CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2018

PPS NO.	PROJECT TITLE	INVESTIGATIONAL FTEs		ANALYTICAL FTEs		TOTAL OPERATIONAL FTEs
		DOMESTIC	FOREIGN	DOMESTIC	FOREIGN	
	TOTAL	190.32	33.28	74.80	7.90	306.30
46	NEW DRUG EVALUATION	9.84	11.71	1.18	4.80	27.53
52	GENERIC DRUG EVALUATION	4.82	15.36	0.70	3.10	23.98
56	DRUG QUALITY ASSURANCE	169.96	6.21	56.24		232.41
63	UNAPPROVED AND MISBRANDED DRUGS	5.70		4.68		10.38
88	INTERAGENCY COOPERATIVE ACTIVITIES			12.00		12.00

PROJECT SUMMARY SHEET
FY 2018

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
			INVESTIGATIONAL		ANALYTICAL			
			DOMESTIC	FOREIGN	DOMESTIC	FOREIGN		
	TOTAL		**9.84**	**11.71**	**1.18**	**4.80**	**27.53**	
1	NDA Pre-Approval - (PDUFA)	46832, B, C	7.84	9.22	1.18	4.80	23.04	46-2
2	Pre-License Biotech (BLA) - (PDUFA)	46832M	1.45	2.49			3.94	46-2
3	Positron Emission Tomography (PET) Pre-Approval	46832P	0.55				0.55	46-3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
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	[ ] ORA [X] CENTER	27.53 [26.98]

6. ACCOMPLISHING ORGANIZATION		DOMESTIC INSPECTIONS 46832	CHEMIST ON DOMESTIC INSPECTIONS (Hours) (1) 46832	FOREIGN INSPECTIONS 46832	CHEMIST ON FOREIGN INSPECTIONS (Hours) (1) 46832	DOMESTIC SAMPLE COLLECTIONS CHEM (2) 46832B,C	DOMESTIC SAMPLE ANALYSIS PROFILE CHEM 46832B	DOMESTIC SAMPLE ANALYSIS BIOTEST CHEM 46832C	DOMESTIC INSPECTIONS (BLA) 46832M	FOREIGN INSPECTIONS (BLA) 46832M
TOTAL ORA		**114**	**703**	**199**	**4560**	**4**	**2**	**2**	**23**	**43**
DIVISIONS	OPQO Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E)								
	DIVISION TOTAL									
	PHRM1 Division of Pharmaceutical Quality Operations I									
	PHRM2 Division of Pharmaceutical Quality Operations II									
	PHRM3 Division of Pharmaceutical Quality Operations III									
	PHRM4 Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**									
	DETL Detroit Lab									
	FCC Forensic Chemistry Center									
	NMPL Northeast Medcial Products Lab									
	PHIL Philidelphia Lab									
	PSMPL Pacific Southwest Medical Products Lab									
	SJNL San Juan Lab									
ESTIMATED HOURS PER OPERATION		64.5		44.0		24.0	248.0	10.0	60.0	55.0
TOTAL HOURS		7353	703	8756	4560	96	496	20	1380	2365
CONVERSION FACTOR		950	950	950	950	950	1180	1180	950	950
TOTAL OPERATIONAL FTEs		7.74	0.74	9.22	4.80	0.10	0.42	0.02	1.45	2.49

9. REMARKS

(1) Includes Microbiologists on Inspections.

(2) Resources available as needed for any division.

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

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

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)			5. OPERATIONAL FTE POSITIONS	
46832, B, C, M, P	[ ] ORA	[X] CENTER	27.53	[0.55]

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS (PET) (3) 46832P								
TOTAL ORA			13								
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7) (E)								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	LABS TOTAL										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			40.0								
TOTAL HOURS			520								
CONVERSION FACTOR			950								
TOTAL OPERATIONAL FTEs			0.55								

9. REMARKS

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

PROJECT SUMMARY SHEET
FY 2018

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
			INVESTIGATIONAL		ANALYTICAL			
			DOMESTIC	FOREIGN	DOMESTIC	FOREIGN		
	TOTAL		**4.82**	**15.36**	**0.70**	**3.10**	**23.98**	
1	ANDA Pre-Approval	52832, B, C, E	3.85	15.36	0.70	3.10	23.01	52-5
2	Positron Emission Tomography (PET) Pre-Approval	52832P	0.51				0.51	52-5
3	Biosimilars	52832S	0.46				0.46	52-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
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, Biosimilars	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	23.98

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS ANDA 52832	DOMESTIC CHEMIST ON INSPECTION (Hours) (1) 52832	DOMESTIC INSPECTIONS ANDA (PET) 52832P	DOMESTIC INSPECTIONS BIOSIMILARS 52832S	FOREIGN INSPECTIONS (2) 52832	FOREIGN CHEMIST ON INSPECTIONS (Hours) 52832	DOMESTIC SAMPLE COLLECTIONS 52832B,C	DOMESTIC SAMPLE ANALYSIS BIOTEST CHEM 52832B,C	
TOTAL ORA			**77**	**542**	**12**	**4**	**278**	**2945**	**16**	**16**	
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION											
TOTAL HOURS			3542	542	480	440	14595	2945	112	150	
CONVERSION FACTOR			950	950	950	950	950	950	950	1180	
TOTAL OPERATIONAL FTEs			3.73	0.57	0.51	0.46	15.36	3.10	0.12	0.13	

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).

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

PROJECT SUMMARY SHEET
FY 2018

1. PROGRAM CATEGORY
Human Drugs

2. PPS PROJECT NAME/NUMBER
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
			INVESTIGATIONAL		ANALYTICAL			
			DOMESTIC	FOREIGN	DOMESTIC	FOREIGN		
	TOTAL		**169.96**	**6.21**	**56.24**		**232.41**	
1	Drug Process Inspections	56002, A-D, F-Q, S	132.15	2.73	22.61		157.49	56-7-8
2	Drug Process Inspections - Compressed Medical Gases	56002E	1.01				1.01	56-9
3	Drug Quality Sampling and Testing Program	56008A, L	3.59		19.97		23.56	56-10-11
4	Drug Quality Reporting System - DQRS	56021A, B	4.81		0.16		4.97	56-12
5	Enforcement of the Prescription Drug Marketing Act (PDMA)	56022, A	0.90				0.90	56-13
6	Post-Approval Inspections/Investigations	56843	2.00	3.48			5.48	56-14
7	Pharmacy Compounding Assignments	56D015, 56D017	25.50		3.50		29.00	56-15
8	Forensic Evaluation and Sample Analysis	56R838			10.00		10.00	56-16

CENTER PROJECT MANAGER/TELEPHONE
Beth Philpy (301) 796-3334

ORA PLANNER/TELEPHONE
Andrew Slarve (510) 337-6777

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, 56A002, 56R012, 56R013	X X CENTER	157.49 [145.37]

6. ACCOMPLISHING ORGANIZATION		INSPECTIONS (1)	DOMESTIC INSPECTIONS (FOR CAUSE)	FOREIGN INSPECTIONS (FOR CAUSE)	CHEMIST ON INSPECTIONS (Hours)	MICRO ON INSPECTIONS (Hours)	INVESTI-GATIONS	DOMESTIC SAMPLE COLLECTIONS (2)	DOMESTIC SAMPLE COLLECTIONS (CHEM)	DOMESTIC SAMPLE COLLECTIONS (MICRO)
TOTAL ORA		**1694**	**71**	**31**	**11771**	**1045**	**2366**	**211**	**140**	**71**
DIVISIONS	OPQO Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL									
	PHRM1 Division of Pharmaceutical Quality Operations I									
	PHRM2 Division of Pharmaceutical Quality Operations II									
	PHRM3 Division of Pharmaceutical Quality Operations III									
	PHRM4 Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**									
	DETL Detroit Lab									
	FCC Forensic Chemistry Center									
	NMPL Northeast Medcial Products Lab									
	PHIL Philidelphia Lab									
	PSMPL Pacific Southwest Medical Products Lab									
	SJNL San Juan Lab									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		113329	5950	2598	11771	1045	2366	1055		
CONVERSION FACTOR		950	950	950	950	950	950	950		
TOTAL OPERATIONAL FTEs		119.29	6.26	2.73	12.39	1.10	2.49	1.11		

9. REMARKS

(1) Divisions should follow CDER's site surveillance inspection list (SSIL) which is available on the ORA Work Planning website. The SSIL contains both foreign and domestic firms.

(2) Resources may be used to collect DOC samples by division as needed.

Note: Shaded columns are a subset of the total sample collections.

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, 56A002, 56R012, 56R013	X ORA X CENTER	157.49 [12.12]

6. ACCOMPLISHING ORGANIZATION			DOMESTIC SAMPLE ANALYSIS (CHEM)	DOMESTIC SAMPLE ANALYSIS (MICRO)	METHOD DEV (Hours) (MICRO)	MUTUAL RECOGNITION AGREEMENT PROGRAM (3) 56A002	SITE ENGAGEMENT PROGRAM (Hours) (4) 56R012	DOMESTIC FDASIA 706 PROGRAM (Hours) (5) 56R013	FOREIGN FDASIA 706 PROGRAM (Hours) (5) 56R013		
TOTAL ORA			**140**	**71**	**3516**	**238**	**475**	**238**	**238**		
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			35.0	33.1		8.0					
TOTAL HOURS			4900	2350	3516	1904	475	238	238		
CONVERSION FACTOR			1180	1180	1180	950	950	950	950		
TOTAL OPERATIONAL FTEs			4.15	1.99	2.98	2.00	0.50	0.25	0.25		

9. REMARKS

(3) Sites that may be subject to the Mutual Recognition Agreement (MRA) with the EU are noted on the SSIL by a column noted as "MRA". Report as "Foreign Inspection" (Op 11) under PAC 56A002.

(4) Report as "Technical Assistance/Coordination" (Op 92) under PAC 56R012.

(5) If operation is in lieu of an inspection, report as an "Investigation" (Op 13 (Domestic firms)) or (Op 15 (Foreign firms)) under PAC 56R013.

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	[ ] ORA [X] CENTER	1.01

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS MEDICAL GAS (1)								
TOTAL ORA			**30**								
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7) (E)								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			32.0								
TOTAL HOURS			960								
CONVERSION FACTOR			950								
TOTAL OPERATIONAL FTEs			1.01								

9. REMARKS

(1) See FY18 Medical Gas Site Surveillance Inspection List (SSIL) located on DPE's Human Drug SharePoint site for specific firms to be inspected.

Note: Division inspection allocations 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	23.56 [4.95]

6. ACCOMPLISHING ORGANIZATION			INVESTI-GATIONS (Hours) (1) 56008A	DOMESTIC SAMPLE COLLECTIONS 56008A	DOMESTIC SAMPLE COLLECTIONS CHEM 56008A	DOMESTIC SAMPLE COLLECTIONS MICRO 56008A	DOMESTIC IMPORT SAMPLE COLLECTIONS 56008L	DOMESTIC IMPORT SAMPLE COLLECTIONS CHEM 56008L	DOMESTIC IMPORT SAMPLE COLLECTIONS MICRO 56008L	DOMESTIC SAMPLE COLLECTIONS (FOR CAUSE) (2) 56008A, L	DOMESTIC SAMPLE ANALYSIS CHEM 56008A
TOTAL ORA			**133**	**186**	**32**	**154**	**221**	**154**	**67**	**76**	**32**
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION				8.0			6.0			6.0	50.0
TOTAL HOURS			133	1488			1326			456	1600
CONVERSION FACTOR			950	950			950			950	1180
TOTAL OPERATIONAL FTEs			0.14	1.57			1.40			0.48	1.36

9. REMARKS

(1) Contact DPE if additional hours are needed.

(2) Contact DPE if additional operations are needed.

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

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

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	23.56 [18.61]

6. ACCOMPLISHING ORGANIZATION			DOMESTIC SAMPLE ANALYSIS MICRO 56008A	DOMESTIC IMPORT SAMPLE ANALYSIS CHEM 56008L	DOMESTIC IMPORT SAMPLE ANALYSIS MICRO 56008L	DOMESTIC SAMPLE ANALYSIS (FOR CAUSE) CHEM 56008A, L	METHODS VAL/DEV (Hours) CHEM				
TOTAL ORA			**154**	**154**	**67**	**76**	**4272**				
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			31.0	46.6	33.0	46.6					
TOTAL HOURS			4774	7176	2211	3542	4272				
CONVERSION FACTOR			1180	1180	1180	1180	1180				
TOTAL OPERATIONAL FTEs			4.04	6.08	1.87	3.00	3.62				

9. REMARKS

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	4.97

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS	DQRS FARS INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLLECTIONS	DOMESTIC SAMPLE ANALYSIS CHEM					
TOTAL ORA			**160**	**1900**	**8**	**8**					
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			16.4		6.0	23.8					
TOTAL HOURS			2624	1900	48	190					
CONVERSION FACTOR			950	950	950	1180					
TOTAL OPERATIONAL FTEs			2.76	2.00	0.05	0.16					

9. REMARKS

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

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

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	0.90

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS (1)	INVESTI-GATIONS (Hours) (2)
		TOTAL ORA	**33**	**200**
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E)	
		DIVISION TOTAL		
	PHRM1	Division of Pharmaceutical Quality Operations I		
	PHRM2	Division of Pharmaceutical Quality Operations II		
	PHRM3	Division of Pharmaceutical Quality Operations III		
	PHRM4	Division of Pharmaceutical Quality Operations IV		
LABS		**LABS TOTAL**		
	DETL	Detroit Lab		
	FCC	Forensic Chemistry Center		
	NMPL	Northeast Medcial Products Lab		
	PHIL	Philidelphia Lab		
	PSMPL	Pacific Southwest Medical Products Lab		
	SJNL	San Juan Lab		
ESTIMATED HOURS PER OPERATION			20.0	
TOTAL HOURS			660	200
CONVERSION FACTOR			950	950
TOTAL OPERATIONAL FTEs			0.69	0.21

9. REMARKS

(1) Every surveillance GMP inspection of a FDF Rx manufacturer should include time reported against this PAC for inquiring if the firm utilizes the drug samling program.
If yes, per CPGM 7356.022 conduct a full inspection per PDMA & report all time to 56022. Division 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 X CENTER	5.48

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS	FOREIGN INSPECTIONS							
TOTAL ORA			**38**	**56**							
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E)								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			50.0	59.0							
TOTAL HOURS			1900	3304							
CONVERSION FACTOR			950	950							
TOTAL OPERATIONAL FTEs			2.00	3.48							

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	29.00

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS 56D015	DOMESTIC INSPECTIONS 56D017	INVESTI-GATIONS (Hours) 56D015	INVESTI-GATIONS (Hours) 56D017	DOMESTIC SAMPLE COLLECTIONS 56D015	DOMESTIC SAMPLE ANALYSIS (Hours)			
TOTAL ORA			**60**	**70**	**276**	**247**	**250**	**4130**			
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E) [redacted]								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			155.5	181.0			6.8				
TOTAL HOURS			9330	12670	276	247	1700	4130			
CONVERSION FACTOR			950	950	950	950	950	1180			
TOTAL OPERATIONAL FTEs			9.82	13.34	0.29	0.26	1.79	3.50			

9. REMARKS

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

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

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	10.00

6. ACCOMPLISHING ORGANIZATION			FORENSIC CHEM (Hours) FORENSIC EVALUATION								
TOTAL ORA			**12050**								
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7) (E)								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
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 2018

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
			INVESTIGATIONAL		ANALYTICAL			
			DOMESTIC	FOREIGN	DOMESTIC	FOREIGN		
	TOTAL		**5.70**		**4.68**		**10.38**	
1	Internet, Health Fraud, & OTC Monographs	63001A, 63D012	3.70		4.68		8.38	63-18
2	New Drugs Prescription without approved NDAs	63002	2.00				2.00	63-19

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Beth Philpy (301) 796-3334; 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 X CENTER	8.38

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLLECTIONS (1)	DOMESTIC SAMPLE ANALYSIS					
TOTAL ORA			**68**	**1093**	**249**	**352**					
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E)	[redacted]	[redacted]	[redacted]					
	DIVISION TOTAL		[redacted]	[redacted]	[redacted]	[redacted]					
	PHRM1	Division of Pharmaceutical Quality Operations I	[redacted]	[redacted]	[redacted]	[redacted]					
	PHRM2	Division of Pharmaceutical Quality Operations II	[redacted]	[redacted]	[redacted]	[redacted]					
	PHRM3	Division of Pharmaceutical Quality Operations III	[redacted]	[redacted]	[redacted]	[redacted]					
	PHRM4	Division of Pharmaceutical Quality Operations IV	[redacted]	[redacted]	[redacted]	[redacted]					
LABS	**LABS TOTAL**		[redacted]	[redacted]	[redacted]	[redacted]					
	DETL	Detroit Lab	[redacted]	[redacted]	[redacted]	[redacted]					
	FCC	Forensic Chemistry Center	[redacted]	[redacted]	[redacted]	[redacted]					
	NMPL	Northeast Medcial Products Lab	[redacted]	[redacted]	[redacted]	[redacted]					
	PHIL	Philidelphia Lab	[redacted]	[redacted]	[redacted]	[redacted]					
	PSMPL	Pacific Southwest Medical Products Lab	[redacted]	[redacted]	[redacted]	[redacted]					
	SJNL	San Juan Lab	[redacted]	[redacted]	[redacted]	[redacted]					
ESTIMATED HOURS PER OPERATION			21.0		4.0	15.7					
TOTAL HOURS			1428	1093	996	5526					
CONVERSION FACTOR			950	950	950	1180					
TOTAL OPERATIONAL FTEs			1.50	1.15	1.05	4.68					

9. REMARKS

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

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 X CENTER	2.00

6. ACCOMPLISHING ORGANIZATION			DOMESTIC INSPECTIONS	INVESTI-GATIONS (Hours) (1)							
		TOTAL ORA	**43**	**181**							
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7)(E)								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
ESTIMATED HOURS PER OPERATION			40.0								
TOTAL HOURS			1720	181							
CONVERSION FACTOR			950	950							
TOTAL OPERATIONAL FTEs			1.81	0.19							

9. REMARKS

(1) Resources available as needed for any division.

PROJECT SUMMARY SHEET
FY 2018

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
			INVESTIGATIONAL		ANALYTICAL			
			DOMESTIC	FOREIGN	DOMESTIC	FOREIGN		
	TOTAL				**12.00**		**12.00**	
1	Shelf Life Extension Projects	88R046			12.00		12.00	88-21

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Beth Philpy (301) 796-3334; Allen Lou (301) 796-5652	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	12.00

6. ACCOMPLISHING ORGANIZATION			DOMESTIC SAMPLE ANALYSIS CHEM (Hours)								
TOTAL ORA			**14160**								
DIVISIONS	OPQO	Office of Pharmaceutical Quality Operations	(b) (5), (b) (7) (E)								
	DIVISION TOTAL										
	PHRM1	Division of Pharmaceutical Quality Operations I									
	PHRM2	Division of Pharmaceutical Quality Operations II									
	PHRM3	Division of Pharmaceutical Quality Operations III									
	PHRM4	Division of Pharmaceutical Quality Operations IV									
LABS	**LABS TOTAL**										
	DETL	Detroit Lab									
	FCC	Forensic Chemistry Center									
	NMPL	Northeast Medcial Products Lab									
	PHIL	Philidelphia Lab									
	PSMPL	Pacific Southwest Medical Products Lab									
	SJNL	San Juan Lab									
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.