CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2017

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	123.2	19.0	4.4	146.6
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	8.1		2.7	10.8
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS, AND DEVICES	115.1	19.0	1.7	135.8

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Animal Drugs and Feeds	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**8.1**		**2.7**	**10.8**	
1	NADA Pre-Approval Inspections	68001, G	1.3		2.3	3.6	68-2
2	Bioresearch Monitoring		6.8		0.4	7.2	68-3
	GLPs - Good Laboratory Practices	68808	[4.3]			[4.5]	68-3
	Spon/Mon/Con - Sponsors, Monitors, Contract Research Organizations	68810			[0.2]		68-3
	Clinical Investigators	68811	[2.5]		[0.2]	[2.7]	68-3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Jeremy Robbi 240-276-9227	Angela Pirooz 301-796-8332

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NADA Pre-Approval Inspections	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68001, G	X ORA X CENTER	3.6

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS	CHEMIST ON INSPEC (Hours)						
	TOTAL ORA	**10**	**35**	**850**						
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									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		41.5	61.5							
TOTAL HOURS		415	2153	850						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		0.44	2.27	0.89						

7. REMARKS

Districts and Laboratories should collect and analyze samples as per the compliance program. Resources for sample collections are included in the inspection resources. Resources for Sample Analysis are included in the "Chemist on Inspections" hours. Report all sample collections and analysis under the appropriate operation codes. Resources for the Generic Animal Drug Pre-Approval Inspections are planned under PAC 68001 and should be reported under PAC 68001G.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring GLPs, Spon/Mon/Con, Clinical Investigators	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68808, 68810, 68811	[X] ORA [ ] CENTER	7.2

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS 68808	DOMESTIC INSPEC-TIONS 68811	FOREIGN INSPEC-TIONS 68810	FOREIGN INSPEC-TIONS 68811					
	TOTAL ORA	**30**	**44**	**2**	**3**					
HQ	HEADQUARTERS									
	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		137.0	54.0	90.0	74.0					
TOTAL HOURS		4110	2376	180	222					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		4.33	2.50	0.19	0.23					

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

7. REMARKS

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

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Animal Drugs and Feeds	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

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		**115.1**	**19.0**	**1.7**	**135.8**	
1	Animal Drug Manufacturing Inspections/Type A Medicated Articles	71001, A, B, 71005, A	9.6	*	1.5	11.1	71-5
2	Feed Contaminants	71003A-C, E, G	25.2	8.4		33.6	71-6 to 71-9
3	Feed Manufacturing	71004, A	5.9		0.2	6.1	71-10
4	Illegal Drug Residues in Meat, Poultry, and Milk	71006, M	33.2			33.2	71-11
5	Ruminant Feed Ban Rule/BSE Program	71009, 71R824, 71R833, 71R843, 71R844, 99R833	13.2	10.0		23.2	71-12 to 71-14
6	Preventative Controls for Animal Feed	71014	7.9			7.9	71-15
7	Methods Validation/Development Program	71R816	5.0			5.0	71-16
8	Forensic Evaluation and Sample Analysis	71R838	1.0			1.0	71-17
9	Center Initiated Assignments	71V800	14.1	0.6		14.7	71-18

* 0.02 FTEs planned for Import operations

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Jeremy Robbi 240-276-9227	Angela Pirooz 301-796-8332

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Animal Drug Manufacturing Inspections/Type A Medicated Articles	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71001, A, B, 71005, A	[X] ORA [X] CENTER	11.1

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	TIER I (1)	TIER II (1)	FOREIGN INSPEC-TIONS	CHEMISTON INSPEC (Hours)	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL (2)	DOMESTIC SAMPLE COLL Chem	IMPORT EXAMS (3)	DOMESTIC SAMPLE ANALYSIS Chem	CENTER INITIATED ASSIGN (Tech Assist) (Hours) (4)
	TOTAL ORA	**178**	**102**	**76**	**33**	**600**	**250**	**50**	**20**	**100**	**20**	**950**
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											
	SOUTHWEST REGIONAL LAB											
	WEAC											
ESTIMATED HOURS PER OPERATION		36.9			43.9			8.0		0.2	20.0	
TOTAL HOURS		6568			1447	600	250	400		20	400	950
CONVERSION FACTOR		950			950	950	950	950		950	1180	950
TOTAL OPERATIONAL FTEs		6.91			1.52	0.63	0.26	0.42		0.02	0.34	1.00

7. REMARKS

(1) Inspections include product defects and adverse drug reaction follow up. The district allocations are estimates based on inventory.
Total Domestic Vet Drug inventory is around 517 firms. This strategy will allow for approximately a 3 year inspectional frequency for the industry.
Pharmacy Compounding facilities are not intended to be included in this strategy.
Teat Dip and Udder Wash facilities are low regulatory significance. See CPG Sec. 654.200 Teat Dips and Udder Washes for Dairy Cows and Goats.
Tier 1 lists are for Performance Goal inspections; Tier 2 lists are for Work Plan inspections.
If substitutions are needed, select a firm next down the list as appropriate, and notify Nadine Nanko at CVM.
Contact the National OEI Coordinator for current information about ORA's CVM District Use Codes which are for work planning purposes.
(2) Domestic Sample Collection (50 samples) consists of 20 physical samples and 30 documentary samples. Samples will be collected only “For Cause”.
(3) Focus on the labeling of Category II drugs and Type A medicated articles containing such drugs to verify manufacturer on label is registered for the product being imported and the consignee is registered as a drug mixing establishment and possesses a medicated feed mill license (MFML). Label review should be recorded as LEX/LBL/71005A.
(4) The Center may issue an assignment in FY17. Since the nature of these assignments is not yet determined, resources have been allocated using OP code 92 (Technical Assistance).
Resources for Type A Medicated Articles Program are planned under PAC 71001 and should be reported under PAC 71005A.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - Domestic	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003A-C, E, G	X ORA ___ CENTER	33.6 [6.3]

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL Metals 71003B	DOMESTIC SAMPLE COLL Myco 71003C	DOMESTIC SAMPLE COLL Micro 71003E (2)(a)	DOMESTIC SAMPLE COLL Chem 71003A	DOMESTIC SAMPLE COLL Dioxin 71003G (b)
	TOTAL ORA	**37**	**1260**	**953**	**115**	**338**	**100**	**250**	**150**
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		24.0		4.0					
TOTAL HOURS		888	1260	3812					
CONVERSION FACTOR		950	950	950					
TOTAL OPERATIONAL FTEs		0.93	1.33	4.01					

7. REMARKS

The shaded columns are a subset of the total Domestic Sample Collections.

(1) Inspections performed as follow up to violative samples and as needed for surveillance.

(2) DSC Micro 71003E - 100 official sample collections and 100 analyses - analyze for four microorganisms (Salmonella, Listeria monocytogenes, E. coli O157:H7 and non E. coli O157:H7 Shiga toxin-producing strains of E. coli) per official sample.

Two Center issued assignments are expected in FY17:

(a) A Micro assignment under 71003E will be issued for raw pet food diets.

(b) A 100 sample dioxin assignment will be issued and 50 samples reserved for follow-up if elevated levels are found.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - Domestic	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003A-C, E, G	[X] ORA [ ] CENTER	33.6 [18.6]

REGION	6. ORGANIZATION	DOMESTIC SAMPLE ANALYSIS Metals 71003B	DOMESTIC SAMPLE ANALYSIS Myco 71003C	DOMESTIC SAMPLE ANALYSIS Micro 71003E (3)	DOMESTIC SAMPLE ANALYSIS Chem 71003A (4)	DOMESTIC SAMPLE ANALYSIS Dioxin 71003G (5)	METHODS VAL/DEV Chem (Hours) 71003A	
	TOTAL ORA	**115**	**338**	**100**	**250**	**150**	**9039**	
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							
	WEAC							
HOURS PER OPERATION		25.5	10.0	13.0	6.2	25.0		
TOTAL HOURS		2933	3380	1300	1550	3750	9039	
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	
TOTAL OPERATIONAL FTEs		2.49	2.86	1.10	1.31	3.18	7.66	

7. REMARKS

(3) DSA Micro 71003E - 100 official sample collections and 100 analyses- analyze for four microorganisms (Salmonella, Listeria monocytogenes, E. coli O157:H7 and non E. coli O157:H7 Shiga toxin-producing strains of E. coli) per official sample.

(4) DSA Chem 71003A to include Pesticides, Industrial Chemicals and Filth (240 samples for Pesticides & Industrial Chemicals plus 10 Filth samples for FY17).

(5) DSA Dioxin samples will be used as follows: 100 samples for a dioxin sampling assignment and 50 samples reserved for follow-up if elevated levels are found.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - Import	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003A-C, E, G	X ORA ☐ CENTER	33.6 [6.6]

REGION	6. ORGANIZATION	IMPORT SAMPLE COLL	IMPORT SAMPLE COLL Chem 71003A (6)	IMPORT SAMPLE COLL Micro 71003E (7)	IMPORT SAMPLE COLL Metals 71003B	IMPORT SAMPLE COLL Myco 71003C	IMPORT SAMPLE ANALYSIS Chem 71003A	IMPORT SAMPLE ANALYSIS Micro 71003E
	TOTAL ORA	**865**	**300**	**350**	**45**	**170**	**300**	**350**
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							
	WEAC							
ESTIMATED HOURS PER OPERATION		2.0					4.8	12.0
TOTAL HOURS		1730					1440	4200
CONVERSION FACTOR		950					1180	1180
TOTAL OPERATIONAL FTEs		1.82					1.22	3.56

7. REMARKS

The shaded columns are a subset of the total Import Sample Collections.

(6) ISC Chem and Others: 300 Import Sample Collections are for Chem [Pesticides and Industrial chemicals (290) and filth (10)], 170 Import Samples are for Myco, and 45 Import Samples will be collected for Metals.

(7) ISC Micro 71003E, 350 official sample collections are for pig ears, pet treats, and pet foods as well as other animal feed and ingredients; 350 analyses for Salmonella.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - Import	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003A-C, E, G	X ORA [ ] CENTER	33.6 [2.1]

REGION	6. ORGANIZATION	IMPORT SAMPLE ANALYSIS Metals 71003B	IMPORT SAMPLE ANALYSIS Myco 71003C				
	TOTAL ORA	**45**	**170**				
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						
	WEAC						
ESTIMATED HOURS PER OPERATION		14.0	11.0				
TOTAL HOURS		630	1870				
CONVERSION FACTOR		1180	1180				
TOTAL OPERATIONAL FTEs		0.53	1.58				

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Manufacturing	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71004, A	[ ] ORA [X] CENTER	6.1

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS	DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL Chem	DOMESTIC SAMPLE ANALYSIS Chem				
	TOTAL ORA	**200**	**5**	**60**	**15**	**15**				
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									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		24.0	30.0	8.0		28.0				
TOTAL HOURS		4800	150	480		420				
CONVERSION FACTOR		950	950	950		1180				
TOTAL OPERATIONAL FTEs		5.05	0.16	0.51		0.36				

7. REMARKS

The shaded column is a subset of the total Domestic Sample Collections.

(1) Domestic Sample Collection (60 samples) consists of 15 physical samples and 45 documentary samples. Samples will be collected only “For Cause”.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Illegal Drug Residues in Meat, Poultry, and Milk	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71006	X ORA X CENTER	33.2

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL (1)	TECH SUPPORT (Hours) (2)	METHODS VAL/DEV Chem (Hours)			
	TOTAL ORA	**450**	**5531**	**788**	**1900**	**360**			
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								
	SOUTHWEST REGIONAL LAB								
	WEAC								
ESTIMATED HOURS PER OPERATION		39.0		8.0					
TOTAL HOURS		17550	5531	6304	1900	360			
CONVERSION FACTOR		950	950	950	950	1180			
TOTAL OPERATIONAL FTEs		18.47	5.82	6.64	2.00	0.31			

7. REMARKS

(1) Documentary samples only.

(2) Tech support hours include supporting State Activities under Illegal Residues in Meat, Poultry, and Milk, and time for Tissue Residue Monitors.

FY 2017 ORA WORK PLAN

October 1, 2016

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71009, 71R844, 71R843 99R833, 71R833, 71R824	X ORA X CENTER	23.2 [20.0]

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours) (2)	IMPORT ENTRY REVIEW (Hours) (3)	IMPORT INVESTI-GATIONS (Hours) (4)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT EXAMS	DOMESTIC SAMPLE ANALYSIS Chem (5)	DOMESTIC SAMPLE ANALYSIS Micro (5)
	TOTAL ORA	**720**	**900**	**8440**	**1530**	**572**	**203**	**1600**	**375**	**197**
HQ	HEADQUARTERS									
	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 DISTRIC									
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		6.0				5.0	1.2	0.2	5.0	4.2
TOTAL HOURS		4320	900	8440	1530	2860	244	320	1875	827
CONVERSION FACTOR		950	950	1200	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		4.55	0.95	7.03	1.61	3.01	0.26	0.33	1.59	0.70

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

[redacted]

7. REMARKS

(1) Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills should be inspected annually and other establishment types handling or not handling prohibited material should be inspected as specified on page 71-13.

(2) Domestic Investigation Hours are to be used for OEI Improvement with a focus on searching for new firms that fall under the high risk category. Report CVM State Contract Inspection Audit time under PAC 71R843 Operation Code 13.

(3) Reporting Guidance: Import Entry Review (Electronic and Manual - Operation Code 14, PAC 71R833) includes resources for Mail Courier review.

(4) Import Investigation Hours are for Filer Evaluations (Op Code 95, PAC 99R833), Follow-Up to Refusals (PAC 71R824), and other operations as required by the district to cover program priorities. Report accomplishments under the appropriate operation and PACs.

(5) Domestic Sample Analysis Planned Hours are split 2/3 Chem and 1/3 Micro, however laboratories may use planned time for either type of analysis as needed.

FY 2017 ORA WORK PLAN October 1, 2016

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71009, 71R844, 71R843 99R833, 71R833, 71R824	X ORA X CENTER	23.2 [3.2]

REGION	6. ORGANIZATION	IMPORT SAMPLE ANALYSIS Chem	TECHNICAL SUPPORT (Hours) (6)					
	TOTAL ORA	**203**	**2247**					
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 DISTRIC							
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							
	WEAC							
ESTIMATED HOURS PER OPERATION		5.0						
TOTAL HOURS		1015	2247					
CONVERSION FACTOR		1180	950					
TOTAL OPERATIONAL FTEs		0.86	2.37					

7. REMARKS

(6) Technical support hours include supporting state activities under the Ruminant Feed Ban Regulation and supporting state activities under the Feed Manufacturing Program, PAC 71004. These hours also include resources for audits of state contract inspections.

(7) Import Sample Collections should be reported using work type SAM/FIL and PAC 71R844.

(8) Import Exams should be reported using work type LEX/LBL and PAC 71R844. Label exams should be to examine ingredients and determine if any are of animal origin (animal protein or byproducts).

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

9. Remarks
Inspection Priorities.

21 CFR 589.2000 and 589.2001 address a wide variety of firms and animal product operations that involve the manufacture, distribution, transportation, and feeding of animals. 21 CFR 589.2000 prohibits the feeding of specific mammalian proteins to ruminant animals, 21 CFR 589.2001 prohibits the use of specific cattle-origin tissues in the feed of all animals, including pet food. As a result, the regulations have broad applications, including at operations that do not involve ruminant feeds or the feeding of ruminant animals. Inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with regulations be encountered. CVM has developed a mathematical system for priotitizing inspections, which ORA has used the last several years to help with the annual work-planning. The following list of firm/industry types generally describes our priorities, in descending order:

- Follow-up to OAI inspections
- Firms that manufacture prohibited material or use prohibited material in their manufacturing (renderers, protein blenders, and feed mills)
- Renderers
- Protein Blenders
- Commercial feed mills (licensed and unlicensed)
- Pet food/livestock feed salvage operations
- Haulers/transporters of animal feeds
- Animal feed distributors/retailers
- On-farm feed manufacturers (with ruminant and non-ruminant animals, or only ruminants)
- Ruminant feeders
- On-farm feed manufacturers (no ruminants on the farm premises)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Preventative Controls for Animal Feed	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71014	[ ] ORA [X] CENTER	7.9

REGION	6. ORGANIZATION	HIGH RISK INSPEC-TIONS (1)								
	TOTAL ORA	**250**								
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									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		30.0								
TOTAL HOURS		7500								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		7.89								

7. REMARKS

(1) The field can expect a high risk feed inspection assignment related to manufacturing practices to inspect such firms as salvagers, pet food/LACF manufacturers, unlicensed medicated/unmedicated feed mills, and feed ingredient manufacturers, all flagged with a risk identifier.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71R816	[X] ORA [ ] CENTER	5.0

REGION	6. ORGANIZATION	METHODS VAL/DEV Chem (Hours)	APPLIED TECH CENTER Chem (Hours)							
	TOTAL ORA	**1205**	**4720**							
HQ	HEADQUARTERS	[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									
	PACIFIC REGIONAL LABORATORY-SW									
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		1205	4720							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		1.00	4.00							

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

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71R838	[X] ORA [ ] CENTER	1.0

REGION	6. ORGANIZATION	FORENSIC ANALYSIS Chem (Hours)								
	TOTAL ORA	**1205**								
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									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		1205								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		1.00								

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71V800, 71V023	X ORA X CENTER	14.7

REGION	6. ORGANIZATION	INVESTIGATIONS (Hours)	TECHNICAL ASSISTANCE ANALYTICAL CHEM (Hours) (1)	TECHNICAL ASSISTANCE ANALYTICAL MICRO (Hours) (2)	IMPORT EXAMS					
	TOTAL ORA	**10318**	**2550**	**1315**	**1305**					
HQ	HEADQUARTERS	[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									
	SOUTHWEST REGIONAL LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION					0.4					
TOTAL HOURS		10318	2550	1315	522					
CONVERSION FACTOR		950	1180	1180	950					
TOTAL OPERATIONAL FTEs		10.86	2.16	1.11	0.55					

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

7. REMARKS

(1) Resources planned as technical assistance (OP code 92). Hours may be used for inspections (chemist on inspection), investigations, sample collections or sample analysis. Resources include time for investigating pet turtle establishments and inspecting pharmacies that compound animal products. Resources may also be applied to sample collections and analyses when investigating adverse events.

(2) Resources planned as technical assistance (OP code 92). Hours may be used for inspections (microbiologist on inspection), investigations, sample collections or sample analysis. Resources include time for investigating pet turtle establishments and inspecting pharmacies that compound animal products. Resources may also be applied to sample collections and analyses when investigating adverse events.

VFD and Foreign Supplier Verification will use this PAC, if assignments issue.