CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2018

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs		TOTAL OPERATIONAL FTEs
		DOMESTIC	FOREIGN	
	TOTAL	104.62	3.99	108.61
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	7.21	2.05	9.26
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS, AND DEVICES	97.41	1.94	99.35

PROJECT SUMMARY SHEET
FY 2018

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	FOREIGN		
	TOTAL		**7.21**	**2.05**	**9.26**	
1	NADA Pre-Approval Inspections	68001, G	7.21	2.05	9.26	68-2

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	Total FTE 9.26

DIVISIONS	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPECTIONS	FOREIGN INSPECTIONS	CHEMIST ON INSPECTION (Hours)	PHARMA ASSIGN-MENTS (Hours)			
	TOTAL ORA	**10**	**30**	**850**	**5605**			
	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**							
	Arkansas Lab							
	Denver Lab							
	Kansas City Lab							
	Northeast Food & Feed Lab							
	Pacific Northwest Lab							
	Pacific Southwest Food and Feed Lab							
	San Francisco Lab							
	Southeast Food and Feed Lab							
	Forensic Chemistry Center							
ESTIMATED HOURS PER OPERATION		40.00	65.00					
TOTAL HOURS		400.00	1950.00	850.00	5605.00			
CONVERSION FACTOR		950	950	950	950			
TOTAL OPERATIONAL FTEs		0.42	2.05	0.89	5.90			

9. 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 Inspection" 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.

PROJECT SUMMARY SHEET
FY 2018

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	FOREIGN		
	TOTAL		**97.41**	**1.94**	**99.35**	
1	Animal Drug Manufacturing Inspections/Type A Medicated Articles	71001, A, B, 71005, A	11.99	1.65	13.64	71-4
2	Feed Contaminants	71003A-C, E, G	28.26		28.26	71-5 to 71-6
3	Feed Manufacturing	71004, A, 71V023	6.87	0.29	7.16	71-7
4	Drug Residues in Animal Derived Foods	71006	26.15		26.15	71-8
5	Ruminant Feed Ban Rule/BSE Program	71009, 71R824, 71R833, 71R843, 71R844, 99R833	8.64		8.64	71-9
6	Preventive Controls for Animal Feed	71014, 71015	9.60		9.60	71-10
7	Methods Validation/Development Program	71R816	4.90		4.90	71-11
8	Forensic Evaluation and Sample Analysis	71R838	1.00		1.00	71-12

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

FORM FDA 2622 (2/16)

1. PROGRAM/ASSIGNMENT TITLE
Animal Drug Manufacturing Inspections/Type A Medicated Articles

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

3. PROGRAM/ASSIGNMENT CODE(S)
71001, A, B, 71005, A

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
Total FTE 13.64

DIVISIONS / LABS	6. ACCOMPLISHING ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	TIER I	TIER II	FOREIGN INSPECTIONS	CHEMIST ON INSPECTION (Hours)	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL (2)	DOMESTIC SAMPLE COLL Chem	DOMESTIC SAMPLE ANALYSIS Chem	CENTER INITIATED ASSIGN (Tech Assist) (Hours)(3)
	TOTAL ORA	**178**	**102**	**76**	**33**	**600**	**250**	**50**	**20**	**20**	**2200**
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**										
	Arkansas Lab										
	Denver Lab										
	Kansas City Lab										
	Northeast Food & Feed Lab										
	Pacific Northwest Lab										
	Pacific Southwest Food and Feed Lab										
	San Francisco Lab										
	Southeast Food and Feed Lab										
	Forensic Chemistry Center										
ESTIMATED HOURS PER OPERATION		41.00			47.63			8.00		40.00	
TOTAL HOURS		7298.00			1571.79	600.00	250.00	400.00		800.00	2200.00
CONVERSION FACTOR		950			950	950	950	950		1180	950
TOTAL OPERATIONAL FTEs		7.68			1.65	0.63	0.26	0.42		0.68	2.32

9. REMARKS

The shaded columns are a subset of the total Domestic Inspections and the total Domestic Sample Collections, respectively.
(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) 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.

FY 2018 ORA WORK PLAN

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants	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 X CENTER	Total FTE 28.26

DIVISION	6. ORGANIZATION	DOMESTIC INSPECTIONS	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL Chem 71003A (1)	DOMESTIC SAMPLE COLL Metals 71003B	DOMESTIC SAMPLE COLL Myco 71003C (2)	DOMESTIC SAMPLE COLL Micro 71003E (3)	DOMESTIC SAMPLE COLL Dioxin 71003G (4)
	TOTAL ORA	**15**	**1260**	**903**	**250**	**115**	**338**	**100**	**100**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**	(b) (5), (b) (7)(E) [redacted]							
DMS	Division of Milk Safety								
DRFP	Division of Retail Food Protection								
DSS	Division of Shellfish Sanitation								
IOG-HAF	International Operations - Human Foods								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**								
HAFE1	Division of Human and Animal Food Operations East I								
HAFE2	Division of Human and Animal Food Operations East II								
HAFE3	Division of Human and Animal Food Operations East III								
HAFE4	Division of Human and Animal Food Operations East IV								
HAFE5	Division of Human and Animal Food Operations East V								
HAFE6	Division of Human and Animal Food Operations East VI								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**								
HAFW1	Division of Human and Animal Food Operations West I								
HAFW2	Division of Human and Animal Food Operations West II								
HAFW3	Division of Human and Animal Food Operations West III								
HAFW4	Division of Human and Animal Food Operations West IV								
HAFW5	Division of Human and Animal Food Operations West V								
HAFW6	Division of Human and Animal Food Operations West VI								
LABS	**FOOD AND FEED LABORATORIES**								
ARKL	Arkansas Lab								
DENL	Denver Lab								
KCL	Kansas City Lab								
NFFL	Northeast Food and Feed Lab								
PNL	Pacific Northwest Lab								
PSFFL	Pacific Southwest Food and Feed Lab								
SANFL	San Francisco Lab								
SFFL	Southeast Food and Feed Lab								
FCC	Forensic Chemistry Center								
ESTIMATED HOURS PER OPERATION		22.00		7.00					
TOTAL HOURS		330.00	1260.00	6321.00					
CONVERSION FACTOR		950	950	950					
TOTAL OPERATIONAL FTEs		0.35	1.33	6.65					

7. REMARKS

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

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

(1) DSC Chem 71003A: Collect 240 Pesticides and Industrial Chemicals (P&IC) samples and 10 Melamine/Cyanuric Acid/Ammeline/Ammelide (MCAA) samples.

(2) DSC Myco 71003C: Collect 338 samples, including 30 complete swine feeds and 50 dry pet food (kibbles) with grains (barley, corn, oats, rice, rye, sorghum and/or wheat products).

(3) DSC Micro 71003E: Micro samples collection will be directed by center initiated assignment.

(4) DSC Dioxin 71003G: Dioxin sample collection will be directed by center initiated assignments.

Three Center-issued Assignments are expected in FY18:

a. A 100 sample Micro assignment under 71003E will be issued for pet foods.

b. A 60 sample Dioxin assignment under 71003G will be issued for anti-caking agents and fats/oils.

c. If the USDA issues a 500 sample Dioxin assignment to collect fat from steers, heifers, barrows, gilts, broilers and turkey poults at slaughter, the FDA will issue on farm inspection/collection assignments under 71003G when elevated dioxins levels are found by USDA (estimate 5 farms and ~8 samples collected per farm).

[8.33]

FY 2018 ORA WORK PLAN

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants	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	Total FTE	28.26

DIVISION	6. ORGANIZATION	DOMESTIC SAMPLE ANALYSIS Chem 71003A (1)	DOMESTIC SAMPLE ANALYSIS Metals 71003B	DOMESTIC SAMPLE ANALYSIS Myco 71003C (2)	DOMESTIC SAMPLE ANALYSIS Micro 71003E (3)	DOMESTIC SAMPLE ANALYSIS Dioxin 71003G	METHODS VAL/DEV Myco 71003C (Hours)(4)	ADDITIONAL HOURS Chem (Hours)	ADDITIONAL HOURS Micro (Hours)
	TOTAL ORA	**250**	**115**	**338**	**100**	**100**	**9039**	**2795**	**2903**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**								
DMS	Division of Milk Safety								
DRFP	Division of Retail Food Protection								
DSS	Division of Shellfish Sanitation								
IOG-HAF	International Operations - Human Foods								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**								
HAFE1	Division of Human and Animal Food Operations East I								
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HAFE3	Division of Human and Animal Food Operations East III								
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HAFE6	Division of Human and Animal Food Operations East VI								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**								
HAFW1	Division of Human and Animal Food Operations West I								
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LABS	**FOOD AND FEED LABORATORIES**								
ARKL	Arkansas Lab								
DENL	Denver Lab								
KCL	Kansas City Lab								
NFFL	Northeast Food and Feed Lab								
PNL	Pacific Northwest Lab								
PSFFL	Pacific Southwest Food and Feed Lab								
SANFL	San Francisco Lab								
SFFL	Southeast Food and Feed Lab								
FCC	Forensic Chemistry Center								
ESTIMATED HOURS PER OPERATION		7.88	12.00	9.50	7.88	14.23			
TOTAL HOURS		1970.00	1380.00	3211.00	788.00	1423.00	9039.00	2795.00	2903.00
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.67	1.17	2.72	0.67	1.21	7.66	2.37	2.46

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

[redacted]

7. REMARKS

(1) DSA Chem 71003A: Analyze 240 Pesticides and Industrial Chemicals (P&IC) samples and 10 Melamine/Cyanuric Acid/Ammeline/Ammelide (MCAA) samples.
When confirming any MCAA residues, use the LC/MS method.
When receiving domestic animal food samples matching one of the product codes from the "CVM Commodities for SRM" list (posted on the DPE website), in addition to running the MRM screen for pesticides, laboratories are requested to perform an additional SRM test per their capabilities (PNL and PSFFL for Glyphosate; and ARKL and NFFL for Acid Herbicides).
(2) DSA Myco 71003C: Analyze each official sample for 2 different mycotoxins.
Analyze the 30 samples of complete swine feeds and 50 samples of dry pet food (kibbles) with grains for the Priority 1 and Priority 2 mycotoxins as listed in Appendix A (Analytical Priority for Mycotoxin Testing in Animal Foods) of the Animal Feed Compliance Program.
(3) DSA Micro 71003E: Analyze 100 official samples. Analyze samples for two microorganisms (Salmonella spp. and Listeria monocytogenes).
(4) FTEs will be devoted for Methods Validation/Development for aflatoxins in DDGs, and for T-2 toxin and other trichothecene mycotoxins in animal feed.

[19.93]

FY 2018 ORA WORK PLAN

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, 71V023			X	ORA	X	CENTER	Total FTE	7.16

DIVISION	6. ORGANIZATION	DOMESTIC INSPECTIONS	Tier 1	Tier 2	VFD INSPECTIONS 71V023 (1)	FOREIGN INSPECTIONS	DOMESTIC SAMPLE COLL (2)	DOMESTIC SAMPLE COLL Chem	DOMESTIC SAMPLE ANALYSIS Chem
	TOTAL ORA	**160**	**122**	**38**	**108**	**5**	**60**	**15**	**15**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	[redacted]							
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**								
DMS	Division of Milk Safety								
DRFP	Division of Retail Food Protection								
DSS	Division of Shellfish Sanitation								
IOG-HAF	International Operations - Human Foods								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**								
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DENL	Denver Lab								
KCL	Kansas City Lab								
NFFL	Northeast Food and Feed Lab								
PNL	Pacific Northwest Lab								
PSFFL	Pacific Southwest Food and Feed Lab								
SANFL	San Francisco Lab								
SFFL	Southeast Food and Feed Lab								
FCC	Forensic Chemistry Center								
ESTIMATED HOURS PER OPERATION		30.00			11.00	56.00	7.83		6.15
TOTAL HOURS		4800.00			1188.00	280.00	469.80		92.25
CONVERSION FACTOR		950			950	950	950		1180
TOTAL OPERATIONAL FTEs		5.05			1.25	0.29	0.49		0.08

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

7. REMARKS

The shaded columns are a subset of the total Domestic Inspections and the total Domestic Sample Collections, respectively.

(1) Approximately one-third of the VFD Assignment (PAC 71V023) inspections are to be combined with the Medicated Feed Manufacturing Program (PAC 71004) inspections.

CVM will direct the number of such combination inspections that each Division should accomplish. CVM will provide clear guidance about what is expected in memos and facilities lists for both 71V023 and 71004.

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

1. PROGRAM/ASSIGNMENT TITLE
Drug Residues in Animal Derived Foods

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

3. PROGRAM/ASSIGNMENT CODE(S)
71006

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
Total FTE 26.15

DIVISION	6. ORGANIZATION	DOMESTIC INSPECTIONS	DOMESTIC INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL (1)	METHODS VAL/DEV Chem (Hours)					
	TOTAL ORA	**525**	**2000**	**207**	**360**					
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		39.00		10.00						
TOTAL HOURS		20475.00	2000.00	2070.00	360.00					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		21.55	2.11	2.18	0.31					

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

7. REMARKS
(1) Documentary samples only.
Tech support hours include supporting State Activities under Drug Residues in Meat, Poultry, and time for Drug Residue Monitors.

FY 2018 ORA WORK PLAN — October 1, 2017

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, 71R824, 71R833, 71R843, 71R844, 99R833	X ORA X CENTER	Total FTE 8.64

DIVISION	6. ORGANIZATION	DOMESTIC INSPECTIONS (1)	DOMESTIC INVESTIGATIONS (Hours)(2)	DOMESTIC SAMPLE COLLECTION	DOMESTIC SAMPLE ANALYSIS Chem (3)	DOMESTIC SAMPLE ANALYSIS Micro (3)	TECHNICAL SUPPORT (Hours)(4)			
	TOTAL ORA	**311**	**900**	**200**	**375**	**197**	**1085**			
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		9.80		5.00	5.00	4.20				
TOTAL HOURS		3047.80	900.00	1000.00	1875.00	827.40	1085.00			
CONVERSION FACTOR		950	950	950	1180	1180	950			
TOTAL OPERATIONAL FTEs		3.21	0.95	1.05	1.59	0.70	1.14			

(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.

(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) 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.

(4) 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.

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 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 prioritizing 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	
Preventive 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, 71015	[ ] ORA [X] CENTER	Total FTE 9.60

DIVISION	6. ORGANIZATION	DOMESTIC HIGH RISK INSPECTIONS 71014								
	TOTAL ORA	**304**								
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**	(b) (5), (b) (7) (E)								
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		30.00								
TOTAL HOURS		9120.00								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		9.60								

7. REMARKS

The field can expect an inspection assignment related to Part 507 CGMPs to inspect such firms as salvagers, pet food/LACF manufacturers, unlicensed medicated, Licensed, medicated feed mills, ethanol plants, pet food warehouses, and feed ingredient manufacturers.

71014 - PCAF CGMP INSPECTIONS (Currently an Active PAC in the LOV of FACTS/ORADSS)

71015 – PCAF PREVENTIVE CONTROL INSPECTIONS (Inspections will not begin until FY19; separate tab will be created for PAC)

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Methods Validation/Development Program

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

3. PROGRAM/ASSIGNMENT CODE(S)
71R816

4. WORK ALLOCATION PLANNED BY
X ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
Total FTE 4.90

DIVISION	6. ORGANIZATION	METHODS VAL/DEV Chem (Hours)	APPLIED TECH CENTER Chem (Hours)							
	TOTAL ORA	**1060**	**4720**							
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		1060.00	4720.00							
CONVERSION FACTOR		1180	1180							
TOTAL OPERATIONAL FTEs		0.90	4.00							

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

[redacted]

7. REMARKS

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Forensic Evaluation and Sample Analysis

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

3. PROGRAM/ASSIGNMENT CODE(S)
71R838

4. WORK ALLOCATION PLANNED BY
X ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
Total FTE 1.00

DIVISION	6. ORGANIZATION	FORENSIC ANALYSIS Chem (Hours)								
	TOTAL ORA	**1180**								
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST (Cadre)**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST (NE)**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		1180.00								
CONVERSION FACTOR		1180								
TOTAL OPERATIONAL FTEs		1.00								

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

7. REMARKS