



Memorandum

Date September 12, 2013

From Director, Division of Planning, Evaluation and Management

Subject Final FY 2014 Office of Regulatory Affairs (ORA) Field Workplan

To Regional Food and Drug Directors
District Directors
Regional Laboratory Directors: Northeast, Southeast, Arkansas, Pacific Northwest, Pacific Southwest, WEAC, and FCC
Investigations Branch Directors
Laboratory Branch Directors

The Final FY 2014 ORA Field Workplan is based primarily on the Centers' compliance program forecasts. The foreign inspections were spread by the ORA Office of Medical Products and Tobacco Operations (OMPTO) and the Office of Food and Feed Operations (OFFO). Laboratory allocations were planned by the ORA Office of Regulatory Science (ORS) using the Lab Program Optimization. Finally, import allocations were reviewed by the Division of Import Operations (DIO).

The FY 2014 Workplan reflects ORA's planning level of 2,363 operational Full-Time Equivalents (FTE). There was no increase in operational FTE for the following four program areas: 1) Foods and Cosmetics, 2) Biologics, 3) Animal Drugs and Feeds, and 4) Devices and Radiological Health. As a result of the Generic Drug User Fee Amendments (GDUFA), the Human Drugs program increased by 10 investigational FTE. In addition, the operational FTE for Center for Tobacco Products (CTP) increased by 7 FTE. The FY 2014 Field Workplan uses the Centers' and ORA's risk-based approaches for allocating resources within the six program areas.

The FY 2014 Workplan only includes resources for ORA investigators and analysts; it does not plan operations conducted by States under contract.

IMPORTANT: Regional offices should be prepared to assist Districts within their jurisdiction to meet workplan obligations because some District workplans have increased above their current on-board staffing levels.

NEW DIRECTOR OF WORK PLANNING BRANCH

Celia Gabrel has joined the Division of Planning, Evaluation and Management (DPEM) as the new Work Planning Branch Director. She can be contacted at (301) 796-3304.

NEW MAJOR MODIFICATION (1):

New to the FY 2014 Foods and Cosmetics Workplan is a set of resources planned under the following program, “Responsive Investigative/Laboratory Operations.” In response to events that occur each year, this new category of resources was developed to address those unexpected events that include Emerging Issues, Outbreaks and Emergency Response, For-Cause Situations (e.g. domestic/import sample collections and analysis for specific programs) and District Discretion activities. In addition, CFSAN will be issuing the FY 2014 Sample Collection Operation Planning Effort (SCOPE); a link to SCOPE is located on the CFSAN intranet site at: <http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm272937.htm> . CFSAN may provide updates regarding the SCOPE throughout the year and therefore this site should be monitored periodically.

NEW MAJOR MODIFICATION (2):

The FY 2014 Human Drugs Workplan has been increased by 10 investigational FTE from FY 2013 for GDUFA inspection activities. In addition, Sterile Drug Process Inspections (56002A) are now planned separately from the main Drug Process Inspection program (56002). A significant shift from domestic to foreign inspections is included across several of the drug programs. Finally, Pharmacy Compounding inspections have increased from 2 to 7 FTE.

ADDITIONAL WORKPLAN DOCUMENTS

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



FY 2014 Workplan Changes:

The “FY 2014 Workplan Changes” spreadsheets provide a comprehensive listing of FY 2014 program levels compared to the FY 2013 ORA Field Workplan. These documents can be used to identify specific resource shifts and programmatic cuts or increases.

Servicing Laboratories Table (Updated for Lab Program Optimization):

The Servicing Laboratories Table is included to serve as a reference. The Office of Regulatory Science (ORS) based FY 2014 laboratory allocations on this Table which has been modified to reflect the ORA Lab Program Optimization report.

Compliance Programs and Reporting Program Assignment Codes (PACs):

This document provides a listing of reporting PACs by Compliance Program, which is included in the Foods and Cosmetics section of the Workplan. DPEM included this list as a reference for Field investigators and analysts, since the Foods Workplan is organized by PPS and only

includes Planning PACs. The listing should match the PODS Report 7E PAC groupings. Since new PACs may be added or archived throughout the year, please check DPEM's intranet site for an up-to-date PAC Master List organized by program Centers:

<http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/PACMasterList/default.htm> .

FY 2014 Workplan CD:

The FY 2014 Workplan also has been published in a CD format. You may make and distribute as many copies of this CD as needed. For further instructions, consult '**A User's Guide – READ ME FIRST**' located on the CD. If you have any technical questions, please e-mail Anita McCurdy at Anita.McCurdy@fda.hhs.gov .

Please address any questions about the attachments or programs in the Field Workplan to the program/project's planning analyst identified on the workplanning sheets (Form FDA 2622). Policy concerns should be directed to Celia Gabrel at (301) 796-3304.



John A. Lechus, Director
Division of Planning, Evaluation and
Management (DPEM)


FOODS AND COSMETICS

FY 2014 WORKPLAN CHANGES

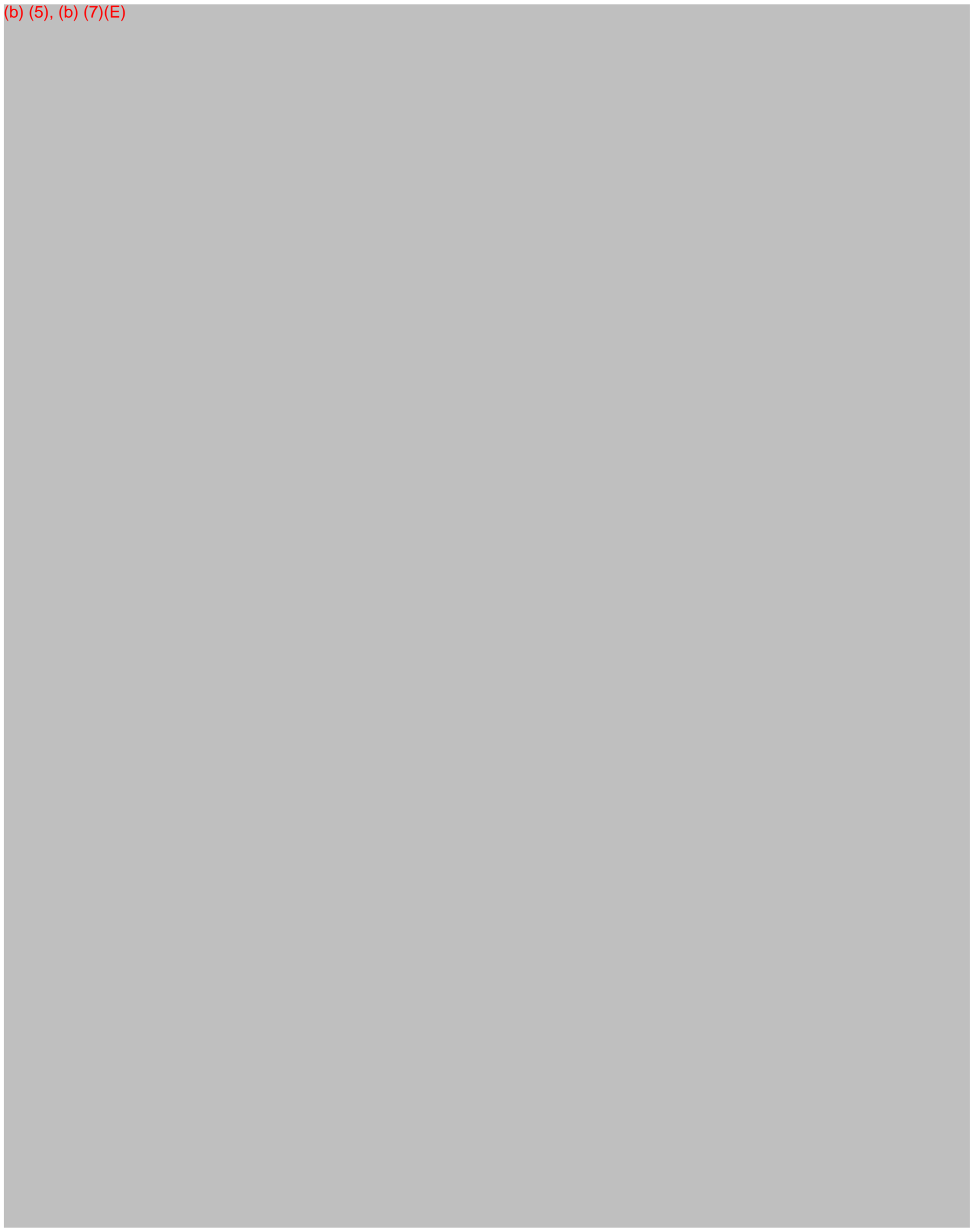
PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2013	WORKPLAN FTEs FY 2014	FTE DIFFERENCE
03F810 ⁺	Foodborne Biological Hazards	460.5	530.8	70.3
03F811 ⁺	Domestic High-Risk Inspections	242.2	162.5	-79.7
03F812 ⁺	Domestic Non-High-Risk Inspections	44.0	38.0	-6.0
03F830 ⁺	CFSAN Environmental Sampling Assignments	97.7	42.4	-55.3
03R233 ⁺	Foreign Food Inspections	44.2	49.9	5.7
03F813 ⁺	Responsive Investigative/Laboratory Operations	116.4	200.7	84.3
03	Foodborne Biological Hazards	1005.0	1024.3	19.3
04F810 ⁺	Pesticides and Chemical Contaminants	172.6	129.4	-43.2
04839	Total Diet Study	28.6	23.6	-5.0
04	Pesticides and Chemical Contaminants	201.2	153.0	-48.2
07001	Mycotoxins in Domestic and Imported Foods	18.9	29.1	10.2
07	Molecular Biology and Natural Toxins	18.9	29.1	10.2
09F810 ⁺	Food and Color Additives Petition Review	15.0	7.7	-7.3
09	Food and Color Additives Petition Review	15.0	7.7	-7.3
18F810 ⁺	Technical Assistance: Food & Cosmetics	3.2	1.9	-1.3
18002	Retail Food Protection- State Program	27.0	27.0	
18003	(NCIMS) Milk Safety Program	20.1	20.0	-0.1
18004	Molluscan Shellfish Evaluation Program	14.5	16.1	1.6
18	Technical Assistance: Food & Cosmetics	64.8	65.0	0.2
21F810 ⁺	Food Composition, Standards, Labeling, & Econ	39.6	52.8	13.2
21	Food Composition, Standards, Labeling, & Econ	39.6	52.8	13.2
29001	Cosmetics: Domestic and Imports	8.6	21.3	12.7
29	Colors and Cosmetics Technology	8.6	21.3	12.7
	Total Mission Direct: Pre and Annual Planned FTEs	1353.1	1353.2	0.1

* Planning PACS ONLY, operations should be reported under the appropriate Compliance Program PAC, see Page I-III (after the Center Resource Summary Sheet) for a detailed listing of reporting PACs.

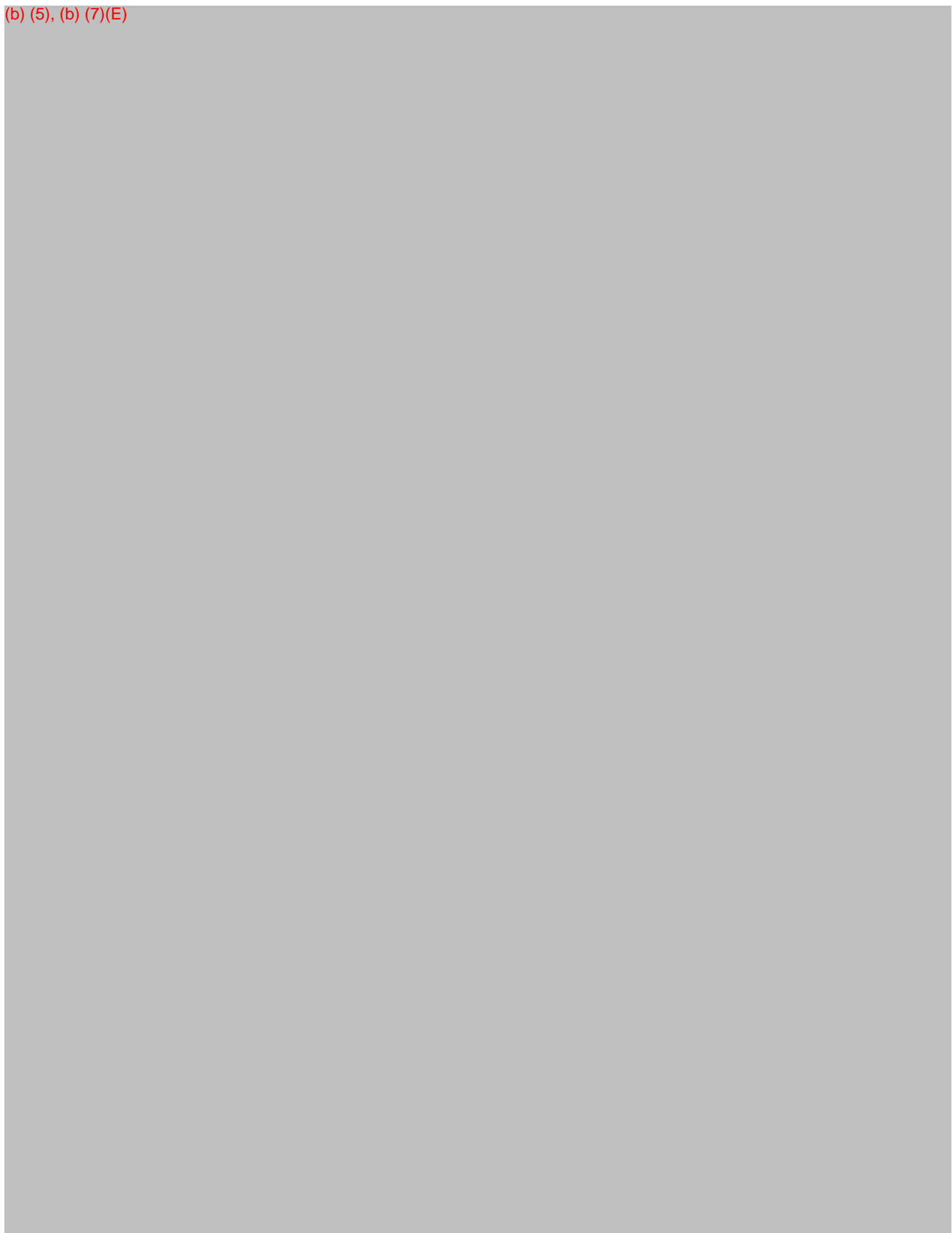
(b) (5), (b) (7)(E)



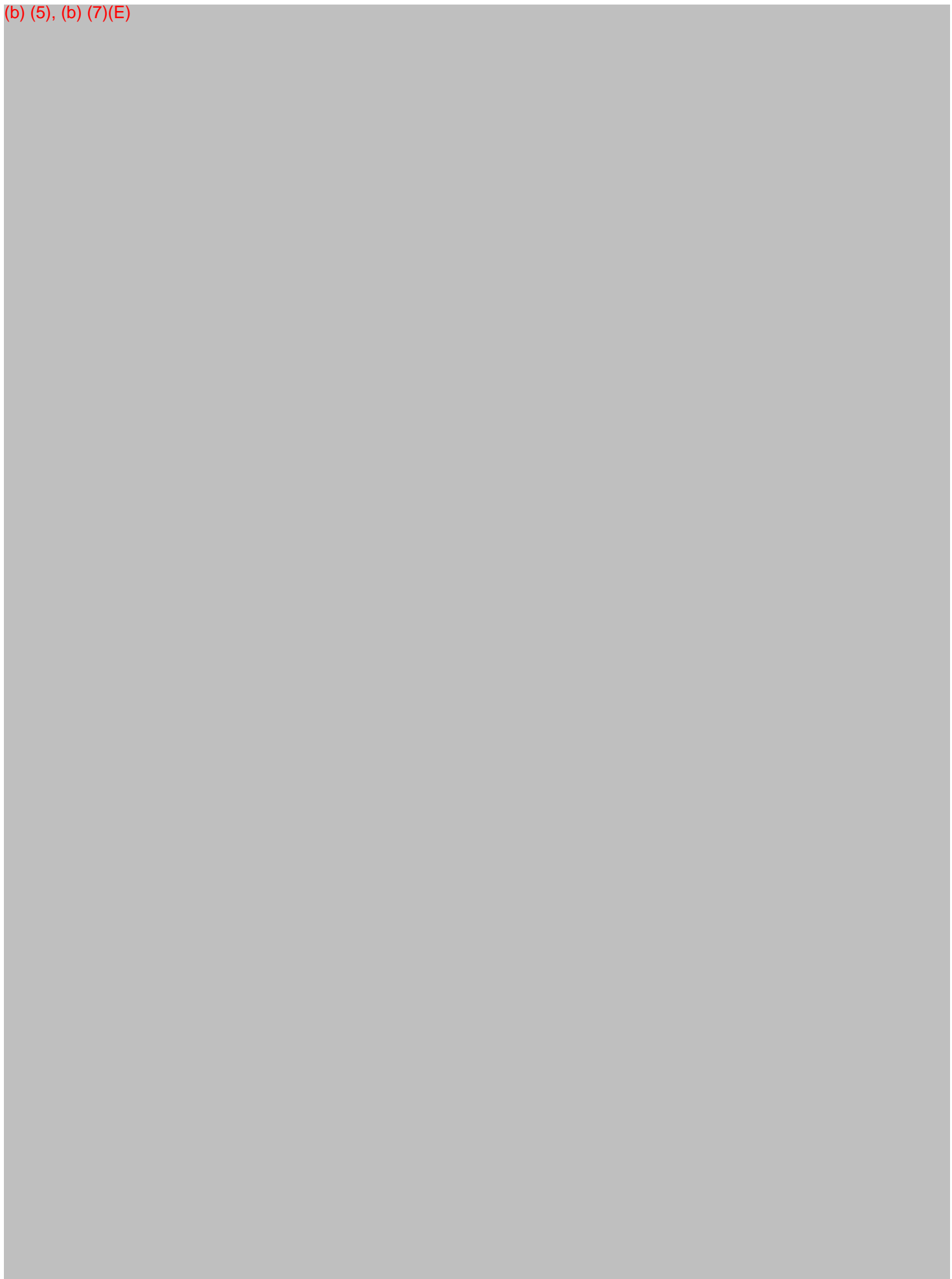
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(b) (5), (b) (7)(E)




Output Reflects: OPR FTE'S (Complete)

TOTAL FIELD	1	2	3	4	6	TOTAL	TOTAL
	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	APPLIED TECH CENTERa	OPR FTE'S	PERSNHRs
GRAND TOTAL	1740.98	347.84	233.51	20.94	20.01	2363.28	2444397.20
FOOD SAFETY/COS	899.02	224.16	216.00	0.00	14.01	1353.19	1431923.60
03	768.87	47.45	204.05	0.00	4.00	1024.37	1057714.40
04	27.20	120.79	0.00	0.00	5.00	152.99	174662.40
07	8.63	16.49	0.00	0.00	4.01	29.13	32403.00
09	1.45	6.24	0.00	0.00	0.00	7.69	8740.00
18	63.93	0.17	0.82	0.00	0.00	64.92	77641.00
21	19.68	31.70	0.46	0.00	1.00	52.84	57828.30
29	9.26	1.32	10.67	0.00	0.00	21.25	22934.50
BIOLOGICS	139.97	0.00	0.00	0.00	0.00	139.97	132989.50
41	44.66	0.00	0.00	0.00	0.00	44.66	42436.40
42	82.10	0.00	0.00	0.00	0.00	82.10	77987.10
45	13.21	0.00	0.00	0.00	0.00	13.21	12566.00
HUMAN DRUGS	343.94	72.77	3.17	0.00	0.00	419.88	416722.30
46	18.88	5.84	0.00	0.00	0.00	24.72	23574.60
48	90.35	0.00	0.00	0.00	0.00	90.35	85819.70
52	16.28	5.45	0.00	0.00	0.00	21.73	21289.70
53	9.75	0.00	0.00	0.00	0.00	9.75	9249.90
56	197.67	45.63	3.17	0.00	0.00	246.47	247626.20
63	11.01	3.85	0.00	0.00	0.00	14.86	15002.20
88	0.00	12.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	105.12	27.06	8.97	0.00	4.00	145.15	148573.60
68	9.50	0.89	0.00	0.00	0.00	10.39	9862.00
71	95.62	26.17	8.97	0.00	4.00	134.76	138711.60
DEVICES & RAD H	244.44	4.35	5.37	20.94	2.00	277.10	281992.20
81	0.93	0.03	0.02	0.03	0.00	1.01	967.00
82	169.90	4.32	5.35	10.11	0.00	189.68	190270.70
83	32.94	0.00	0.00	0.00	0.00	32.94	31298.00
84	0.00	0.00	0.00	5.90	2.00	7.90	9322.00
85	14.59	0.00	0.00	0.00	0.00	14.59	16962.00
86	26.08	0.00	0.00	4.90	0.00	30.98	33172.50
TOBACCO PROD	8.49	19.50	0.00	0.00	0.00	27.99	32196.00
96	8.49	19.50	0.00	0.00	0.00	27.99	32196.00


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




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




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



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



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



Output Reflects: OPR FTE'S (Complete)

TOTAL FIELD

	1	2	3	4	5	6		
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTERa	TOTAL OPR FTE'S	TOTAL PERSNHRs
GRAND TOTAL	1740.92	320.41	226.53	20.94	34.42	20.01	2363.23	2444397.20
FOOD SAFETY/COS	898.97	218.13	210.00	0.00	12.00	14.01	1353.10	1431923.60
03	768.85	47.45	198.05	0.00	6.00	4.00	1024.35	1057714.40
04	27.21	116.78	0.00	0.00	4.00	5.00	152.99	174662.40
07	8.63	15.48	0.00	0.00	1.00	4.01	29.12	32403.00
09	1.45	6.24	0.00	0.00	0.00	0.00	7.69	8740.00
18	63.90	0.17	0.82	0.00	0.00	0.00	64.90	77641.00
21	19.67	30.69	0.46	0.00	1.00	1.00	52.82	57828.30
29	9.27	1.32	10.66	0.00	0.00	0.00	21.24	22934.50
BIOLOGICS	139.99	0.00	0.00	0.00	0.00	0.00	139.99	132989.50
41	44.67	0.00	0.00	0.00	0.00	0.00	44.67	42436.40
42	82.09	0.00	0.00	0.00	0.00	0.00	82.09	77987.10
45	13.23	0.00	0.00	0.00	0.00	0.00	13.23	12566.00
HUMAN DRUGS	343.90	72.79	3.18	0.00	0.00	0.00	419.87	416722.30
46	18.88	5.85	0.00	0.00	0.00	0.00	24.73	23574.60
48	90.34	0.00	0.00	0.00	0.00	0.00	90.34	85819.70
52	16.26	5.46	0.00	0.00	0.00	0.00	21.72	21289.70
53	9.74	0.00	0.00	0.00	0.00	0.00	9.74	9249.90
56	197.67	45.63	3.18	0.00	0.00	0.00	246.48	247626.20
63	11.02	3.84	0.00	0.00	0.00	0.00	14.86	15002.20
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	105.12	26.06	8.98	0.00	1.00	4.00	145.16	148573.60
68	9.49	0.90	0.00	0.00	0.00	0.00	10.38	9862.00
71	95.64	25.16	8.98	0.00	1.00	4.00	134.78	138711.60
DEVICES & RAD H	244.44	3.36	4.37	20.94	2.00	2.00	277.11	281992.20
81	0.92	0.03	0.02	0.03	0.00	0.00	1.00	967.00
82	169.90	3.33	4.35	10.11	2.00	0.00	189.69	190270.70
83	32.95	0.00	0.00	0.00	0.00	0.00	32.95	31298.00
84	0.00	0.00	0.00	5.90	0.00	2.00	7.90	9322.00
85	14.59	0.00	0.00	0.00	0.00	0.00	14.59	16962.00
86	26.09	0.00	0.00	4.90	0.00	0.00	30.99	33172.50
TOBACCO PROD	8.49	0.08	0.00	0.00	19.42	0.00	28.00	32196.00
96	8.49	0.08	0.00	0.00	19.42	0.00	28.00	32196.00

**RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2014**

	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
	DOMESTIC	IMPORT	FOREIGN	
TOTAL ALL PROGRAMS	1470.8	649.6	243.0	2363.4
FOODS AND COSMETICS	787.0	516.3	49.9	1353.2
BIOLOGICS	129.7	4.0	6.3	140.0
HUMAN DRUGS	232.5	48.9	138.6	420.0
ANIMAL DRUGS AND FEEDS	121.0	18.8	5.4	145.2
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	176.1	58.1	42.8	277.0
TOBACCO	24.5	3.5		28.0

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2014**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	787.0	516.3	49.9	1353.2
3	FOODBORNE BIOLOGICAL HAZARDS	558.2	416.2	49.9	1024.3
4	PESTICIDES AND CHEMICAL CONTAMINANTS	94.1	58.9		153.0
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	19.6	9.5		29.1
9	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		7.7		7.7
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	65.0			65.0
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	32.9	19.9		52.8
29	COLOR AND COSMETICS TECHNOLOGY	17.2	4.1		21.3

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 530.8 [123.8]
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	2	2	3	3	3
		IMPORT ENTRY REVIEW (Hours) (1)	IMPORT INTERNATIONAL MAIL FACILITY (Hours)	IMPORT EXPRESS COURIER REVIEW (Hours) (2)	EXPORTER CERTIFI- CATION ACTIVITIES	IMPORTER INSPECTION (3)	IMPORT INVESTI- GATIONS HOURS	DOMESTIC SAMPLE COLL PRODUCE 03F100	DOMESTIC SAMPLE COLL PILOT CHEESE 03F860 (4)	DOMESTIC SAMPLE COLL PILOT AVOCADO 03F860 (4)
	TOTAL FIELD	90804	1900	2850	50	553	12350	2000	480	480
	HEADQUARTERS	(b) (5), (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION				18.0	17.2		6.0	7.0	6.0
	TOTAL HOURS	90804	1900	2850	900	9512	12350	12000	3360	2880
	CONVERSION FACTOR	1200	950	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	75.67	2.00	3.00	0.95	10.01	13.00	12.63	3.54	3.03

7. REMARKS

NOTE: PAC 03F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

(1) - Import Entry Review Hours: Resources for these activities cover All Import Food Programs.

(2) - Exporter certification column to be used for EU activities (dairy/gelatin assignments).

(3) - Inspections of Importers are to ascertain if the importer has complied with Seafood HACCP Regulations, not to perform filer inspections.

(4) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), and Raw Milk Cheese are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot. Please see memo that CFSAN will issue for more instruction on sample collection/analyses. Report time under PAC 03F860 - CFSAN Surveillance Sampling Program.

NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards					2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section.			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 530.8 [59.0]				
R E G I O N	6.	3	4	4	4	4	4	4	4	4
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL PILOT SPROUTS 03F860 (1)	SCREENING STATION SAMPLE COLLECTION (2)	IMPORT SAMPLE COLL PRODUCE ASSIGN 03F098	IMPORT SAMPLE COLL SEAFOOD 03844	IMPORT SAMPLE COLL IMPORT FOODS 03819	IMPORT SAMPLE COLL PILOT CHEESE 03F860 (1)	IMPORT SAMPLE COLL PILOT AVOCADO 03F860 (1)	IMPORT SAMPLE COLL ALLERGEN PRODUCT ASSIGN (3)	IMPORT SAMPLE COLL ALLERGEN LABELS ASSIGN (3)
TOTAL FIELD		1600	1100	2500	3300	7125	1120	1120	500	1000
HEADQUARTERS		(b) (5), (b) (7) (E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		6.0	3.0	3.0	3.0	2.4	2.0	3.0	2.4	1.9
TOTAL HOURS		9600	3300	7500	9900	17100	2240	3360	1200	1900
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTES		10.11	3.47	7.89	10.42	18.00	2.36	3.54	1.26	2.00
7. REMARKS										
<p>(1) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), and Raw Milk Cheese are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot. Please see memo that CFSAN will issue for more instruction on sample collection/analyses. Report time under PAC 03F860 - CFSAN Surveillance Sampling Program.</p> <p>(2) - Includes Time for Port Everglades Screening Station in FLA-DO and Mobile Lab Sample Collections.</p> <p>(3) - Allergen Label Review & Testing- see FY 14 Allergen Assignment for more details.</p>										

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 530.8 [147.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	5 FIELD EXAMS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED PILOT CHEESE MICRO (3)	7 DOMESTIC SAMPLES TO BE ANALYZED PILOT AVOCADO MICRO (3)	7 DOMESTIC SAMPLES TO BE ANALYZED PILOT SPROUTS MICRO (3)	7 SCREENING STATION SAMPLES TO BE ANALYZED MICRO (Hours) (4)	7 SCREENING STATION SAMPLES TO BE ANALYZED CHEM (4)	7 DOMESTIC SAMPLES TO BE ANALYZED FILTH CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED PRODUCE 03F100 MICRO
	TOTAL FIELD	1520	156943	480	480	1600	4400	300	364	2000
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST MPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	1.0	0.5	21.8	13.0	13.0		5.0	14.8	13.0
	TOTAL HOURS	1520	78472	10464	6240	20800	4400	1500	5387	26000
	CONVERSION FACTOR	950	950	1180	1180	1180	1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	1.60	82.60	8.87	5.29	17.63	3.73	1.27	4.57	22.03

7. REMARKS

(1) - Field Exams are to include pH and canned seam evaluation.

(2) - Import Field Exams are for Field Exams as required by the District to cover program priorities. Import Field Exams are to routinely include: Verification that the imported product is the same as declared (Reconciliation Exam); and assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc.); traditional safety concerns. These activities are to be reported as a single Import Field Exam under this Compliance Program and PAC. Only one exam should be reported per line entry. Only in the event of a Pre-Determined "for cause" CT Exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should the CT Exam be reported under the CT PAC (03R845, 04R845, etc.). Time can also be used for Histamine detection kit pilot.

(3) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), and Raw Milk Cheese are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot. Please see memo that CFSAN will issue for more instruction on sample collection/analyses. Report time under PAC 03F860 - CFSAN Surveillance Sampling Program.

(4) - Includes Time for Port Everglades Screening Station in FLA-DO and Mobile Lab analyses.

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 530.8 [131.9]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8	8	8	8	8	8	8	8	8
		IMPORT SAMPLES TO BE ANALYZED PILOT CHEESE MICRO (1)	IMPORT SAMPLES TO BE ANALYZED PILOT AVOCADO MICRO (1)	IMPORT SAMPLES TO BE ANALYZED ALLERGEN PRODUCT CHEM	IMPORT SAMPLES TO BE ANALYZED SEAFOOD 03844 CHEM	IMPORT SAMPLES TO BE ANALYZED SEAFOOD 03844 MICRO	IMPORT SAMPLES TO BE ANALYZED FILTH/HIST CHEM (2)	IMPORT SAMPLES TO BE ANALYZED PRODUCE 03F098 MICRO	IMPORT SAMPLES TO BE ANALYZED IMPORT FOOD 03819 CHEM	IMPORT SAMPLES TO BE ANALYZED IMPORT FOOD 03819 MICRO
	TOTAL FIELD	1120	1120	500	3000	299	1753	2500	1014	7125
	HEADQUARTERS	(b) (5), (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST MPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		16.0	13.0	6.4	5.2	8.2	7.0	13.0	6.4	7.1
TOTAL HOURS		17920	14560	3200	15600	2452	12271	32500	6490	50588
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		15.19	12.34	2.71	13.22	2.08	10.40	27.54	5.50	42.87

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

(1) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), and Raw Milk Cheese are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot. Please see memo that CFSAN will issue for more instruction on sample collection/analyses. Report time under PAC 03F860- CFSAN Surveillance Sampling Program.

(2) - Time can also be used for Histamine detection kit pilot.

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards					2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 530.8 [68.5]				
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY		9 LEVEL II AUDITORS CERTI- FICATION (Hours) (1)	9 APPLIED TECH CENTER MICRO 03R816 (Hours)	9 METHODS VAL/DEV MICRO 03R816 (Hours)	9 PRIOR NOTICE REVIEW (Hours) (2)	9 OP CODE 92 PRIVATE LAB REVIEW IMPORT (Hours) (3)	9 BETTER PROCESSING SCHOOL TRAINING (Hours) (4)	9 CONTRACT MANAGE- MENT (Hours) 03R843 (5)	
	TOTAL FIELD		1600	4720	7230	32400	11800	760	18050	
HEADQUARTERS			(b) (5), (b) (7) (E)							
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION										
TOTAL HOURS			1600	4720	7230	32400	11800	760	18050	
CONVERSION FACTOR			950	1180	1205	1200	1180	950	950	
TOTAL OPERATIONAL FTEs			1.68	4.00	6.00	27.00	10.00	0.80	19.00	
7. REMARKS										
<p>(1) - Level II Auditors Certification Time: These hours are to provide auditors the time to evaluate/train other investigators trying to maintain Level II Certification. District allocation was based on the current on board staffing provided by DHRD.</p> <p>(2) - Resources in Headquarters are for review of prior notices at the Division of Food Defense Targeting (DFDT) formally known as the Prior Notice Center.</p> <p>(3) - Private Laboratory Review Time is planned under PAC 03R320. Accomplished work must be reported against the appropriate Private Lab PAC. Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field. Without consistency in reporting, your time will not be found and credited for future workplan FTE allocations.</p> <p>(4) - Resources are for the attendance at Better Processing Schools (BPS).</p> <p>(5) - Time planned for Contract management includes resources to conduct audits. Report Foods State Contract Inspection Audit time under operation 13 (Investigation Operations) PAC 03R843. NOTE: Non-operational FTE's, i.e. supervisors, should not report contract management time.</p> <p>NOTE: Laboratory allocations were planned by ORS.</p>										

1. PROGRAM/ASSIGNMENT TITLE Domestic High Risk Inspections		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 162.5					
R E G I O N	b.	1 FDA FSMA HIGH RISK INSPECTIONS (1)	1 FDA NON-FSMA HIGH RISK INSPECTIONS ONLY (2)	NON-FSMA INTERSTATE TRAVEL WATERING PT INSPECTIONS GUIDANCE ONLY (2)	NON-FSMA EGG FARM INSPECTIONS GUIDANCE ONLY (2)				
	TOTAL FIELD	3384	700	500	200				
	HEADQUARTERS	(b) (5), (b) (7) (E)							
NE	REGIONAL STAFF	(b) (5), (b) (7) (E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF	(b) (5), (b) (7) (E)							
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF	(b) (5), (b) (7) (E)							
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB	(b) (5), (b) (7) (E)							
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT	(b) (5), (b) (7) (E)							
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	37.8	37.8						
	TOTAL HOURS	127915	26460						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	134.65	27.85						

7. REMARKS

NOTE: PAC 03F811 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

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

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

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

NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.

1. PROGRAM/ASSIGNMENT TITLE Domestic Non-High Risk Inspections	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 38.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FDA NON-HIGH RISK FSMA INSPECTIONS (1)	ITP NON-AIRLINE WATERING POINT INSPECTIONS GUIDANCE ONLY						
	TOTAL FIELD	1439	200						
NE	HEADQUARTERS	(b) (5), (b) (7) (E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
HOURS PER OPERATION		25.1							
TOTAL HOURS		36119							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		38.02							

7. REMARKS

NOTE: PAC 03F812 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

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

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

NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.

1. PROGRAM/ASSIGNMENT TITLE CFSAN Environmental Sampling Assignments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 42.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	Environmental SAMPLE CSO HOURS EGG RULE INSPECTIONS (1)	Environmental SAMPLE CSO HOURS PEANUT BUTTER INSPECTIONS (2)	Environmental SAMPLE CSO HOURS MILK POWDER FACILITY FOR CRONOBACTER (3)	Environmental DOMESTIC LAB ANALYST (Hours) MICRO				
	TOTAL FIELD	10000	20000	7000	4107				
	HEADQUARTERS	(b) (5), (b) (7) (E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS	10000	20000	7000	4107				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	10.53	21.05	7.37	3.48				

7. REMARKS
 NOTE: PAC 03F830 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.
 CSO time to include inspections and sample collections. Report hours utilized under the appropriate operation code.
 (1) - Estimated (b) firms
 (2) - Estimated (b) firms
 (3) - Estimated (b) firms

Hours based on estimated 75 hours per inspection and 25 hours per sample collection. Additional time for inspections is included under the High Risk Inspections planned separately. **District spread of resources is for planning purposes only.** Above numbers are estimates only -- assignment parameters will dictate the final number of firms to be covered. Environmental sampling to follow-up on Outbreaks and Emergency Response activities is planned separately (See Responsive Investigative/Laboratory Operations Sheet).
 Report inspections and analyses conducted in response to an outbreak and emergency against the appropriate Foodborne Emergency PAC (e.g. 03R855) Salmonella in Peanut Butter Emergency/Recall - Human Food Use, 03R266 Listeria Emergency, or another PAC to be created in response to a future emergency. Assignments and district inventories will determine resource usage.

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Foreign Foods Inspections			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 49.9			
R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS INCLUDES CADRE (1)								
	TOTAL FIELD	1200								
NE	HEADQUARTERS	(b) (5),								
	REGIONAL STAFF	(b) (7)								
	NEW ENGLAND	(E)								
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		39.5								
TOTAL HOURS		47400								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		49.89								

7. REMARKS

NOTE: PAC 03R233 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

(1) - Foreign Inspections planned in HQ are for Foreign Food Cadre.

NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.

1. PROGRAM/ASSIGNMENT TITLE Responsive Investigative/Laboratory Operations	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 200.7 [142.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 EMERGING ISSUES INSPECTIONS	2 EMERGING ISSUES INVESTIGATIONS (Hours) (1)	2 DOMESTIC INVESTIGATIONS CSO (Hours)	2 OUTBREAK EMERGENCY RESPONSE CSO (Hours) (2)	2 ENVIRONMENTAL SAMPLE CSO F/U	3 DOMESTIC SAMPLE COLL EMERGING ISSUES	3 DOMESTIC SAMPLE COLL SEAFOOD	3 DOMESTIC SAMPLE COLL JUICE HACCP	3 DOMESTIC SAMPLE COLL LACF/AF
	TOTAL FIELD	225	25882	15200	68780	88	789	280	75	209

	HEADQUARTERS	(b) (5), (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	25.1					100.0	9.1	7.6	7.0	6.4
TOTAL HOURS	5648	25882	15200	68780	8800	7180	2128	525	1338	
CONVERSION FACTOR	950	950	950	950	950	950	950	950	950	
TOTAL OPERATIONAL FTEs	5.95	27.24	16.00	72.40	9.26	7.56	2.24	0.55	1.41	

7. REMARKS
 NOTE: 03F813 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resources Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

Time to be used for all outbreak, emergency activities, emerging issues, OAI follow-ups, follow-up to avocado, raw milk cheese and sprout sampling. District spread is for planning purposes and other unplanned activities related to food and cosmetics only. Report inspections and analyses against the appropriate PAC.
 Foodborne Emergency PAC (e.g. 03R855 Salmonella in Peanut Butter Emergency/Recall-Human Food Use, 03R266 Listeria Emergency, or another PAC to be created in response to a future emergency).
 Also, report related inspections and analyses in response to pesticides and chemical contaminants against the appropriate Foodborne Emergency PAC (e.g. 04R078 Deep Water Horizon Water Spill Activities, or another PAC to be created in response to a future emergency).

(1) - Includes time for Registration Verification.
 (2) - Includes investigational hours for all domestic investigations, follow-up to RFR-RCR, and Food Defense Assignments. District allocations are based on 3 year accomplishment data.
 NOTE: The FY13 Energy Drink (PPS 21) and Lemon Juice (PPS 21) assignments will be extended into FY14. Resources from Emerging Issues or Outbreaks and Emergency Response may be used for these assignments.

1. PROGRAM/ASSIGNMENT TITLE Responsive Investigative/Laboratory Operations	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section.	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 200.7 [40.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL FOOD SAFETY	4 IMPORT SAMPLE COLL LACF/AF 03003A	6 EMERGING ISSUES IMPORT FIELD EXAM	7 DOMESTIC LAB ANALYST HOURS EMERGING ISSUES CHEM (1)	7 DOMESTIC LAB ANALYST HOURS EMERGING ISSUES MICRO	7 DOMESTIC LAB ANALYST HOURS OUTBREAK EMERGENCY CHEM	7 DOMESTIC LAB ANALYS HOURS OUTBREAK EMERG. MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED ENV F/U MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED SEAFOOD 03842 MICRO
	TOTAL FIELD	1822	1425	1273	7742	3658	1440	3505	88	280

	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
CE	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	9.2	2.0	0.5					11.1	18.8
TOTAL HOURS	16762	2850	637	7742	3658	1440	3505	977	5264
CONVERSION FACTOR	950	950	950	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs	17.64	3.00	0.67	6.56	3.10	1.22	2.97	0.83	4.46

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

(1) - Resources include time for Honey Analysis under the EU Assignment.

NOTE: The FY13 Energy Drink (PPS 21) and Lemon Juice (PPS 21) assignments will be extended into FY14. Resources from Emerging Issues or Outbreaks and Emergency Response may be used for these assignments.

1. PROGRAM/ASSIGNMENT TITLE Responsive Investigative/Laboratory Operations	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section.	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 200.7 [17.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED JUICE HACCP 03847H MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED LACF/AF 03803A MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED FOOD SAFETY CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED FOOD SAFETY MICRO	8 IMPORT SAMPLES TO BE ANALYZED LACF/AF 03003A MICRO				
	TOTAL FIELD	75	80	176	455	1424				
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	12.5	15.4	13.4	13.9	7.0				
	TOTAL HOURS	938	1232	2358	6325	9968				
	CONVERSION FACTOR	1180	1180	1180	1180	1180				
	TOTAL OPERATIONAL FTEs	0.79	1.04	2.00	5.36	8.45				

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY
Food and Cosmetics

2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants - 04

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		94.1	58.9		153.0	
1	Pesticides and Chemical Contaminants	04F810 *	70.5	58.9		129.4	04-15-17
2	Total Diet Study	04839	23.6			23.6	04-18
* These PACS are for planning purposes only.							
Accomplished work must be reported against the appropriate program or assignment PAC.							

CENTER PROJECT MANAGER/TELEPHONE
Monali Yajnik 240-402-1616

ORA PLANNER/TELEPHONE
Kristen Kamas 301-796-4391

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04							
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 129.4 [21.5]		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	3	3	3	3	4	4	4
		DOMESTIC SAMPLE COLL PESTICIDE 04004A	DOMESTIC SAMPLE COLL MILK ASSIGN (1)	DOMESTIC SAMPLE COLL CHEMO 04018	DOMESTIC SAMPLE COLL TOXIC ELE 04019A	DOMESTIC SAMPLE COLL SHELL EGG ASSIGN (1)	DOMESTIC SAMPLE COLL RADIO- NUCLIDES 04019C (2)	IMPORT SAMPLE COLL PESTICIDE 04004A	IMPORT SAMPLE COLL CHEMO 04018	IMPORT SAMPLE COLL TOXIC ELEMENTS 04019A
TOTAL FIELD		950	320	100	402	300	50	3300	1000	986
HEADQUARTERS		(b) (5), (b) (7) (E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		4.6	4.0	7.5	5.7	4.0	2.0	1.8	2.4	2.1
TOTAL HOURS		4370	1280	750	2291	1200	100	5940	2400	2071
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		4.60	1.35	0.79	2.41	1.26	0.11	6.25	2.53	2.18

7. REMARKS

NOTE: PAC 04F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.

(1) - Please refer to the EU-Audit specific CFSAN assignment for collection of multiple subs per sample and distribution of those subs to the different servicing labs for different analyses.

(2) - CFSAN spread DSC's based on location of nuclear power plants. See compliance program for collection details. This includes time for radionuclide testing of domestic seafood under the Toxic Elements / Radionuclides Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 129.4 [42.7]			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	4	5	6	7	7	7	7	7	7
		IMPORT SAMPLE COLL RADIO- NUCLIDES 04019C	FIELD EXAMS/ TESTS	IMPORT FIELD EXAM (3)	DOMESTIC SAMPLES TO BE ANALYZED PESTICIDE 04004A	DOMESTIC SAMPLES TO BE ANALYZED MILK CHEM (4)	DOMESTIC SAMPLES TO BE ANALYZED DIOXIN 04004D (5)	DOMESTIC SAMPLES TO BE ANALYZED CHEMO 04018	DOMESTIC SAMPLES TO BE ANALYZED TOXIC ELEMENTS 04019A	DOMESTIC SAMPLES TO BE ANALYZED SHELL EGG ASSIGN (4)
TOTAL FIELD		200	25	6406	950	320	620	100	402	300
HEADQUARTERS		(b) (5), (b) (7) (E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		2.5	0.7	0.5	5.9	28.2	28.0	18.0	10.3	25.9
TOTAL HOURS		500	18	3203	5605	9024	17360	1800	4141	7770
CONVERSION FACTOR		950	950	950	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.53	0.02	3.37	4.75	7.65	14.71	1.53	3.51	6.58

7. REMARKS

(3) - Import Field Exams are for Toxic Elements in Foodware (PAC 04019B)

(4) - Milk and shell egg samples need several different types of contaminant analyses. The numbers in these columns capture pesticides, vet drug residues, and metal analyses. Dioxin analyses on these samples are captured under "Domestic Samples to be Analyzed Dioxin 04004D" column. Please note ARL will exhaust all its domestic dioxin analysis resources by serving the milk and egg samples associated with the continued EU surveillance. They should not get additional samples under the Dioxin Surveillance program.

(5) - These samples include the total of (b) milk and (b) shell egg samples from the EU assignment that will also receive dioxin analysis in addition to chemical contaminants. These (b) EU samples are NOT separate collections.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 129.4 [65.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	8	8	8	8	9	9	9	
		DOMESTIC SAMPLES TO BE ANALYZED RADIO- NUCLIDES 04019C	IMPORT SAMPLES TO BE ANALYZED CHEMO 04018	IMPORT SAMPLES TO BE ANALYZED TOXIC ELEMENTS 04019A	IMPORT SAMPLES TO BE ANALYZED RADIO- NUCLIDES 04019C	IMPORT SAMPLES TO BE ANALYZED PESTICIDE 04004A	APPLIED TECH- NOLOGY CENTER CHEM (Hours)	METHODS VAL/DEV CHEM (HOURS)	IMPORT PRIVATE LAB REVIEW OP CODE 92 (Hours) CHEM (6)	FORENSICS (Hours)
	TOTAL FIELD	50	1000	986	200	3300	5900	4820	2360	14460
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		5.0	20.0	9.9	5.0	5.7				
TOTAL HOURS		250	20000	9761	1000	18810	5900	4820	2360	14460
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1205	1180	1205
TOTAL OPERATIONAL FTEs		0.21	16.95	8.27	0.85	15.94	5.00	4.00	2.00	12.00

7. REMARKS
 Laboratory allocations were planned by ORS.

(6) - Private Laboratory Review Time is planned under PAC 04R320. Accomplished work must be reported against the appropriate Private Lab PAC. Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field. Without consistency in reporting, your time will not be found and credited for future workplan FTE allocations.

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04839	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 23.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL (TOTAL) (DIET) (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	7 DOMESTIC SAMPLES TO BE ANALYZED RADIO- NUCLIDE (3)				
	TOTAL FIELD	60	1207	2				

	HEADQUARTERS	(b) (5), (b) (7) (E)						
	REGIONAL STAFF							
NE	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							

HOURS PER OPERATION	28.7	16.7	2800.0				
TOTAL HOURS	1722	20157	5600				
CONVERSION FACTOR	950	1180	1180				
TOTAL OPERATIONAL FTEs	1.81	17.08	4.75				

7. REMARKS

(1) - Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over a four (4) week period and involves 3 separate districts. Four market baskets are planned annually.

(2) - Represents the total number of food items analyzed for various attributes. VOC analyses will no longer be conducted on TDS foods.

(3) - All TDS food items from two market baskets analyzed by WEAC for selected radionuclides.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001, 07R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 29.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (1)	8 IMPORT SAMPLES TO BE ANALYZED CHEM	9 METHOD VAL/DEV CHEM (Hours) 07R816	9 APPLIED TECHN- OLOGY CTR. MICRO (Hours) 07R816	9 APPLIED TECHN- OLOGY CTR. CHEM (Hours) 07R816		
	TOTAL FIELD	1000	1000	1320	1000	1205	600	4130		

	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	6.0	2.2	7.4	8.5					
TOTAL HOURS	6000	2200	9768	8500	1205	600	4130		
CONVERSION FACTOR	950	950	1180	1180	1205	1180	1180		
TOTAL OPERATIONAL FTEs	6.32	2.32	8.28	7.20	1.00	0.51	3.50		

7. REMARKS

Districts allocations were planned by CFSAN.
 Laboratory allocations were planned by ORS.
 (1) Domestic sample analyses for SRL includes (b) milk samples for the EU-Audit related surveillance. For sample collections see pac code 04F810.

1. PROGRAM/ASSIGNMENT TITLE Food & Color Additive Petition Review & Development	2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE FOOD ADDITIVES COLL	4 IMPORT SAMPLE COLOR ADDITIVES COLL	8 IMPORT SAMPLES TO BE ANALYZED FOOD ADD. CHEM	8 IMPORT SAMPLES TO BE ANALYZED COLOR ADD/ CHEM				
	TOTAL FIELD	310	500	310	500				

	HEADQUARTERS	(b) (5), (b) (7) (E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	1.7	1.7	12.3	7.1				
TOTAL HOURS	527	850	3813	3550				
CONVERSION FACTOR	950	950	1180	1180				
TOTAL OPERATIONAL FTEs	0.55	0.89	3.23	3.01				

7. REMARKS

NOTE: PAC 09F810 is for planning purpose only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

Hours per operation modules are for guidance only. Report actual time spent on operations. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845,09R845, etc.) See IOM Section 5.4.1.4.1. for additional information on Food and Cosmetic Securities Activities.

Laboratory allocations were planned by ORS.

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Food and Cosmetics	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics -18
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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		65.0			65.0	
1	Technical Assistance - Food and Cosmetics	18F810*	1.9			1.9	18-24
2	Retail Food Protection - State Program	18002	27.0			27.0	18-25-26
3	(NCIMS) Milk Safety Program	18003	20.0			20.0	18-27-28
4	Molluscan Shellfish Evaluation	18004	16.1			16.1	18-29-30
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the appropriate program or assignment PAC.						
	See page I-III (after the Center Resource Summary Sheet)						
	for a listing of compliance programs and corresponding reporting PACS.						

CENTER PROJECT MANAGER/TELEPHONE Monali Yajnik 240-402-1616	ORA PLANNER/TELEPHONE Lorraine B. Boykin 301-796-4393
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1. PROGRAM/ASSIGNMENT TITLE Technical Assistance - Food and Cosmetics	2. PPS PROJECT NAME/NUMBER Technical Assistance- Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL FOR CAUSE CHEM	3 DOMESTIC SAMPLE COLL SURV. MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO				
	TOTAL FIELD	20	180	20	180				

	HEADQUARTERS	(b) (5), (b) (7) (E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	4.8	4.0	10.0	5.4				
TOTAL HOURS	96	720	200	972				
CONVERSION FACTOR	950	950	1180	1180				
TOTAL OPERATIONAL FTEs	0.10	0.76	0.17	0.82				

7. REMARKS

NOTE: PAC 18F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

Districts allocations were planned by CFSAN.

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18002	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 27.0 [17.2]
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R E G I O N	6.	9	9	9	9	9	9	9	9	9
	DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL FOOD PROG. STAND- ARDS SUPP. FOR JURISDICTIONS (1)	STANDARD- IZATION (ITP,CDC,IHS STATE & LOCAL) (2)	RE-STANDARD IZATION (ITP,STATE & LOCAL) (3)	TEAM LEADER SCI/ NATIONAL (4)	NATIONAL TEAM WORK GROUP (5)	REGIONAL SEMINARS (6)	NATL. RETAIL FOOD PROG. STANDARDS ENROLLMENT OF NEW JURIS. (7)	TECHNICAL ASSISTANCE (8)	CONFERENCE FOR FOOD PROTECTION COMMITTEE WORK (9)
	TOTAL FIELD	4368	1920	2016	1200	2160	1620	480	5759	1080
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
CE	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SV									
	PACIFIC REGIONAL LABORATORY-NV									
HOURS PER OPERATION										
TOTAL HOURS		4368	1920	2016	1200	2160	1620	480	5759	1080
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3.64	1.60	1.68	1.00	1.80	1.35	0.40	4.80	0.90

7. REMARKS
 Report Counter Terrorism work performed only under 18R845.
 (1) - Includes time for meetings, consultations, conference calls, and any other direct contact with jurisdictions currently enrolled in the program standards to facilitate their continuous improvement in meeting the standards criteria.
 (2) - Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting inspections.
 (3) - Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections.
 (4) - Time allocated for team leaders for retail food program planning, development, and coordination.
 (5) - Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards and initiatives of national importance.
 (6) - Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the Annual Regional Retail Food Seminars.
 (7) - Includes time from meetings, presentations, workshops, conference calls and other direct contact with jurisdiction to facilitate their enrollment in the program standards.
 (8) - Includes providing assistance to external partners in interpreting and applying FDA's guidance and regulations and the effective use of interventions, inspection and enforcement to reduce the occurrence of foodborne illness risk factors at the retail level.
 (9) - Includes work on committees established at the 2012 meeting of the Conference for Food Protection.

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18002	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 27.0 [9.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9	9		
		FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (10)	DHRD TRAINING COURSE WORKSHOP (11)	REGIONAL NON-DHRD TRAINING/ COURSES WORKSHOPS (12)	RETAIL FOOD PROG TRACKING DATABASE PILOT (13)	FDA FOOD- BORNE ILL- NESSES RISK FACTOR STUDY DATA COLL. (14)	FDA FOOD BORNE ILL- NESSES RISK FACTOR STUDY WORKGROUP (15)	CONFERENCE FOR PROTEC- TION ATTEN- DANCE & POSI- TION PAPERS (16)		
	TOTAL FIELD	1080	2240	1658	1080	3344	775	1620		
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		1080	2240	1658	1080	3344	775	1620		
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200		
TOTAL OPERATIONAL FTEs		0.90	1.87	1.38	0.90	2.79	0.65	1.35		

7. REMARKS

(10) - Time allocated for the presentation and distribution of FDA materials related to food defense. Includes Specialist activities related to CFSAN priority assignments in response to National Food Safety needs.

(11) - Includes support provided to DHRD in the development and delivery of DHRD training courses on topics such as the Food Code, Preparation for Standardization, Managing Retail Food Safety (HACCP), Conducting Risk-Based Inspections, Special Processes at Retail, Foodborne Illness Investigations, Plan Review, Trace-back Investigations, Regulations of Temporary Food Establishments.

(12) - Includes development and delivery of regionally-coordinated training courses and workshops offered to state, tribal and local partners, excluding workshops related to program standards.

(13) - Includes updating and maintaining a database of retail food protection program information related to state/local/tribal jurisdictions, including information regarding enrollment in the FDA Voluntary National Retail Food Regulatory Program Standards.

(14) - Includes the collection and reporting of data from on-site assessments of roughly (b) full service and (b) fast food restaurant facilities as part of a 10 year FDA study to assess the control of foodborne illness risk factors at the retail level.

(15) - Includes time of workgroup members responsible for developing the data collection tools, analyzing data and drafting a report on the occurrence of foodborne risk factors in the different retail facility types.

(16) - Includes preliminary work on issues/position papers development and attendance at CFP Biennial Meeting in May 2014.

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18003	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 20.0 [16.9]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9	9	9	9
		CHECK RATING PLANT (1)	CHECK RATING TRANSFER AND RECEIVING (1)	CHECK RATING BTU (1)	SINGLE SERVICE AUDITS (1)	STATE SAMPLING SURVEILL- ANCE OFF. CERTIFICA- TION (2)	STATE MILK SANITATION RATING OFF. CERTIFICA- TION (2)	STATE PROGRAM EVALUATION (3)	TECHNICAL ASSISTANCE	RMS STANDARD- IZATION
	TOTAL FIELD	157	34	275	68	50	44	17	51	13
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
REGIONAL STAFF										
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	24.0	12.0	20.0	8.0	24.0	40.0	120.0	90.0	40.0
TOTAL HOURS	3768	408	5500	544	1200	1760	2040	4590	520
CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs	3.14	0.34	4.58	0.45	1.00	1.47	1.70	3.83	0.43

7. REMARKS

(1) - Check Ratings of Plants and RS/TS every 3 years, BTUs every 4 years and SS Audits every 5 Years.

(2) - Activities include the initial (including HACCP) and continuous Certifications of State Rating Officers and Sampling Surveillance Officers.

(3) - State Program Evaluations conducted of 1/3 of the states (including Puerto Rico) every 3 Years.

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program					2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18				
3. PROGRAM/ASSIGNMENT CODE(S) 18003			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 20.0 [3.1]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 FOOD DEFENSE COORDI- NATION	9 TRAINING GIVEN	9 FSMA	9 NATIONAL TEAM				
		(4)	(5)	(6)	(7)				
	TOTAL FIELD	20	33	20	27				
	HEADQUARTERS	(b) (5), (b) (7) (E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST MPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	25.0	40.0	25.0	50.0				
	TOTAL HOURS	500	1320	500	1350				
	CONVERSION FACTOR	1200	1200	1200	1200				
	TOTAL OPERATIONAL FTEs	0.42	1.10	0.42	1.13				
7. REMARKS (4) - Includes time for presentation and distribution of the food defense preventive measures guidance document for dairy products to the state regulatory agencies during check ratings, routine field work, and state program assessments. Presentations may be made at local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of food defense activities and field activities related to food defense. Report time against PAC 18R845. (5) - Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops and RMS Teaching Cadre. (6) - Includes time for presentation and distribution of Food Safety Modernization Act (FSMA) guidance document for dairy products to the state regulatory agencies during check ratings, routine field work, and state program assessments. Presentations may be made at local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of FSMA field activities. (7) - Activities include the National Steering Team Meetings and conference calls and time for team leader activities (2 RMSs with additional 150 hours each identified).									

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation					2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18					
3. PROGRAM/ASSIGNMENT CODE(S) 18004			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 16.1 [13.3]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 GROWING AREA EVALUATION	9 CONTROL OF HARVEST	9 VIBRO SPECIES MANAGEMENT (Hours)	9 TECHNICAL ASSISTANCE (Hours)	9 FOREIGN EVALUATION	9 NATIONAL TEAM REPS	9 CENTER INITIA- TIVES/LAB	9 PLANT EVALUATION	9 STANDARD IZATION & RE-STAN- DARD IZATION (9)
	TOTAL FIELD	187	15	2416	3857	4	1	11	237	19
	HEADQUARTERS	(b) (5), (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST MPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		20.0	90.0			200.0	180.0	40.0	10.0	40.0
TOTAL HOURS		3740	1350	2416	3857	800	180	440	2370	760
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3.12	1.13	2.01	3.21	0.67	0.15	0.37	1.98	0.63
7. REMARKS (1) - Time is allocated for planning, field evaluations, file reviews to determine state program conformity to the requirements of National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). (2) - Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity Model Ordinance. (3) - Activities include technical assistance, education and evaluation of state shellfish program and management programs. (4) - Includes interpretations and consultation on NSSP MO requirements. (5) - Activities include planning, field evaluations, file reviews and report writing for countries with MOU's or agreements with FDA. Current MOU's include Canada, South Korea, Mexico and New Zealand. (6) - Includes time for shellfish program planning, development and coordination. (7) - Time allocated for CFSAN priority assignments in response to national shellfish safety. (8) - Includes time for planning field evaluations of processing plants, file reviews, and final report writing. (9) - Standardization conducted every 5 years for all FDA and state standardization officers. Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs.										

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18													
3. PROGRAM/ASSIGNMENT CODE(S) 18004		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 16.1 [2.8]											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 NATIONAL TEAM WORKSHOP	9 TRAINING WORKSHOPS	9 REGIONAL SEMINARS	9 FOOD DEFENSE COORDINATION	9 ISSC COMMITTEE	9 FSMA WORKGROUP									
	TOTAL FIELD	(10)	(11)	(12)	(13)	(14)	(15)									
	HEADQUARTERS	(b) (5), (b) (7) (E)														
NE	REGIONAL STAFF															
	NEW ENGLAND															
	NEW YORK															
	REGIONAL LAB															
	WEAC															
CE	REGIONAL STAFF															
	BALTIMORE															
	CHICAGO															
	CINCINNATI															
	DETROIT															
	MINNEAPOLIS															
	NEW JERSEY															
	PHILADELPHIA															
SE	FORENSIC CHEM. CTR															
	REGIONAL STAFF															
	ATLANTA															
	FLORIDA															
	NEW ORLEANS															
SW	SAN JUAN															
	REGIONAL LAB															
	REGIONAL STAFF															
	DALLAS															
	DENVER															
PA	KANSAS CITY															
	SOUTHWEST MPORT DISTRICT															
	REGIONAL LAB															
	REGIONAL STAFF															
	LOS ANGELES															
	SAN FRANCISCO															
	SEATTLE															
	PACIFIC REGIONAL LABORATORY-SW															
	PACIFIC REGIONAL LABORATORY-NW															
HOURS PER OPERATION		40.0	30.0	30.0	20.0	90.0	20.0									
TOTAL HOURS		520	450	510	280	1440	140									
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200									
TOTAL OPERATIONAL FTEs		0.43	0.38	0.43	0.23	1.20	0.12									
7. REMARKS																
<p>(10) - Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, initiatives of national importance.</p> <p>(11) - Includes training workshops coordinated and delivered by the specialists.</p> <p>(12) - Includes time for the Regional Shellfish Specialists to attend regional shellfish conferences.</p> <p>(13) - Time allocated for presentation and distribution of the Food Producers, Processors, and Transporter: Food Security Preventive Measures Guidance to the state regulatory agencies and industries during field work and state program evaluations.</p> <p>(14) - Time allocated for the specialists to attend the biennial Interstate Shellfish Sanitation Conference to address program related issues and new ISSC proposals.</p> <p>(15) - Time is allocated for participating and or providing information to the workgroups for the Food Safety Modernization Act.</p>																
(b) (5), (b) (7) (E)																

1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 52.8 [9.7]			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL MEDICAL FOODS 21002	3 DOMESTIC SAMPLE COLL ECONO. 21003	3 DOMESTIC SAMPLE COLL NLEA 21005	3 DOMESTIC SAMPLE COLL INFANT FORMULA 21006	3 DOMESTIC SAMPLE COLL DIETARY SUPPL 21008	3 DOMESTIC SAMPLE COLL SEAFOOD SPEC. SUB 21842	4 IMPORT SAMPLE COLL MEDICAL FOOD 21002	4 IMPORT SAMPLE COLL ECONO 21004 (1)	4 IMPORT SAMPLE COLL NLEA 21005
	TOTAL FIELD		30	200	340	26	333	100	8	200
HEADQUARTERS		(b) (5), (b) (7) (E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		6.7	6.0	6.0	7.0	5.7	7.6	2.3	6.0	1.9
TOTAL HOURS		201	1200	2040	182	1898	760	18	1200	1729
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		0.21	1.26	2.15	0.19	2.00	0.80	0.02	1.26	1.82

7. REMARKS

NOTE: PAC 21F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

For Pac 21008 ~
Domestic Sample Collections and Field Exams (on page 21-32) may be conducted at packers/repackers, distributors, or warehouses if levels planned cannot be performed during the inspections.

(1) ~ Also includes resources for the Lemon Juice Assignment

1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 52.8 [24.6]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	5	6	7	7	7	7	7
		IMPORT SAMPLE COLL INFANT FORMULA 21006	IMPORT SAMPLE COLL DIETARY SUPPL. 21008	DOMESTIC FIELD EXAMS	IMPORT FIELD EXAMS (1)	DOMESTIC SAMPLES TO BE ANALYZED MED. FOODS CHEM 21002	DOMESTIC SAMPLES TO BE ANALYZED MED FOODS MICRO 21002	DOMESTIC SAMPLES TO BE ANALYZED ECON CHEM 21003	DOMESTIC SAMPLES TO BE ANALYZED NLEA CHEM 21005	DOMESTIC SAMPLES TO BE ANALYZED INFANT FOR. CHEM 21006
TOTAL FIELD		15	713	2400	11209	21	12	200	340	18
HEADQUARTERS		(b) (5), (b) (7) (E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		1.5	2.0	1.0	0.5	100.2	24.3	33.5	18.2	109.5
TOTAL HOURS		23	1426	2400	5605	2104	292	6700	6188	1971
CONVERSION FACTOR		950	950	950	950	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.02	1.50	2.53	5.90	1.78	0.25	5.68	5.24	1.67

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

(1) - All import field exams are to routinely include verification that the imported product is the same as that which was declared (reconciliation exams); and assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are reported as a single Import Field Exams for label review under this compliance program and PAC. Only one exam should be reported per line entry.

Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845,04R845, etc.) See IOM Section 5.4.1.4.1. for additional information on Food and Cosmetic Securities Activities.

1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 52.8 [16.5]
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	7	7	8	8	8	8	8
		DOMESTIC SAMPLES TO BE ANALYZED INFANT FOR. MICRO 21006	DOMESTIC SAMPLES TO BE ANALYZED DIETARY SUP CHEM 21008	DOMESTIC SAMPLES TO BE ANALYZED TDS CHEM 21839	DOMESTIC SAMPLES TO BE ANALYZED SEAFD. SPEC. CHEM 21842	IMPORT SAMPLES TO BE ANALYZED MED FOODS CHEM 21002	IMPORT SAMPLES TO BE ANALYZED ECONO CHEM 21004	IMPORT SAMPLES TO BE ANALYZED NLEA CHEM 21005	IMPORT SAMPLES TO BE ANALYZED INFANT FOR. CHEM 21006	IMPORT SAMPLES TO BE ANALYZED DIET. SUPPL. CHEM 21008
	TOTAL FIELD	8	206	1040	100	8	200	125	15	114

	HEADQUARTERS	(b) (5), (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	31.7	21.0	2.4	13.0	63.7	33.5	6.7	74.9	17.2
TOTAL HOURS	254	4326	2496	1300	510	6700	838	1124	1961
CONVERSION FACTOR	1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs	0.22	3.67	2.12	1.10	0.43	5.68	0.71	0.95	1.66

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 52.8 [2.0]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 METHODS VAL/DEV CHEM (Hours)	9 APPLIED TECHN- OLOGY CENTER CHEM (Hours)						
	TOTAL FIELD	1205	1180						
	HEADQUARTERS	(b) (5), (b) (7) (E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		1205	1180						
CONVERSION FACTOR		1205	1180						
TOTAL OPERATIONAL FTEs		1.00	1.00						

7. REMARKS	
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NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics - 29
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3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 21.3 [11.8]
---	--	--

	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECT- IONS	1 DOMESTIC INSPECT- IONS TATTOO ASSIGN- MENT	3 DOMESTIC SAMPLE COLL TATTOO ASSIGN- MENT	3 DOMESTIC SAMPLES TO BE COLLECTED PRESERVATIVE ASSIGNMENT	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	6 IMPORT FIELD EXAMS (1)	7 DOMESTIC SAMPLES TO BE ANALYZED PRESERVATIVE ASSIGNMENT (Micro)	7 DOMESTIC SAMPLES TO BE ANALYZED (Micro)
	TOTAL FIELD	100	30	600	150	60	230	1600	150	60

	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	21.9	21.9	6.5	3.0	6.5	1.8	0.5	13.0	16.9
TOTAL HOURS	2190	657	3900	450	390	414	800	1950	1014
CONVERSION FACTOR	950	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs	2.31	0.69	4.11	0.47	0.41	0.44	0.84	1.65	0.86

7. REMARKS

Import district allocations are based on OASIS Import Entry Review Lines.

(1) - Import Field Exams are to routinely include: Verification that the imported products are the same as that which were declared (Reconciliation Exams); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety or label concerns. These activities are to be reported as a single Import Field Exam or label review under this compliance program and PAC. Only one exam should be reported per line entry.

Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC 29R845.
See IOM Section 5.4.1.4.1. for additional information on Food and Cosmetic Securities Activities.

Note: If the Center initiates any assignments to follow up on drug claims on cosmetics, the field resources will be taken from this program.

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports		2. PPS PROJECT NAME/NUMBER Colors and Cosmetics - 29								
3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 21.3 [9.5]		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7. DOMESTIC SAMPLES TO BE ANALYZED (Micro) TATTOO	8. IMPORT SAMPLES TO BE ANALYZED (Micro)	8. IMPORT SAMPLES TO BE ANALYZED (Chem)						
	TOTAL FIELD	600	115	115						
	HEADQUARTERS	(b) (5), (b) (7) (E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		13.0	15.8	13.5						
TOTAL HOURS		7800	1817	1553						
CONVERSION FACTOR		1180	1180	1180						
TOTAL OPERATIONAL FTEs		6.61	1.54	1.32						

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

Compliance Programs and Reporting PACs

03 FOODBORNE BIOLOGICAL HAZARDS

Import Acidified & Low Acid Canned Foods

Reporting PACS: 03003, 03003A

Domestic and Imported Cheese & Cheese Products

Reporting PACS: 03037, 03037B, 03037D

Domestic Food Safety

Reporting PACS: 03803, 03803B, 03803C, 03803D, 03803E, 03803U, 04803, 09803, 09803E, 09803F

Domestic Acidified and Low Acid Canned Foods

Reporting PACS: 03803A

Import Foods General / FU to Refusals / Electronic Entry Review / Filer Eval / Prior Notice Review

Reporting PACS: 03819A, 03819, 03819B, 03819C, 03819U, 03R833, 03R824, 07819, 07R824, 09R824, 99R833

Domestic Fish and Fishery Products Inspection Program

Reporting PACS: 03842, 03842B, 03842C, 03842D, 03842H, 03482J, 04842A, 04842H, 07842, 07842H, 09842, 09842E, 09842F, 09842H, 21842

Imported Seafood Products

Reporting PACS: 03844, 03844B, 03844C, 03844D, 03844H, 03844U, 07844, 09844E, 09844F, 21844

Juice HACCP Inspection Program

Reporting PACS: 03847H, 03847J, 03847, 04847, 04847H, 07847, 07847H, 09847, 09847H, 21847H

Import & Domestic Micro Assignments

Reporting PACS: 03F098, 03F100

CFSAN Environmental Sampling Assignments

Reporting PACS: 03F831, 03F833, 03F834, 03F835, 03F836, 03F837, 03F838, 03F839, 03F840, 03F841, 03F842, 03F843, 03F844, 03F845, 03F109

Unspecified Foreign Inspections / Assessments

Reporting PACS: 03R233

Outbreak and Emergency Response

Reporting PACS: 03R839, 04R839, 07R839, 09R839, 21R839, 03R050, 03R175, 03R224/225/262/263/264/265/266/267/277/278/282, 03R855/856/857/858/859, 04R078, 04R854/858/859, 07R279/R280, 21R281, 03C001, 04C001, 21C001, 21C002, 29C001

Food Defense

Reporting PACS: 03R845, 04R845, 07R845, 09R845, 18R845, 21R845

04 PESTICIDES & CHEMICAL CONTAMINANTS

Pesticides & Industrial Chemicals in Domestic & Imported Foods

Reporting PACS: 04004A, 04004D, 04004U, 04R824, 04R833

Chemotherapeutics in Seafood

Reporting PACS: 04018

Toxic Elements in Foods (Domestic and Import)

Reporting PACS: 04019A, 04019U, 04019X

Toxic Elements in Foodware (Domestic and Import)

Reporting PACS: 04019B

Radionuclides in Foods (Domestic & Import)

Reporting PACS: 04019C

Total Diet Study

Reporting PACS: 04839

Field Assignments for Chemical Contaminants

Reporting PACS: 04F800, 04F106, 04F107

Forensic Evaluation and Sample Analysis

Reporting PACS: 04R838, 04R831

07 MOLECULAR BIOLOGY / NATURAL TOXINS: FOOD & COSMETICS

Mycotoxins in Domestic & Imported Foods

Reporting PACS: 07001

09 FOOD & COLOR ADDITIVES PETITION REVIEW & POLICY

Imported Foods – Food & Color Additives
Reporting PACS: 09006A, 09006B

18 TECHNICAL ASSISTANCE: FOOD & COSMETICS

Interstate Travel Program – Conveyances & Support Facilities
Reporting PACS: 18029A, 18029B, 18029C, 18029D, 18029E, 18029F

21 FOOD COMPOSITION, STANDARDS, LABELING & ECONOMICS

Medical Foods (Domestic & Import)
Reporting PACS: 21002

Domestic Food Labeling and Economics Program
Reporting PACS: 21003

Domestic & Import NLEA, Nutrient Sample Analysis & General Food Labeling Program
Reporting PACS: 21005, 21R824

Infant Formula Program
Reporting PACS: 21006

Dietary Supplements (Domestic & Import)
Reporting PACS: 21008, 21008A, 21R829

Selected Nutrient in Foods Survey – Total Diet
Reporting PACS: 21839

29 COLORS AND COSMETICS TECHNOLOGY

Cosmetics (Domestic & Import)
Reporting PACS: 29001, 29R824, 29R829, 29R833, 29R845

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2014**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	129.7	4.0	6.3	140.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	44.7			44.7
42	BLOOD AND BLOOD PRODUCTS	75.1	4.0	3.0	82.1
45	VACCINE AND ALLERGENIC PRODUCTS	9.9		3.3	13.2

1. PROGRAM/ASSIGNMENT TITLE Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41002B, C, D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 39.0
--	--	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP CTIONS (1)	1 CBER PRIORITY ESTABS (2)							
	TOTAL FIELD	781	(69)							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	47.4								
	TOTAL HOURS	37019								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	38.97								

9. REMARKS

(1) - There are no separate resources planned for Foreign Inspections, use Domestic Resources if needed.

(2) - Refer to CBER's memo for inspectional priorities. These inspections are included in the planned inspection numbers.

C.P. 7341.002 - Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
(covers HCT/Ps recovered on or after 5/25/2005)

C.P. 7341.002A - Inspection of Tissue Establishments (covers human tissue recovered before 5/25/2005)

NEW PAC TITLES created in FY2011:
 PAC 41002B Inspection of HCT/Ps-361 Reproductive, for product codes: 57K Reproductive Tissue
 PAC 41002C Inspection of HCT/Ps-361 Hematopoietic Stem Cells, for product codes: 57M Hematopoietic Stem Cells
 PAC 41002D Inspections of HCT/Ps-361 ALL Other 361 HCT/Ps Products, for product codes: 57J Musculoskeletal Tissue;
 57L Ocular Tissue; 57Q Skin; 57R Veins and Arteries; 57S Heart Tissue; 57T Dura Mater; 57 P 99 Human Tissue, N.E.C.

There will be NO separate reporting of AIDS time, report AIDS time under the appropriate compliance program and PAC.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapeutics - 41
---	---

3. PROGRAM/ASSIGNMENT CODE(S) 41808-GLPs, 41809-IRBs, 41810-Spon/Mon/CROs 41811 Clinical Investigators	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	40							
NE	HEADQUARTERS	(b) (5), (b)							
	REGIONAL STAFF	(7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	118.8								
TOTAL HOURS	4752								
CONVERSION FACTOR	950								
TOTAL OPERATIONAL FTEs	5.00								

9. REMARKS

(1) - Resources for PACs 41808, 41809, 41810, and 41811 are planned under PAC 41811 Clinical Investigators. Use above resources for Foreign Inspections as needed. Report Foreign Inspections under Operation Code 11. Inspections are to be conducted only when assignments are received from CBER. Report accomplishments under appropriate PAC.

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Cell and Gene Therapy Products (Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapeutics - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41848A,F,G and 41848B,C,D*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.7
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC (1)							
	TOTAL FIELD	5							
NE	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		133.0							
TOTAL HOURS		665							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		0.70							

9. REMARKS

New Workplanning Sheet in FY2013, resources previously included on PAC 42848's Workplanning Sheet.
 (1) - Resources for all 41848 PACs are planned under PAC 41848F. Use above resources for Domestic and Foreign Inspections as needed and report time under appropriate PAC and Operation Code. Report Foreign Inspections under Operation Code 11.

* PACs include:
 41848A Pre-License Inspection - Somatic Cell and Gene Therapy
 41848F Level 1 CGMP Inspection - Somatic Cell and Gene Therapy
 41848G Level 2 CGMP Inspection - Somatic Cell and Gene Therapy
 41848B Pre-License Inspection - Licensed Hematopoietic Progenitor Cell
 41848C Level 1 CGMP Inspection - Licensed Hematopoietic Progenitor Cell
 41848D Level 2 CGMP Inspection - Licensed Hematopoietic Progenitor Cell

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.
 Compliance Program New in FY05 - Inspection of Biological Drug Products (CBER).

Personnel Types required: Team Biologics Investigators

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Biologics	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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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		75.1	4.0	3.0	82.1	
1	Inspection of Licensed & Unlicensed Blood Banks	42001F,G,H	49.6		0.3	49.9	42-6
	National Experts		2.5		0.1	2.6	
	Inspection of Donor Centers						
	Inspection of Reference Laboratories						
	Inspection of Blood/Plasma Brokers						
	Inspection of Blood Product Contractors						
	Technical Assistance and Coordination *		3.0			3.0	
2	Inspection of Source Plasma Establishments	42002A,F,G	11.9			11.9	42-7
3	Imported CBER - Regulated Products	42007,42R833, 42R824,99R833		4.0		4.0	42-8
4	Inspection of Licensed In-Vitro Diagnostic (IVD) Devices	42008A,F,G	1.4		0.6	2.0	42-9
	Regulated by CBER (Team Biologics)						
	Field Investigations		0.5			0.5	
5	Bioresearch Monitoring Programs **		4.4			4.4	42-10
	Good Laboratory Practices (Nonclinical Labs)	42808	*				
	Institutional Review Boards	42809	*				
	Sponsors, Monitors, and Contract Research Organizations	42810	*				
	Clinical Investigators **	42811	(4.0)				
	National Experts	42808, 42811	(0.4)				
		45808, 45811					
6	Inspection of Medical Device Manufacturers	42845A,B,C	0.5			0.5	42-11
7	Inspection of Plasma Derivatives of Human Origin	42848A-D,F,G	1.3		2.0	3.3	42-12
	(Team Biologics)						

* For BLT-DO to Assist & Coordinate ARC Information.

** All Domestic & Foreign Resources are planned under Domestic PAC 42811. Foreign Resources to cover PPS 41, 42, 45.

CENTER PROJECT MANAGER/TELEPHONE
 Janet Ishimoto 301-827-6220

ORA PLANNER/TELEPHONE
 Harriet R. Gerber 301-796-4396

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G,H	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 55.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	9				
		DOMESTIC INSP CTIONS (1)	FOREIGN INSP CTIONS (2)	DOMESTIC INVESTI- GATIONS (Hours) (3)	TECH ASST & COORDIN- ATION (Hours) OP CODE 92 (4)				
	TOTAL FIELD	1000	8	2400	2850				
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		47.1	42.0						
TOTAL HOURS		47100	336	2400	2850				
CONVERSION FACTOR		950	950	950	950				
TOTAL OPERATIONAL FTEs		49.58	0.35	2.53	3.00				

9. REMARKS

All listed resources are planned under PAC 42001F. Resources cover all facilities listed in compliance program. Blood Bank PAC's: 42001F, Level 1 Inspection, 42001G, Level 2 Inspection, NEW in FY2013: 42001H Donor Center Inspection. Pre-License Inspections for PPS 41, 42, 45 and Field Investigation Hours are not planned separately; use above resources as needed at District discretion.

(1) - Domestic Blood Bank Inspections: Started in FY10 ALL AIDS time will be reported under the appropriate compliance program and PAC. There will be NO separate reporting of AIDS time.

(2) - Foreign Blood Bank Inspections spread by OGROP/ORAO/OMPTO/DMPTPO.

(3) - Domestic Investigation Time is for National Expert Domestic Investigations and Follow-Up Inspections and may be used as needed for other CBER programs.

(4) - Technical Assistance & Coordination (Hours) are for BLT-DO to assist and coordinate ARC information; report time under Operation Code 92.

CBER will lead pre-license and pre-approval inspections.

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE Inspections of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
---	--

3. PROGRAM/ASSIGNMENT CODE(S) 42002A,F,G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.9
--	--	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	203							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	55.7							
	TOTAL HOURS	11307							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	11.90							

9. REMARKS

(1) - Resources may be used for Domestic/Foreign/Follow-up Inspections/Investigations, DSCs as needed.
 The above resources are planned under PAC 42002F, use resources as needed to accomplish this compliance program.
 Source Plasma PACs:
 42002A Pre-License Inspection,
 42002F Level 1 CGMP Inspection,
 42002G Level 2 CGMP Inspection.

Report operations under appropriate PAC and Operation Code.
 Started in FY2010 ALL AIDS time will be reported under the appropriate Compliance Program and PAC.
 There will be NO separate reporting of AIDS time.
 CBER will perform pre-license and pre-approval inspections.

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Imported CBER-Regulated Products	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42007, 42R833, 42R824, 99R833, 41R824, 45R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT INVESTI- GATION HOURS (1)							
	TOTAL FIELD	3800							
	HEADQUARTERS	(b) (5), (b)							
	REGIONAL STAFF	(7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS	3800							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	4.00							

9. REMARKS

(1) - ALL resources are planned under PAC 42007 as Import Investigation Hours.
 Planned Resources are to cover ALL Import Operations: Entry Review 42R833; Follow-Up to Refusals 41R824, 42R824, 45R824;
 Filer Evaluation 99R833 Op 95 and any resources needed under compliance program for PAC 42007. Resources also include time
 for Mail Courier and International Mail Facilities Reviews.

Report accomplishments under appropriate PAC and Operation Code.

Note: C.P. 7342.007 "Imported CBER-Regulated Products," and Addendum "Imported Human Cells, Tissues, and Cellular
 and Tissue-Based Products (HCT/Ps)" provides product specific guidance.

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42008A,F,G Domestic & Foreign (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2					
		DOMESTIC INSP EC- TIONS	FOREIGN INSP EC- TIONS	DOMESTIC INVESTI- GATIONS (Hours) (2)					
	TOTAL FIELD	11	5	441					
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	124.0	114.0						
	TOTAL HOURS	1364	570	441					
	CONVERSION FACTOR	950	950	950					
	TOTAL OPERATIONAL FTEs	1.44	0.60	0.46					

9. REMARKS

In FY2013 Compliance Program Title changed to Licensed In-Vitro Diagnostic (IVD) Devices from Licensed Viral Marker Test Kits.

(1) In FY2013 PACs changed to:
 42008A Pre-License Inspection - IVDs;
 42008F - Level 1 Inspection - Licensed IVDs;
 42008G - Level 2 Inspection - Licensed IVDs.
 PAC 42008 retired.

No separate resources are planned for Pre-License Inspections, use above resources as needed.

(2) - Field Investigation time is for District support to Team Biologics. Field Investigation Hours may be used for any Team Biologics Program.

Report accomplishments under appropriate PAC and Operation Code.
 Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

Personnel Types Required: Team Biologics, Investigator

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42808-GLPs, 42809-IRBs, 42810-Spon/Mon/CROs, 42811 Clinical Investigators	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.4
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	44							
NE	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	95.0								
TOTAL HOURS	4180								
CONVERSION FACTOR	950								
TOTAL OPERATIONAL FTEs	4.40								

9. REMARKS

(1) - Resources for PACs 42809, 42810, and 42811 are planned under PAC 42811 Clinical Investigators. Use above resources for Foreign Inspections as needed. Report Foreign Inspections under Operation Code 11. Inspections are to be conducted only when assignments are received from CBER. Report accomplishment hours under appropriate PAC.

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC T I O N S							
	TOTAL FIELD	6							
	HEADQUARTERS	(b) (5).							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	80.0							
	TOTAL HOURS	480							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	0.51							

9. REMARKS

(1) - All Resources are planned under PAC 42845A. No Foreign Inspections are planned, use above resources as needed. Report all operations under appropriate PAC and Operation Code.

PACs changed from 42830C,L to 42845A,B,C in FY05
 42845A Level 1 Inspection;
 42845B Level 2 Inspection;
 42845C Level 3 Inspection.

Note: Inspections of Manufacturers of Blood Bank Software should be reported under this program.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Plasma Derivatives of Human Origin	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42848A,F,G; 42848B,C,D Domestic & Foreign (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSP ECTIONS	1 FOREIGN LICENSED INSP ECTIONS							
	TOTAL FIELD	7	9							
NE	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST MPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		180.0	211.0							
TOTAL HOURS		1260	1899							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.33	2.00							

9. REMARKS
 (1) - No separate resources are planned for Pre-License Inspections, use above resources as needed.
 All resources are planned under PAC 42848F.
 42848A Pre-License Inspection - Plasma Derivatives;
 42848F Level 1 CGMP Inspection - Plasma Derivative;
 42848G Level 2 CGMP Inspection - Plasma Derivatives.
 Additional PACs added in FY2011:
 42848B Pre-License Inspection - Recombinant Analogues;
 42848C Level 1 CGMP Inspection - Recombinant Analogues;
 42848D Level 2 CGMP Inspection - Recombinant Analogues.
 Report ALL Accomplishments under Appropriate PAC and Operation Code.

 Compliance Program New in FY05 - Inspection of Biological Drug Products (CBER), previously covered by PACs 42006,A.
 Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY		2. PPS PROJECT NAME/NUMBER					
Biologics		Vaccines and Allergenic Products - 45					
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
TOTAL			9.9		3.3	13.2	
1	Bioresearch Monitoring Programs *		7.0			7.0	45-14
	Good Laboratory Practices (Nonclinical Labs)	45808	*				
	Institutional Review Boards	45809	*				
	Sponsors, Monitors, and Contract Research Organizations	45810	*				
	Clinical Investigators *	45811	(7.0)				
2	Licensed Allergenic Products (Team Biologics)	45848A,F,G	0.4		0.3	0.7	45-15
3	Licensed Vaccine Products (Team Biologics)	45848B,C,D	2.5		3.0	5.5	45-16
* All resources are planned under PAC 45811.							

CENTER PROJECT MANAGER/TELEPHONE
Janet Ishimoto 301-827-6220

ORA PLANNER/TELEPHONE
Harriet R. Gerber 301-796-4396

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45808-GLPs, 45809-IRBs, 45810-Spon/Mon/CROs, 45811 Clinical Investigators	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	61							
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF	(b) (5), (b) (7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	109.0								
TOTAL HOURS	6649								
CONVERSION FACTOR	950								
TOTAL OPERATIONAL FTEs	7.00								

9. REMARKS

(1) - Use above resources for Foreign Inspections as needed. Report Foreign Inspections under Operation Code 11. Resources for PACs 45809, 45810, and 45811 are planned under PAC 45811 Clinical Investigators. Inspections are to be conducted only when assignments are received from CBER. Report accomplishment hours under appropriate PAC.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products (Post-Market & Pre-License)		2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45									
3. PROGRAM/ASSIGNMENT CODE(S) 45848A,F,G Domestic & Foreign (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 0.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1								
		DOMESTIC INSP CTIONS	FOREIGN INSP CTIONS								
	TOTAL FIELD	3	2								
	HEADQUARTERS	(b) (5), (b) (7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		118.0	165.0								
TOTAL HOURS		354	330								
CONVERSION FACTOR		950	950								
TOTAL OPERATIONAL FTEs		0.37	0.35								

9. REMARKS

(1) - Resources are planned under PAC 45848F. Use resources as needed for domestic or foreign inspections, and report under appropriate PAC and Operation Code (foreign inspection is operation code 11).
 45848A Pre-License Inspection - Allergenic;
 45848F Level 1 CGMP Inspection - Allergenic;
 45848G Level 2 CGMP Inspection - Allergenic.

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.
 Compliance Program New in FY05 - Inspection of Biological Drug Products (CBER), previously covered by PACs 45001,A.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic & Foreign (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1						
		DOMESTIC INSP EC- TIONS	FOREIGN INSP EC- TIONS						
	TOTAL FIELD	9	11						
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	260.0	263.0						
	TOTAL HOURS	2340	2893						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	2.46	3.05						

9. REMARKS

(1) - Resources are planned under PAC 45848C. Use resources as needed and report under appropriate PAC and Operation Code. Report Foreign Inspections under Operation Code 11. All Inspections will be performed by Team Biologics.

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

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections. Compliance Program New in FY05 - Inspection of Biological Drug Products (CBER), previously covered by PACs 45002,A.

**CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2014**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	232.5	48.9	138.6	420.0
46	NEW DRUG EVALUATION	10.8		14.0	24.8
48	BIORESEARCH MONITORING HUMAN DRUGS	64.0		26.4	90.4
52	GENERIC DRUG EVALUATION	6.7		15.0	21.7
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	8.7		1.1	9.8
56	DRUG QUALITY ASSURANCE	115.4	48.9	82.1	246.4
63	UNAPPROVED AND MISBRANDED DRUGS	14.9			14.9
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.3
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	6. DISTRICT/SPECIALIZED LABORATORY	1 INSPECTIONS	1 CHEMIST ON INSPECTIONS (Hours) (1)	3 DOMESTIC SAMPLE COLL CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED PROFILE CHEM				
	TOTAL FIELD	131	703	15	35				
	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	58.3		8.2	11.8				
	TOTAL HOURS	7637	703	123	413				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	8.04	0.74	0.13	0.35				

9. REMARKS

(1) - Includes Microbiologists on Inspections.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) (1) 46832, 46832B, 46832C, 46832D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS (2)	1 CHEMIST ON INSPECTIONS (Hours) (3)					
		TOTAL FIELD	(b) (5), (b) (7)(E)					
NE	HEADQUARTERS							
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION		63.3						
TOTAL HOURS		7849	4522					
CONVERSION FACTOR		950	950					
TOTAL OPERATIONAL FTEs		8.26	4.76					

9. REMARKS

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

(2) - Report as follows: Insp./Chem on Insp. under foreign operation code 11, Pac Code 46832;
M. Valid.- 46832; Profile ISCs & ISAs - 46832B; Biotest ISCs & ISAs (not planned) if collected - 46832C.

(3) - Includes Microbiologists on Inspections. Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Pre-Licensed Biotech (BLA) Inspections/Investigations - Domestic and Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46							
3. PROGRAM/ASSIGNMENT CODE(S) 46832M			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.0			
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)	1 INSPECTIONS Foreign							
	TOTAL FIELD	6	9							
NE	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		156.6	101.0							
TOTAL HOURS		940	909							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.99	0.96							

9. REMARKS

(1) - Includes Microbiologists on Inspections.

1. PROGRAM/ASSIGNMENT TITLE Positron Emission Tomography (PET) Pre-Approval Inspections/Investigations		2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46									
3. PROGRAM/ASSIGNMENT CODE(S) <p style="text-align: center;">46832P</p>			4. WORK ALLOCATION PLANNED BY <p style="text-align: center;"> <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER </p>					5. OPERATIONAL FTE POSITIONS <p style="text-align: center;">0.5</p>			
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)									
	TOTAL FIELD	15									
NE	HEADQUARTERS	(b) (5),									
	REGIONAL STAFF	(b) (7)									
	NEW ENGLAND	(E)									
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
SE	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
SW	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		31.9									
TOTAL HOURS		479									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTEs		0.50									
9. REMARKS (1) - Includes Microbiologists on Inspections. Inspections are to verify that NDA applicant has facilities, equipment, controls, etc. as specified in the application.											

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Human Drugs	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	MPORT	FOREIGN		

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	DOMESTIC	MPORT	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL		64.0		26.4	90.4	
1	In Vivo Bioequivalence - ANDAs & NDAs	48001, A	7.5			7.5	48-07
	PDUFA (NDAs)		(3.3)				
	Foreign Inspections (In Vivo Bioequivalence, GLPs) *	48001, A; 48808			9.2	9.2	48-08
	* Foreign Inspections PEPFAR (AIDS Relief) (planned under 48001A and 48001)	48001D, E; 48808, 48811D					
2	Bioresearch Monitoring						48-09
	Good Laboratory Practices (Non-Clinical Lab)	48808	3.1			3.1	
	National Experts		(0.1)				
	** Institutional Review Board	48809, 48809A	10.0			10.0	
	Sponsors, Contract Research Organizations, and Monitors	48810	6.3			6.3	
3	Clinical Investigators	48811, F	37.1		17.2	54.3	48-10
	National Experts		(0.1)		(2.2)		

* - PEPFAR work is not planned separately, NDA PEPFAR resources are planned under 48001A and ANDA PEPFAR resources are planned under 48001.

** - Resources in the Radioactive Drug Research Committee (48809A) have been collapsed into Institutional Review Board (48809).

CENTER PROJECT MANAGER/TELEPHONE
Paul Okwesili, (301) 796-0173

ORA PLANNER/TELEPHONE
Anita T. McCurdy 301-796-4395

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence - Pre-Approval (PDUFA)	2. PPS PROJECT NAME/NUMBER BioResearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs), 48001A (NDAs)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.5
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPECTIONS *	1 48001A NDA INSPECTIONS							
	TOTAL FIELD	46	39							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	88.1	79.7							
	TOTAL HOURS	4053	3108							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	4.27	3.27							

9. REMARKS

Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification.

An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 45%, PDUFA 48001A (NDA) 55%.

* - Includes 1 GDUFA FTE.

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA; ANDA - PRE-APPROVAL)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48001D,E, 48811D NDA & ANDA (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.2
---	--	--

E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPECTIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPECTIONS (PRE-APPVL) *						
	TOTAL FIELD	39	52						
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	90.7	99.6						
	TOTAL HOURS	3537	5179						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	3.72	5.45						

9. REMARKS

(1) - Planned inspections include: 48001,A In Vivo Bioequivalence, 48808 GLPs (PDUFA), PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence, and 48811D PEPFAR Clinical Investigations .

Report Inspections under Appropriate PAC, Foreign Inspections under Operation Code 11.
 HIGH PRIORITY for NDA inspections.
 48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigations.
 NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001.
 PEPFAR work is not planned separately.

Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs.
 Data audit under PEPFAR will be verified by on site inspections.

* - Includes 2 GDUFA FTE.

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48808, 48809, 48809A, 48810	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.4
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	1	1				
		GLP INSP CTIONS 48808	NAT'L EXPERT INVESTI- GATIONS (Hours) 48808 - GLP	IRB (1) INSP CTIONS 48809, 48809A (2)	SPONSOR, CRO, MONITORS INSP CTIONS 48810 (3)				
	TOTAL FIELD	27	142	116	47				
NE	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		104.1		82.1	125.9				
TOTAL HOURS		2811	142	9524	5917				
CONVERSION FACTOR		950	950	950	950				
TOTAL OPERATIONAL FTEs		2.96	0.15	10.03	6.25				

9. REMARKS

48808: Resources planned for Inspections may also be used for DSCs.

Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER. CDER assignments, i.e. Directed Inspections, cover studies associated with IND's and NDA's.

Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-06).

(1) - Institutional Review Board
 (2) - 48809A: Resource (1 FTE) for the Radioactive Drug Research Committee (RDRC) is not planned separately. However, please use above resources as needed and report RDRC work under PAC 48809A.
 (3) - Sponsors, Contract Research Organizations, and Monitors

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

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48							
3. PROGRAM/ASSIGNMENT CODE(S) 48811, F*			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 54.3				
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC- TIONS	2 NAT'L EXPERT INVESTI- GATIONS (Hours)	1 DOMESTIC INSPIC- TIONS Follow-Up & Complaints 48811F	1 FOREIGN INSPIC- TIONS					
	TOTAL FIELD	176	118	118	175					
NE	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		119.4		119.1	93.5					
TOTAL HOURS		21014	118	14054	16363					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		22.12	0.12	14.79	17.22					

9. REMARKS

* - Report domestic follow-up and complaints as **inspections** under PAC 48811F.

Foreign Inspections planned under HQ includes inspections for National Experts and Foreign Cadre.

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Investigations - Domestic	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.2
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAS TO INSPECT	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED PROFILE CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED BIOTEST CHEM				
	TOTAL FIELD	64	44	59	37				
	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	58.5	5.0	11.0	16.8				
	TOTAL HOURS	3744	220	649	622				
	CONVERSION FACTOR	950	950	1180	1180				
	TOTAL OPERATIONAL FTEs	3.93	0.23	0.55	0.53				

9. REMARKS

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Investigations - Foreign	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B ,52832C, 52832E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	4	8	8																																																
		* INSPECTIONS (1) (Foreign) (2)	CHEMIST INSPECTIONS (Hours) (Foreign) (3)	INVESTI- GATIONS (Hours)	IMPORT SAMPLE COLL (4)	IMPORT SAMPLES TO BE ANALYZED PROFILE CHEM (5)	IMPORT SAMPLES TO BE ANALYZED BIOTEST CHEM (5)																																																
	TOTAL FIELD	134	2503	159	151	75	52																																																
NE	HEADQUARTERS	(b) (5), (b) (7)(E)																																																					
	REGIONAL STAFF																																																						
	NEW ENGLAND																																																						
	NEW YORK																																																						
	REGIONAL LAB																																																						
WEAC																																																							
CE	REGIONAL STAFF										(b) (5), (b) (7)(E)																																												
	BALTIMORE																																																						
	CHICAGO																																																						
	CINCINNATI																																																						
	DETROIT																																																						
	MINNEAPOLIS																																																						
	NEW JERSEY																																																						
	PHILADELPHIA																																																						
	FORENSIC CHEM. CTR																																																						
SE	REGIONAL STAFF																			(b) (5), (b) (7)(E)																																			
	ATLANTA																																																						
	FLORIDA																																																						
	NEW ORLEANS																																																						
	SAN JUAN																																																						
REGIONAL LAB																																																							
SW	REGIONAL STAFF																												(b) (5), (b) (7)(E)																										
	DALLAS																																																						
	DENVER																																																						
	KANSAS CITY																																																						
	SOUTHWEST MPORT DISTRICT																																																						
REGIONAL LAB																																																							
PA	REGIONAL STAFF																																					(b) (5), (b) (7)(E)																	
	LOS ANGELES																																																						
	SAN FRANCISCO																																																						
	SEATTLE																																																						
	PACIFIC REGIONAL LABORATORY-SW																																																						
PACIFIC REGIONAL LABORATORY-NW																																																							
HOURS PER OPERATION																																															70.4			3.0	16.8	15.5			
TOTAL HOURS																																															9434	2503	159	453	1260	806			
CONVERSION FACTOR																																															950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs																																															9.93	2.63	0.17	0.48	1.07	0.68			

9. REMARKS

(1) - Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;

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

Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C.

(3) - Includes microbiologists on inspections

(4) - Samples are collected at foreign manufacturers.

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

Laboratory allocations were planned by ORS.

* - Includes 2 GDUFA FTEs.

1. PROGRAM/ASSIGNMENT TITLE Positron Emission Tomography (PET) Pre-Approval Inspections/Investigations		2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52							
3. PROGRAM/ASSIGNMENT CODE(S) 52832P			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 1.5		
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDA PET INSP EC- TION S (1)							
	TOTAL FIELD	67							
NE	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)							
	NEW ENGLAND	(E)							
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		21.5							
TOTAL HOURS		1441							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		1.52							
9. REMARKS (1) - Inspections are to determine compliance of establishments with GMPs prior to approval of pending ANDAs. ANDA bulk products are collected for profile analysis.									

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Human Drugs	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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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			8.7		1.1	9.8	
1	Enforcement of the Adverse Drug Experience Reporting Regulation (Domestic/Foreign)	53001A	6.6		1.1	7.7	53-16
2	Experience Reporting Regulation REMS (PDUFA)	53001C	2.1			2.1	53-17

CENTER PROJECT MANAGER/TELEPHONE Tamika White, (301) 796-0310	ORA PLANNER/TELEPHONE Anita T. McCurdy 301-796-4395
--	--

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulation	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001A (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.7
--	---	--

E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC- TIONS	1 FOREIGN INSP EC- TIONS						
	TOTAL FIELD	93	15						
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	67.0	69.5						
	TOTAL HOURS	6231	1043						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	6.56	1.10						

9. REMARKS

(1) - Report both Domestic and Foreign inspections under 53001A.

CDER will issue inspection assignments using a risk site selection model. The field should contact CDER for guidance if a site selection is not from the CDER model.

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

1. PROGRAM/ASSIGNMENT TITLE Risk Evaluation and Mitigation System (REMS)	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001C	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.1
--	--	--

E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	36							
NE	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)							
	NEW ENGLAND	(E)							
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	54.9							
	TOTAL HOURS	1976							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	2.08							

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, B-D, *56002H, I, J, K, L, 56832, 56R359	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 39.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	1	1	3	3	3	7	7
		INSP EC T I O N S	CERTI F I C A T I O N A U D I T S (INV Hours) (1)	CHEMIST ON INSP EC T I O N S (Hours)	MICRO ON INSP EC T I O N S (Hours)	DOMESTIC S A M P L E C O L L (2)	DOMESTIC S A M P L E C O L L (CHEM) (3)	DOMESTIC S A M P L E C O L L (MICRO) (3)	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M	DOMESTIC S A M P L E S T O B E A N A L Y Z E D M I C R O
	TOTAL FIELD	352	1900	2499	1200	196	156	40	156	40

	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		70.2				7.9			36.8	18.0
TOTAL HOURS		24710	1900	2499	1200	1548			5741	720
CONVERSION FACTOR		950	950	950	950	950			1180	1180
TOTAL OPERATIONAL FTEs		26.01	2.00	2.63	1.26	1.63			4.87	0.61

9. REMARKS

(1) - Hours for certification audits in support of Level II Drug Certification Audits and the Pharmaceutical Inspectorate (PI). Report Certification Audit hours under 56R359.

(2) - DSCs not analyzed are documentary samples.

(3) - Shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.

* The following PACS are for Abbreviated Inspections
 56002H - ABBREVIATED DRUG PROCESS INSPECTIONS (DPI)
 56002J - ABBREVIATED DPI / DRUG REPACKERS AND RELABELLERS
 56002K - ABBREVIATED DPI / RADIOACTIVE DRUGS
 56002L - ABBREVIATED ACTIVE PHARMACEUTICAL INGREDIENT PROCESS INSPECTIONS

Laboratory allocations were planned by ORS.

FORM FDA 2621a (10/09)

ORA WORKPLANNING SHEET (Continued)

PAGE NO. 56-19

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, B, C, D, 56832, 56R359	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 55.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC- TIONS * (1)	1 CHEMIST ON INSPECTIONS FOREIGN (Hours) (2)							
	TOTAL FIELD	682	7200							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	67.3								
	TOTAL HOURS	45899	7200							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	48.31	7.58							


9. REMARKS

(1) - Report time under appropriate PACs (56002, B, C, D, 56832, 56R359) under operation 11.

(2) - Time planned in this column may be used by chemists or microbiologists.

* - Foreign Inspections include the Foreign Cadre inspection time and 2 GDUFA FTEs.

Laboratory allocations planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Sterile Drug Process Inspections - (Domestic & Foreign) 				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56				
3. PROGRAM/ASSIGNMENT CODE(S) 56002A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 23.0		
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC- TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLES TO BE ANALYZED			1 FOREIGN INSP EC- TIONS	
	TOTAL FIELD	61	32	15			122	
	HEADQUARTERS	(b) (5), (b) (7)(E)						
	REGIONAL STAFF							
NE	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALT MORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION	142.9	9.2	39.4			101.4	
	TOTAL HOURS	8717	294	591			12371	
	CONVERSION FACTOR	950	950	1180			950	
	TOTAL OPERATIONAL FTEs	9.18	0.31	0.50			13.02	

9. REMARKS

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Gas Manufacturers (Domestic)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.0
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6.	DISTRICT/ SPECIALIZED LABORATORY	1	INSPEC- TIONS	MEDICAL	GAS						
	TOTAL FIELD	212									
NE	HEADQUARTERS	(b) (5),									
	REGIONAL STAFF	(b) (7)									
	NEW ENGLAND	(E)									
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	35.8									
	TOTAL HOURS	7590									
	CONVERSION FACTOR	950									
	TOTAL OPERATIONAL FTEs	7.99									

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Active Pharmaceutical Ingredients (APIs) - (Domestic and Foreign)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002F, 56002L	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1							
		DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS *							
	TOTAL FIELD	62	167							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		58.2	63.7							
TOTAL HOURS		3608	10638							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		3.80	11.20							

9. REMARKS

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

The following PAC is for Abbreviated Inspections:
56002L - ABBREVIATED ACTIVE PHARMACEUTICAL INGREDIENT PROCESS INSPECTIONS

* - Includes 2 GDUFA FTEs.

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Biotech Manufacturers (Domestic)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002M	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS							
	TOTAL FIELD	70							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	81.7							
	TOTAL HOURS	5719							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	6.02							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Positron Emission Tomography (PET) Inspections/Investigations			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3. PROGRAM/ASSIGNMENT CODE(S) <p style="text-align: center;">56002P</p>			4. WORK ALLOCATION PLANNED BY <div style="display: flex; justify-content: space-around;"> <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER </div>				5. OPERATIONAL FTE POSITIONS <p style="text-align: center;">2.0</p>			
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)								
	TOTAL FIELD	31								
NE	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		61.5								
TOTAL HOURS		1907								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		2.01								
9. REMARKS (1) - Inspections are to evaluate the conditions under which drug products are manufactured, tested, packaged and held. Manufacturers are required to adhere to USP <823>; 21 CFR Part 212.										

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Sampling and Testing Program					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56008A, L (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 18.0 [3.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	3	3	3	3	3	3	7	7
		INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	DOMESTIC IMPORT SAMPLE COLL 56008L (1)	DOMESTIC IMPORT SAMPLE COLL CHEM 56008L	DOMESTIC IMPORT SAMPLE COLL MICRO 56008L	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	219	36	21	15	380	300	80	21	15
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION		6.3			5.5			48.5	15.6
	TOTAL HOURS	219	227			2090			1019	234
	CONVERSION FACTOR	950	950			950			1180	1180
	TOTAL OPERATIONAL FTEs	0.23	0.24			2.20			0.86	0.20
9. REMARKS										
<p>The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.</p> <p>(1) Reporting Guidance: Report domestic sample collections and sample analyses under 56008A. ALL domestic-import sample collections and sample analyses should be reported under NEW PAC 56008L.</p> <p>Analytical resources for Pharmacy Compounding (PAC 56D015) are included in this program. Laboratory allocations were planned by ORS.</p>										

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Sampling and Testing Program	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008A, L (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 18.0 [14.3]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC IMPORT SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC IMPORT SAMPLES TO BE ANALYZED MICRO	9 METHODS VAL/DEV (Hours) CHEM (2)					
	TOTAL FIELD	350	33	4661					
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	31.1	39.7						
	TOTAL HOURS	10885	1310	4661					
	CONVERSION FACTOR	1180	1180	1180					
	TOTAL OPERATIONAL FTEs	9.22	1.11	3.95					

9. REMARKS

(1) Reporting Guidance: Report domestic sample collections and sample analyses under 56008A.
ALL domestic-import sample collections and sample analyses should be reported under NEW PAC 56008L.

(2) - Methods Validation/Development hours include resources for development activities coordinated through DFS.

Analytical resources for Pharmacy Compounding (PAC 56D015) are included in this program.
 Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 48.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	6	2	2	4	8	8	
		IMPORT ENTRY REVIEW HOURS	IMPORT INVESTIGA- TIONS HOURS (1)	IMPORT FIELD EXAM HOURS	INTERNATIONAL MAIL FACILITY REVIEWS INV HOURS	MAIL COURIER REVIEWS INV HOURS	IMPORT SAMPLE COLL	IMPORT SAMPLES TO BE ANALYZED API CHEM	IMPORT SAMPLES TO BE ANALYZED FIN-DOSE CHEM	
	TOTAL FIELD	22224	4523	8480	8607	1715	393	155	178	
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION			1.0				2.7	20.1	13.5
TOTAL HOURS	22224	4523	8480	8607	1715	1061	3116	2403	
CONVERSION FACTOR	1200	950	950	950	950	950	1180	1180	
TOTAL OPERATIONAL FTEs	18.52	4.76	8.93	9.06	1.81	1.12	2.64	2.04	

9. REMARKS

Reporting Guidance:

- Import Entry Reviews (electronic and manual-- operation code 14) PAC 56R833;
- Filer Evaluations (operation code 95) PAC 99R833;
- Follow-Up to Refusals 56R824, 63R824
- Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001, 63002;
- Report finished dosage form drugs and APIs collected at the site of entry under 56008H.

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

Use CT PAC 56R845 only when specific CT work is performed.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.5
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 DQRS FARS INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES TO BE ANALYZED (Hours) CHEM				
	TOTAL FIELD	52	1425	25	29				
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		34.1		5.0	41.7				
TOTAL HOURS		1773	1425	125	1209				
CONVERSION FACTOR		950	950	950	1180				
TOTAL OPERATIONAL FTEs		1.87	1.50	0.13	1.02				

9. REMARKS

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56022, 56022A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM				
	TOTAL FIELD	30	294	27	34				
	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	42.5		2.5	11.0				
	TOTAL HOURS	1275	294	68	374				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	1.34	0.31	0.07	0.32				

9. REMARKS

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Domestic and Foreign			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3. PROGRAM/ASSIGNMENT CODE(S) 56843			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.0				
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC TIONS	1 FOREIGN INSP EC TIONS							
	TOTAL FIELD	35	59							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		55.0	32.5							
TOTAL HOURS		1925	1918							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.02	2.02							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56									
3. PROGRAM/ASSIGNMENT CODE(S) 56D015			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 7.1			
E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	INSPEC- TIONS								
	TOTAL FIELD		73								
NE	HEADQUARTERS		(b) (5),								
	REGIONAL STAFF		(b) (7)								
	NEW ENGLAND		(E)								
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
SE	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
SW	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION			92.0								
TOTAL HOURS			6716								
CONVERSION FACTOR			950								
TOTAL OPERATIONAL FTEs			7.07								

9. REMARKS
 Resources for collection and analysis of any samples under this program should be taken from Drug Quality Sampling and Testing Program (56008A).

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Global Parity Initiative	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
--	--	--

E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Desk Audits INVESTIG- ATIONS (Hours)								
	TOTAL FIELD	1900								
NE	HEADQUARTERS	(b) (5),								
	REGIONAL STAFF	(b) (7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		1900								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		2.00								

9. REMARKS

The Global Parity Initiative is a new collaboration between CDER and ORA that implements the Commissioner's "Pathway to Global Product Safety and Quality" initiative. Specifically, this program will support our aim to leverage foreign regulatory authority inspections. The program will use domestic inspection resources toward improving our knowledge of foreign manufacturing operations, facilities, and counterpart inspectorates. Resources will be assigned to initiate and implement the desk audit program.

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - OEI Clean Up	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
--	--	--

E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Desk Audits INVESTI- GATIONS (Hours)							
	TOTAL FIELD	950							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)							
	NEW ENGLAND	(E)							
NE	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
CE	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
SE	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
SW	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS	950							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	1.00							

9. REMARKS

Investigation hours are to be used to update and maintain the foreign inventory contact information.

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R838, 56R831	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC CHEM (Hours) FORENSIC EVALUATION								
	TOTAL FIELD	12050								
	HEADQUARTERS	(b) (5),								
	REGIONAL STAFF	(b) (7)(E)								
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		12050								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		10.00								

9. REMARKS

The hours planned above are estimates. Report Forensic activities under the appropriate PAC 56R838; PODs operation code 03, Petition Evaluation, Methods Development or Forensic Evaluation; PODs operation 41 or 43 domestic or import sample analysis, PAC 56R838 or OCI PAC 56R831.

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Human Drugs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs: - Human Drugs - 63
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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		14.9			14.9	
1	Internet, Health Fraud, & OTC Monographs	63001A,	11.4			11.4	63-37
		63D012					
2	New Drugs Rx Not Covered by Approved NDAs	63002	3.5			3.5	63-38

CENTER PROJECT MANAGER/TELEPHONE John Pace, (301) 796-3538; Sakineh Walther, (301) 796-3349	ORA PLANNER/TELEPHONE Anita T. McCurdy 301-796-4395
--	--

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.4
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL (1)				7 DOMESTIC SAMPLES TO BE ANALYZED
	TOTAL FIELD	114	1520	251				199
	HEADQUARTERS	(b) (5), (b) (7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
NE	NEW YORK							
	REGIONAL LAB							
	WEAC							
	REGIONAL STAFF							
	BALT MORE							
CE	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
SE	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION	36.5		5.9				22.8
	TOTAL HOURS	4161	1520	1481				4537
	CONVERSION FACTOR	950	950	950				1180
	TOTAL OPERATIONAL FTEs	4.38	1.60	1.56				3.85

9. REMARKS

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

Report Health Fraud and OTC Monograph work to PAC 63001A.
Report Internet Drugs work to PAC 63D012.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Without Approved NDAs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.5
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2									
		INSPEC- TIONS	INVESTI- GATIONS (Hours)									
	TOTAL FIELD	77	200									
	HEADQUARTERS	(b) (5), (b) (7)(E)										
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
FORENSIC CHEM. CTR												
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW											
	PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION		40.3										
TOTAL HOURS		3103	200									
CONVERSION FACTOR		950	950									
TOTAL OPERATIONAL FTEs		3.27	0.21									

9. REMARKS

Report work under New Drugs (Rx) without Approved NDAs (formerly PAC 52002) to PAC 63002.

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Human Drugs		2. PPS PROJECT NAME/NUMBER ICA (Interagency Cooperative Activities) - 88					
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		12.0			12.0	
1	Shelf Life Extension Projects	*	12.0			12.0	88-40

*For appropriate project reporting PACs, please refer to the list of Active PACs at:
<http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/PACMasterList/default.htm#cdcr>

CENTER PROJECT MANAGER/TELEPHONE Donna A. Porter, 301-796-6583	ORA PLANNER/TELEPHONE Anita T. McCurdy 301-796-4395
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1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
---	--

3. PROGRAM/ASSIGNMENT CODE(S) All Appropriate PACs	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM							
	TOTAL FIELD	14160							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
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.

Laboratory allocations were planned by ORS.

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2014**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	121.0	18.8	5.4	145.2
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	6.9		3.5	10.4
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	114.1	18.8	1.9	134.8

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

3. PROGRAM/ASSIGNMENT CODE(S) 68001, 68001G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP CTIONS (1)	1 DOMESTIC INSP CTIONS (2)	1 CHEMIST ON INSP				
	TOTAL FIELD	40	10	850				

	HEADQUARTERS	(b) (5), (b) (7)(E)						
	REGIONAL STAFF							
NE	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
	REGIONAL STAFF							
CE	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
SE	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
PA	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							

HOURS PER OPERATION	75.0	55.0				
TOTAL HOURS	3000	550	850			
CONVERSION FACTOR	950	950	950			
TOTAL OPERATIONAL FTEs	3.16	0.58	0.89			

7. REMARKS

(1) - Foreign inspections spread by Medical Products and Tobacco Inspections Coordination Branch. Use Operation Code 11 to report foreign inspections.

(2) - Analyst will participate on inspections as necessary.

Districts and Laboratories should collect and analyze samples as needed by the program, time for these operations is planned under inspections and chemist on inspections.

Resources for the Generic Animal Drug Pre-Approval Inspections PAC (68001G) are planned under 68001.

Workload Source: FACTS database (registered firms in IND 56, 67, and 68; Workload Obligation is "Yes" and Status is "Operational".)

1. PROGRAM/ASSIGNMENT TITLE GLPs Sponsor-Monitors, Clinical Investigators (Pre-Market)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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3. PROGRAM/ASSIGNMENT CODE(S) PACs 68808, G, 68810, G, 68811, G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC- TIONS 68810	1 FOREIGN INSPEC- TIONS 68811	1 DOMESTIC INSPEC- TIONS 68808	1 DOMESTIC INSPEC- TIONS 68811				
	TOTAL FIELD	2	3	30	44				

	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
SW	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
PA	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	90.0	60.0	85.0	5E(
TOTAL HOURS	180	180	2550	2552				
CONVERSION FACTOR	950	950	950	950				
TOTAL OPERATIONAL FTEs	0.19	0.19	2.68	2.69				

7. REMARKS

(1) - Domestic resources for 68808 and 68810 are planned under 68808. Report Inspections under the appropriate PAC.

Foreign inspections are for sponsor/monitors (68810) and clinical investigators (68811).

Inspections are to be conducted only when assignments are received from CVM.

Resources for Generic Good Laboratory Practices (68808G) and Generic Sponsors, Contract Research Organizations & Monitors (68810G) are planned under 68808. Report Inspections under the appropriate PAC.

Resources for Generic Clinical Investigators (68811G) are planned under 68811. Report Inspections under the appropriate PAC.

Workload Source: FACTS database (BIMO firms in IND 67, 68, and 69 with Status of "Operational").

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

3. PROGRAM/ASSIGNMENT CODE(S) PACs 71001, A, B, 71005, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	3	3	6	7	
		FOREIGN INSPEC- TIONS (1)	DOMESTIC INSPEC- TIONS (2)	CHEM ON INSPEC (Hours)	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL (3)	DOMESTIC SAMPLE COLL CHEM	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM	
	TOTAL FIELD	33	205	600	250	50	20	100	20	
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	49.0	40.0			7.0		0.8	35.0
TOTAL HOURS	1617	8200	600	250	350		80	700
CONVERSION FACTOR	950	950	950	950	950		950	1180
TOTAL OPERATIONAL FTEs	1.70	8.63	0.63	0.26	0.37		0.08	0.59

7. REMARKS

(1) - Foreign Inspections spread by Medical Products and Tobacco Inspections Coordination Branch.

(2) - Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples.

(3) - Investigational or official samples should be collected as appropriate.

Resources for Type A Medicated Articles Program (71005/A) are now under 71001.

The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples sent to the laboratories for analysis.

Workload Source: CVM allocated the number of Domestic Inspections to Districts based on their risk model for ranking firms.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Domestic	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 36.8 [8.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	3	3	3	3	3	3
		INSPEC- TIONS (1)	DOMESTIC SAMPLE COLL (2)	DOMESTIC SAMPLE COLL Metals 71003B	DOMESTIC SAMPLE COLL Myco 71003C	DOMESTIC SAMPLE COLL Micro 71003E (2) (a)	DOMESTIC SAMPLE COLL Micro 71003E (b)	DOMESTIC SAMPLE COLL Chem 71003A	DOMESTIC SAMPLE COLL Dioxin 71003G (c)	DOMESTIC SAMPLE COLL Antibiotics 71003K (3)
	TOTAL FIELD	37	1688	80	338	600	200	300	150	20

	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										

HOURS PER OPERATION	35.0	4.2								
TOTAL HOURS	1295	7090								
CONVERSION FACTOR	950	950								
TOTAL OPERATIONAL FTEs	1.36	7.46								

7. REMARKS

The shaded area serves as a guide for the districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.

(1) - Inspections performed as F/U to violative samples and as needed as surveillance.

(2) - Domestic Sample Collection and Analysis:
71003E - sample collection/analyses for Direct Human Contact animal feed/ingredients are for pig ears, pet treats, pet foods, and supplements for pets. 300 of the 600 samples collected for this assignment will be sent to CVM's Office of Research for micro analysis.

(3) - An assignment for antibiotics in ethanolic byproducts used in feeds/ingredients is planned, and may not issue, if not, use resources for metals/pesticides/dioxins, as needed.

EXPECT THREE CENTER ASSIGNMENTS:

a. Continuation of the assignment for collecting Direct Human Contact Feeds and analyzing for *Salmonella*. For more details please see the assignment.

b. A second micro assignment under 71003E will cover 100 milk replacers samples collected at commercial feed stores/mills, analyzing for *Salmonella*. 100 of the 200 milk replacers samples collected to be sent to CVM's Office of Research.

c. A 60 sample dioxin assgt, and inspection/collection assgts (expect ~90 samples), will issue pursuant to USDA 5 year Dioxin survey.

Workload source: FACTS database; firms in IND 69-72 with Workload Obligation of "YES" and Firm Status of "OPERATIONAL".

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Domestic	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="checked" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 36.8 [20.5]
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REGION	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC	DOMESTIC	DOMESTIC	DOMESTIC	DOMESTIC	DOMESTIC	DOMESTIC	METHODS	METHODS
		SAMPLES TO BE ANALYZED Metals 71003B	SAMPLES TO BE ANALYZED Mycology 71003C	SAMPLES TO BE ANALYZED Microbiology 71003E	SAMPLES TO BE ANALYZED Microbiology 71003E	SAMPLES TO BE ANALYZED Chemistry 71003A (4)	SAMPLES TO BE ANALYZED Dioxin 71003G (5)	SAMPLES TO BE ANALYZED Antibiotics 71003K	VAL/DEV CONTAM ID CHEM (Hours) 71003A (6)	VAL/DEV MICRO (Hours) 71003E (7)
	TOTAL FIELD	80	672	300	100	300	150	20	2065	1180

	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	18.0	11.0	13.0	13.0	6.6	30.0	23.0		
TOTAL HOURS	1440	7392	3900	1300	1980	4500	460	2065	1180
CONVERSION FACTOR	1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTES	1.22	6.26	3.31	1.10	1.68	3.81	0.39	1.75	1.00

7. REMARKS

Laboratory allocations were planned by ORS.

(4) - CHEM DSA to include Pesticides, Industrial Chemicals and Filth (290 samples for Pesticides & Industrial Chemicals plus 10 Filth samples for FY14)

(5) - Dioxin samples will be used for two assignments, 60 samples for a dioxin sampling assignment and 90 samples for a collection assignment to be issued pursuant with the USDA 5 year Dioxin survey.

(6) - 1.0 FTE will be devoted for method development for aflatoxins in DDGs, and the remaining 0.75 FTE for T-2 toxin and other trichothecene mycotoxins in animal feed.

(7) - Micro resources used for one research project: Development of an assay for serotyping *Salmonella Pullorum*, *Salmonella Gallinarum*, *Salmonella Enteritidis*, *Salmonella Choleraesuis*, *Salmonella Abortusovis*, *Salmonella Abortusequi*, *Salmonella Newport* or *Salmonella Dublin*.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Import	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 36.8 [7.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	4	4	6	8	8	8	8									
		IMPORT SAMPLE COLL (8)	IMPORT SAMPLE COLL Chem & Myco (9)	IMPORT SAMPLE COLL Micro 71003E	IMPORT SAMPLE COLL Antibiotics	IMPORT FIELD EXAMS	IMPORT SAMPLES TO BE ANALYZED Chem	IMPORT SAMPLES TO BE ANALYZED Micro (8)	IMPORT SAMPLES TO BE ANALYZED Antibiotics	IMPORT SAMPLES TO BE ANALYZED Myco									
	TOTAL FIELD	645	345	280	20	300	250	280	20	95									
	HEADQUARTERS	(b) (5), (b) (7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB	30																		
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
REGIONAL LAB	30																		
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY-SW																		
PACIFIC REGIONAL LABORATORY-NW	35																		
HOURS PER OPERATION											2.5				0.6	7.0	12.0	23.0	11.0
TOTAL HOURS											1613				180	1750	3360	460	1045
CONVERSION FACTOR		950				950	1180	1180	1180	1180									
TOTAL OPERATIONAL FTEs		1.70				0.19	1.48	2.85	0.39	0.89									

7. REMARKS

The shaded area serves as a guideline for districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.

(8) - Import Sample Collections and Analyses: 71003E, sample collections are for pig ears, pet treats, and pet foods as well as other animal feed ingredients.

(9) - 250 Import Sample Collections are for CHEM; and the remainder 95 are Myco.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) PACs 71004, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	7											
		FOREIGN INSPEC- TIONS	DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL GUIDANCE (CHEM)	DOMESTIC SAMPLES TO BE ANALYZED CHEM											
	TOTAL FIELD	4	141	60	15	15											
NE	HEADQUARTERS	(b) (5), (b) (7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
	HOURS PER OPERATION									50.0	28.0	7.8		25.0			
	TOTAL HOURS									200	3948	468		375			
	CONVERSION FACTOR									950	950	950		1180			
	TOTAL OPERATIONAL FTEs									0.21	4.16	0.49		0.32			

7. REMARKS

Resources are allocated for 15 physical samples, remaining resources may be used for the collection of documentary samples.

Non-potency feed sample analysis should be charged to 71003 A/E.

There are 309 State Contract inspections. Charge inspectional time for these contracts under 71S004.

Resources for audit inspections are in the BSE program (71009) under "Technical Support" hours.

Shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis. The remaining 45 collected samples are available for documentary collection.

Workload Source: CVM allocated the number of District Inspections to Districts based on their risk model for ranking firms.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71006, M	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 34.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	7	9	9					
		DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED CHEM	METHODS VAL/DEV CHEM	TECH SUPPORT	(Hours) (4)	(Hours) (5)			
TOTAL FIELD		600	930	100	100	360	1900					
	HEADQUARTERS	(b) (5), (b) (7)(E)										
	REGIONAL STAFF											
NE	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW											
	PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION		39.0	7.0	2.5	9.4							
TOTAL HOURS		23400	6510	250	940	360	1900					
CONVERSION FACTOR		950	950	950	1180	1180	950					
TOTAL OPERATIONAL FTEs		24.63	6.85	0.26	0.80	0.31	2.00					

7. REMARKS

The Center will issue FACTS assignments to request Federal inspections when the risk score of the residue reported by FSIS exceeds the annually calculated budget-defined risk-informed threshold. Districts may issue assignments as well, but because resources for this program are limited, Districts should discuss issuing other assignments with CVM to determine if they fall within CVM priorities.

(1) - Documentary samples collected during inspections.
 (2) - 100 Milk samples will be collected by the FDA; however, not for the purpose of the previous milk assignment begun in FY12.
 (3) - Planned analytical time may be converted to methods development (including bridging methods) per CVM's concurrence. Methods development work will be assigned by CVM.
 (4) - Additional time for methods validation and methods development studies. Report time under OP 3.
 (5) - Tech support hours include supporting state activities under Illegal Residues in Meat & Poultry and time for Tissue Residue Monitors.

Laboratory allocations were planned by ORS.

Workload Source: CVM allocated the number of Inspections and Sample Collections based on their risk model for ranking residue violations in this program.

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71009, 71R844, 71R843 (99R833, 71R833, 71R824)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 30.1 [27.0]
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REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	3	4	6	7	7
		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 FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (5)
	TOTAL FIELD	1105	1000	8440	1530	640	200	3200	425	215

	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	8.5				4.0	2.5	0.4	6.0	4.0
TOTAL HOURS	9393	1000	8440	1530	2560	500	1280	2550	860
CONVERSION FACTOR	950	950	1200	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs	9.89	1.05	7.03	1.61	2.69	0.53	1.35	2.16	0.73

7. REMARKS

(1) - Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills should be covered once per year and other establishment types handling or not handling prohibited material as specified in the inspectional priorities listed on the next page 71-13.

(2) - Domestic Investigation Hours are to be utilized 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 71R843 Operation 13 (Investigation Operations)

(3) - Reporting Guidance: Import Entry Review (Electronic and Manual—Operation Code 14, PAC 71R833); Filer Evaluations (Operation Code 95, PAC 99R833); and Follow-up to Refused Import Entries (PAC 71R824). Includes time for mail courier review.

(4) - Import Investigation Hours are for filer evaluations, follow-up to refusals, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate Operation and PAC for the activities performed.

(5) - Domestic sample analysis hours are split between chem (planned for 2/3 of analytical hours) and micro (planned for 1/3 of analytical hours), based on historical data. Laboratories may utilize chem and micro hours as needed.

Laboratory allocations were planned by ORS.

Workload Distribution: CVM allocated the number of Domestic Inspections to Districts based on their risk model for ranking firms in this program.

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) PACs 71009, 71R844, 71R843 (99R833, 71R833, 71R824)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 30.1 [3.1]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8. IMPORT SAMPLES TO BE ANALYZED CHEM	9. TECHNICAL SUPPORT (Hours) (6)							
	TOTAL FIELD	200	2248							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	4.3						
TOTAL HOURS	860	2248					
CONVERSION FACTOR	1180	950					
TOTAL OPERATIONAL FTEs	0.73	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, 71004. These hours also include resources for audits of state contract inspections.

Laboratory allocations were planned by ORS.

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program

2. PPS PROJECT NAME/NUMBER

Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

9. Remarks

Inspection Priorities.

The first inspectional priority under this program is to inspect those firms that have a violative history classified by the FDA "Official Action Indicated" or OAI. These inspections should be conducted with the intent that regulatory action will be pursued should the firm be unwilling or unable to take immediate actions to correct the violations. 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 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 with a violative history
- 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 FY 14 High Risk Feed Inspection Pilot Assignment (FSMA)	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71V030	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.2
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 HIGH RISK INSP EC- TIONS (1)							
	TOTAL FIELD	228							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	30.0							
	TOTAL HOURS	6840							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	7.20							

7. REMARKS
 (1) - Expect a high risk feed inspection pilot assignment to inspect such firms as salvagers, pet food/LACF manufacturers, unlicensed medicated/unmedicated feed mills, and feed ingredient manufacturers based on assignment questions related to manufacturing practices, flagged with a risk identifier, and a newly established PAC- 71V030 for FY14.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 METHODS VAL/DEV CHEM (Hours)	9 APPLIED TECHNOLOGY CENTER CHEM (Hours)					
	TOTAL FIELD	1205	4720					
	HEADQUARTERS	(b) (5), (b) (7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION								
TOTAL HOURS		1205	4720					
CONVERSION FACTOR		1205	1180					
TOTAL OPERATIONAL FTEs		1.00	4.00					

7. REMARKS
 Workload Source - Determined by Office of Regulatory Science

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)							
	TOTAL FIELD	1205							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		1205							
CONVERSION FACTOR		1205							
TOTAL OPERATIONAL FTEs		1.00							

7. REMARKS
 Workload Source - Determined by Office of Regulatory Science

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71V800, 71V022	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP CTIONS 71V022 (1)	3 INVESTI- GATIONS (Hours)	7 DOMESTIC LAB ANALYST CHEM				
	TOTAL FIELD	90	574	890				
	HEADQUARTERS	(b) (5), (b) (7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION		10.0						
TOTAL HOURS		900	574	890				
CONVERSION FACTOR		950	950	1180				
TOTAL OPERATIONAL FTEs		0.95	0.60	0.75				

7. REMARKS

These resources include time for investigating pet turtle establishments, and to inspect pharmacies compounding animal products. They also may be applied to sample collections and analyses when investigating adverse events.

71V800 Workload Source: Based the Feed Manufacturing, Feed Contaminants and Pre-Approval program inventories.

(1) - The FY14 Poultry Hatchery Assignment instructs the Field to inspect designated poultry hatcheries (chicken and turkey) for possible misuse/extralabel use of antimicrobials. Report Inspections under PAC 71V022 Op 12.

Laboratory allocations were planned by ORS.

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2014**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	176.1	58.1	42.8	277.0
81	POSTMARKET ASSURANCE: DEVICES	1.0			1.0
82	COMPLIANCE: DEVICES	102.7	50.0	37.0	189.7
83	PRODUCT EVALUATION: DEVICES	29.4		3.5	32.9
84	SCIENCE: DEVICES	7.9			7.9
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.5		0.1	14.6
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	20.6	8.1	2.2	30.9

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM/ASSIGNMENT CODE(S) 81010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	3	7	7	7
		INSPEC- TIONS (1)	INVESTI- GATIONS (Hours) (2)	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL STER	DOMESTIC SAMPLE COLL ENG	DOMESTIC SAMPLES TO BE ANALYZED CHEM (3)	DOMESTIC SAMPLES TO BE ANALYZED STER (4)	DOMESTIC SAMPLES TO BE ANALYZED ENG (5)
	TOTAL FIELD	45	40	1	1	1	1	1	1
	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	18.0	40	8.0	8.0	8.0	36.0	20.0	37.0
TOTAL HOURS	810	40	8	8	8	36	20	37
CONVERSION FACTOR	950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs	0.85	0.04	0.01	0.01	0.01	0.03	0.02	0.03

9. REMARKS

(1)-Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.

(2)-Investigational hours for MDR followup at medical facilities.

(3)-Performance testing of chemical and serological test kits.

(4)-Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.

(5)-MDR samples to confirm reported defects.

PROJECT SUMMARY SHEET

FY 2014

1. PROGRAM CATEGORY Medical Devices and Radiological Health		2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
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		102.7	50.0	37.0	189.7	
1	Monitoring Devices of Foreign Origin - Import	82008*		44.0		44.0	82-4-5
2	Inspection of Medical Device Manufacturers:		95.1		37.0	132.1	82-6-8
	GMP Inspections	82845A-S	(94.4)		(37.0)	(131.4)	
	Accredited Persons Audit Investigations	82845J	(0.2)			(0.2)	
	Accredited Persons Audit Inspections	82845P	(0.5)			(0.5)	
3	Condom Assignment	82Z002		2.0		2.0	82-9
4	Manufacturers and Importers of Surgical/Examination Gloves	82Z003		4.0		4.0	82-10
5	Center Initiated Assignments	82Z800	5.3			5.3	82-11
6	Methods Validation/Development Program	82R816	2.0			2.0	82-12
7	Forensic Evaluation & Sample Analysis	82R838	0.3			0.3	82-13
	* In addition to PAC 82008, includes reporting PACs 82R824, 82R833, and 99R833.						

CENTER PROJECT MANAGER/TELEPHONE Steven Silverman 301-796-5500	ORA PLANNER/TELEPHONE John Aydinian 301-796-4394
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1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 44.0 [43.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	4	6	8	8
		ENTRY REVIEW (Hours)	IMPORT INVESTI- GATION HOURS (1)	IMPORT EXPRESS MAIL COURIER REVIEW	INTERNATIONAL MAIL FACILITY REVIEW	IMPORT SAMPLE COLL (Physical) MICRO (2)	IMPORT SAMPLE COLL (Physical) ENG	IMPORT FIELD EXAMS	IMPORT SAMPLES TO BE ANALYZED MICRO (3)	IMPORT SAMPLES TO BE ANALYZED ENG
	TOTAL FIELD	26217	3912	2201	300	60	120	20900	60	150
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION						2.2	2.2	0.4	30.4	30.4
TOTAL HOURS		26217	3912	2201	300	132	264	8360	1824	4560
CONVERSION FACTOR		1200	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		21.85	4.12	2.32	0.32	0.14	0.28	8.80	1.55	3.86
9. REMARKS (1)-Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams are planned in a separate column. (2)-Audit samples for problems other than failure to register or list (eg. special assignment, import alert). (3)-Sterile devices to be tested by USP XX method. Reporting Guidance: - Import Entry Reviews (Electronic and Manual--operation code 14, PAC 82R833); - Filer Evaluations (operation code 95, PAC 99R833); and - Follow-up to Refusals (PAC 82R824). Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.										

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 44.0 [0.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED CHEM							
	TOTAL FIELD	30							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		30.5							
TOTAL HOURS		915							
CONVERSION FACTOR		1180							
TOTAL OPERATIONAL FTEs		0.78							

9. REMARKS									
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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,H,J,K,P,S,81845R,T,81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 132.1 [126.4]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	1	1
		INSPEC- TIONS LEVEL I DOMESTIC CLASS 1 82845A	INSPEC- TIONS LEVEL I DOMESTIC 82845A	INSPEC- TIONS LEVEL II DOMESTIC 82845B	INSPEC- TIONS LEVEL III COMPLIANCE DOMESTIC 82845C	INSPEC- TIONS FOREIGN 82845B	INSPEC- TIONS FOR CAUSE DOMESTIC 82845G	INSPEC- TIONS FOR CAUSE HIGH RISK DOMESTIC 82845H	INSPEC- TIONS FOR CAUSE HIGH RISK FOREIGN 82845H	INSPEC- TIONS ACCRED PERSONS DOMESTIC 82845P
	TOTAL FIELD	108	588	451	124	467	115	42	47	9

	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	39.6	39.6	63.2	115.0	65.1	85.9	101.7	101.0	53.0
TOTAL HOURS	4277	23285	28503	14260	30402	9879	4271	4747	477
CONVERSION FACTOR	950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs	4.50	24.51	30.00	15.01	32.00	10.40	4.50	5.00	0.50

9. REMARKS

NEW For FY 2014, CDRH has requested ORA conduct a limited number of Class I medical device inspections as a result of an increasing number of recalls by Class I device firms and inconsistencies in their device registration and listing information. CDRH has also noted that some Class II and Class III device firms that are inspected every 2-5 years as part of the Performance Goal (PG) are consistently NAI and those resources could be better used in inspecting a select number of higher risk Class I device firms. CDRH has prepared a list of Class I firms for each District based on risk. Where CDRH has available data, the last inspection date and multiple PACs have been provided. Each District will receive a final list with more Class I firms than planned from which they can choose which Class I firms to inspect based on their OEI information. This would also allow for a 'washout' or other problem that may occur with a firm selected by the District. With more firms on the list that are planned for inspection, there would be no need to call CDRH to make a substitution.

In the FY 2014 Workplan, there is a separate column for each Districts' assigned Level I, Class I PAC 82845A inspections and another column for the Level I, Class II, III PAC 82845A inspections. As specified in the CPGM 7382.845- Level 1 inspections, this level of inspection (CAPA plus P&PC or Design Controls) may be used for routine surveillance and initial inspections of all firms, other than firms that manufacture Class III devices.

Inspections conducted at these Class I firms will count towards the FY14 CDRH Performance Goal. Note however that this change will not result in any increase to your Performance Goal obligations as these Class 1 firms will be inspected in place of lower risk or consistently NAI Class II firms.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,H,J,K,P,S,81845R,T,81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 132.1 [2.2]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	3	3	3	3	3	3	3
		INVESTIGATIONS (Hours) 82845B	INVESTIGATIONS (Hours) A.P. AUDITS MDUFMA 82845J	DOMESTIC SAMPLE COLL 82845C	DOMESTIC SAMPLE COLL ENG 82845C	DOMESTIC SAMPLE COLL MICRO 82845C	DOMESTIC SAMPLE COLL CHEM 82845C	DOMESTIC SAMPLE COLL 82845H	DOMESTIC SAMPLE COLL 82845S	DOMESTIC SAMPLE COLL BIOBURDEN BIOINDIC'R 82845S
	TOTAL FIELD	1516	190	42	10	26	6	12	15	10

	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF	(b) (5), (b) (7)(E)								
	NEW ENGLAND	(b) (5), (b) (7)(E)								
	NEW YORK	(b) (5), (b) (7)(E)								
	REGIONAL LAB	(b) (5), (b) (7)(E)								
	WEAC	(b) (5), (b) (7)(E)								
CE	REGIONAL STAFF	(b) (5), (b) (7)(E)								
	BALTIMORE	(b) (5), (b) (7)(E)								
	CHICAGO	(b) (5), (b) (7)(E)								
	CINCINNATI	(b) (5), (b) (7)(E)								
	DETROIT	(b) (5), (b) (7)(E)								
	MINNEAPOLIS	(b) (5), (b) (7)(E)								
	NEW JERSEY	(b) (5), (b) (7)(E)								
	PHILADELPHIA	(b) (5), (b) (7)(E)								
SE	FORENSIC CHEM. CTR	(b) (5), (b) (7)(E)								
	REGIONAL STAFF	(b) (5), (b) (7)(E)								
	ATLANTA	(b) (5), (b) (7)(E)								
	FLORIDA	(b) (5), (b) (7)(E)								
	NEW ORLEANS	(b) (5), (b) (7)(E)								
	SAN JUAN	(b) (5), (b) (7)(E)								
SW	REGIONAL LAB	(b) (5), (b) (7)(E)								
	REGIONAL STAFF	(b) (5), (b) (7)(E)								
	DALLAS	(b) (5), (b) (7)(E)								
	DENVER	(b) (5), (b) (7)(E)								
	KANSAS CITY	(b) (5), (b) (7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b) (5), (b) (7)(E)								
	REGIONAL LAB	(b) (5), (b) (7)(E)								
	REGIONAL STAFF	(b) (5), (b) (7)(E)								
	LOS ANGELES	(b) (5), (b) (7)(E)								
	SAN FRANCISCO	(b) (5), (b) (7)(E)								
	SEATTLE	(b) (5), (b) (7)(E)								
	PACIFIC REGIONAL LABORATORY-SW	(b) (5), (b) (7)(E)								
	PACIFIC REGIONAL LABORATORY-NW	(b) (5), (b) (7)(E)								

HOURS PER OPERATION			6.0				6.0	4.0	
TOTAL HOURS	1516	190	252				72	60	
CONVERSION FACTOR	950	950	950				950	950	
TOTAL OPERATIONAL FTEs	1.60	0.20	0.27				0.08	0.06	

9. REMARKS

The hours/operation module for Level I inspections has been planned at 39.6 hours/operation to include additional time for MDR review. Level II inspection hours/operation modules have also been adjusted to reflect actual work. Quality Systems Inspection Technique (QSIT) Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G,H) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "For Cause" inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Reprogram any unused resources into Level 1 and 2 inspections. Inspectional modules include time for Sterilization (82845S), MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections. Investigational Hours resources have also been planned for National Experts (HQ line) and State Contract Monitoring (DAL-DO line). Foreign inspections include resources for Level I, II, III, and For Cause-related inspections. For planning purposes Foreign inspections will be planned under the Level II inspection PAC (82845B); use the appropriate reporting PAC to record accomplishments associated with these Foreign inspections. The Headquarters line includes 30 Foreign National Expert and 146 Foreign Cadre inspections. Accredited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program. Accredited Person Audits are conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO. NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,H,J,K,P,S,81845R,T,81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 132.1 [3.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL STERILITY 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845H	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82845S									
	TOTAL FIELD	5	10	26	6	12	10	5									
	HEADQUARTERS	(b) (5), (b) (7)(E)															
NE	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
FORENSIC CHEM. CTR																	
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
SW	REGIONAL LAB																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
PA	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
HOURS PER OPERATION			80.0	62.0	38.0	88.3	25.0	29.5									
TOTAL HOURS			800	1612	228	1060	250	148									
CONVERSION FACTOR			1180	1180	1180	1180	1180	1180									
TOTAL OPERATIONAL FTEs			0.68	1.37	0.19	0.90	0.21	0.13									

9. REMARKS
MICRO Sample Analyses: Antisera and Products Media Testing to support GMP observations at WEAC; Disinfectant/Cold Sterilant Testing at WEAC Lab.

CHEM Sample Analyses: Test Kit or Reagent Testing to support GMP observations at WEAC; Sporicidal and Tuberculocidal at WEAC Lab.

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	4 IMPORT SAMPLE COLL (Physical) CHEM	4 IMPORT SAMPLE COLL (Physical) ENG	8 IMPORT SAMPLES TO BE ANALYZED (Physical) CHEM	8 IMPORT SAMPLES TO BE ANALYZED (Physical) ENG			
	TOTAL FIELD	1	127	77	127	77			
	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	20.0	2.7	2.7	8.1	8.1			
TOTAL HOURS	20	343	208	1029	624			
CONVERSION FACTOR	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs	0.02	0.36	0.22	0.87	0.53			

9. REMARKS
 Import Samples are estimated and should be collected to cover the districts' workload.
 Resources for Condom Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin. Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z003, 82R320	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	8	8	9			
		IMPORT SAMPLE COLL (Physical) CHEM	IMPORT SAMPLE COLL (Physical) ENG	IMPORT SAMPLES TO BE ANALYZED (Physical) CHEM	IMPORT SAMPLES TO BE ANALYZED (Physical) ENG	IMPORT PRIVATE LAB REVIEW (Hours)			
	TOTAL FIELD	250	190	250	190	1180			
	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	2.2	2.2	5.3	5.3				
	TOTAL HOURS	550	418	1325	1007	1180			
	CONVERSION FACTOR	950	950	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	0.58	0.44	1.12	0.85	1.00			

9. REMARKS

Resources to cover Glove Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin.

Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).

Private Laboratory Review Time is planned under PAC 82R320. Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field. Without this consistency in reporting, your time will not be found and credited for future workplan FTE allocations.

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z005, 82Z800	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS CENTER- INITIATED 82Z800	3 DOMESTIC SAMPLE COLL (1) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY (3) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82Z800	9 OTHER OPER- ATIONS (Hours) ENG (5) 82Z800		
	TOTAL FIELD	25	50	5	11	15	11	1600		

	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	54.0	8.0	15.0	50.0	50.0	100.0		
TOTAL HOURS	1350	400	75	550	750	1100	1600	
CONVERSION FACTOR	950	950	1180	1180	1180	1180	1180	
TOTAL OPERATIONAL FTEs	1.42	0.42	0.06	0.47	0.64	0.93	1.36	

9. REMARKS
 Planned BSE Inspections (82Z005) were cancelled in FY 2008; PAC will remain active for reporting purposes and any Center-Initiated Assignments involving BSE should be reported in PAC 82Z005.

(1)-Includes Documentary Samples and Analytical Samples.
 (2)-WEAC--Ad Hoc testing of test kits or reagents.
 (3)-WEAC--Sterility samples.
 (4)-WEAC--Ad Hoc testing of media.
 (5)-WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 METHODS VAL/DEV CHEM (Hours)	9 METHODS VAL/DEV MICRO (Hours)							
	TOTAL FIELD	1205	1205							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		1205	1205							
CONVERSION FACTOR		1205	1205							
TOTAL OPERATIONAL FTEs		1.00	1.00							

9. REMARKS
 Workload Source: Determined by Office of Regulatory Science.

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC ANALYSIS CHEM (Hours)							
	TOTAL FIELD	360							
NE	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION									
TOTAL HOURS	360								
CONVERSION FACTOR	1205								
TOTAL OPERATIONAL FTEs	0.30								

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83001, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS MDUFMA USER FEE 83001	1 FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	1 INSPEC- TIONS POST- APPROVAL 83001A	1 FOREIGN INSPEC- TIONS POST- APPROVAL 83001A				
	TOTAL FIELD	67	22	34	19				

	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	70.9	49.0	33.8	44.0				
TOTAL HOURS	4750	1078	1149	836				
CONVERSION FACTOR	950	950	950	950				
TOTAL OPERATIONAL FTEs	5.00	1.13	1.21	0.88				

9. REMARKS

Report all time used for evaluating compliance with domestic pre-market requirements in PAC 83001, OP CODE 12; report all time used for domestic post-market requirements in PAC 83001A, OP CODE 12.

Report all time used for evaluating compliance with foreign pre-market requirements in PAC 83001, OP CODE 11; report all time used for foreign post-market requirements in PAC 83001A, OP CODE 11.

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 24.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN							
	TOTAL FIELD	300	19							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	73.5	75.5							
TOTAL HOURS	22050	1435							
CONVERSION FACTOR	950	950							
TOTAL OPERATIONAL FTEs	23.21	1.51							

9. REMARKS

Device Bioresearch Monitoring inspections should be prioritized according to the following scheme:

- For Cause with 30-day due dates;
- Directed data audit for expedited PMA;
- Directed data audit for non-expedited PMA;
- For Cause with 60-90 day due dates;
- OAI Follow-up (6 months);
- Early Intervention (Probability Sampling, Vulnerable Population, and IDE-based);
- Routine Surveillance.

Please contact Ruth Hinckley (301-796-5658) or Jim Saviola (301-796-5432) with any questions.

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84Z002	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) METH DEV ENG							
	TOTAL FIELD	6962							
	HEADQUARTERS	(b) (5), (b) (7) (E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		6962							
CONVERSION FACTOR		1180							
TOTAL OPERATIONAL FTEs		5.90							

9. REMARKS
 Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by the CDRH Laboratory Staff.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 APPLIED TECHNOLOGY CENTER (Hours) MICRO							
	TOTAL FIELD	2360							
	HEADQUARTERS	(b) (5),							
	REGIONAL STAFF	(b) (7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		2360							
CONVERSION FACTOR		1180							
TOTAL OPERATIONAL FTEs		2.00							

9. REMARKS
 Workload Source: Determined by Office of Regulatory Science.

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program			2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85							
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 14.6 [10.5]		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	9	9
		INSP CTIONS 85014 (1)	INSP CTIONS FOREIGN 85014 (2)	INSP CTIONS 85014 (3)	INSP CTIONS 85014 (4)	INSP CTIONS 85014F (5)	INSP CTIONS 85014F (6)	INVESTI GATIONS (Hours) 85014A (7)	OTHER OPERA TIONS (Hours) 85014C (8)	OTHER OPERA TIONS (Hours) 85014C (9)
TOTAL FIELD		525	14	118	47	9	9	2222	2996	1200
HEADQUARTERS		(b) (5), (b) (7)(E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.0	8.0	8.0	8.0	11.0	11.0			
TOTAL HOURS		4200	112	944	376	99	99	2222	2996	1200
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1200
TOTAL OPERATIONAL FTEs		3.62	0.10	0.81	0.32	0.09	0.09	1.92	2.58	1.00

7. REMARKS
 RRRHs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS
 (1) - Inspection of Certified Mammography Facilities not covered by the states.
 (2) - Inspection of Domestic Establishment Mammography Facilities in Foreign Countries.
 (3) - Federal Facility Inspections (does not include VHA Facility inspections).
 (4) - VHA Facility Inspections.
 (5) - Follow-up Inspections.
 (6) - Follow-up Inspections after Warning Letter.
 (7) - Audit Investigations.
 (8) - Compliance Activities: Inspection Follow-Up Activities (Non-Warning Letter).
 (9) - Technical Assistance and Coordination Activities: RRRHs.

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [4.1]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERA- TIONS (Hours) 85014C (10)	9 OTHER OPERA- TIONS (Hours) 85014C (11)					
	TOTAL FIELD	4655	59					
	HEADQUARTERS	(b) (5), (b) (7)(E)						
	REGIONAL STAFF							
NE	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
	REGIONAL STAFF							
CE	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							

HOURS PER OPERATION							
TOTAL HOURS	4655	59					
CONVERSION FACTOR	1160	1160					
TOTAL OPERATIONAL FTEs	4.01	0.05					

7. REMARKS
 RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS
 (10) - Technical Assistance and Coordination Activities: non-RRHRs.
 (11) - Compliance Activities: Warning Letters.

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.0 [4.3]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2		3	5	5
		INSPEC- TIONS 86001 (1)	INSPEC- TIONS FOREIGN 86001 (2)	INSPEC- TIONS 86002 (3)	INSPEC- TIONS 86004 (4)	INVESTI- GATIONS (Hours) 86001 (5)	INVESTI- GATIONS (Hours) 86004	DOMESTIC SAMPLE COLL 86001	FIELD EXAMS/ TESTS 86001 (6)	FIELD EXAMS/ TESTS 86002 (7)
TOTAL FIELD		105	30	3	22	350	30	5	75	30
HEADQUARTERS		(b) (5), (b) (7)(E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		17.3	36.0	36.0	20.0			3.0	5.0	4.4
TOTAL HOURS		1817	1080	108	440	350	30	15	375	132
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		1.91	0.92	0.11	0.46	0.37	0.03	0.02	0.39	0.14

7. REMARKS

Laser products (86001): (1) - Inspections should be conducted on manufacturers of Class IIIb and Class IV products. Medical laser systems should be highest priority, followed by industrial, and commercial lasers (including laser light shows) or inspections directed based on a for cause request. For medical lasers, a joint QSIT and electronic product radiation control inspection should be conducted. (2) - Number of inspections to be conducted by WEAC Analysts and other EOS Specialists. (5) - Investigation Hours-refer to Compliance Program for reporting information. (6) - Field tests may be conducted for any laser products located at a user facility, following the same priority scheme as for inspections. (Class IIIb or IV medical, industrial and commercial lasers, including laser light show projectors).

Sunlamps and sunlamp products (86002): (3) - Inspectional figures are only for biennial or for cause inspections of manufactures of sunlamp products (e.g. sunlamps, booths, or beds). Because sunlamp products are also medical devices, a joint QSIT and electronic product radiation control inspection should be conducted. Examination of sunlamp products at a user facility (e.g. tanning parlor, athletic club) are NOT counted as inspections because they are field tests. (7) - Each sunlamp product tested may be counted as a separate field test, even if located in a single facility. NOTE: RRHR's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

Cabinet x-ray products (86004): (4) - Cabinet x-ray manufacturer inspections are to be comprehensive electronic product radiation control inspections. Cabinet x-ray field tests are no longer to be performed routinely under this program. The hours previously associated with field tests have been reprogrammed to inspections.

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
--	--

3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0 [1.7]
--	--	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPER- ATIONS (Hours) 86001 (8)	9 OTHER OPER- ATIONS (Hours) 86002	OEI IMPROVE- MENT (Hours) (9)					
	TOTAL FIELD	750	75	760					
	HEADQUARTERS	(b) (5), (b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		750	75	760					
CONVERSION FACTOR		950	950	950					
TOTAL OPERATIONAL FTEs		0.79	0.08	0.80					

7. REMARKS

Laser products (86001):
 (8) - To include all other activities such as technical assistance, coordination, and training.
 (9) - OEI Improvement Hours will be used for OEI Improvement Activities of EPRC Firms across PACS 86001, 86002, 86003, and 86004

Counter Terrorism PAC 86R845 is no longer used for planning purposes, but is still active for reporting purposes.

1. PROGRAM/ASSIGNMENT TITLE Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 8.7 [6.9]			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2	2	5	5B	5
		INSP CTIONS DOMESTIC (1)	INSP CTIONS FOREIGN (2)	INSP CTIONS DIRECTED (3)	INSP CTIONS (4)	INVEST IGATIONS (Hours) (5)	INVEST IGATIONS (Hours) (6)	FIELD EXAMS/ TESTS (7)	AUDITS (7)	FIELD EXAMS/ TESTS ENG
TOTAL FIELD		52	15	5	18	884	1051	295	30	50
HEADQUARTERS		(b) (5), (b) (7)(E)								
REGIONAL STAFF										
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		40.0	65.0	40.0	16.0			3.0	4.0	3.0
TOTAL HOURS		2080	975	200	288	884	1051	885	120	150
CONVERSION FACTOR		950	950	950	950	950	950	950	950	1180
TOTAL OPERATIONAL FTEs		2.19	1.03	0.21	0.30	0.93	1.11	0.93	0.13	0.13

7. REMARKS

(1) - Domestic inspections to be conducted based on the OEI of diagnostic x-ray equipment manufacturers. Joint QSIT and electronic product radiation control inspections should be conducted if possible.

(2) - Foreign inspections should be joint QSIT and electronic product radiation control inspections if possible.

(3) - Directed Inspections based on the OEI of diagnostic x-ray equipment manufacturers.

(4) - Inspections based on the OEI of diagnostic x-ray equipment assemblers.

(5) - Investigation hours for review and planning of activities under columns 1 (Domestic), 2 (Foreign), and 3 (Directed) Inspections.

(6) - Investigation hours for review of 2579 forms (reports of assembly) in preparation for performing field tests and field test follow up activities.

(7) - Field tests and audits are obtained from Attachment A and provided by CDRH's OCER/DMQRP Diagnostic Devices Branch, HFZ-240. Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor.

1. PROGRAM/ASSIGNMENT TITLE Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.7 [1.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERA- TIONS (Hours) (8)	OEI IMPROVE- MENT (Hours) (9)							
	TOTAL FIELD	965	760							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION									
TOTAL HOURS	965	760							
CONVERSION FACTOR	950	950							
TOTAL OPERATIONAL FTEs	1.02	0.80							

7. REMARKS
 (8) - Coordination/technical assistance hours for field test activities.
 (9) - OEI Improvement Hours are to be used for OEI Improvement Activities of EPRC firms across PACS 86001, 86002, 86003, and 86004.

**ATTACHMENT A - 2014 WORKPLAN
INSPECTIONS OF MANUFACTURERS (FOREIGN AND
DOMESTIC) AND FIELD COMPLIANCE TESTING
OF DIAGNOSTIC X-RAY EQUIPMENT**

NEW ENGLAND DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed	Tests	F/U	
CT	(b) (5), (b) (7)(E)			
ME				
MA				
NH				
RI				
VT				
Total				

NEW YORK DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed	Tests	F/U	
NY	(b) (5), (b) (7)(E)			

CE REGIONAL STAFF (STATES IN BALTIMORE DISTRICT)

State	Number	FDA	FDA	Audits
	Systems Installed	Tests	F/U	
DC	(b) (5), (b) (7)(E)			
MD				
VA				
WV				
Total				

CE REGIONAL STAFF (STATES IN CHICAGO DISTRICT)

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
IL	(b) (5), (b) (7)(E)			

CE REGIONAL STAFF (STATES IN CINCINNATI DISTRICT)

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
KY	(b) (5), (b) (7)(E)			
OH				
Total				

CE REGIONAL STAFF (STATES IN DETROIT DISTRICT)

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
IN	(b) (5), (b) (7)(E)			
MI				
Total				

CE REGIONAL STAFF (STATES IN MINNEAPOLIS DISTRICT)

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
MN	(b) (5), (b) (7)(E)			
ND				
SD				
WI				
Total				

CE REGIONAL STAFF (STATES IN NEW JERSEY DISTRICT)

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
NJ	(b) (5), (b) (7)(E)			

CE REGIONAL STAFF (STATES IN PHILADELPHIA DISTRICT)

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
DE	(b) (5), (b) (7)(E)			
PA				
Total				

ATLANTA DISTRICT

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
GA	(b) (5), (b) (7)(E)			
NC				
SC				
Total				

FLORIDA DISTRICT

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
FL	(b) (5), (b) (7)(E)			

NEW ORLEANS DISTRICT

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
AL	(b) (5), (b) (7)(E)			
LA				
MS				
TN				
Total				

SAN JUAN DISTRICT

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
PR	(b) (5), (b) (7)(E)			

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
AR	(b) (5), (b) (7)(E)			
OK				
TX				
Total				

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
CO	(b) (5), (b) (7)(E)			
NM				
UT				
WY				
Total				

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
IA	(b) (5), (b) (7)(E)			
KS				
NE				
MO				
Total				

LOS ANGELES DISTRICT

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
AZ	(b) (5), (b) (7)(E)			
CA				
Total				

SAN FRANCISCO DISTRICT

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
CA	(b) (5), (b) (7)(E)			
HI				
NV				
Total				

SEATTLE DISTRICT

State	Number	FDA Tests	FDA F/U	Audits
	Systems Installed			
AK	(b) (5), (b) (7)(E)			
ID				
MT				
OR				
WA				
Total				

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86006 A,D,E	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC- TIONS PL 90- 602 STANDARD	7 DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	7 DOMESTIC SAMPLES TO BE ANALYZED NON-MED LASERS	7 DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS			
	TOTAL FIELD	5	61	4	42	10			

	HEADQUARTERS	(b) (5), (b) (7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								

HOURS PER OPERATION	68.0	18.0	345.0	15.0	25.0			
TOTAL HOURS	340	1098	1380	630	250			
CONVERSION FACTOR	1180	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs	0.29	0.93	1.17	0.53	0.21			

7. REMARKS

Workplan includes both foreign inspection and laboratory testing activities for electronic products.

(b) (5), (b) (7)(E) For any inspections of radiation-emitting medical device manufacturers, a joint QSIT and electronic product radiation control inspection should be conducted by a trained investigator. Instructions for performing inspections are provided in Compliance Program 7386.001, with time reported under PAC 86006.

Report time for specific lab analyses under PAC 86006, using the appropriate column and an accurate description of the type of product tested (e.g. hand-held laser product, mobile diagnostic x-ray system, household microwave oven) in FACTS.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INV (Hours) (1)	4 IMPORT FIELD EXAMS	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED ENG				
	TOTAL FIELD	6515	1400	400	50	50				
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION				0.7	2.8	17.0				
TOTAL HOURS		6515	1400	280	140	850				
CONVERSION FACTOR		1200	950	950	950	1180				
TOTAL OPERATIONAL FTEs		5.43	1.47	0.29	0.15	0.72				

7. REMARKS

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

Reporting Guidance:
 Import Entry Reviews (Electronic and Manual--operation code 14, PAC 86R833)
 Filer Evaluations (operation code 95, PAC 99R833); and
 Follow-up to Refusals (PAC 86R824).

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9									
		MISC (Hours) RRHR 86008 (1)	TECHNICAL ASSISTANCE (Hours) RRHR 86009									
	TOTAL FIELD	3600	2400									
	HEADQUARTERS	(b) (5), (b) (7)(E)										
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
FORENSIC CHEM. CTR												
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW											
	PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION												
TOTAL HOURS		3600	2400									
CONVERSION FACTOR		1200	1200									
TOTAL OPERATIONAL FTEs		3.00	2.00									

7. REMARKS
 See Continuation Sheet for footnotes, guidance, etc.

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

Radiation Control and Health Safety Act (RCHSA)
Authority - 86

7. Remarks

FOOTNOTES FOR MEDICAL DEVICE AND RAD HEALTH USE CONTROL & POLICY IMPLEMENTATION ACTIVITIES (86008):

(1) - RRHR time for CDRH programs is planned under this program, the Emergency Response and Planning Activities program, and the Mammography Facilities Inspection Program; 1200 hours will be shown in Mammography. A portion of this total block of time per RRHR position includes Federal/State liaison activities and use consultation to conduct this program.

This block of time also includes coordination, technical assistance, and other activities performed by RRHRs under the following programs:

- Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended (PAC 86002);
- Field Compliance Testing of Diagnostic X-Ray Equipment (PAC 86003);
- Field Compliance Testing of Cabinet X-Ray Equipment (PAC 86004);
- Medical Device and Radiological Health Use Control and Policy Implementation (PAC 86008);
- Emergency Planning and Response Activities (PAC 86009);

Any time in excess of 0.5 hours used for these programs should be reported into FACTS against the applicable PAC.

FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):

Technical Assistance hours will be performed by RRHRs.

Program activities include: providing technical assistance to state and local agencies regarding emergency response planning; reviewing and evaluating emergency plans related to nuclear power plants.

**CENTER FOR TOBACCO
RESOURCE SUMMARY
FY 2014**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	24.5	3.5		28.0
96	REGULATED TOBACCO PRODUCTS: DOMESTIC AND IMPORT	24.5	3.5		28.0

1. PROGRAM/ASSIGNMENT TITLE Regulated Tobacco Products: Domestic and Import	2. PPS PROJECT NAME/NUMBER Tobacco - 96
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3. PROGRAM/ASSIGNMENT CODE(S) 96R800, 96T800, 96R824, 96R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 28.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PRE- APPROVAL INSP EC- TIONS DOMESTIC (1)	1 INSP EC- TIONS DOMESTIC (2)	1 INSP EC- TIONS ASSIGN- MENTS DOMESTIC (1)	2 INVESTI- GATIONS (Hours) (3)	2 IMPORT INVESTI- GATIONS (Hours) (4)	2 IMPORT ENTRY REVIEW (Hours) (5)	3 DOMESTIC SAMPLE COLL (5)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (6)	9 METHODS VAL/DEV CHEM (Hours) (6)
	TOTAL FIELD	5	40	15	665	950	3000	30	10	23402
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALT MORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	65.0	65.0	65.0					6.0	9.9	
TOTAL HOURS	325	2600	975	665	950	3000	180	99	23402	
CONVERSION FACTOR	950	950	950	950	950	1200	950	1180	1205	
TOTAL OPERATIONAL FTEs	0.34	2.74	1.03	0.70	1.00	2.50	0.19	0.08	19.42	

7. REMARKS

(1) - The Domestic Pre- Approval and Inspection Assignment columns represent the Center's potential need for Inspections. There may not be any Pre-Approval Inspections conducted in the FY.

(2) - Represents the locations of half the registered tobacco facilities. FDA is required to inspect each registered facility at least once in a two year period.
 Note 1: All Inspections are to be conducted by investigators trained in tobacco regulation and not all Districts have such investigators. Additionally, ORA plans to implement a dedicated Tobacco Cadre to report to ORA Headquarters within this FY. Therefore, a tobacco-trained investigator may perform a tobacco Inspection in other Districts.
 Note 2: Inspectional module includes time for label exams to be conducted on inspections. Please refer to the Assignment Memo when issued for more detailed guidance.

(3) - Represents assignments that include complaint follow-up, smokeless free sample events, and other similar investigative assignments.

(4) - Includes Import Assignments for Label Exams.

(5) - Represents samples that may be collected during an Inspection, Investigation, or Sample Assignments.

(6) - The total hours allocated for FCC equal 6.5 FTEs and SRL equals 13.0 FTEs.

Program Description Reports
Table of Contents
FY2014

PROGRAM CENTER	PAGE NO.
CENTER FOR FOOD SAFETY & APPLIED NUTRITION	FC1-FC32
CENTER FOR BIOLOGICS EVALUATION & RESEARCH	BI1-BI13
CENTER FOR DRUG EVALUATION & RESEARCH	HD1-HD29
CENTER FOR VETERINARY MEDICINE	AD1-AD12
CENTER FOR DEVICES & RADIOLOGICAL HEALTH	DE1-DE18
CENTER FOR TOBACCO	TP-1

<p>1. PROGRAM/ASSIGNMENT TITLE Imported Acidified & Low Acid Canned Foods PACs 03003,A</p>	<p>2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03</p>
<p>3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES To detain Acidified and Low-Acid Canned Food which are packed in food canning establishments not in compliance with 21 CFR 108, 113, and 114.</p> <p>Resources for foreign inspections are planned under PAC 03R233.</p>	
<p>5. PROGRAM JUSTIFICATION Acidified and Low-Acid Canned Foods continue to be the source of sporadic problems from improper processing (e.g., under-processing, inadequate pH or Aw control, leakage). Inspections of foreign firms have shown many firms (and their products) to be out of compliance with CFR Parts 108, 113, and 114.</p> <p>The number of foreign AF/LACF firms submitting registration has been increasing significantly each year.</p>	
<p>6. FIELD OBLIGATIONS The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements. All import field exams are to routinely include: pH determination, can examination and verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc); and traditional safety concerns. See the full program for more detail.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED</p> <p style="text-align: center;"> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH </p>	
<p>b. INSPECTION TYPE</p> <p style="text-align: center;"> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED </p>	
<p>c. PRODUCT(S) Refer to Compliance Program (7303.003)</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 03, 04, 09, 12-18, 20-25, 27, 29, 30, 31, 33-41</p>
<p>e. EXAM TYPE</p> <p style="text-align: center;"> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>) </p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES pH, Water Activity, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program</p>	

1. PROGRAM/ASSIGNMENT TITLE Domestic & Imported Cheese & Cheese Products. PACs 03037,B,D		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections of domestic and foreign cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered. Inspection and analytical resources have been planned separately for outbreak and emergency operations (PAC 03R839) and foreign inspections (03R233).			
5. PROGRAM JUSTIFICATION Cheese and cheese products have been demonstrated to contain pathogenic microorganisms that can cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.			
6. FIELD OBLIGATIONS The field is requested to conduct inspections of domestic and foreign cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings. The field is also requested to conduct sample collections and analyses of imported cheese focusing on soft cheese as high priority. Refer to the instructions in the Compliance Program regarding the collection of domestic samples not resulting from inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Hard and soft cheeses.		d. INDUSTRY/PRODUCT CODE(S) 12	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES <i>Salmonella</i> , <i>Listeria</i> , <i>E. coli</i> , <i>Enterotoxigenic E. Coli</i> (ETEC), <i>Enterohemorrhagic E. Coli</i> EHEC 0157:H7 - <i>S. aureus</i> , Phosphatase, and Filth.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified & Low-Acid Canned Foods PAC 03803A	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine if the firms comply with 21 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act. To perform inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods. A continued priority will remain with out-of-compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Please refer to the compliance program for instructions.	
5. PROGRAM JUSTIFICATION Low-Acid Canned Foods: Inspections conducted in prior year's programs have demonstrated that the degree of compliance with low-acid canned food regulations relate directly to the degree of freedom from hazard to consumers found in the food produced. High risk industry segments, identified under previous programs, as well as re-inspection of the remaining portions of the industry are needed to establish and maintain compliance with the low-acid canned food regulations. Acidified Foods: The program is needed to ensure that the acidified food industry's degree of freedom from public health hazard continues and to monitor industry's compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas which need emphasis in future programs.	
6. FIELD OBLIGATIONS Special situation firms are to be inspected according to the instructions in the Compliance Program (see program). State contract inspections are to be used to increase firm coverage under this program. State inspections may be conducted in addition to the number of inspections assigned per District. Resources include coverage of food security issues (see IOM) at domestic processors. See full program for more detail.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) See Compliance Program.	d. INDUSTRY/PRODUCT CODE(S) 02-11, 13-41, 45-46, 50
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety PACs 03803,B,C,D,E	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. Non-clinical Good Laboratory Practices inspections, which will be directed by CFSA, with the appropriate District will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. Also, resources needed for inspections of domestic firms for FDA E.U. certification will be taken from this program. Food security issues are to be covered during all inspections (See IOM).	
5. PROGRAM JUSTIFICATION Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibility of assuring that foreign and domestic manufacturers produce these products under current Good Manufacturing Practices.	
6. FIELD OBLIGATIONS To conduct domestic and foreign inspections, focusing on high-risk firms with additional program resources to provide coverage consistent with priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk and non-high-risk firms. Resources provided for sample collections and analyses are projections based on recent data, and not absolute workplan obligations.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products (except Industry Code 12, 16)	d. INDUSTRY/PRODUCT CODE(S) All human food codes (use appropriate product codes)
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES Filth, Decomposition and Microbiological Contamination (See Compliance Program)	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - General PACs 03819,A,B,C	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.</p> <p>Resources for foreign inspections are planned under PAC 03R233.</p>	
5. PROGRAM JUSTIFICATION <p>Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or are not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.</p>	
6. FIELD OBLIGATIONS <p>To conduct activities directed by CFSAN, identified through compliance programs, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth, disease vector, or decomposition.</p> <p>Districts should emphasize priority products from CFSAN's Import Risk-Based Priorities List posted on the intranet. Districts should deemphasize coverage of products that are not consistent with priorities noted in the list. See full Program for more details.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products	d. INDUSTRY/PRODUCT CODE(S) All applicable food codes except Industry Code 12, 16, 40, 41
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Microbiological Contamination, Filth, and Decomposition (See Compliance Program)	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program PACs 03842,B,C,D,H		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the Act. Inspections and analytical resources have been planned separately for outbreak and emergency response (03R839).			
5. PROGRAM JUSTIFICATION FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices, the Seafood HACCP Regulation, and the FD&C Act.			
6. FIELD OBLIGATIONS HACCP verification samples are not to be routinely collected. Collection of environmental samples may be conducted at Ready-To-Eat (RTE) firms. CFSAN will issue separate instructions for collecting environmental samples. See full program for more detail.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Domestic Fish and Fishery Products		d. INDUSTRY/PRODUCT CODE(S) 16	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>PSP, ASP, Standards, Economic Deception, Labeling</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fishery Products Hazards & Controls Guidance Manual (most recent edition) for hazards associated with each specific seafood product.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program PACs 03844,B,C,D,H	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and regulations promulgated under the Act. Resources for foreign inspections are planned under PAC 03R233.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP Regulation.	
6. FIELD OBLIGATIONS The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. Equally important is that products be analyzed for the health hazard as identified in the HACCP Guide. For example, raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw. See full program for more detail.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>PSP, ASP, Standards, Labeling</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fishery Products Hazards & Controls Guidance Manual (most recent edition) for hazards associated with each specific seafood product.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program PACs 03847,H	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure that domestic and imported juice processing establishments are in compliance with the Juice HACCP Regulations as well as the FD&C Act and other regulations promulgated under the Act. Resources for foreign inspections are planned under PAC 03R233.	
5. PROGRAM JUSTIFICATION The Juice HACCP regulation was adopted to ensure safe and sanitary processing of fruit and vegetable juices after reports of many outbreaks of foodborne illnesses, some of which directly affected children. FDA is responsible for assuring that juice processing firms establish and implement the principles of HACCP. HACCP plans must include a minimum five-log pathogen reduction process control (or performance standard) for juices that are not thermally processed concentrates or that are not shelf-stable according to the regulation. The collection of verification samples will be conducted to help validate the firm's HACCP plans.	
6. FIELD OBLIGATIONS (b) (5), (b) (7) (E) (b) (5), (b) (7) (E) (b) (5), (b) (7) (E) See full program for more detail.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Juice Products	d. INDUSTRY/PRODUCT CODE(S) 20-22, 24, 25
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Importer Verification of HACCP</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to Compliance Program	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Environmental Sampling PACs 03F830	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Inspectional approach for inspecting certain high risk food manufacturers will include the collection of environmental samples from areas in the plant where bacteria may be surviving and able to grow to high numbers under certain conditions. High risk firms will be targeted for environmental sampling as identified by CFSAN and the instructions provided to the field through special assignments developed in coordination with ORA.	
5. PROGRAM JUSTIFICATION The purpose for environmental sampling is to determine whether harmful bacteria are present in the food processing environment in high risk food plants and thus present a risk of product contamination.	
6. FIELD OBLIGATIONS The field will be requested to conduct inspections and perform environmental sampling in firms identified by CFSAN through special assignments coordinated with ORA. The inspections will be conducted by a team which will include an investigator and a microbiologist, if possible.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) To be specified in assignments	d. INDUSTRY/PRODUCT CODE(S) To be provided in assignments
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES To be specified in assignments.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to assignments and to DDFI Food Bulletins #30 and #32 for equipment and special instructions	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 03R816	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Office of Regulatory Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response PAC 03R839, 04R839	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03 Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct follow-up investigations, inspections, sample collections, and analyses related to outbreak and illness attributed to microbiological contamination of food products. Follow-Up to Reportable Foods Registry reports and Food Defense Assignments are also planned under this category.	
5. PROGRAM JUSTIFICATION Each year the field expends increasing amounts of resources to follow-up on reports of outbreaks and illnesses linked to contaminated food products. Resources are set aside in the Workplan specifically to conduct emergency operations associated with these investigations.	
6. FIELD OBLIGATIONS Based on directives issued by CFSAN and ORA, Districts will be requested to conduct investigations and collect documents and samples needed to determine whether a link exists between a reported illness or outbreak and a specific product or firm.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) To be specified in assignments.	d. INDUSTRY/PRODUCT CODE(S) To be specified in assignments.
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING To be specified in assignments.	

1. PROGRAM/ASSIGNMENT TITLE Food Defense PAC 03R845	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To maintain food defense preparedness by means of joint CFSAN/ORa field assignments, FDA collection and analysis of proficiency samples for the Food Emergency Response Network, providing resources for general laboratory preparedness activities including instrument, reagent, and standards maintenance, and related activities. Maintain and expand food defense alertness to the food industry. Resources for Food Defense are planned under PAC 03R839 (Outbreak and Emergency Response).	
5. PROGRAM JUSTIFICATION A secure food supply is considered part of the nation's infrastructure. FDA, along with other federal agencies, is responsible for responding to threats to the security of the food supply. The resources and activities planned under this program will help the Agency maintain a necessary state of readiness to respond to threats and activities planned for periods of heightened alert, as well as initiate and/or maintain food defense alertness to expanding industry groups.	
6. FIELD OBLIGATIONS Actual emergency and code-red alert status activities, when needed, will be directed jointly by CFSAN and ORa, and the Field will be instructed on planned work that will be halted. Food Defense Assignments, cleared by CFSAN and ORa, are to be carried out expeditiously.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products	d. INDUSTRY/PRODUCT CODE(S) All food industry/ product codes.
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING To be directed by assignment and protocols jointly developed by CFSAN and ORa.	

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods PAC 04004A,D	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To sample and analyze domestic and imported foods for pesticide residues to determine compliance with EPA residue tolerances and FDA enforcement levels. To take enforcement action when violations are detected, including DWPE for imports and Warning Letters for domestic growers. There is an ongoing emphasis on dioxins to obtain comprehensive data of background levels of dioxin in a variety of foods. This information will help the Agency determine ways to reduce exposure to dioxin.	
5. PROGRAM JUSTIFICATION The food supply requires monitoring for both pesticides and industrial chemicals to protect the public health. The residue data obtained are also used to estimate dietary exposure for risk assessments performed by the Agency and EPA as well as by other national and international organizations.	
6. FIELD OBLIGATIONS Emphasis on pesticide/commodity combinations with high exposure residue potential, especially foods of dietary significance and foods consumed in large amounts by infants and young children. See compliance program for detailed commodity emphasis. CFSAN plans on issuing a sample collection schedule at the beginning of each fiscal year focusing on violations and problem areas detected in recent years by FDA monitoring available foreign pesticide usage data and data provided by USDA's Pesticide Data Program. Dioxin collections will be handled by bi-annual collection schedules issued by CFSAN. Dioxin investigation assignments and follow-up sampling may be used by CFSAN under this program when unusually high dioxin levels are found.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 02-41, 45-47, 50, 52, 54
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Pesticides and industrial chemicals as directed by compliance program.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program, PAM, IOM, etc.	

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood PAC 04018	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To sample and analyze selected imported and domestic aquaculture seafood products. To determine the presence of unapproved chemical compounds such as drugs or antifungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.	
5. PROGRAM JUSTIFICATION Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.	
6. FIELD OBLIGATIONS Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 14 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or as additional validated methods are ready to implement. As a budget relief, two agent analyses should be run per sample for all products except crab, provided the second agent is one of interest for that product. Individual subsample analyses will only be required for crab and shrimp samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining samples will be a composite of 12 sub-samples. Refer to the FY 14 Collection Schedule for additional instruction.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved drugs per the Compliance Program and the Collection Schedule.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic) PAC 04019A,B,C		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine the incidence and levels of lead, arsenic, cadmium, mercury and other toxic elements of significance and radionuclides in domestic and imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in foodware and to take regulatory action against any food or foodware found to contain levels of toxic elements or radionuclides of regulatory significance.			
5. PROGRAM JUSTIFICATION The continuing monitoring of domestic and imported foods (including seafoods) for toxic elements and radionuclides as necessary to determine the occurrence of toxic elements and radionuclides in the U.S. food supply that may pose a health hazard and to take regulatory action to remove those products from human food channels. Also, this monitoring will provide additional data on background levels of toxic elements and radionuclides in foods that will assist in identifying unusual levels that may be of health significance for follow up regulatory action.			
6. FIELD OBLIGATIONS Foods that may be significant sources of lead in children are candy, chocolate/cocoa, and seafood. These products are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" Program and assignments (to be issued). CFSAN will issue collection schedules and direct other FY 14 food work. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides. The Program should be maintained to keep expertise and proficiency in this area. Surveillance activities will be reported under, and credited to the Program PAC.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) All food codes except 53.	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Lead, cadmium, mercury and other toxic elements as directed. Domestic - tritium, 90 Sr & gamma ray emitters; IMPORTS; 134 Cs, 137 Cs, 90 Sr			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Radiochemical analysis capability. (Available only at WEAC). Graphite furnace atomic absorption with Zeeman background correction.			

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study PAC 04839	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/gender groups through analyses of table-ready foods. In addition, to observe differences or trends in the intake of these chemicals and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.	
5. PROGRAM JUSTIFICATION The continuing study has provided valuable information on dietary intakes of residues and nutrients and has often been used to gauge intakes in ready-to-eat foods. EPA relies on the data for hazard assessment in special review and other proceedings. Portions of the Total Diet samples are used for other analysis (e.g., radionuclides, selected nutrients, pesticides, industrial chemicals, and toxic elements). Additionally, selected Total Diet Study foods are analyzed for dioxins under the pesticide program by ARL.	
6. FIELD OBLIGATIONS The collection and analysis of four market baskets each consisting of three separate samplings of approximately 280 food items are to be collected from three locales in the region over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, toxic elements, and selected nutrients. WEAC will analyze all foods from two market baskets for radionuclides.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Various Human Foods	d. INDUSTRY/PRODUCT CODE(S) All Human Food Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY) <i>Moisture Content</i>	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 04R816	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Office of Regulatory Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 04R838	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of Investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 04R838 or OCI PAC 04R831. Conduct operation supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS operation Code 03, PAC 04R838; Petition Validation, Methods Development or Forensic Evaluation.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved drugs per the Compliance Program	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods PAC 07001		2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze domestic and import samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin. To remove from interstate commerce, or detain upon entry, those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established. Data from current monitoring will be used to establish enforcement levels.			
5. PROGRAM JUSTIFICATION Mycotoxins are metabolic products of specific molds commonly found on foods, some (the aflatoxins) of which are hepatocarcinogens in a number of animal species, and until proven otherwise must be assumed to be carcinogenic. The FDA, in conjunction with other agencies and the food industries, has devised and will continue to improve on practical programs for ensuring minimum exposure of the population to mycotoxins without jeopardizing the food supply. Descriptions of the following specific mycotoxins included in this program are located in the Mycotoxins in Domestic and Imported Foods compliance program (C.P. 7307.001). 1. Aflatoxins 2. Patulin 3. Deoxynivalenol (DON) 5. Ochratoxin A			
6. FIELD OBLIGATIONS The field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic and imported products as directed by the compliance program. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed. Aflatoxins, Fumonisin (Fumonisin FB ₁ , FB ₂ , and FB ₃), Deoxynivalenol (DON), Ochratoxin A, and Patulin.			
SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) See Attachment "A" C.P. 7307.001 for list of Products.		d. INDUSTRY/PRODUCT CODE(S) See Attachment "A" C.P. 7307.001 for list of Product Codes.	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program (C.P.) 7307.001			

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 07R816	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07
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3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
 Develop new and/or improved methodology in support of regulatory analysis.

5. PROGRAM JUSTIFICATION
 Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS
 Conduct activities under this program as directed by the Office of Regulatory Science.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED
 BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*SPECIFY*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives PAC 09006A,B	2. PPS PROJECT NAME/NUMBER Food and Color Additives - 09
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To direct examination of imported food products to determine their compliance with the Federal Food, Drug and Cosmetic Act (the Act) and regulations with respect to food and color additives, and to detain those entries found to be in violation of the Act.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the Act and implementing regulations for food and color additives. The compliance program directs sample collections and label review of imported foods for unapproved or undeclared food additives, and for non-permitted or undeclared color additives.	
6. FIELD OBLIGATIONS Districts should conduct label reviews, collect and analyze imported foods for potential food and color additive violations and take appropriate regulatory actions when violations are found. Import Field Exams: See remarks section on the ORA workplan sheet form 2621a under PAC 09F810. Surveillance activities planned under this program may be pre-empted by enforcement initiative agreed upon by ORA and CFSA. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All human foods	d. INDUSTRY/PRODUCT CODE(S) All food codes (Industry 16 and 13)
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Review</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved or undeclared food additives, and non-permitted or undeclared color additives.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.	

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program PAC 18002	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide guidance, support, and assistance to the federal, state, tribal, and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in foodborne illnesses. This program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, National Food Safety needs at retail level, CFSAN directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.	
5. PROGRAM JUSTIFICATION There are more than 3,000 federal, tribal, state, and local regulatory food control agencies which together represent the regulatory resource through which federal food policy is implemented at the retail level. This segment totals more than one million commercial and institutional food establishments, locations, and operations. Each year the Centers for Disease Control and Prevention's Annual Report shows that a major percentage of foodborne outbreaks, where mishandling of food is implicated, occur in retail food establishments. Therefore, an important part of FDA's mission is to provide assistance to federal, tribal, state, and local regulatory agencies with control over this segment of the food industry.	
6. FIELD OBLIGATIONS Provide technical assistance to federal, tribal, state, and local regulatory food agencies. Provide technical assistance to CFSAN and Headquarters in the preparation of position papers. Conduct periodic baseline and follow-up studies to measure trends on the occurrence of foodborne illness risk factors nationwide in selected food service and retail food establishment. Promote the adoption of retail program standards. Provide training on the provisions of FDA Food Code, HACCP, Facility Plan Review, the Egg Rule and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events impacting retail food safety.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Foods	d. INDUSTRY/PRODUCT CODE(S) Inspections: 51 NY
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES A major goal in this program is the reduction in the occurrence of CDC identified risk factors associated with foodborne illness in retail establishments and the national promotion of Food Code Interventions.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Work assigned in this program is to be conducted by persons who are Center standardized in the application of the relevant retail establishments Food Code provisions and related program documents.	

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program PAC 18003	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To implement FDA's responsibility under the Public Health Service Act, 42 USC 214; 42 USC 243; and 42 USC 246a and the Memorandum of Understanding (MOU) between FDA and the National Conference on Interstate Milk Shipments. This responsibility includes all Grade "A" dairy products processing plants, and all dairy farms supplying raw milk to these plants.	
5. PROGRAM JUSTIFICATION This program will promote a uniform, safe, and wholesome supply of Grade "A" Milk and Milk products throughout the United States. This program enables FDA to exert influence on the application of Uniform Sanitary Standards for Grade "A" Milk produced in the United States. This program provides a mechanism for reciprocity between states, thereby eliminating the need for costly duplicative inspection across jurisdictional lines. Without this program, FDA would have direct responsibility for duplicative inspection across jurisdictional lines. Without this program, FDA would have direct responsibility for inspecting Grade "A" Milk products moving in Interstate commerce. This program also provides a mechanism for promoting greater sanitation uniformity of all dairy products. Due to the increasing consumer interest in chemical contaminants in the food supply, the perception and the potential for animal drug residues in milk and dairy products has become an important issue. This program will place additional emphasis toward continuous vigilance in maintaining a safe wholesome milk supply that is free of illegal animal drug residues.	
6. FIELD OBLIGATIONS To promote the adoption, implementation and enforcement of the uniform technical guidelines, administrative procedures and regulatory standards provided in the Pasteurized Milk Ordinance (PMO) and related documents through provision of technical assistance and consultation; conduct check ratings of IMS listed shippers and audits of listed single service facilities; participation in regional seminars, state workshops and other training courses and evaluate state programs to measure effectiveness in maintaining adequate level of conformity with the PMO and related documents.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Grade "A" Milk and Milk Products, (Cheese, Butter, Dry Milk and Frozen Dessert - when produced in IMS Plants)	d. INDUSTRY/PRODUCT CODE(S) 09, 12, 13, 14
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES Listeria, Yersinia, Salmonella, Coliform and animal drug residues in milk and milk products.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Work assigned in this program is to be conducted by persons who are standardized in the use of the Grade "A" Pasteurized Milk ordinance and related documents and in the case of non-IMS products, persons trained to conduct GMP inspections.	

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation PAC 18004	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Evaluate the shellfish sanitation program of ISSC participating states and the 5 nations with whom the Agency has MOU in place with regard to the sanitary control of shellfish intended for interstate and overseas commerce under the cooperative arrangements for the federal-state National Shellfish Sanitation Program (NSSP). Provide standardization, technical assistance, training evaluation of state and international shellfish control programs.	
5. PROGRAM JUSTIFICATION Shellfish, by virtue of their habitat, physiological characteristics, and the manner in which they are consumed, require specialized comprehensive sanitary control measures to ensure the safety of human consumption. The management of the program requires a cooperative federal-state effort as defined in the National Shellfish Sanitation Program (NSSP). Consumption of raw or partially cooked shellfish presents a high risk factor to a portion of the population, and requires specialized health control measures to oversee. FDA is committed to improving the safety of molluscan shellfish through the NSSP, a program of newly developed safety controls. These initiatives are the direct result of Congressional and public comments directed toward the establishment of a "level playing field" for both domestic and international producers of molluscan shellfish. These program improvements are intended to provide improved shellfish safety through improved program criteria, procedures, and technical support under the NSSP. FDA is committed to improved safety of shellfish through program enhancement activities. FDA has committed support to the NSSP both administratively and technically through an MOU with ISSC.	
6. FIELD OBLIGATIONS Provide technical assistance and training to states and foreign programs in the prevention of shellfish-borne illness and enforcement of appropriate public health controls. Oversee national standardization program for inspecting shellfish processing plants and evaluation of state and foreign shellfish growing areas. Participate in the evaluation of national shellfish control programs in countries applying to import molluscan shellfish into the U.S. Program time has been allocated for each Regional Shellfish Specialist to hold one regional workshop. Regional workshops provide the opportunity for the specialists to exchange information and provide technical assistance and guidance to their state.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh and fresh frozen molluscan shellfish	d. INDUSTRY/PRODUCT CODE(S) 52B, 16E
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Work assigned in this program is to be conducted by persons who are Center Standardized in the application of the NSSP MO.	

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities PAC 18029		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To inspect and investigate passenger conveyances to certify and approve sanitary systems on conveyances and approve their watering points, their support facilities and their food sources based on the Public Health Service Act, the Food, Drug and Cosmetic Act, regulations, program guidance, Food Code, and in cooperation with the regulated industry and cooperating third party organizations. Also, to identify risk factors related to environmental conditions or management practices that may lead to foodborne illnesses, waterborne illnesses, and the transmission of communicable diseases. The program includes administrative compliance and regulatory actions as appropriate to ensure conformance with the public health principles embodied in the Acts and their regulations. The goals of the program are to cooperate with the regulated industries, trade associations, and others to promote voluntary compliance and to coordinate activities with FAA, CDC, DOT, EPA, Department of Homeland Security (USCG, TSA) and other domestic and foreign government health officials to ensure the protection of the traveling public, and crew member of conveyances under construction and in operation and at related watering points, caterers, commissaries and servicing area on conveyances.			
5. PROGRAM JUSTIFICATION This program directs agency efforts in fulfilling Public Health Service Act responsibilities delegated to the Commissioner of Food and Drugs [21 CFR 5.10(a)(2) and (4)]. Sections 311, 361, and 368 of the Act address federal-state cooperation, the controls of communicable disease, and penalties of noncompliance. The agency also bases the Interstate Travel Program, in part, on provisions of the Federal Food, Drug and Cosmetic Act and related regulations. The United States must comply with the updated International Health Regulations (IHR 2005) as of July 17, 2007 that protect the health of people around the world. As one of the competent authorities, FDA as an agency is responsible for monitoring baggage, cargos, containers, conveyances and goods so that they are maintained free from sources of infection or contamination including vectors and reservoirs. There are specific requirements for ships and aircraft and delivery of food and water to affected conveyances.			
6. FIELD OBLIGATIONS The field is to perform the operations assigned in the ORA Workplan, conduct comprehensive inspections of food operations and support facilities, initiate administrative or regulatory actions as needed to ensure compliance, support the maintenance of official classification list of FDA's approved support facilities, establish and maintain technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication between CFSAN and ORA Headquarters regarding significant program issues and activities.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human food, water, and waste; conveyance environmental conditions		d. INDUSTRY/PRODUCT CODE(S) Inspections/Investigations: Industry 51, All food codes including water 29W (Y 30).	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Food & water surveillance and contamination, mostly Micro analysis. Chem analysis; heavy metals in water "FOR CAUSE" basis e.g. lead, cadmium, cooper in portable water systems at new support facilities and conveyances after construction or major renovation			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Catering point inspections will be conducted by persons standardized in the use of FDA's Food Code and procedures established for the Interstate Travel Program.			

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import PAC 21002		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods. To collect and analyze domestic and imported medical foods to assure that they are properly formulated and labeled and free from microbial contaminants. Resources for foreign inspections are planned under PAC 03R233.			
5. PROGRAM JUSTIFICATION Medical foods are formulated to be consumed or administered enterally under the supervision of a physician and are intended for specific dietary management of specific disease or condition with distinctive nutritional requirements, based on recognized scientific principles established by medical evaluation. The products are often used for life support and are subject to compositional errors and microbiological contamination. In addition to four infant deaths in 1986, there have been a number of medical food recalls associated with compositional deviations and under processing. Foreign inspections of medical foods firms are also planned in this program. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03F810. Resources are planned in this program for collection and analysis of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food security issues are to be covered during all inspections. CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Medical Foods		d. INDUSTRY/PRODUCT CODE(S) 41G[[]] Use appropriate product identification number	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> and Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis and General Food Labeling Program PAC 21005		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine the compliance of domestic and imported food product labels with regulations promulgated under the Federal Food Drug and Cosmetic Act; including the Nutrition Labeling and Education Act (NLEA) and the Food Allergen Labeling and Consumer Protection Act (FALCPA). This objective is to be accomplished by reviewing labels of domestic and imported food products and by collecting compliance and surveillance samples for label review and analyses to assure: (1) that the nutrition label is in compliance with the regulations in Title 21 Code of Federal Regulations 101.9; (2) that labeled nutrient content and health claims are made in a manner that complies with applicable regulations; (3) that the label complies with FALCPA; and (4) that all labels include all required label elements.			
5. PROGRAM JUSTIFICATION All domestic and imported foods must disclose the presence of any ingredient that is or contains protein derived from one of the 8 major food allergens so that individuals with allergies will be able to easily identify the presence of substances that they must avoid. In addition, most food products in interstate commerce must list trans fat in the nutrition label. The FD&C Act also mandates other required label information and valid nutrient content and health claims to provide useful information that assists consumers in selecting foods that promote good health and weight management. Continuous monitoring of food labels is necessary to ensure that consumers are provided with truthful information that they need to select foods that are appropriate for their specific dietary needs and health maintenance.			
6. FIELD OBLIGATIONS Districts will review import and domestic product labels for compliance with FALCPA, NLEA, and other mandatory label requirements by conducting field exams. Districts will collect labels that do not appear to comply with FDA's food labeling laws and regulations for review by the district's compliance branch. Physical samples will be collected for lab analyses as follows: (1) compliance samples that do not appear to qualify for labeled health or nutrient content claims (see C.P. Area of Emphasis #5); and (2) surveillance samples collected for general nutrient analyses.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All food products (except vitamins/minerals)		d. INDUSTRY/PRODUCT CODE(S) 02-41	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Label review and nutrient analyses as appropriate, focus should be given to allergen and trans fat labeling.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Samples for nutrient analyses to be sent to SRL/ACNA. See compliance program for details.			

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import PAC 21006		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To ensure compliance with the Infant Formula Act and regulations promulgated there under by inspection of domestic and foreign manufacturers of infant formula and collection and analysis of infant formula samples. Resources for foreign inspections are planned under PAC 03R233.			
5. PROGRAM JUSTIFICATION Serious infant health problems arising from inadequate nutrient content of infant formula prompted Congress to pass the Infant Formula Act of 1980. This inspection and analysis program assures adherence to the provisions of the Act. Violations and recalls over the past several years (and the continuing keen interest by Congress, as evidenced in part by the 1986 amendments to the Act) indicate the need for continued compliance monitoring. The large number of applications for approval of the formulas exempt from the Act requires expansion of oversight activities into this area. Additional resources have been budgeted to allow annual inspection and sample collection from infant formula firms. Inspections of foreign infant formula are planned in this program. Investigation time to determine admissibility of import lots of infant formula from foreign manufacturers are planned under PAC 03F810. Resources are planned in this program for collection and analysis of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples. Atlanta Center for Nutrient Analysis (ACNA) will perform nutrient analyses and label reviews. Southeast Regional Laboratory, Microbiology Branch will perform microbiological analyses. CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed. Food security issues (see IOM) are to be covered during all inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Infant Formula		d. INDUSTRY/PRODUCT CODE(S) 40C	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrients as required by the Act. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import PAC 21008		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure compliance with the Dietary Supplement Health and Education Act and regulations promulgated there under by inspections of dietary supplement manufacturers both domestic and foreign. Dietary supplements of both domestic and import origin will be collected and analyzed for nutrient content vs. label declarations. All non-exempt dietary supplements must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these requirements will be determined by domestic and import field exams and documentary sample collections. Resources for foreign inspections are planned under PAC 03R233.			
5. PROGRAM JUSTIFICATION Dietary supplements are a special class of products consisting of such dietary ingredients as vitamins, minerals, amino acids, glandulars, herbs, and other botanicals. These products are subject to specific safety and labeling requirements. This program provides instructions to FDA district offices regarding inspections, import investigations, sample collections and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994. Investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on labels and supplements being marketed with claims to treat diseases.			
6. FIELD OBLIGATIONS Field obligations include inspections, domestic and import investigations, sample collections and analyses of dietary ingredients in dietary supplements. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSPAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER	
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input checked="" type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Dietary supplements		d. INDUSTRY/PRODUCT CODE(S) 54	
e. EXAM TYPE			
<input checked="" type="checkbox"/> CHEMICAL		<input type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
		<input type="checkbox"/> ENGINEERING	
<input type="checkbox"/> MICROANALYTICAL		<input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Analyze selected nutrients and compare with levels declared on product label.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrients in Food Survey -Total Diet PAC 21839		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To monitor the mineral nutrients in foods from typical American diets. To identify mineral and vitamin nutrient intake trends. To provide baseline data on mineral nutrient and vitamin intake for intervention studies and other nutrition studies. To function as an important component in the National Nutrition Monitoring System.			
5. PROGRAM JUSTIFICATION Congress has given the Secretaries of DHHS and USDA a mandate to set up a National Nutrition Monitoring System (NNMS). The current Selected Nutrients in Food Survey is an important segment of the NNMS that provides the only continuous analysis of nutrient minerals in the American food supply. This permits identification of trends in nutrient intake over time as well as information on the general nutritional status of the population at any point in time.			
6. FIELD OBLIGATIONS KAN-DO will analyze Total Diet Study foods from all market baskets for the nutrients identified below in 7F, and all TDS foods from one market basket annually for moisture.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Various foods as required by the Total Diet Studies Program		d. INDUSTRY/PRODUCT CODE(S) 37, 40	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Manganese, iodine, calcium, copper, iron, magnesium, phosphorus, potassium, sodium and water.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 21R816	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
 Develop new and/or improved methodology in support of regulatory analysis.

5. PROGRAM JUSTIFICATION
 Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS
 Conduct activities under this program as directed by the Office of Regulatory Science.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED
 BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*SPECIFY*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Import PAC 29001	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine by inspection, sample collection, and label exam if domestic cosmetic manufacturing or repacking establishments, and cosmetics offered for importation, comply with regulations enforced by the Food and Drug Administration. To initiate corrective action when violations of the FD & C Act are identified.	
5. PROGRAM JUSTIFICATION Both domestically manufactured and imported products must be: 1) safe under intended conditions of use, 2) properly labeled, and 3) not otherwise adulterated or misbranded under the provisions of the Act. Major safety concerns associated with cosmetics involve microbial contamination of eye-area products and the use of non-approved color additives. Many cosmetic violations also involve products which fail to comply with the labeling regulations of 21 CFR 701.	
6. FIELD OBLIGATIONS Districts will conduct inspections, perform import field exams, collect and analyze samples for non-permitted ingredients, conduct microbiological analyses and perform evaluations for labeling compliance. Food & Cosmetic security issues (see IOM 5.4.1.4.1) are to be covered during all inspections. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSA. Such initiatives will be reported under, and credited to the Program PAC unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Cosmetic Products	d. INDUSTRY/PRODUCT CODE(S) 53
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Non-permitted ingredients (including color additives), microbiological/contaminants, labeling statement.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) PACs 41002B,C,D	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine if human cells, tissue, and cellular & tissue-based product (HCT/P) establishments are in compliance with the regulations (21 CFR, Part 1270 and 1271), promulgated under the Public Health Service Act, Section 361, to assure that HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing. C.P.7341.002 - Inspection Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (covers HCT/Ps recovered on or after 5/25/2005) C.P.7341.002A - Inspection Tissue Establishments (covers human tissue recovered before 5/25/2005)	
5. PROGRAM JUSTIFICATION Human cells, tissues, and cellular & tissue-based products (HCT/Ps) are important products for medical treatment. Monitoring the recovery, processing, and storage of HCT/Ps and the testing and screening of the donors is critical to assure consumer protection from unsuitable products which may endanger public health.	
6. FIELD OBLIGATIONS ORA will perform the inspections, prepare EIRs, and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), and recommend administrative/regulatory actions when appropriate.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 K; 57 M; 57L; 57 J; 57 Q; 57 R; 57 S; 57 T; All Other HCT/Ps N.E.C. 57 P 99
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE GLPs (Nonclinical Lab), IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA) PACS 41808-41811	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>GLPs: To assure compliance with Good Laboratory Practices (GLPs) regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.</p> <p>IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by Institutional Review Boards (IRBs) Regulations (21 CFR 56, 21 CFR 50).</p> <p>Spon/M on/CROs: To assess the adherence of Sponsors, Monitors, and Contract Research Organizations (Spon./Mon./CROs) to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies.</p> <p>Clinical Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of Clinical Investigators with the relevant regulations (21 CFR 312 and 812).</p>	
5. PROGRAM JUSTIFICATION <p>GLPs: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.</p> <p>IRBs: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.</p> <p>Spon/M on/CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.</p> <p>Clinical Investigators: The Kefauver Harris Amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.</p>	
6. FIELD OBLIGATIONS <p>GLPs: Conduct inspections and forward reports to the assigning office in CBER. IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward report(s) to the assigning CBER office.</p> <p>Spon/M on/CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office.</p> <p>Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products N.E.C.
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES 	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING 	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Cell and Gene Therapy Products PACs 41848A,F,G & 41848B,C,D	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which cell and gene therapy products are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.	
5. PROGRAM JUSTIFICATION Cell and gene therapy products are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.	
6. FIELD OBLIGATIONS ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a Biennial Basis . Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Device Specific</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks PACs 42001F,G,H	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations: a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products; (b) Blood Donor Centers which collect blood and ship to the Blood Banks of which they are a part; (c) Laboratories that perform testing on blood products and donors, e.g. donor screening for communicable disease agents (HIV 1 and 2, Hepatitis B and C, HTLV I and II, Syphilis) and supplemental testing on reactive tests (HIV Western Blot, HCV RIBA); (d) Laboratories that perform Quality Control Testing for licensed blood establishments, e.g., platelet Quality Control (Q.C.) GMP evaluation to determine the level of competency and adherence to contractual agreements with the licensed establishments.	
5. PROGRAM JUSTIFICATION Blood and Blood Products are vitally important products in medical treatment. Monitoring the collection of whole blood and the processing, manufacturing, and preparation of products derived from human blood assures consumer protection from defective products which may endanger public health.	
6. FIELD OBLIGATIONS ORA will perform the inspections, prepare EIRs, and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Blood and Blood Products	d. INDUSTRY/PRODUCT CODE(S) 57 D
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments PACs 42002A,F,G	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine through inspections if Source Plasma establishments are operating in compliance with applicable regulations to assure donor protection and to assure that Source Plasma is safe, effective, and adequately labeled.	
5. PROGRAM JUSTIFICATION The collection of Source Plasma as source material for further manufacturing into products used in the prevention and treatment of disease is of immeasurable value to the consumer. Through this program the Agency can accomplish its objectives of donor protection and product safety, purity, and potency.	
6. FIELD OBLIGATIONS ORA will perform inspections, prepare and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Source Plasma	d. INDUSTRY/PRODUCT CODE(S) 57 D
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Imported CBER-Regulated Products PACs 42007, 41/42/45R824, 42R833, 99R833 *	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 1) Determine if import entries comply with the requirements of appropriate Federal regulations. 2) Assure that import entries declared as Import for Export are CBER approved pursuant to section 801(d)(4) of FD & C Act. 3) Detain all import entries not in compliance with applicable regulations, including 21 CFR 600-680 and 1271. * PACs Include: 42007; 41R824; 42R824; 45R824; 42R833; 99R833	
5. PROGRAM JUSTIFICATION In 1995, a Blood Working Group (consisting of personnel from CBER and ORA) reviewed cases in which imported blood and blood components were identified as being illegally distributed in domestic commerce. Analysis of available information identified a need for a compliance program to clarify existing CBER procedures for the importation of blood products and ensure consistent handling of imported blood products by the Field. In 2005 new regulations for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) became effective.	
6. FIELD OBLIGATIONS To review electronic line entries or examine entry documentation for imported biological products offered for entry into the United States. To determine whether biological products offered for import are licensed or unlicensed; and to conduct investigations as necessary and determine whether an entry is in compliance with Federal Regulations	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biological Products	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed <i>In Vitro</i> Diagnostic (IVD) Devices PACs 42008A,F,G	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the manufacturing process for licensed <i>in vitro</i> diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including the Quality System Regulations (21 CFR 820), <i>In Vitro</i> Diagnostic Products Regulations (21 CFR 809), Biologics Regulations (21CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.	
5. PROGRAM JUSTIFICATION <i>In Vitro</i> Diagnostic Kits are important tools in medical treatment and blood and plasma donor screening. This program enables the Agency to continue to protect the public health by assuring safety, purity, potency, and efficacy of blood and plasma products.	
6. FIELD OBLIGATIONS Conduct comprehensive inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a Biennial Basis . Inspections will be conducted by a Team Biologics Member and may include a District Representative and / or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) <i>In Vitro</i> Diagnostic Products accordance with the stated objective.	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Device Specific</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA) PACs 42808, 42809, 42810, 42811	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by Institutional Review Boards (IRBs) Regulations (21 CFR 56, 21 CFR 50).</p> <p>Spon./Mon./CROs: To assess the adherence of Sponsors, Monitors, and Contract Research Organizations (Spon./Mon./CROs) to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies.</p> <p>Clinical Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of Clinical Investigators with the relevant regulations (21 CFR 312 and 812).</p> <p>GLPs: To assure compliance with Good Laboratory Practices (GLPs) regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.</p>	
5. PROGRAM JUSTIFICATION <p>IRBs: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of biological products are protected.</p> <p>Spon./Mon./CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.</p> <p>Clinical Investigators: The Kefauver Harris Amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.</p> <p>GLPs: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.</p>	
6. FIELD OBLIGATIONS <p>IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward report(s) to the assigning CBER office.</p> <p>Spon./Mon./CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office.</p> <p>Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed.</p> <p>GLPs: Conduct inspections and forward reports to the assigning office in CBER.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products N.E.C.
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers(Biologics) PACs 42845A,B,C	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the manufacturing processes for those medical devices and <i>in vitro</i> diagnostic products regulated by the Center for Biologics Evaluation and Research (CBER) through the use of the Medical Device Authorities (e.g. PMA, 510K) and other generic devices outlined in the October 31, 1991 intercenter agreement between CBER and the Center for Devices and Radiological Health (CDRH).	
5. PROGRAM JUSTIFICATION As described in the October 31, 1991 intercenter agreement, CBER is the focal point for the review and evaluation of several categories of medical devices. Our strategy for inspecting those firms not regulated under the licensing provisions of Section 351 of the Public Health Service Act are for Biennial Inspection . The product categories are primarily in the area of devices used in blood banking and human cell, tissue, and cellular and tissue-based products.	
6. FIELD OBLIGATIONS Conduct inspections pursuant to the instructions in the CDRH OMD Program - Inspection of Medical Device Manufacturers, CP 7382.845. Report findings/observations to the Center for Biologics Evaluation and Research (CBER). Recommend/initiate regulatory follow-up consistent with the compliance program guidance and Agency policy.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All devices in the product categories transferred to CBER.	d. INDUSTRY/PRODUCT CODE(S) 81 (Device Categories), 57 Y 99 (<i>In vivo</i> + <i>In vitro</i> Diagnostic Products)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Device Specific</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspections of Plasma Derivatives of Human Origin PACs 42848A,F,G & 42848B,C,D	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which Plasma Derivatives are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.	
5. PROGRAM JUSTIFICATION Plasma Derivatives are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.	
6. FIELD OBLIGATIONS ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a Biennial Basis. Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fractionation Products	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA) PACs 45808, 45809, 45810, 45811	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by Institutional Review Boards (IRBs) Regulations (21 CFR 56, 21 CFR 50). Spon./Mon./CROs: To assess the adherence of Sponsors, Monitors, and Contract Research Organizations (Spon./Mon./CROs) to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies. Clinical Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of Clinical Investigators with the relevant regulations (21 CFR 312 and 812). GLPs: To assure compliance with Good Laboratory Practices (GLPs) regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.	
5. PROGRAM JUSTIFICATION IRBs: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected. Spon./Mon./CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate, clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies. Clinical Investigators: The Kefauver Harris Amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products. GLPs: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.	
6. FIELD OBLIGATIONS IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office. Spon./Mon./CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office. Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed. GLPs: Conduct inspections and forward reports to the assigning office in CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products N.E.C.
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products PACs 45848A,F,G	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which Licensed Allergenic Products and Unlicensed Allergenic Source Materials are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, Standards and commitments made in license applications and/or supplements, and applicable regulations.	
5. PROGRAM JUSTIFICATION Allergenic Products are biological products which are administered to man for the diagnosis, prevention, or treatment of allergies. The products are manufactured from source materials that may include pollen, insects, mold, food, and animals, used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.	
6. FIELD OBLIGATIONS ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a Biennial Basis . Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 G
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products PACs 45848B,C,D	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure the safety and effectiveness of biological products by determining through inspections, the conditions under which vaccines are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, Standards and commitments made in license applications and/or supplements, and applicable regulations.	
5. PROGRAM JUSTIFICATION Vaccine and Vaccine Related Products are biological products which are administered to man for the diagnosis and prevention of microbial disease and for the therapeutic treatment. Products are manufactured from viral and bacterial organisms and components and may include live attenuated, inactivated, and recombinant vaccines. These products are used in the prevention of childhood diseases and in the treatment, diagnosis, and prevention of diseases and thus are of immeasurable value to the consumer.	
6. FIELD OBLIGATIONS ORA will perform inspections that assess the adequacy of all significant processes and systems. Inspections should be performed on at least a Biennial Basis. Inspections will be conducted by a Team Biologics Member and may include a District Representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 H, I
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations PAC 46832B, C	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before NDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign PAC 46832B,C,D	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before NDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE BLA Pre-Approval Inspections/Investigations – Domestic and Foreign, PAC 46832M	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that BLA applicant has the facilities, equipment, and controls as described in the application, and to verify the integrity of the submitted data. To determine compliance of manufacturing establishments with CGMPs prior to approval of pending BLAs.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before BLA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs; specifically, Licensed Biological Therapeutic Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 57
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE PET NDA Pre-Approval Inspections/Investigations PAC 46832P	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before NDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.	

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (PDUFA) - Domestic PAC 48001,A	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.	
5. PROGRAM JUSTIFICATION Bioequivalence studies are conducted mainly by private and university affiliated contract laboratories. Previous inspections noted deviations from protocols, poor recordkeeping, inadequate controls over test subjects, poor analytical procedures and fraud. Results of bioequivalence inspections have a direct relationship to approvability of NDA and ANDA applications.	
6. FIELD OBLIGATIONS Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (PDUFA) - Foreign Inspections PAC 48001,A,D,E	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine through audit procedures whether: (a) bioequivalence data, (b) non-clinical laboratory study data, and (c) clinical data are substantiated by on-site documentation, are valid, scientifically accurate and the studies were conducted according to appropriate regulations. GLP inspections in foreign laboratories may also provide an assessment of the effectiveness of an existing Memorandum of Understanding with that named nation.	
5. PROGRAM JUSTIFICATION An increasing number of bioequivalence studies are conducted by contract laboratories, private and university affiliated, located in India, Canada and Europe. In addition, large numbers of animal studies (GLP) and clinical studies are conducted in Europe and other foreign countries. Serious problems associated with lack of adherence to protocols, lack of and inadequate record keeping, inadequate and inaccurate analytical procedures, and fraud have been documented in such studies. These studies are required for drug approval in the United States. The President's Emergency Plan for AIDS Relief (PEPFAR) requires inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs. Data audit under PEPFAR will be verified by on site inspections.	
6. FIELD OBLIGATIONS Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up. The audit of data from bioequivalence manufacturers and clinical studies will be verified.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-Clinical Laboratory) PAC 48808	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure compliance with current Good Laboratory Practice Regulations (21 CFR 58) by nonclinical laboratories and to assure validity of data through associated data audits.	
5. PROGRAM JUSTIFICATION Animal Studies are vital prerequisites to human clinical trials of drugs and other FDA regulated products. Past experience has shown serious deficiencies in the conduct of nonclinical laboratories in recordkeeping, adherence to study protocol, and in some cases fraudulent practices.	
6. FIELD OBLIGATIONS Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board (IRB); Radioactive Drug Research Committee (RDRC), PAC 48809,A	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>IRB: To assure compliance and integrity of institutional review boards (21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.</p> <p>RDRC: To assure the quality and integrity of Radioactive Drug Research Committees and assure they are operating in compliance with (21 CFR 361.1).</p>	
5. PROGRAM JUSTIFICATION <p>IRB: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected. The inspectional program assures that IRBs protect the safety and welfare of clinical trial subjects and ensures that the informed consent form and the process of obtaining informed consent comply with current regulations.</p> <p>RDRC: The Nuclear Regulatory Commission and the FDA have decided that certain protocols involving radioactive drugs do not need an IND, but must be reviewed by an institutional RDRC. These protocols are those intended for basic research purposes, not those protocols intended to determine the safety and efficacy of the drug in humans. The RDRC assures that the radiation doses and pharmacological doses are within specified limits. The Division of Scientific Investigations, Office of Compliance, CDER, issues assignments to the districts, reviews all complete EIRs and their classification, and issues letters as needed to RDRCs after such review.</p>	
6. FIELD OBLIGATIONS <p>IRB: Conduct inspections of IRBs which are involved in the review of clinical trials of human drug studies and forward the reports to the Division of Scientific Investigations, CDER.</p> <p>Assist in presentation of IRB workshops.</p> <p>RDRC: Conduct inspections of RDRCs and forward the EIRs to the Division of Scientific Investigations, CDER.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, & Monitors PAC 48810	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure adherence by sponsors, contract research organizations, and monitors to the regulations (21 CFR 312) and to assess their interaction with clinical investigators and the sponsors development of safety and efficacy data in NDAs.	
5. PROGRAM JUSTIFICATION Sections of the FD&C Act and the Public Health Service Act require the submission of data to FDA ensuring the safety of human drugs, as well as the filing of an Investigational New Drug Application and New Drug Applications. An inspectional program is required to assess compliance with current regulations.	
6. FIELD OBLIGATIONS Conduct inspections of sponsors, contract research organizations, and monitors for the IND/NDAs identified in the assignments. Forward reports directly to the Division of Scientific Investigations, CDER, for final classification, including District recommendations for compliance follow-up.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators - Domestic and Foreign PAC 48811, D, F	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assess through audit procedures whether data submitted to FDA in a specific study are substantiated by source documents and whether clinical investigators have complied with regulations (21 CFR 312).	
5. PROGRAM JUSTIFICATION Clinical data are submitted to FDA in support of a marketing permit (IND, NDA). The clinical studies that generated the data are evaluated for accuracy, completeness, and regulatory compliance.	
6. FIELD OBLIGATIONS Conduct inspections and forward EIRs directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre-Approval Inspections/Investigations PAC 52832,B,C	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending ANDAs. ANDA bulk products are collected for profile analysis.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before ANDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre-Approval Inspections/Investigations - Foreign, PAC 52832,B,C,E	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of foreign manufacturing establishments with GMPs prior to approval of pending ANDAs.	
5. PROGRAM JUSTIFICATION Compliance of foreign manufacturing establishments must be assessed before ANDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval inspections of foreign establishments as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE PET ANDA Pre-Approval Inspections/Investigations PAC 52832P	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending ANDAs. ANDA bulk products are collected for profile analysis.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before ANDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.	

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations, PAC 53001A	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide assignments, guidance and instructions to field offices for inspecting drug firms to determine compliance with the ADE reporting requirements of 21 CFR 310.305,314.80 and 318.98 and Section 760 of the FDCA (21 U.S.C. 379aa. Regulatory and/or administrative follow-up will be coordinated between the field and headquarters in cases where significant following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by violations of reporting regulations or deficiencies in following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by responsible parties, including applicants, manufacturers, packers and distributors.	
5. PROGRAM JUSTIFICATION The postmarketing adverse drug experience (ADE) regulations (21CFR 310.305,314.80 and 314.98) became effective on August 22, 1985, September 2, 1986 and June 29, 1992 and cover prescription drugs. The regulations also apply to OTC drugs that have approved applications, including those initially marketed as prescription drugs under approved applications (i.e., Rx to OTC switched drugs). Section 760 of the FDCA applies to nonprescription drug products marketed without an approved application. This part of the Act became effective on December 22, 2007. The purpose of postmarketing ADE surveillance is to obtain information on rare, latent or long term drug effects not identified during pre-market testing. Accurate, complete, and timely reporting of ADE information is essential to the safety evaluation of marketed drug products. It enables FDA to act when information concerning the use and safety of marketed drug products suggests that new labeling, market withdrawal or other action is required.	
6. FIELD OBLIGATIONS Conduct inspections and forward reports directly to the Division of Compliance Risk Management and Surveillance (DCRMS)/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up. Issue regulatory letters as approved by DCRMS. Notify DCRMS of findings from other inspectional program activities which are relevant to ADE reporting.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, 60-66
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Risk Evaluation and Mitigation Strategy (REMS) (PDUFA), PAC 53001C		2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide assignments, guidance and specific instructions to field offices for inspecting drug firms to determine compliance with the Risk Evaluation and Mitigation Strategies (REMS) required under Federal Food, Drug, and Cosmetic Act (FDCA) section 505-1. Regulatory and/or administrative follow-up will be determined by CDER headquarters.			
5. PROGRAM JUSTIFICATION On September 27, 2007, the Food and Drug Administration Amendments Act (FDAAA) (Public Law 110-85) was enacted. Title IX, Subtitle A, section 901 of this statute created new section 505-1 of the FDCA, which authorizes FDA to require a REMS if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug. Section 505-1 applies to applications for approval of prescription drugs submitted under sections 505(b) or 505(j) of the Act and applications submitted under section 351 of the Public Health Service Act. This subtitle of FDAAA took effect on March 25, 2008, 180 days after enactment of FDAAA. The purpose of this program is to ensure that the required REMS programs are being implemented.			
6. FIELD OBLIGATIONS Conduct inspections and forward EIRs directly to the Division of Risk Management and Surveillance, CDER. There will be no Field- initiated inspections in this program. At this time, all regulatory actions will be determined by CDER headquarters.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input checked="" type="checkbox"/> BY CENTER	
		<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input checked="" type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 55, 56, 57, 59, 60-66, 99	
e. EXAM TYPE			
<input type="checkbox"/> CHEMICAL		<input checked="" type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> ENGINEERING	
		<input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections PAC 56002A-D, F, H-L	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To minimize the consumer's risk of exposure to defective drug products by preventing the marketing of, or removing from the market, violative drug products that are observed as a result of activities performed under this program. To assess the adequacy of the CGMP regulations, guidelines and agency regulatory policies by gathering industry-wide data on changing practices and technology.	
5. PROGRAM JUSTIFICATION The Drug Process Inspections program is FDA's primary means for evaluating the conditions under which drug products are manufactured, tested, packaged and held.	
6. FIELD OBLIGATIONS The field will conduct drug process inspections and maintain profiles or other monitoring systems which will insure that each drug firm receives the inspection coverage provided for in the inspectional strategy.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections PAC 56002A-D,F	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Inspectonal work is to minimize the consumer's risk of exposure to defective drug products by preventing the marketing of or removing from the market, violative drug products that are observed as a result of inspections performed under this Program.	
5. PROGRAM JUSTIFICATION The international Drug Process Inspection program is FDA's primary means for evaluating the conditions under which foreign drug products are manufactured, tested, packaged and held.	
6. FIELD OBLIGATIONS The field will conduct drug process inspections and maintain profiles of foreign drug manufacturers.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections: Inspections of Licensed Biological Therapeutic Drug Products, PAC 56002M		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To minimize the consumer's risk of exposure to defective licensed biological therapeutic drugs by preventing the marketing of, or removing from the market, violative licensed biological therapeutic drugs that are observed as a result of activities performed under this program. To assess the adequacy of the CGMP regulations, guidelines and agency regulatory policies by gathering industry-wide data on changing practices and technology.			
5. PROGRAM JUSTIFICATION The Drug Process Inspections program, Inspections of Licensed Biological Therapeutic Drug Products, is FDA's primary means for evaluating the conditions under which licensed biological therapeutic drugs are manufactured, tested, packaged and held.			
6. FIELD OBLIGATIONS The field will conduct drug process inspections and maintain profiles or other monitoring systems which will insure that each drug firm receives the inspection coverage provided for in the inspectional strategy. CDER will maintain the Biological Product Defect Report system.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER	
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input checked="" type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs; specifically, Licensed Biological Therapeutic Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 57	
e. EXAM TYPE			
<input checked="" type="checkbox"/> CHEMICAL		<input checked="" type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
		<input type="checkbox"/> ENGINEERING	
<input checked="" type="checkbox"/> MICROANALYTICAL		<input checked="" type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - PET Domestic PAC 56002P, Q	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To minimize the consumer's risk of exposure to defective drug products by preventing the marketing of, or removing from the market, violative drug products that are observed as a result of activities performed under this program. To assess the adequacy of the CGMP regulations, guidelines and agency regulatory policies by gathering industry-wide data on changing practices and technology.	
5. PROGRAM JUSTIFICATION The Drug Process Inspections program is FDA's primary means for evaluating the conditions under which drug products are manufactured, tested, packaged and held.	
6. FIELD OBLIGATIONS The field will conduct drug process inspections and maintain profiles or other monitoring systems which will insure that each drug firm receives the inspection coverage provided for in the inspectional strategy.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.	

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance PAC 56008A, 56008L, 56008H	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To obtain information about the quality of the nation's drug supply through analyses of selected domestic and imported finished dosage form products and active pharmaceutical ingredients (APIs). To direct analytical coverage towards drug products, firms, and countries which pose a heightened risk to the consuming public relative to the risk-based management system. To obtain information about the identifying characteristics (forensic testing) of APIs from domestic/foreign sources in order to establish a forensic database to evaluate formulation changes and uncover possible counterfeiting.	
5. PROGRAM JUSTIFICATION FDA has the mandate to assure that the nation's drug supply is safe and effective. The Drug Product Surveillance program is FDA's primary means for monitoring the quality of finished drug products and APIs through sampling and analysis.	
6. FIELD OBLIGATIONS To collect samples and perform laboratory examinations. Upon assignment from CDER, conduct inspections to obtain specific information, such as analytical results, production data, and formulation.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56 and 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Potency, content uniformity, disintegration, dissolution, time release patterns, identification, microbial contamination, and other selected analyses are directed in Drug Surveillance Requests at CDER/District assignments.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System - DQRS NDA-Field Alert Reporting, PAC 56021A,B	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>To establish and operate a structured system for accumulating and evaluating data generated by Drug Quality Reporting System (DQRS) a voluntary reporting program, and NDA Field Alert Reports (FARs), a program mandated by 21CFR 314.81 for reporting by drug manufacturers.</p> <p>To maintain a flexible capability for rapid investigations and product corrections of any drug product quality problems ascertained from health professionals, consumers and drug product manufacturers.</p>	
5. PROGRAM JUSTIFICATION <p>The DQRS and FAR programs respectively, provide a means for centralizing drug quality reports received by FDA from health professionals, consumers and drug product manufacturers</p>	
6. FIELD OBLIGATIONS <p>Each FDA district Office will appoint a DQRS/FAR program coordinator(s) who will monitor the District's activity/follow-up activity and, serve as a contact person. Districts will perform inspections, sample collections, analyze samples and perform other assignments generated by CDER.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA), PAC 56022	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide general guidance in conducting inspections and investigations of individuals, prescription drug manufacturers, distributors, and other parties that may be involved in the diversion of prescription drug samples, American Goods Returned, or the resale of drugs by hospitals or other health care entities, thereby disrupting legitimate domestic prescription drug distribution channels.	
5. PROGRAM JUSTIFICATION FDA has the mandate to enforce the Prescription Drug Marketing Act amendments to the Federal Food, Drug and Cosmetic Act. These amendments are designed to curtail diversion of prescription drug products from legitimate channels of distribution.	
6. FIELD OBLIGATIONS To follow-up on routine reports referred from CDER during regularly scheduled inspections; upon CDER assignment to perform investigations of possible drug diversion reports; and to collect samples and perform laboratory examinations as appropriate to support regulatory activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Analysis as directed in CDER/district assignments.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations (Domestic and Foreign), PAC 56843	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>To minimize the consumer's risk of exposure to defective drug products due to significant process design and control issues by preventing the marketing of, or removing from the market, violative drug products that are observed as a result of activities performed under this program. To assess the adequacy of the associated agency regulatory policies by gathering industry-wide data on changing practices and technology for specific drug products.</p>	
5. PROGRAM JUSTIFICATION <p>The Post-Approval Inspections/Investigations program is designed to detect significant process design and control problems at a drug manufacturer early in a product lifecycle. The post-approval inspection is planned for six to eighteen months after approval/marketing of the drug product or biotech product. Focused objectives for inspections/investigations include issues related to ongoing events and evolving agency priorities, including supplier qualification/materials handling, process validation, stability program and laboratory data, and conformance to the application/license commitments.</p>	
6. FIELD OBLIGATIONS <p>The field will conduct post-approval inspections as assigned by the Center. Inspection assignments will typically include the area that the investigator should focus on during the inspection. The field will also recommend firms to inspect to ensure that the highest risk products are targeted.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments PAC 56D015	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Monitor, investigate and take regulatory action, (including working jointly with state regulatory officials), on complaints involving pharmacy compounded drug products and pharmacy compounding operations that are in violation of applicable sections of the Federal Food, Drug, and Cosmetic Act (the Act).	
5. PROGRAM JUSTIFICATION FDA ensures the availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. The agency investigates complaints reports of illnesses associated with compounded drug products. The agency will consider regulatory action, where necessary, to protect the public health and address applicable violations of the Act.	
6. FIELD OBLIGATIONS Districts will conduct inspections and investigations, collect evidence, samples and develop cases in accordance with Assignments from CDER/OC/ODLDC and completed in accordance with CPGM 7352.002, Unapproved New Drugs.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56 and 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Global Parity Program PAC 56R010	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The Global Parity Initiative is a collaborative effort between CDER and ORA and will include the participation of ten (10) ORA employees in a 3-6 month detail performing training modules and reviewing foreign regulatory authority inspection reports. This program will use domestic inspection resources toward improving our knowledge of foreign manufacturing operations, facilities, and counterpart inspectorates.	
5. PROGRAM JUSTIFICATION The Global Parity Initiative is a new collaboration between CDER and ORA that implements the Commissioner's "Pathway to Global Product Safety and Quality" initiative. Specifically, this program will support our aim to leverage foreign regulatory authority inspections.	
6. FIELD OBLIGATIONS <ul style="list-style-type: none"> • Identify districts that will benefit from the detail work • Manage current workload adjustments and leave requests for detailed staff 	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING The hours assigned for inspection report completion can be adjusted as employee efficiency increases.	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 56R838	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> N/A COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic activities PAC 56R838 or OCI PAC 56R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report time spent on these activities as PODS Operation Code 03, PAC 56R838 Petition Validation, Methods Development, or Forensic Evaluation. Please consult DFS and/or DPEM for additional reporting guidance.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, and OTC Monographs PAC 63001A, 63D012	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 1) To identify and evaluate OTC drug products and to assure their compliance with specific OTC drug monographs or other regulations; 2) to minimize consumer exposure to health fraud drugs that make fraudulent drug claims for serious disease states, contain hidden drug ingredients, and/or target vulnerable populations. 3) To identify and take appropriate action against health fraud products, as previously described, that are unapproved new and/or misbranded drugs sold in interstate commerce.	
5. PROGRAM JUSTIFICATION 1) In the Federal Register of 1/5/72, the Commissioner announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory panels. As a result, final monographs are published (21 CFR Part 330 through Part 358) which establish conditions under which OTC drugs can be generally recognized as safe and effective and not misbranded; 2) Health Fraud drugs pose serious risks to consumers and threaten the drug approval process. Moreover, health fraud drugs are illegal because they violate the Federal Food, Drug, and Cosmetic Act (FDCA) in various ways. For example, health fraud drugs are unapproved new drugs under 21 U.S.C §§ 321(p) and 355(a). Health fraud drugs are also misbranded under 21 U.S.C. §352 when such products contain drug ingredients that are not declared on the product labeling or when the labeling contains misleading claims.	
6. FIELD OBLIGATIONS The Field conducts inspections and investigations, develops evidence, collects and analyzes samples, evaluates product labeling, performs surveillance activities, and recommends compliance actions concerning OTC drugs, fraudulent drugs and drugs sold on the Internet as set forth in applicable compliance programs and CDER guidance and requests for follow-up.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, and 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE New Drug (Prescription) Without Approved NDAs PAC 63002	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To establish uniform procedures for removal from the market of all prescription drug products described by FDA to be new drugs not covered by approved New Drug Applications consistent with the enforcement policy articulated in Compliance Policy Guide (CPG) 440.100 "Marketed Unapproved Drugs."	
5. PROGRAM JUSTIFICATION The Drug Amendments of 1962 to the FD&C Act require that all marketed drug products be safe and effective. However, some drugs are available in the United States that lack the required FDA approval. FDA's Marketed Unapproved Drugs Initiative is aimed at efficiently and rationally bringing all marketed unapproved new drugs into the approval process. The Agency's final guidance, "Marketed Unapproved Drugs—Compliance Policy Guide (CPG)," outlines FDA's enforcement policies in this regard. FDA uses a risk-based enforcement program in order to concentrate its resources on those products that pose the highest threat to public health and without imposing undue burdens on consumers, or unnecessarily disrupting the market. Unapproved new drugs introduced onto the market after September 19, 2011 are subject to immediate enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in the CPG. For unapproved new drugs commercially used or sold as of September 19, 2011, the CPG gives highest enforcement priority to the following: 1) Drugs with potential safety risks, 2) Drugs that lack evidence of effectiveness, 3) Health fraud drugs, 4) Drugs that present direct challenges to the new drug approval and OTC drug monograph systems, 5) Unapproved new drugs that are also violative of the Act in other ways, and 6) Drugs that are reformulated to evade an FDA enforcement action.	
6. FIELD OBLIGATIONS -Assign District Coordinator, whose name shall be supplied to CDER/OC/OU DLC -Maintain records of all activities under this program, including a list of drug products voluntarily removed from the market in compliance with the warning letters, products removed by recall, etc. -Initiate regulatory actions, where appropriate, to assure compliance with program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Prescription Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56 and 60-66
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects PAC 88 SHELF	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To develop an effective program for extending the shelf Life of about-to expire drugs and medical devices.	
5. PROGRAM JUSTIFICATION Congress has placed a high priority on maintaining the military in a state of readiness. This includes purchasing and storing for contingency use sufficient quantities of medical products needed to sustain our military forces under wartime conditions. This project is established to assist DOD in reducing the cost of replacement stocks as the stockpiled materials expire.	
6. FIELD OBLIGATIONS Selected laboratories, on assignment from MPQAS.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56, and 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Environmental chambers used to stress drug products.	

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections PAC 68001, 68001G	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives 68
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities to fulfill their NADA commitments to manufacture, process, and pack new animal drugs that are safe and effective for their intended use. Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION Domestic and foreign plant inspections are necessary to determine whether the establishment can produce the new animal drug in accordance with current good manufacturing practice regulations and comply with the commitments in the NADA. Inspections will be issued by assignment. Priority will be specified by CVM. Outcome: Reduce new animal drug development and review time.	
6. FIELD OBLIGATIONS The Field will conduct NADA Pre-Approval Inspections at domestic and foreign plants in accordance with the assignment. Establishment inspection reports will be submitted to the New Animal Drug Evaluation (NADE) Program Manager (HFV-140) according to the procedures outlined for field reporting requirements in the compliance program. Field laboratories on an assignment basis will validate methodology submitted with NADAs.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs, Type A Medicated Feed Articles	d. INDUSTRY/PRODUCT CODE(S) 57, 67, 68
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Petition validation work.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-clinical Laboratory) PAC 68808, G	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives 68
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections of facilities and non-clinical laboratories engaged in the collection of data to determine whether the GLP regulations (21 CFR 58) are followed. To take appropriate action whenever a situation involving a serious violation of the GLPs is encountered or when fraud or other deliberate falsifications of test data has occurred.	
5. PROGRAM JUSTIFICATION FDA requires that extensive animal and other types of testing be carried out before approving new animal drug applications or animal food petitions. The FDA's reliance on the basic accuracy of data submitted is essential to the review and approval of Agency-regulated products. The submission of faulty, erroneous, or distorted data increases the potential for wrong decisions and makes it difficult, if not impossible, to draw conclusions regarding the health hazards of the tested product. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS ORA will perform the inspections and submit EIRs in accordance with established procedures set forth in the basic compliance program 7368.808.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 67,68 and 69
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors PAC 68810, G	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives 68
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure the adherence of sponsors, contract research organizations and monitors to the regulations (21 CFR 511.1) New Animal Drugs for investigational use.	
5. PROGRAM JUSTIFICATION As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. Part of this comprehensive program was directed to sponsors, monitors, and clinical investigators under the above stated objective. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS Conduct inspections of sponsors, contract research organizations, and monitors, identified by the Center in accordance with the guidance set forth in the basic compliance program 7368.810.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 67, 68 and 69
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators PAC 68811, G	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives 68
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assess through audit procedures (21 CFR 511.1 (b)) whether data submitted by clinical investigators to FDA in a specific clinical study are substantiated by records.	
5. PROGRAM JUSTIFICATION As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. The program determines the validity of data submitted to FDA by inspecting clinical investigators' records. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS Conduct inspections of clinical investigators identified by the Center in accordance with the guidance set forth in the basic compliance program 7368.811.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 67, 68, and 69
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Animal Drug Manufacturing Inspections Type A Medicated Articles PAC 71001, A, B, 71005, A	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21 CFR 211 for approved and unapproved finished dosage form products and 21 CFR 226 for the Type A Medicated Articles. To obtain accurate listing and labeling information for animal drug establishments. To check and verify the existence and scope of stability testing programs, protocols and commitments, and the validity of storage conditions, testing criteria and methodology together with reporting of results in the Drug Experience Report (DER) as specified in the approved New Animal Drug Application (NADA)/ Abbreviated New Animal Drug Application (ANADA).	
5. PROGRAM JUSTIFICATION Section 510(h) of the Act obligates the Agency to inspect (pursuant to 704 of the Act) drug establishments required to register with FDA. In addition, it is one of the primary purposes of establishment inspections to assure that the drug product is being manufactured, processed, controlled, etc. under the same conditions as approved and that it maintains the same stability profile as originally demonstrated. Outcome: Ensure the safety and effectiveness of animal drugs.	
6. FIELD OBLIGATIONS The field will conduct CGMP inspections of registered animal drug establishments.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Animal Drug Dosage forms and Type A Medicated Articles. Medicated feeds or blocks are not included.	d. INDUSTRY/PRODUCT CODE(S) 54, 56, 60-66, 67, 68
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Purity, identity, potency, decomposition	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants PAC 71003 A,B,C,E,G-K	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To monitor domestic and imported animal feed and feed ingredients to prevent widespread contamination of the nation's food supply. Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION The use of contaminated feed ingredients has resulted in adulterated animal feeds and in economic losses to producers and processors when food-producing animals consume adulterated feeds. A hazard to human health may result from subsequent deposition of residues in meat, poultry, eggs, fish and dairy products. These foods constitute a significant portion of the human diet and fraud. Outcome: Prevention or containment of potential human or animal health hazard.	
6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis. Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Complete animal feeds and feed ingredients.	d. INDUSTRY/PRODUCT CODE(S) 54 and 69-72
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Mycotoxins, Pesticides, Industrial Chemicals, Metals, Microbiologicals, Antibiotics and Dioxins.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing PAC 71004, A	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine compliance with GMP elements of registered establishments producing medicated feeds. To determine whether a firm has an approved license to make certain medicated feeds.	
5. PROGRAM JUSTIFICATION Under Sec. 510(h) of the Act, the Agency is obligated to inspect registered medicated feed establishments. Outcome: Ensure the safety and effectiveness of animal feeds.	
6. FIELD OBLIGATIONS To conduct inspections of registered medicated feed establishments and State audit inspections as needed. Districts will collect and analyze samples when appropriate. Field will coordinate federal/state operations.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Medicated Feeds	d. INDUSTRY/PRODUCT CODE(S) 69
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Illegal Drug Residues in Meat and Poultry PAC 71006	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections when illegal residues are reported to FDA. To initiate regulatory actions against those firms causing drug residues in food. To reduce future residues in edible animal tissues. FDA will partner with USDA FSIS and will develop educational initiatives, and, as necessary, regulatory actions.	
5. PROGRAM JUSTIFICATION FDA is charged with the responsibility to ensure that food is free of adulterants which may render it injurious to health. FDA conducts inspections as a follow-up to residue findings to identify the source of adulteration and take corrective action to prevent it from re-occurring. This is a cooperative program involving FDA, USDA, EPA, and a number of state governments. Outcome: To provide a safe human food supply.	
6. FIELD OBLIGATIONS To conduct inspections in accordance with the compliance program requirements and sample assignments based on the Memoranda of Understanding (MOU) between FDA, USDA, and EPA. Coordinate state activities with states having MOUs, informal and formal agreements or contracts with FDA to conduct inspections at establishments below the Risk Score Threshold for FDA inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Meat and Poultry, Animal Feeds and Drugs	d. INDUSTRY/PRODUCT CODE(S) 16, 17, 67, 68, and 69
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Tissue Sample analysis by Denver laboratory when required.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE BSE/Ruminant Feed Ban Inspections PAC 71009, 71R844, 71R843	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To enhance the FDA's uniformity in inspection and compliance of firms subject to the regulation prohibiting the use of specified animal proteins in ruminant feeds. 21 CFR 589.2000. A second rule 21 CFR 589.2001, prohibits the use of certain cattle origin-materials in all animal feed. To ensure that specified animal proteins do not enter the U.S. from BSE-at-risk countries.	
5. PROGRAM JUSTIFICATION Bovine Spongiform Encephalopathy (BSE) is the bovine form of a group of uniformly fatal neurological diseases known as Transmissible Spongiform Encephalopathies (TSEs). BSE appears to be spread through the feeding of infected material to cattle. BSE is a public health issue for the U.S. This disease has been linked to the human TSE known as variant Creutzfeldt-Jakob Disease (vCJD), presumably through people consuming ruminant tissues infected with the BSE agent. In addition, BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected. Outcome: To prevent the establishment and amplification of BSE through feed in the United States.	
6. FIELD OBLIGATIONS To conduct inspections, investigations, and sample collections/analyses to implement this program. All firms that handle animal feed and feed ingredients that may contain ruminant-based material are the subject of this program. To provide guidance concerning the importation of animal feeds and feed ingredients from BSE at-risk countries, in accordance with Import Alert #99-25. See full program for more detail.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All feeds and feed ingredients	d. INDUSTRY/PRODUCT CODE(S) 67-72
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<p>1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 71R816</p>	<p>2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71</p>
<p>3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.</p>	
<p>5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.</p>	
<p>6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Office of Regulatory Science.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S)</p>	<p>d. INDUSTRY/PRODUCT CODE(S)</p>
<p>e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 71R838	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To analyze domestic and imported animal feed and feed ingredients in support of criminal investigations. To prevent widespread abuses by the nation's food suppliers.	
5. PROGRAM JUSTIFICATION	
6. FIELD OBLIGATIONS	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments, Pandemic Preparedness PAC 71V800	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.	
5. PROGRAM JUSTIFICATION A number of potential or emerging problems which cannot be predicted must be handled. The resources for these Center initiated assignments are planned under this umbrella program.	
6. FIELD OBLIGATIONS Conduct inspections, investigations, sample collections and analyses as directed by Center assignments.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All veterinary products	d. INDUSTRY/PRODUCT CODE(S) 54, 56, 67-72
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting – MDR Follow-up PAC 81010	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Rapidly identify immediate hazards to health; Identify significant problems by analyzing recurring problems and performing trends analysis; Provide data on complaints, significant problems and potential hazards so that corrective action can be initiated for hazardous products in the marketplace.	
5. PROGRAM JUSTIFICATION Early detection of device problems is necessary to protect the public from health hazards. Reports of device defects are often the first warning of manufacturing or other problems. When the Center receives notices from manufacturers that a device has been associated with a death or serious injury, it may issue a priority assignment to the field for follow-up at the manufacturer reporting site (usually a medical facility). When the Center's evaluation of the problem report suggests that there is an actual or potential health hazard it issues an assignment to the field for immediate follow-up.	
6. FIELD OBLIGATIONS On assignment, follow up on MDR reports either at the medical facility or manufacturer.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Sterility Performance	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.	

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import PAC 82008	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine compliance of imported devices with the medical device registration and listing requirements, and other general controls.	
5. PROGRAM JUSTIFICATION There are indications that some foreign manufacturers are not registered or listed. Foreign manufacturers of Class II and III devices must be identified for scheduling GMP inspections. In addition, because foreign device manufacturers cannot be inspected as readily as domestic manufacturers, their products must be monitored at the port of entry.	
6. FIELD OBLIGATIONS The field will conduct electronic examinations and/or examine entry documentation for medical devices and ascertain, in conjunction with information provided by CDRH, whether the manufacturer is listed and the initial distributor is registered with CDRH.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to Compliance Program for procedures to handle initial distributors and/or foreign establishments which are not registered.	

<p>1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers PAC 82845</p>	<p>2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82</p>
<p>3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES To evaluate the manufacturing processes used for general and radiation-emitting medical devices and in vitro diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations.</p>	
<p>5. PROGRAM JUSTIFICATION The Center's inspectional strategy requires that all manufacturers of Class II and III devices be inspected under the GMP Compliance Program on a biennial basis. FDA selects certain establishments for intensive GMP coverage. Establishments with a history of good GMP systems are subject to less-intensive inspections. All establishments are subject to complaint file reviews to assess compliance with the MDR regulation.</p>	
<p>6. FIELD OBLIGATIONS Under the Quality Systems/GMP strategy, the field should conduct biennial inspections of high-risk device manufacturers and Class III device manufacturers that are not considered to be high risk. The remaining manufacturers (Class III, II, and I devices) should be inspected as each district's resources allow, and scheduled according to the priority outline described in Part II of the compliance program. For more detailed instructions on QSIT/GMP inspections as they relate to device manufacturers, refer to the Workplanning Sheet's Remarks section.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) All Class II and III Devices and all Class I Devices which have been finally classified for one year.</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 73-91</p>
<p>e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Engineering Samples: Subs/Sample will vary depending on cost, size, etc. Contact Center for guidance if the device presents such problems.</p>	

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment PAC 82Z002	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine the extent to which manufacturers of condoms comply with the Device GMP requirements; Assure that both domestic and imported condoms comply with the FDA standards.	
5. PROGRAM JUSTIFICATION The Surgeon General has recommended the use of condoms to reduce the spread of AIDS. Consequently, FDA is committed to assuring that condoms are safe and effective.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic condom manufacturers and major repackers. Districts will also sample both domestic and imported condoms and conduct tests to assure conformance with the FDA standard.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 85
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves PAC 82Z003	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine the extent to which manufacturers of both surgical and examination gloves comply with the Device GMP requirements; Assure that both domestic and imported gloves comply with the applicable FDA standard.	
5. PROGRAM JUSTIFICATION Healthcare providers rely heavily on gloves to prevent the transmission of the AIDS virus. Consequently, FDA is committed to assure that both surgical and examination gloves comply with published standards.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic manufacturers. Districts will also sample gloves for testing by the designated laboratories.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 85
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments PAC 82Z800	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.	
5. PROGRAM JUSTIFICATION A number of potential or emerging problems which cannot be predicted must be handled rapidly. This workplan activity provides resources for Center assignments which can rapidly address potential or emerging problems.	
6. FIELD OBLIGATIONS Conduct inspections and investigations as directed by Center assignments.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Sterility/Performance	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 82R816	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Office of Regulatory Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 82R838	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related Acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize, and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. Please consult ORS and/or the DPEM for additional reporting guidance.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections PAC 83001	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that both prior to and subsequent to approval of a PMA application, the manufacturer has the capability of manufacturing the PMA device in accordance with (1) the conditions specified in the PMA application and (2) the requirements of the device GMP regulation.	
5. PROGRAM JUSTIFICATION Section 515 of the Act requires that devices subject to Premarket Approval must be manufactured in conformance with the requirements of the device GMP regulation. Consequently, no PMA application can be approved until the Center has inspectional evidence that the manufacturer complies with the requirements set forth in the Premarket Approval application.	
6. FIELD OBLIGATIONS The field will conduct pre-approval inspections on assignment and submit an EIR to the Center along with the District's recommendation. The field will be responsible for scheduling (b) (5), (b) (7)(E) Under certain conditions, a post-approval inspection will not be necessary. The Center will advise the district when a post-approval inspection is not necessary.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring PAC 83808, 83809, 83810, 83811	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure the quality, reliability and integrity of data and information supporting device applications (PMA's, 510(k)s or IDEs) and their claims of safety and effectiveness; To ensure that human subjects taking part in clinical trials involving medical devices are protected from undue hazard or risk; To coordinate, implement and enforce the provisions of the Agency's Application Integrity Policy (AIP) for medical devices; To enforce the prohibition against promotion and/or commercialization of investigational devices.	
5. PROGRAM JUSTIFICATION Congress has mandated that the Agency maintain close surveillance of bioresearch activities done in support of application. CDRH issues assignments and provides inspectional/investigational support documents for transmission to the field through ORA's Office of Enforcement (HFC-230). The Center reviews and evaluates all Establishment Inspection Reports (EIRs) from the field and is responsible for the final classification of all bioresearch monitoring inspection reports and the issuance of all associated correspondence.	
6. FIELD OBLIGATIONS To conduct inspections, investigations and other activities related to the bioresearch monitoring programs or the Agency's Application Integrity Policy for medical devices and to submit EIRs to the Center for review, evaluation and final classification. The field is encouraged to review and initially classify inspection reports generated under the bioresearch monitoring program. However, final classification authority rests with the Center and decisions will be communicated promptly to the field.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73Z, 74Z and 94Z, 95Z
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation PAC 84Z002	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the quality of devices through product analysis and data evaluation.	
5. PROGRAM JUSTIFICATION Product evaluation study projects provide comprehensive postmarket surveillance information about devices.	
6. FIELD OBLIGATIONS Conduct laboratory analysis using test methods from a variety of sources.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) To be assigned	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 84R816	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Office of Regulatory Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program PAC 85014	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To inspect certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA); To bring uncertified facilities into compliance with MQSA.	
5. PROGRAM JUSTIFICATION MQSA (Public Law 102-539) establishes uniform, national quality standards for mammography. It establishes a comprehensive statutory mechanism for certification and inspection of all mammography facilities under the regulatory jurisdiction of the United States. Under the MQSA, only certified facilities that are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation starting October 1, 1994. Operation after that date is contingent on receipt of a certificate from the FDA. The authority to implement the MQSA was delegated by the Secretary of Health and Human Services (HHS) to FDA in June 1993.	
6. FIELD OBLIGATIONS Inspect certified mammography facilities in accordance with procedures specified in the compliance program. Conduct follow up inspections to determine whether the facility has complied with the terms of their corrective action plan, based on noncompliances found during a prior inspection. Perform on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Mammography equipment	d. INDUSTRY/PRODUCT CODE(S) 90
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products PAC 86001, 86002, 86004	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of inspections and tests conducted under this program are <ul style="list-style-type: none"> • To evaluate an electronic product manufacturer's quality control testing program for its ability to ensure such product compliance and radiation safety; • To identify certified electronic products which fail to comply with the requirements of applicable performance standards; • To obtain correction of deficient quality control testing programs and noncompliant products identified by initiating appropriate administrative/regulatory action; • To provide guidance to manufacturers regarding compliance with the laws and regulations administered by FDA. 	
5. PROGRAM JUSTIFICATION Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Manufacturers are responsible for producing products that do not emit hazardous or unnecessary radiation and that comply with all applicable radiation safety performance standards. All electronic product manufacturers must comply with applicable requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. If a mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with Title 21 CFR 1010 and the product must comply with the requirements of the specific standard found in 21 CFR 1020 – 1050. Manufacturers are required to self-certify their own products to be compliant with an applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. EPRC inspections and field tests verify that electronic products comply with performance standards, and that manufacturer quality control testing programs ensure product compliance and radiation safety.	
6. FIELD OBLIGATIONS Field personnel will initiate and schedule inspections of electronic product manufacturers as instructed in Compliance Program 7386.001. CDRH is generally responsible for the final review of inspections and field tests made under this program and for the issuance of letters resulting from inspections and field tests performed by field radiological health staff. Exceptions where the district has direct reference authority are noted in Compliance Program 7386.001. Joint EPRC/medical device (QSIT) inspections may be conducted under both Compliance Program 7386.001 and 7382.845.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Lasers and laser products, Sunlamp and sunlamp products Cabinet x-ray products, Televisions and Microwave Ovens	d. INDUSTRY/PRODUCT CODE(S) 94-RXX, 95-RXX See Compliance Program 7386.001 for complete listing
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Specific product inspection and field test checklist or forms, if available, are included as Compliance Program Attachments. These checklists may be used to the extent practicable to record inspection and test observations.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Caution: laser product may be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.	

<p>1. PROGRAM/ASSIGNMENT TITLE Insp. of Manuf. (For and Dom) and Field Compliance Testing of Diag. X-Ray Equipment PAC 86003</p>	<p>2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86</p>
<p>3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES</p> <p>The objectives of inspections and tests conducted under this program are:</p> <ol style="list-style-type: none"> 1. To ensure that the regulated products and manufacturer quality control programs conform to EPRC regulations; 2. To identify diagnostic x-ray products which fail to comply with the applicable performance standard requirements; 3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and 4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA. 	
<p>5. PROGRAM JUSTIFICATION</p> <p>Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Diagnostic x-ray manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary x-radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Because diagnostic x-ray equipment is also subject to performance standards, the manufacturer must also comply with Title 21 CFR 1010 and the equipment must comply with the specific standards found in 21 CFR 1020.30 – 1020.33. Manufacturers are required to self-certify their products comply with the applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. EPRC inspections and field tests verify that electronic products comply with performance standards, and that the manufacturer's quality control testing program ensures product compliance and radiation safety.</p>	
<p>6. FIELD OBLIGATIONS</p> <p>Field personnel will initiate and schedule inspections of diagnostic x-ray manufacturers and field tests of diagnostic x-ray equipment as instructed in Compliance Programs 7386.003 and 7386.003a. CDRH is generally responsible for the final review of inspections and field tests made under this program and for the issuance of letters resulting from inspections and field tests performed by field radiological health staff. Exceptions where the district has direct reference authority are noted in Compliance Program 7386.003 and 7386.003a. Joint EPRC/medical device (QSIT) inspections may be conducted under both Compliance Programs 7386.003a and 7382.845.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED</p> <p style="text-align: center;"> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH </p>	
<p>b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) Diagnostic X-Ray Equipment</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 94DS--</p>
<p>e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING</p> <p style="text-align: center;"> <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>) </p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p> <p>Field tests will be performed by consumer safety officers who have received specialized training which includes approximately two weeks of on-the-job training with a qualified auditor.</p>	

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC PAC 86006	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority-86
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of laboratory tests conducted under this program are: <ol style="list-style-type: none"> 1. To ensure that the regulated products conform to EPRC regulations; 2. To identify products which fail to comply with the applicable performance standard requirements; 3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and 4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA. 	
5. PROGRAM JUSTIFICATION Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Electronic product manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Products also subject to performance standards must comply with the specific standards found in 21 CFR 1020 – 1050. EPRC laboratory tests verify that electronic products comply with performance standards at the point of manufacture, and that the manufacturer's quality control testing program ensures product compliance and radiation safety.	
6. FIELD OBLIGATIONS WEAC will test all products in accordance with the appropriate Compliance Program and/or test methods. Products will be identified for testing by both WEAC and CDRH for either routine or for cause testing. WEAC will request samples for direct shipment from manufacturer or distributor of product. WEAC will retain products tested until all compliance actions have been completed or upon notification from CDRH. WEAC will also conduct all foreign inspections for electronic product manufacturers, other than diagnostic x-ray manufacturers. See Compliance Program for joint EPRC/medical device (QSIT) inspections. CDRH is responsible for the final review of inspections and lab tests conducted under this program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Lasers, sunlamps, mercury vapor lamps, x-ray systems, ultrasound therapy products, televisions, and microwaves.	d. INDUSTRY/PRODUCT CODE(S) 96MS, 94VS, 94DS, 95US, 97US
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products PAC 86007	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of laboratory tests conducted under this program are: <ol style="list-style-type: none"> 1. To ensure that the regulated products conform to EPRC regulations; 2. To identify products which fail to comply with the applicable performance standard requirements; 3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and 4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA. 	
5. PROGRAM JUSTIFICATION Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Electronic product manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Products also subject to performance standards must comply with the specific standards found in 21 CFR 1020 – 1050. EPRC imports entry reviews verify that electronic products subject to performance standards have been reported to FDA as required.	
6. FIELD OBLIGATIONS (b) (5), (b) (7)(E)	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All radiation emitting electronic products that are subject to a performance standard contained in 21 CFR 1020 – 1050.	d. INDUSTRY/PRODUCT CODE(S) 94-97
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities PAC 86008, 86009	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Use Control: Provide technical assistance to State and Federal radiological health programs implementing FDA use control programs, including DENT (see the compliance program for a more complete statement of objectives and laboratory support); Maintain liaison with State radiological health programs; Provide support for regional training activities and regional videotape library; Promote implementation of programs to optimize radiation exposure; Communicate FDA policies to State and local health agencies. Emergency Planning & Response Activities: To act as a focal point for emergency readiness response planning by States.	
5. PROGRAM JUSTIFICATION Medical Device and Radiological Health Use Control and Policy Implementation: Rapidly changing technology requires that the FDA develop use control programs whose effective implementation will require training beyond that possessed by most State radiological health program personnel. Emergency Planning & Response Activities: The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.	
6. FIELD OBLIGATIONS Use Control: RRHRs will maintain liaison and provide technical assistance to State/Federal radiological health program personnel; assist in the planning and presentation of quality assurance training with the region; help select State participants in new use control programs; serve as managers of the regional videotape library; and attend the following meetings: National Conference of State Program Directors; Regional meetings with state and local radiological health agencies; and HQ annual meetings with CDRH, ORA and other FDA officials. WEAC will provide Laboratory Support for the DENT programs. Emergency Planning & Response Activities: Provide consultation to states and attend regional emergency planning meetings.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) Emergency Planning & Response Activities: 94YN-99
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Regulated Tobacco Products - Domestic and Import PACs 96R800, 96T800, 96R824, 96R833	2. PPS PROJECT NAME/NUMBER Tobacco - 96
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Using a Tobacco Cadre Team of approximately five investigators who will report to a supervisor in ORA headquarters, ORA will inspect and investigate domestic establishments of regulated and imported tobacco product to determine compliance with the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act and its implementing regulations. ORA will conduct inspections, investigations and sample collections to support Center-initiated administrative and/or enforcement action when violations are observed.	
5. PROGRAM JUSTIFICATION The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act requires the agency to conduct inspections at least once during a two-year period.	
6. FIELD OBLIGATIONS CTP plans to issue multi-district inspection and investigation assignments as needed in lieu of any compliance program(s) during the fiscal year to cover all statutory and regulatory provisions in effect. CTP anticipates approximately half the universe of registered tobacco establishments to be inspected during the fiscal year. Further, CTP anticipates the collection of domestic samples for laboratory analysis to either support enforcement actions or to ensure compliance with certain provisions in effect. CTP plans to develop import alerts and assignments as needed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco	d. INDUSTRY/PRODUCT CODE(S) All tobacco codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label, Labeling, Advertising Reviews</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Cigarette, cigarette tobacco, components, parts & accessories labeled with flavor; "low," "light," "mild" descriptor provision for all tobacco products. Labeling/promotion information as requested in each assignment.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Liquid chromatography coupled to triple quadrupole mass spectrometer (LC/MS-MS); Gas Chromatography coupled with flame-ionization-detector and mass spectrometer (GC/FID/MS); GC/MS; GC/MS-MS among other instruments.	