							
TOTAL HOURS		963							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		1.01							

9. REMARKS

Note: District inspection allocation may be subject to change as a result of CDER's final site selections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Sampling and Testing Program	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008A, L	[X] ORA [X] CENTER	25.0 [11.3]

REGION	6. ORGANIZATION	INVESTI-GATIONS (Hours) 56008A	DOMESTIC SAMPLE COLL 56008A	DOMESTIC SAMPLE COLL CHEM 56008A	DOMESTIC SAMPLE COLL MICRO 56008A	DOMESTIC IMPORT SAMPLE COLL 56008L	DOMESTIC IMPORT SAMPLE COLL CHEM 56008L	DOMESTIC IMPORT SAMPLE COLL MICRO 56008L	DOMESTIC SAMPLE ANALYSIS CHEM 56008A	DOMESTIC SAMPLE ANALYSIS MICRO 56008A
	TOTAL ORA	**247**	**282**	**80**	**202**	**350**	**187**	**163**	**80**	**202**
HQ	*HEADQUARTERS*									
NE	**TOTAL FIELD**	[redacted]								
	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			6.0			4.5			40.4	28.6
TOTAL HOURS		247	1692			1575			3232	5777
CONVERSION FACTOR		950	950			950			1180	1180
TOTAL OPERATIONAL FTEs		0.26	1.78			1.66			2.74	4.90

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

9. REMARKS

Reporting Guidance: Report domestic sample collections and sample analyses under 56008A. Report import sample collections and sample analyses under 56008L.

Note: Shaded columns are a subset of the total domestic sample collected and import sample collected.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Sampling and Testing Program	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008A, L	[X] ORA [X] CENTER	25.0 [13.6]

REGION	6. ORGANIZATION	DOMESTIC IMPORT SAMPLE ANALYSIS CHEM 56008L	DOMESTIC IMPORT SAMPLE ANALYSIS MICRO 56008L	METHODS VAL/DEV (Hours) CHEM					
	TOTAL ORA	**187**	**163**	**3941**					
HQ	*HEADQUARTERS*								
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		48.6	19.0						
TOTAL HOURS		9088	3097	3941					
CONVERSION FACTOR		1180	1180	1180					
TOTAL OPERATIONAL FTEs		7.70	2.62	3.34					

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

9. REMARKS

FY 2017 ORA WORK PLAN

October 1, 2016

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance - Imported Drugs	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008H, 56R833, 56R824, 99R833	[X] ORA [ ] CENTER	46.3

REGION	6. ORGANIZATION	IMPORT ENTRY REVIEW (Hours)	IMPORT INVESTIGA-TIONS (Hours) (1)	IMPORT EXAM (2)	INTERNATIONAL MAIL FACILITY REVIEWS INV (Hours)	MAIL COURIER REVIEWS (Hours)	IMPORT SAMPLE COLL	IMPORT SAMPLE ANALYSIS API CHEM	IMPORT SAMPLE ANALYSIS FIN-DOSAGE CHEM
	TOTAL ORA	**18828**	**6669**	**17309**	**9336**	**1872**	**304**	**177**	**125**
HQ	*HEADQUARTERS*								
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				0.5			1.0	17.9	19.6
TOTAL HOURS		18828	6669	8655	9336	1872	304	3168	2450
CONVERSION FACTOR		1200	950	950	1200	1200	950	1180	1180
TOTAL OPERATIONAL FTEs		15.69	7.02	9.11	7.78	1.56	0.32	2.69	2.08

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

9. REMARKS

(1) Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC .

(2) All Label Exams should be reported as LEX/LBL/56008H - Op Code 52. All routine label exams should include reconciliation exams and time associated to these activities are to be reported under the LEX.

Reporting Guidance:
- Import Entry Reviews (electronic and manual - operation code 14) PAC 56R833;
- Filer Evaluations (operation code 95) PAC 99R833;
- Follow-Up to Refusals 56R824, 63R824
- Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001/X;
- Report finished dosage form drugs and APIs collected at the site of entry under 56008H.
- Use CT PAC 56R845 when specific CT work is performed.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Reporting System (DQRS)/NDA-Field Alert Reporting	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56021A, 56021B	X ORA X CENTER	8.0

REGION	6. ORGANIZATION	INSPECTIONS	DQRS FARS INVESTI-GATIONS (Hours)	DOMESTIC SAMPLES COLL	DOMESTIC SAMPLE ANALYSIS CHEM				
	TOTAL ORA	**160**	**1929**	**62**	**62**				
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		22.4		7.5	32.5				
TOTAL HOURS		3584	1929	465	2015				
CONVERSION FACTOR		950	950	950	1180				
TOTAL OPERATIONAL FTEs		3.77	2.03	0.49	1.71				

9. REMARKS

Note: Contact DPEM if additional hours are needed for any of the above operations.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Prescription Drug Marketing Act (PDMA)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56022, 56022A	X ORA X CENTER	0.9

REGION	6. ORGANIZATION	INSPECTIONS (1)	INVESTI-GATIONS (Hours) (2)						
	TOTAL ORA	**32**	**228**						
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		20.0							
TOTAL HOURS		640	228						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		0.67	0.24						

9. REMARKS

(1) Every surveillance GMP inspection of a FDF Rx manufacturer should include time reported against this PAC for inquiring if they utilize the drug samling program. If yes, per CPGM 7356.022 conduct a full inspection per PDMA & report all time to 56022. District allocations may change based on assignments issued by the Center. Sample collection and associated analysis is not required unless requested by Center/HQ.

(2) 56022A should only to be used for Center/HQ-directed investigations, and not part of surveillance inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Post-Approval Inspections/Investigations	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56843	[X] ORA [ ] CENTER	4.0

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS	FOREIGN INSPECTIONS						
	TOTAL ORA	**41**	**37**						
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		46.3	51.6						
TOTAL HOURS		1898	1909						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		2.00	2.00						

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pharmacy Compounding Assignments	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56D015, 56D017	[X] ORA [X] CENTER	27.2

REGION	6. ORGANIZATION	INSPECTIONS 56D015	INSPECTIONS 56D017	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLES COLL 56D015	DOMESTIC SAMPLE ANALYSIS (Hours)			
	TOTAL ORA	**92**	**55**	**200**	**86**	**2704**			
HQ	*HEADQUARTERS*								
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		147.0	171.4		6.0				
TOTAL HOURS		13524	9427	200	516	2704			
CONVERSION FACTOR		950	950	950	950	1180			
TOTAL OPERATIONAL FTEs		14.24	9.92	0.21	0.54	2.29			

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

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R831, 56R838	[X] ORA [ ] CENTER	10.0

REGION	6. ORGANIZATION	FORENSIC CHEM (Hours) FORENSIC EVALUATION							
	TOTAL ORA	**12050**							
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									
TOTAL HOURS		12050							
CONVERSION FACTOR		1205							
TOTAL OPERATIONAL FTEs		10.00							

9. REMARKS

Report Forensic activities under the appropriate PAC 56R838; Op code 03, Petition Evaluation, Methods Development or Forensic Evaluation; Op code 41 or 43 domestic or import sample analysis, 56R838. Report OCI related work to 56R831.

PROJECT SUMMARY SHEET
FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Unapproved and Misbranded Drugs: - Human Drugs - 63

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		**8.9**	**1.6**		**10.5**	
1	Internet, Health Fraud, & OTC Monographs	63001A, 63D012	6.9	1.6		8.5	63-24
2	New Drugs Prescription without approved NDAs	63002	2.0			2.0	63-25

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Allen Lou (301) 796-5652	Andrew Slarve (510) 337-6777

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Internet, Health Fraud, & OTC Monographs	Unapproved and Misbranded Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63001A, 63D012	X ORA [ ] CENTER	8.5

REGION	6. ORGANIZATION	INSPEC-TIONS	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL (1)	IMPORT SAMPLE COLL	DOMESTIC SAMPLE ANALYSIS CHEM	IMPORT SAMPLE ANALYSIS (2)			
	TOTAL ORA	**71**	**1093**	**214**	**72**	**131**	**99**			
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		22.0		4.0	2.0	28.9	17.9			
TOTAL HOURS		1562	1093	856	144	3786	1772			
CONVERSION FACTOR		950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs		1.64	1.15	0.90	0.15	3.21	1.50			

9. REMARKS

(1) Not all samples collected will require analysis; some will be collected for documentary and label review.

(2) Internet/health fraud samples to be collected by OEIO, Health Fraud Team and the districts.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
New Drugs Prescription without approved NDAs	Unapproved and Misbranded Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63002	[X] ORA [ ] CENTER	2.0

REGION	6. ORGANIZATION	INSPECTIONS	INVESTIGATIONS (Hours) (1)						
	TOTAL ORA	**45**	**190**						
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		38.0							
TOTAL HOURS		1710	190						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		1.80	0.20						

9. REMARKS

(1) Resources available as needed for any district.

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	ICA (Interagency Cooperative Activities) - 88

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		**12.0**			**12.0**	
1	Shelf Life Extension Projects	88R046	12.0			12.0	88-27

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Donna A. Porter (301) 796-6583	Andrew Slarve (510) 337-6777

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Shelf Life Extension Projects	Interagency Cooperative Activities - 88

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
88R046	[X] ORA [ ] CENTER	12.0

REGION	6. ORGANIZATION	DOMESTIC SAMPLE ANALYSIS CHEM (Hours)							
	TOTAL ORA	**14160**							
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									
TOTAL HOURS		14160							
CONVERSION FACTOR		1180							
TOTAL OPERATIONAL FTEs		12.00							

9. REMARKS

Five FTEs are assigned to this Program using dollars reimbursed by DOD.
Seven additional FTEs are assigned to this Program using dollars reimbursed by the Department of Homeland Security.
Samples are not collected by FDA.