

**Memorandum**

Date September 20, 2010

From Director, Program Planning and Workforce Management Branch

Subject Final FY 2011 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 enclosed Final FY 2011 ORA Field Workplan is based on the Centers' compliance program forecasts which incorporate input of the Centers and the Field Committees during their review of the draft Workplan sheets. The FY 2011 Workplan is based on ORA's planning level of 2,196 Operational FTEs. This represents an overall increase of 233 Operational FTEs from the FY 2010 Workplan. This increase reflects the substantial hiring that has occurred over the past few years.

During the previous two years, the Field Workplans have included the Centers and ORA's risk based approaches in allocating resources within the five program areas. (b) (7)(E)

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(b) (7)(E) Please contact DPWM if you would like to discuss our approach during the upcoming FY 2012 Workplanning Process.

The risk based approaches that are included in the Foods Workplan may result in resource questions, but we want to emphasize that Districts will have enough resources to meet their performance goals. Please note that the Workplan only includes resources for ORA investigators and analysts and does not plan operations to be conducted by States under contract. Districts will have specific lists of high risk firms to inspect, based on risk modeling by CFSAN. While it is difficult to plan for inspection of the high risk firms on a program by program basis, overall each District should have sufficient planned inspectional resources and state contracts to cover all their high risk food firms. For a District, it means you may overburn in the Domestic Cheese Program, and underburn in the Domestic Food Safety Program, but overall the resources

should balance out.

As in the FY 2010 Workplan, the FY 2011 Workplan includes resources to meet Congressional Targets. These Targets are linked to the level of appropriations in the Congressional budget. ORA's appropriated funding increased and Congress directed a specific corresponding increase in operational activities. These increases are directed towards foreign inspections, domestic inspections, import field exams, and sample collection/analyses. The FY 2011 Workplan provides sufficient resources to meet both the Congressional Targets and Performance Goals. Please see below for a listing by program area of the significant planning measures that are included in the FY 2011 Workplan:

Foods and Cosmetics:

- 160,158 Import Field Exams
- 6,806 Domestic Food Inspections
- 994 Foreign Food Inspections, with 400 planned in HQ

Biologics

- 533 Domestic Human Tissue Establishment Inspections
- 2 Foreign Human Tissue Inspections

Human Drugs:

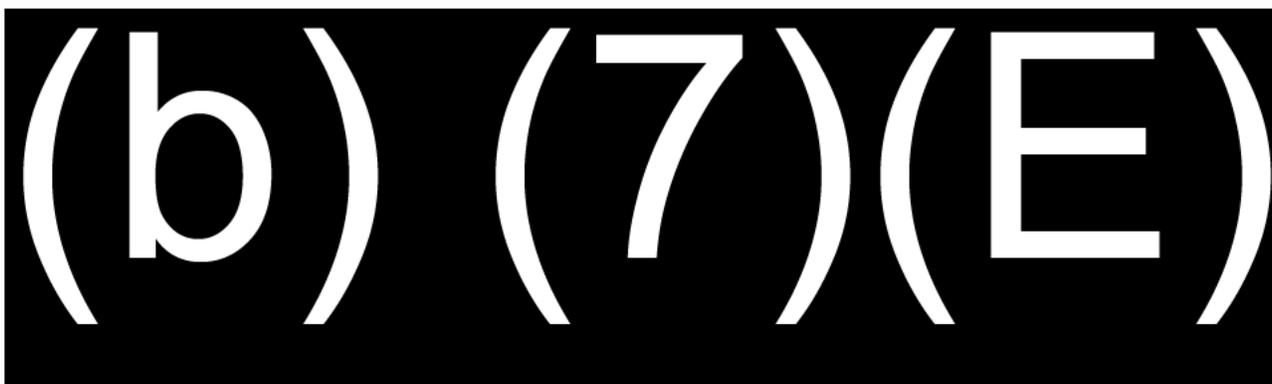
- 750 High Risk Post-Approval Human Drug Inspections (some of which may be included in the 419 Congressional Expectation Inspections)
- 419 Post-Approval Human Drug Foreign Inspections, with 250 planned in HQ

Animal Drugs & Feeds:

- 10 Foreign Feed Inspections
- 33 Foreign Post-Approval Animal Drug Inspections
- 250 High Risk Foreign and Domestic Animal Drug and Feed Manufacturer Inspections (some of which may be included in the 10 Foreign Feed Congressional Expectation Inspections)

Devices and Radiological Health:

- 313 Post Market Devices/Rad Health Foreign Inspections, with 180 planned in HQ
- 300 Foreign and Domestic BIMO Inspections
- 1,445 Foreign and Domestic Class II and III Medical Device Manufacturer Inspections (some of which may be included in the 313 Post Market Device Congressional Expectation Inspections)



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Additional Workplan Documents

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FY 2011 Workplan Changes:

The “FY 2011 Workplan Changes” spreadsheets provide a listing of programs compared to the FY 2010 ORA Field Workplan, and will enable you to identify where specific resource shifts and programmatic cuts occurred.

FY 2011 Servicing Laboratories Table:

The FY 2011 Servicing Laboratories Table continues to reflect the laboratory servicing changes consistent with ORA’s Laboratory capabilities determined by the Division of Field Science. Please note that there may be conflict between the National Sample Distributor (NSD) and the Servicing Laboratories Table. **If a conflict is identified, overrides to the NSD will only be allowed on exception and with proper approval.** Please direct issues or concerns regarding the Table and NSD to the Division of Field Sciences.

To effectively utilize ORA’s National Laboratory Resource (NLR) and strategically coordinate field sample collections, a new ORA-wide procedure is being developed to manage and maintain the NSD. The procedure will include a collaborative process to define lab capacities and set the NLR capacity for the entire work week. The procedure will require all samples collected by field personnel to utilize the NSD for assigning samples to specific laboratories.

FY 2011 Workplan CD:

The FY 2011 Workplan has been published to a CD format. Your CD is non-writable and cannot be used to store or save data; however you may save any of the files to your PC system or to another media, i.e., zip drive, diskette, etc. 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.

Any questions about the attachments or programs in the Field Workplan should be addressed to the program/project’s planning analyst identified on the workplanning sheets (Form FDA 2622). Policy concerns should be directed to Carrie Mampilly at (301) 796-4390.


Carrie M. Mampilly

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FOODS AND COSMETICS

FY 2011 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2010	WORKPLAN FTEs FY 2011	FTE DIFFERENCE
03003,A	Import Acidified and Low Acid Canned Foods	19.8	15.3	-4.5
03037,D	Domestic and Imported Cheese and Cheese Products	22.2	24.3	2.1
03803A	Domestic Acidified and Low Acid Canned Food	13.9	31.7	17.8
03803,B	Domestic Food Safety	107.2	122.2	15.0
03819A,B	Import Foods - General	246.4	250.1	3.7
03842,B	Domestic Fish and Fishery Products Inspections	44.1	49.5	5.4
03844,B	Import Seafood Products	91.7	89.7	-2.0
03847H	Juice HACCP Inspection Program	7.7	6.6	-1.1
03R233	Unspecified Foreign Inspections/Assessments	1.6	2.5	0.9
03F098	Imported/Domestic Micro Assignment	48.9	48.9	
03F830	CFSAN Environmental Sampling Assignments	61.1	172.8	111.7
03R839	Outbreak and Emergency Response	51.2	77.8	26.6
03R843	Contract Management	12.0	12.0	
03R845	Food Defense	28.0	8.0	-20.0
03R816	Methods Validation/Development Program	10.0	7.0	-3.0
03	Foodborne Biological Hazards	765.8	918.4	152.6
04004A,D	Pesticides & Industrial Chemicals in Domestic & Import Food	59.5	59.5	
04018	Seafood Chemotherapeutics Sampling	33.0	32.7	-0.3
04019A,B,C	Toxic Elements in Foods & Foodware (Domestic & Import)	19.2	19.6	0.4
04839	Total Diet Study	28.6	28.6	
04F800	Field Assignments for Chemical Contaminants	6.5	6.5	
04R816	Methods Validation/Development Program	10.6	7.0	-3.6
04R838	Forensic Evaluation and Sample Analysis	12.0	12.0	0.0
04R839	Outbreak and Emergency Response	11.9	38.3	26.4
04	Pesticides and Chemical Contaminants	181.3	204.2	22.9
07001	Mycotoxins in Domestic and Imported Foods	14.6	14.6	
07R816	Methods Validation/Development Program	4.5	4.5	
07	Molecular Biology and Natural Toxins	19.1	19.1	
09006A,B	Imported Foods-Food and Color Additives	14.6	15.6	1.0
09	Food and Color Additives Petition Review	14.6	15.6	1.0
18002	Retail Food Protection- State Program	26.0	26.0	
18003	(NCIMS) Milk Safety Program	20.4	20.0	-0.4
18004	Molluscan Shellfish Evaluation Program	14.7	14.7	
18029A-F	Interstate Travel Program Conveyances & Support Facilities	21.8	15.8	-6.0
18	Technical Assistance: Food & Cosmetics	82.9	76.5	-6.4
21002	Medical Foods - Domestic and Import	3.7	3.8	0.1
21003	Domestic Food Labeling and Economics Program	3.1	3.1	
21005	Domestic & Import NLEA	12.6	11.8	-0.8
21006	Infant Formula Program	5.6	5.3	-0.3
21008	Dietary Supplements	22.2	21.1	-1.1
21839	Selected Nutrients in Foods - Total Diet	3.4	3.4	
21R816	Methods Validation/Development Program	1.5	1.5	
21	Food Composition, Standards, Labeling, & Econ	52.1	50.0	-2.1
29001	Cosmetics: Domestic and Imports	7.6	8.4	0.8
29	Colors and Cosmetics Technology	7.6	8.4	0.8
	Total Mission Direct: Pre and Annual Planned FTEs	1123.4	1292.2	168.8

BIOLOGICS

FY 2011 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2010	WORKPLAN FTEs FY 2011	FTE DIFFERENCE
41002	Tissue Establishments	25.5	31.0	5.5
41808	Good Laboratory Practices	*	*	
41809	Institutional Review Board	*	*	
41810	Sponsors, CROs, Monitors	*	*	
41811	Clinical Investigators	4.4	5.0	0.6
41	Human Cellular, Tissue, & Gene Therapies	29.9	36.0	6.1
42001F,G	Blood Banks	53.5	54.5	1.0
42002	Source Plasma Establishments	10.9	11.9	1.0
42007	Exam of Blood/Components - Import	3.5	4.0	0.5
42008,A	Licensed Viral Marker Test Kits	2.5	2.5	
42809	Institutional Review Board	*	*	
42810	Sponsors, CROs, Monitors	*	*	
42811	Clinical Investigators	4.0	4.4	0.4
42811	Foreign BIMO Inspection	**	**	
42845A,B,C	Medical Device Manufacturers (Biologics)	0.5	0.5	
42848A,F,G	Plasma Derivatives of Human Origin	3.0	3.5	0.5
42	Blood & Blood Products	77.9	81.3	3.4
45809	Institutional Review Board	*	*	
45810	Sponsors, CROs, Monitors	*	*	
45811	Clinical Investigators	7.0	7.0	
45848A,F,G	Licensed Allergenic Products	0.7	0.7	
45848B,C,D	Vaccine Products	5.5	6.0	0.5
45	Vaccines & Allergenic Products	13.2	13.7	0.5
	Total Mission Direct: Pre and Annual Planned FTEs	121.0	131.0	10.0

* BIMO: 41808, 41809, and 41810 are planned under 41811; 42809 & 42810 are planned under 42811; 45809 & 45810 are planned under 45811.

** Foreign BIMO Inspections include GLPs and Clinical Investigators in PPS 41, 42, & 45 and are planned under 42811.

HUMAN DRUGS

FY 2011 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2010	WORKPLAN FTEs FY 2011	FTE DIFFERENCE
46832B,C	NDA Pre-Approval Inspections/Investigations (Domestic)	9.5	9.5	
46832B,C	NDA Pre-Approval Inspections/Investigations (Foreign)	13.0	13.0	
46832M	Pre-License Biotech (BLA) Inspections/Investigations (DOM/FOR)	2.0	2.0	
46832P	Positron Emission Tomography (PET)		0.5	0.5
46	New Drug Evaluation	24.5	25.0	0.5
48001/A	In Vivo Bioequivalence (Domestic)	4.5	6.0	1.5
48001/A	Foreign Inspections (In Vivo, GLP, CI)	3.5	5.0	1.5
48808	Good Laboratory Practices	2.0	3.0	1.0
48809	Institutional Review Boards	6.8	7.8	1.0
48810	Sponsors, Contract Research Orgs, Monitors	4.3	5.3	1.0
48811	Clinical Investigators (Domestic)	28.1	29.9	1.8
48811	Clinical Investigators (Foreign)	16.0	16.2	0.2
48	Bioresearch Monitoring	65.2	73.2	8.0
52832,B,C	ANDA Pre-Approval Inspections/Investigations (Domestic)	5.0	5.0	
52832,B,C,E	ANDA Pre-Approval Inspections/Investigations (Foreign)	10.0	11.0	1.0
52832P	Positron Emission Tomography (PET)		1.0	1.0
52	Generic Drug Evaluation	15.0	17.0	2.0
53001A,B	Adverse Drug. Exp. Rpt. Regul (Domestic)	8.0	8.0	
53001A,B	Adverse Drug. Exp. Rpt. Regul (Foreign)	1.0	1.0	
53001C	Risk Evaluation Mitigation System (REMS)	2.0	2.0	
53	Postmarket Surv. & Epidemiology	11.0	11.0	
56002A,B,D	Drug Process Inspections-Domestic	69.4	64.9	-4.5
56002A-D	Foreign Drug Inspections	40.0	42.0	2.0
56002E	Drug Process Inspections - Gas Manufacturers	6.0	9.0	3.0
56002F	Drug Process Inspections API Manufs (Dom/For)		13.0	13.0
56002M	Drug Process Inspections - Biotech Manufacturers	4.0	6.0	2.0
56002P	Positron Emission Tomography (PET)		0.5	0.5
56008A	Drug Quality Sampling and Testing Program	17.0	18.5	1.5
56008H	Drug Product Surveillance (Import)	33.9	37.9	4.0
56021A,B	Drug Quality Reporting Systems-DQRS	4.5	4.5	
56022	Enforcement of Rx Drug Marketing Act	2.0	2.0	
56843	Post-Approval Inspections/Investigations (Domestic)	2.0	2.0	
56843	Post-Approval Inspections/Investigations (Foreign)	2.0	2.0	
56D015	Pharmacy Compounding Assignments	5.0	5.0	
56R838	Forensic Evaluation and Sample Analysis	10.0	10.0	
56	Drug Quality Assurance	195.8	217.3	21.5
63001	Internet, Health Fraud, & OTC Monographs	4.5	6.5	2.0
63002	New Drugs (Prescription) Not Covered by Approved NDAs	5.0	5.0	
63	Unapproved & Misbranded Drugs	9.5	11.5	2.0
88--	Shelf Life Extension Projects	12.0	12.0	
88	Interagency Cooperative Activities	12.0	12.0	
	Total Mission Direct: Pre and Annual Planned FTEs	333.0	367.0	34.0

ANIMAL DRUGS AND FEEDS

FY 2011 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2010	WORKPLAN FTEs FY 2011	FTE DIFFERENCE
68001	NADA Pre-Approval Inspections	4.0	4.9	0.9
68808	(Pre-Market) GLP and Spon/Mon/Com	2.0	2.2	0.2
68810*	Sponsors Contract Research Orgs./Monitors	*	*	
68811	(Pre-Market) Clinical Investigators	2.4	2.6	0.2
68	Pre-Approval Eval. of Animal Drugs & Food Additives	8.4	9.7	1.3
71001A,B**	Animal Drug Manufacturing Inspections	12.3	13.0	0.7
71003A-J	Feed Contaminants	19.4	25.6	6.2
71004A	Feed Manufacturing	4.5	5.1	0.6
71006	Illegal Drug Residues in Meat and Poultry	31.9	38.3	6.4
71009, 71R844***	Ruminant Feed Ban Rule (BSE) Program	39.6	33.1	-6.5
71R816	Methods Validation/Development Program	5.0	5.0	
71R831, 71R838	Forensic Evaluation and Sample Analysis	1.0	1.0	
71V800	Center Initiated Assignments	1.0	1.3	0.3
71	Monitoring of Marketed Animal Drugs, Feed, & Devices	114.7	122.4	7.7
	Total Mission Direct: Pre and Annual Planned FTEs	123.1	132.1	9.0

* 68810 planned under 68808

** 71005 / A planned under 71001

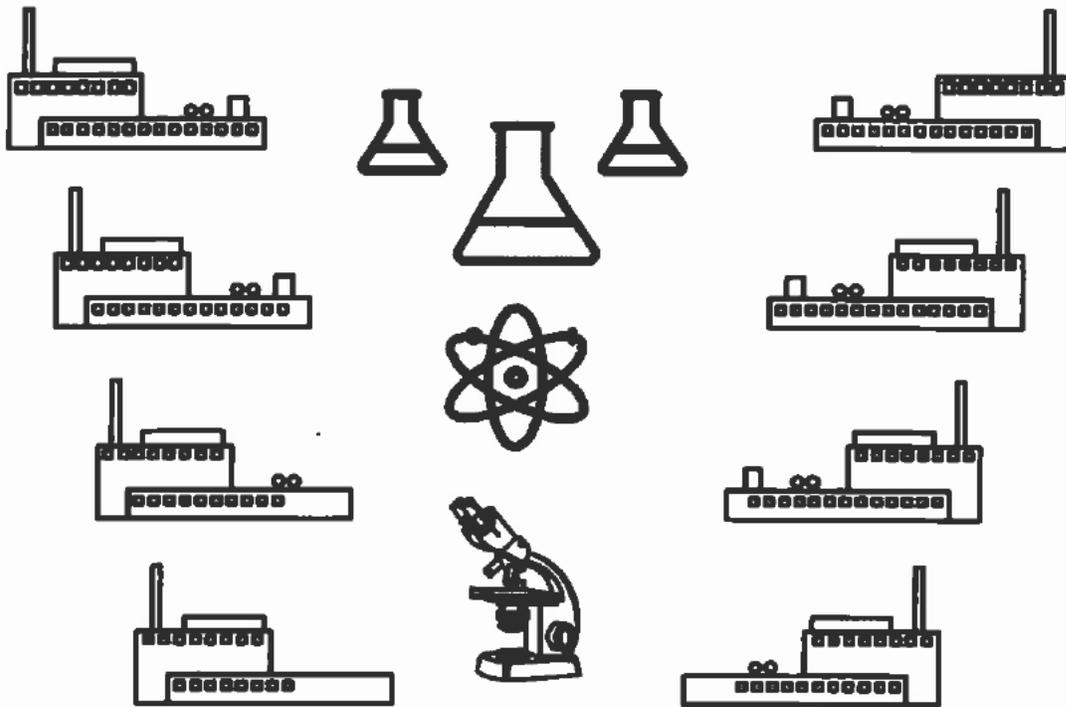
*** Includes 71R833, 99R833, and 71R824

MEDICAL DEVICES AND RADIOLOGICAL HEALTH

FY 2011 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2010	WORKPLAN FTEs FY 2011	FTE DIFFERENCE
81010	Med Dev Problem Reporting-MDR/DEN F/U	0.5	0.5	
81	Postmarket Assurance: Devices	0.5	0.5	
82008	Monitoring Device of Foreign Origin-Imports	38.5	44.0	5.5
82845A,B,C,G,H,S	Inspection of Medical Dev Mfgs: GMP Domestic	97.6	102.4	4.8
82845B	Inspection of Medical Dev Mfgs: GMP Foreign	19.6	22.6	3.0
82845P	Inspection of Accredited Persons: MDUFMA	0.5	1.0	0.5
82845J	Audits of Accredited Persons	0.3	0.3	
82Z002	Condom Assignment	3.6	3.6	
82Z003	Mfgs & Importers of Surgical/Exam Gloves	7.5	8.8	1.3
82Z800	Center Initiated Assignments	1.0	2.0	1.0
82R816	Methods Validation/Development Program	2.0	2.0	
82R838	Forensic Evaluation and Sample Analysis	0.3	0.3	
82	Compliance: Devices	170.9	187.0	16.1
83001/A	Med Dev Premkt/Postmkt Insp Domestic	7.1	7.1	
83001/A	Med Dev Premkt/Postmkt Insp Foreign	2.6	2.6	
83808-11	Bioresearch Monitoring Domestic	24.1	23.3	-0.8
83810-11	Bioresearch Monitoring Foreign	1.2	2.0	0.8
83	Project Evaluation: Devices	35.0	35.0	
84Z002	Test Method Development & Evaluation	3.7	3.7	
84R816	Methods Validation/Development Program	1.0	2.0	1.0
84	Science: Devices	4.7	5.7	1.0
85014	Mammography Facilities Insp Program Domestic	14.5	14.5	
85014	Mammography Facilities Insp Program Foreign	0.1	0.1	
85	Mammography Quality Standards Act (MQSA)	14.6	14.6	
86001	Inspection of Mfgs of Laser Products Domestic	4.3	4.3	
86001	Inspection of Mfgs of Laser Products Foreign	0.2	0.5	0.3
86002	Field Implementation of Sunlamp Products	0.3	0.3	
86003	Field Compliance Testing of Diag X-Ray Equip Domestic	7.6	7.6	
86003	Field Compliance Testing of Diag X-Ray Equip Foreign	1.0	1.0	
86004	Field Compliance Testing of Cab X-Ray Equip	0.5	0.5	
86006A,B,D,E	Compliance Testing of Elec Prod at WEAC Domestic	3.1	3.1	
86006	Compliance Testing of Elec Prod at WEAC Foreign	0.8	0.4	-0.4
86007	Imported Electronic Products	7.5	8.5	1.0
86008	Med Dev & Rad Hlth Use Control & Policy Implementation	3.0	3.0	
86009	Emergency Planning & Response Activities	2.0	2.0	
86	Radiation Control & Health Safety Act (RCHSA)	30.3	31.2	0.9
	Total Mission Direct: Pre and Annual Planned FTEs	256.0	274.0	18.0

FY 2011 SERVICING LABORATORIES



*THE FOLLOWING PAGES SHOW THE SERVICING
LABORATORIES FOR EACH COLLECTING DISTRICT
AND FOR EACH COMPLIANCE PROGRAM OR SUB PART*

OCTOBER 2010

**RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2011**

	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
	DOMESTIC	IMPORT	FOREIGN	
TOTAL ALL PROGRAMS	1390.5	635.1	170.7	2196.3
FOODS AND COSMETICS	748.3	513.0	30.9	1292.2
BIOLOGICS	120.4	4.0	6.6	131.0
HUMAN DRUGS	231.4	37.9	97.7	367.0
ANIMAL DRUGS AND FEEDS	108.5	17.3	6.3	132.1
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	181.9	62.9	29.2	274.0
TOBACCO (GUIDANCE ONLY)				

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2011**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	748.3	513.0	30.9	1292.2
3	FOODBORNE BIOLOGICAL HAZARDS	492.2	395.5	30.7	918.4
4	PESTICIDES AND CHEMICAL CONTAMINANTS	126.9	77.3		204.2
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	13.8	5.3		19.1
8	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		15.6		15.6
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	76.5			76.5
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	35.9	13.9	0.2	50.0
29	COLOR AND COSMETICS TECHNOLOGY	3.0	5.4		8.4

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low Acid Canned Foods			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03												
3. PROGRAM/ASSIGNMENT CODE(S) 03003, 03003A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 15.3									
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT INVESTIGATIONS (HOURS)	4 IMPORT SAMPLE COLL	3 GUIDANCE IMPORT SAMPLE COLL MICRO	3 GUIDANCE IMPORT SAMPLE COLL CHEM	6 IMPORT FIELD EXAMS (1)	8 IMPORT SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED CHEM							
	TOTAL FIELD	684	1400	1300	100	6410	1300	100							
NE	HEADQUARTERS	(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										1.8			0.5	7.0	10.0
TOTAL HOURS									684	2520			3205	9100	1000
CONVERSION FACTOR									950	950			950	1160	1160
TOTAL OPERATIONAL FTEs									0.72	2.65			3.37	7.71	0.85

9. REMARKS

(b) (7)(E)

(1) - Import Field Exams Hours 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.).

See IOM Section 5.4.1.4 for additional information on Food & Cosmetic activities.

Surveillance activities 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, this program unless otherwise directed.

Note: send SWID samples collected from TX & NM to ARL; send SWID samples collected from CA & AZ to PRS.

1. PROGRAM/ASSIGNMENT TITLE Domestic & Imported Cheese & Cheese Products					2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03037, 03037B, 03037D			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 24.3				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	4	5	7	8	8
		FOREIGN INSPEC- TIONS	DOMESTIC INSPECTIONS INCLUDING HIGH RISK	DOMESTIC INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL MICRO	COMPLIANCE IMPORT SAMPLE COLL CHEM/PH	DOMESTIC SAMPLES TO BE ANALYZED MICRO	IMPORT SAMPLES TO BE ANALYZED MICRO	IMPORT SAMPLES TO BE ANALYZED CHEM
	TOTAL FIELD	63	204	760	290	630	75	290	630	75
NE	HEADQUARTERS	(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		40.0	18.0		4.0	2.0		18.0	18.0	6.1
TOTAL HOURS		2520	3672	760	1180	1260		5220	11340	458
CONVERSION FACTOR		950	950	950	950	950		1180	1180	1180
TOTAL OPERATIONAL FTEs		2.65	3.87	0.80	1.22	1.33		4.42	9.61	0.39
9. REMARKS										
(1) - Foreign inspections planned at HQ will be conducted by the Foreign Food Cadre. Foreign inspection resources spread by DFI.										
(2) - Domestic resources are to complete the domestic high-risk performance goal. Additional resources are set aside under the Domestic Food Safety, Domestic LACF, and Domestic Fish programs. Does not include time for high risk inspections that will be conducted under state contracts.										
(3) - Investigation Hours are provided for assignments to cover the investigation of raw milk cheese (based on inspection time).										
(4) - Domestic Sample Collection - Districts may collect both compliance and surveillance samples according to the guidance obligations in the compliance program to fulfill their sampling obligation. If no problems are observed at the firm, the districts may accomplish sampling obligations by collecting samples during the inspection, or by collecting samples at the wholesale / retail level.										
(5) - Filth analysis should be done as needed on split import samples collected for more than one attribute. Note: send SWID samples collected from TX & NM to NRL; send SWID samples collected from CA & AZ to NRL.										

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low Acid Canned Foods				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03						
3. PROGRAM/ASSIGNMENT CODE(S) 03803A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 31.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	3	5	7	7	9	
		FOREIGN INSPEC- TIONS (1)	DOMESTIC INSPECTIONS INCLUDING HIGH RISK (2)	DOMESTIC SAMPLE COLL (3)	GUIDANCE DOMESTIC SAMPLE COLL MICRO	GUIDANCE DOMESTIC SAMPLE COLL CHEM	FIELD EXAM/ TESTS (Hours) (4)	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	BETTER PROCESSING SCHOOL TRAINING (Hours) (5)
TOTAL FIELD		230	545	210	165	21	1520	189	21	760
NE	HEADQUARTERS	(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		22.2	35.0	6.0			14.0	14.0		
TOTAL HOURS		5106	19075	1260			1520	2646	294	760
CONVERSION FACTOR		950	950	950			950	1180	1180	950
TOTAL OPERATIONAL FTEs		5.37	20.08	1.33			1.60	2.24	0.25	0.80
9. REMARKS										
Report all resources expended for NLEA under PAC 21005.										
PAC 03R839 Response to Foodborne Emergencies - use resources when needed.										
PAC 03803 is for inspections of central distribution warehouses where unlabeled cans are shipped for labeling and casing, and follow up inspections of LACF/AF products for filth only.										
(1) - Foreign inspections planned at HQ will be conducted by the Foreign Food Cadre. Foreign inspection resources are spread by DFI.										
(2) - Domestic resources are to complete the domestic high-risk performance goal. Additional resources are set aside under the Domestic Domestic Cheese, Domestic Food Safety, and Domestic Fish programs. Does not include time for high risk inspections that will be conducted under state contracts.										
Inspect NAI firms on a 3 year inspection cycle. State inspections may be conducted in addition to the number of inspections assigned per district.										
(3) - Planned DSC are for projected "for cause" sampling.										
(4) - Field Exams are to include pH and canned seam evaluation.										
(5) - Resources are for attendance at Better Processing Schools (BPS).										
Surveillance activities 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.										

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03						
3. PROGRAM/ASSIGNMENT CODE(S) 03803, B, C, D, E, U *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 122.2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	4	5	7	7	7
		FOREIGN INSPEC- TIONS (1)	DOMESTIC INSPCTIONS INCLUDING HIGH RISK (2)	INVESTI- GATIONS (HOURS) INCLUDES NAT'L EXPERT	DOMESTIC SAMPLE COLL (3)	GUIDANCE DOMESTIC SAMPLE COLL TRNG	GUIDANCE DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DSA MICRO SALMONELLA SEROTYPING (HOURS) (4)
TOTAL FIELD		418	4383	11798	633	280	283	380	253	2075
NE	HEADQUARTERS	(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		32.9	18.0		6.0			12.0	12.0	
TOTAL HOURS		13785	78894	11798	3798			4560	3036	2075
CONVERSION FACTOR		950	950	950	950			1180	1180	1180
TOTAL OPERATIONAL FTEs		14.51	83.05	12.42	4.00			3.86	2.57	1.76
9. REMARKS										
Resources for PACs 04803 and 09803E,F are included. Resources for audits are under State Contracts Program PAC 03R843.										
Assignments for sprout producers and egg farms, if needed, will be taken from this program.										
Non Seafood Inspections for EU and Chilean Certification will be handled by CFSAN Assignment and counted against inspectional obligations of this program.										
(1) - Foreign inspections planned at HQ will be completed by the Foreign Food Cadre. Foreign inspection resources are spread by DFI.										
(2) - Domestic resources are to complete the domestic high-risk performance goal. Additional resources are set aside under the Domestic Cheese, Domestic LACF, and Domestic Fish programs. Does not include time for high risk inspection that will be conducted under state contracts.										
(3) - A portion of Domestic Sample Collection resources are set aside for targeted Risk Based Surveillance Assignments in FY10.										
(4) - Salmonella Serotyping: Samples generated from SRL & ARL go to ARL; Samples generated from other labs go to Denver.										

1. PROGRAM/ASSIGNMENT TITLE Imported Foods General				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03															
3. PROGRAM/ASSIGNMENT CODE(S) 03819, A,B,C (03R833,03R824,99R833)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 250.1 [201.3]												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	2	6	8										
		MAIL COURIER REVIEW (Hours)	INTERNATIONAL MAIL FACILITY (Hours)	IMPORT INVESTI- GATIONS (Hours) (1)	IMPORT ENTRY REVIEW (Hours) (2)	IMPORT SAMPLE COLL	GUIDANCE IMPORT SAMPLE COLL MICRO	IMPORT FIELD EXAMS (3)	IMPORT SAMPLES TO BE ANALYZED MICRO										
TOTAL FIELD		2850	950	10165	90804	7500			113713	4850									
NE	HEADQUARTERS	(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																		
	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			0.5	8.2
TOTAL HOURS											2850	950	10165	90804	16500			56857	39770
CONVERSION FACTOR											950	950	950	1200	950			950	1180
TOTAL OPERATIONAL FTEs											3.00	1.00	10.70	75.67	17.37			59.85	33.70

B. REMARKS

(b) (7)(E)

Note: Please Review CFSAN's Import Risk Priorities List Available on Inside.FDA.Gov.
Resources in this program can be used to report Import Food Activities under the following PACs: 03R833 - Import/Entry Review Hours 99R833 - Evaluation Hours; 03R824 - Follow-Up to Refusal.

- (1) - Investigation Hours: Resources are for Import Filer Evaluations, Follow-up to Refusals (marking and tracking the deposition of detained lots) 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.
- (2) - Import Entry Review Hours: Resources for these activities cover All Import Food Programs.
- (3) - All Import Field Exams are to routinely include the following:
 - (a) Verification that the imported product is the same as that which was declared (Reconciliation Exam);
 - (b) An assessment of security concerns related to labeling & source Country (Including container integrity, signs of intentional adulteration, etc.);
 - (c) 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 conducting routine Follow-Up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, ect.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

1. PROGRAM/ASSIGNMENT TITLE Imported Foods General	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03
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3. PROGRAM/ASSIGNMENT CODE(S) 03819, A,B,C (03R833,03R824,99R833) *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 250.1 [48.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLE ANALYSIS SALMONELLA RESISTANCE (4)	9 OP CODE 92 PRIVATE LAB REVIEW (5)	9 PRIOR NOTICE REVIEW (Hours) (6)					
	TOTAL FIELD	2650	1180	4720	32400					
NE	HEADQUARTERS	(b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b) (7)(E)								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b) (7)(E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB	(b) (7)(E)								
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT	(b) (7)(E)								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE	(b) (7)(E)								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW	(b) (7)(E)								
	HOURS PER OPERATION	7.5								
	TOTAL HOURS	19875	1180	4720	32400					
	CONVERSION FACTOR	1180	1180	1180	1200					
	TOTAL OPERATIONAL FTEs	16.84	1.00	4.00	27.00					

9. REMARKS

(4) - Import Samples to be Analyzed - Salmonella Resistant (Hours) will be performed by Denver Laboratory.

(5) - Private Laboratory Review Time is for NRL, SRL, ARL, PRS analysts to review private lab results submitted for imported foods. 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.

(6) - Resources in Headquarters are for review of prior notices at the Prior Notice Center.

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish & Fishery Products				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03													
3. PROGRAM/ASSIGNMENT CODE(S) 03842,B, C, D, H			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 49.5										
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	3	7	7	7	9								
		FOREIGN INSPEC- TIONS (1)	DOMESTIC INSPECTIONS INCLUDING HIGH RISK (2)	DOMESTIC SAMPLE COLL (3)	GUIDANCE DOMESTIC SAMPLE COLL MICRO	GUIDANCE DOMESTIC SAMPLES COLL CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	Nat'l Expert DSA ORGANO EXAM (Hours) (4)	LEVEL II AUDITORS CERTI- FICATION HOURS (5)							
TOTAL FIELD		230	1361	280	210	210	70	320	1600								
NE	HEADQUARTERS	(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										23.3	25.6	5.0			17.0	13.0	
TOTAL HOURS										5359	34842	1400			3570	910	320
CONVERSION FACTOR										950	950	950			1180	1180	1180
TOTAL OPERATIONAL FTEs										5.64	36.68	1.47			3.03	0.77	0.27
9. REMARKS																	
Additional PACs: 03R839; 04842A,H; 07842F,F,H; 09842; 21842, 21R829																	
(1) - Foreign Inspections planned under HQ will be conducted by the Foreign Food Cadre. Foreign inspection resources are spread by DFI.																	
(2) - Domestic resources are to complete the domestic high-risk performance goal. Additional resources are set aside under the Domestic Cheese, Domestic LACF and Domestic Food Safety programs. Does not include time for high risk inspections that will be conducted under state contracts.																	
High Risk Potential Products (HRPP) processors whose last two inspections were NAI can be considered for a 2-year inspection cycle unless the firm has added a new high risk seafood product to their line.																	
(3) - Domestic Sample Collections: Seafood collections are planned "For Cause Only." The number of samples planned per district are not to be considered a goal or target. Only collect "For Cause" samples following the guidance in Part III, page 5, Section E.1 of the compliance program. Verification samples are not to be collected.																	
(4) - Organoleptic National Expert time																	
(5) - Level II Auditors Certification Time: These hours are to provide auditors the time to evaluate/train other investigators trying to maintain Level II Certification.																	
Note: EU Certification has been deleted because in June 2009 this responsibility was transferred to NOAA.																	

1. PROGRAM/ASSIGNMENT TITLE Imported Seafood Products				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03															
3. PROGRAM/ASSIGNMENT CODE(S) 03844, B,C,D, H, U			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 89.7												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	4	1	1	6	6	6	6									
		IMPORTER INSP CTIONS 03844H (1)	IMPORT INVEST GATIONS (Hours) (2)	IMPORT SAMPLE COLL PHYSICAL (3)	GUIDANCE IMPORT SAMPLE COLL MICRO (2)	GUIDANCE IMPORT SAMPLE COLL CHEM (2)	IMPORT FIELD EXAMS (4)	IMPORT SAMPLES TO BE ANALYZED MICRO (4)	IMPORT SAMPLES TO BE ANALYZED CHEM (4)	Nat'l Experts ISA's ORGANO ANALYSIS HOURS (4)									
TOTAL FIELD		375	1700	6400	1420	1420	16016	4480	3050	1180									
NE	HEADQUARTERS	(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											14.0		2.6			0.5	11.0	5.3	
TOTAL HOURS											5250	1700	16640			8008	49280	16165	1180
CONVERSION FACTOR											950	950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs											5.53	1.79	17.52			8.43	41.76	13.70	1.00
9. REMARKS Other PACs include: 07844; 09844E,F; 21844																			
(1) - Inspections of Importers are to ascertain if the importer has complied with Seafood HACCP Regulations, not to perform filer inspections.																			
(2) - Import Investigations Hours are for Field Exams, Label exams, & other operations as required by the District to cover program priorities. Report time under the appropriate operations & PAC for activities performed.																			
(3) - All Districts should concentrate on collections as per the priorities set in the Import Seafood Compliance Program (C.P.) For more detail please see the continuation sheet on page 03-10.																			
(4) - Multiple Analyses will be run on numerous samples, both Micro & Chem, therefore analyses outnumber collections.																			
Note: NWE-DO will collect 76 MICRO & 119 CHEM samples to be sent to WEAC Lab for analyses. SWID samples collected for TX & NM are to be sent to ARL; SWID samples collected for CA & AZ are to be sent to PRS.																			

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Imported Seafood Products

2. PPS PROJECT NAME/NUMBER

Foodborne Biological Hazards -03

9. Remarks

When physical samples are collected for analysis, the guidance in the C.P. should be followed in determining what the product should be analyzed for specifically: Raw scombrototoxic fish should be analyzed for histamine, not for MICRO; raw shrimp should be analyzed for undeclared sulfite (and/or chemotherapeutics under PAC 04018 following the guidance in the C.P.), not for MICRO.

All Import Field Exams are to routinely include the following: a) Verification that the imported product is the same as that which was declared (Reconciliation Exam); b) An assessment of security concerns related to labeling & source country, including container integrity, signs of intentional adulteration, etc.; c) Traditional safety concerns.

These activities are to be reported as a single Import Field Exam under this C.P. & 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 conducting routine follow-up, should an exam & time be reported under the CT PAC (03R845,04R845,etc.). See IOM Section 5.4.1.4 for additional information on Food & Cosmetic Defense Activities.

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03																																							
3. PROGRAM/ASSIGNMENT CODE(S) 03847H, 03847			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.6																																					
R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	3	3	7	7																																			
		DOMESTIC INSPECT- TIONS	IMPORTER INSPECT- TIONS	DOMESTIC SAMPLE COLL	GUIDANCE DOMESTIC SAMPLE COLL MICRO	GUIDANCE DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM																																			
TOTAL FIELD		200	50	75	55	25	55	20																																			
NE	HEADQUARTERS	(b) (7) (E)																																									
	REGIONAL STAFF																																										
	NEW ENGLAND																																										
	NEW YORK																																										
	REGIONAL LAB																																										
	WEAC																																										
CE	REGIONAL STAFF								(b) (7) (E)																																		
	BALTIMORE																																										
	CHICAGO																																										
	CINCINNATI																																										
	DETROIT																																										
	MINNEAPOLIS																																										
	NEW JERSEY																																										
	PHILADELPHIA																																										
	FORENSIC CHEM. CTR																																										
SE	REGIONAL STAFF															(b) (7) (E)																											
	ATLANTA																																										
	FLORIDA																																										
	NEW ORLEANS																																										
	SAN JUAN																																										
REGIONAL LAB																																											
SW	REGIONAL STAFF																						(b) (7) (E)																				
	DALLAS																																										
	DENVER																																										
	KANSAS CITY																																										
	SOUTHWEST IMPORT DISTRICT																																										
	REGIONAL LAB																																										
PA	REGIONAL STAFF																													(b) (7) (E)													
	LOS ANGELES																																										
	SAN FRANCISCO																																										
	SEATTLE																																										
	PACIFIC REGIONAL LABORATORY-SW																																										
PACIFIC REGIONAL LABORATORY-NW																																											
HOURS PER OPERATION																																					22.0	13.0	5.0			15.0	11.0
TOTAL HOURS																																					4400	650	375			825	220
CONVERSION FACTOR																																					950	950	950			1180	1180
TOTAL OPERATIONAL FTEs																																					4.63	0.68	0.39			0.70	0.19
9. REMARKS																																											
<p>Additional related PACs: 04847; 07847H; 09847,H; 21847H. Use PAC 03847 for General Sanitation Issues (non-HACCP).</p> <p>Use "H" PACs for HACCP Verification Samples and the HACCP component of inspection. Use Non "H" PACs for "For Cause" samples and filth/sanitation component of inspection.</p> <p>State inspections may be conducted in addition to the number of inspections assigned per district (PAC 03S004). Resources have been added to cover food security issues at all domestic processor inspections. Inspectional priority is as follows: Firms associated with recent outbreaks, unpasteurized juice firms, firms whose previous inspections were OAI, and firms that have not yet been inspected.</p> <p>DSC resources have been provided for anticipated "for cause" and "verification" samples.</p> <p>Note: 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.</p>																																											

1. PROGRAM/ASSIGNMENT TITLE CFSAN Environmental Sampling Assignments				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03													
3. PROGRAM/ASSIGNMENT CODE(S) 03F830, 03R858, 04R858			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 172.8											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	Environmental SAMPLE CSO HOURS SMOKED FISH FIRMS (1)	Environmental SAMPLE CSO HOURS RTE SANDWICH FIRMS (2)	Environmental SAMPLE CSO HOURS CRAB MEAT FIRMS (3)	Environmental SAMPLE CSO HOURS EGG RULE INSPEC- TIONS (4)	Environmental SAMPLE CSO HOURS SOFT CHEESE FIRMS (5)	Environmental SAMPLE CSO HOURS UNIDENTIFIED INDUSTRIES (6)	Environmental SAMPLE ANALYSES HOURS	Environmental HIGH THROUGHPUT LAB (7)								
		TOTAL FIELD	6160	27980	4480	52500	6580	38220	28007	7080							
NE	HEADQUARTERS	(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																	
TOTAL HOURS										6160	27980	4480	52500	6580	38220	28007	7080
CONVERSION FACTOR										950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs										6.48	29.45	4.72	55.26	6.93	40.23	23.73	6.00
9. REMARKS Additional hours were added to CSO time to allow approximately 140 hours for each firm to be utilized and reported as either an inspection (op 12) or sample collection (op 31). (1) - Estimated [REDACTED] firms. (2) - Estimated [REDACTED] firms. (3) - Estimated [REDACTED] firms. (4) - Egg Rule Inspections are High-risk Domestic Performance Goal Inspections, report inspections, sample collections and analyses under PAC 03F836. See pages 03-3, 03-4, 03-5, 03-8 for additional resources to conduct the remaining domestic performance goal inspections. Estimated [REDACTED] egg producers to be inspected. (5) - Estimated [REDACTED] firms. (6) - Resources are set aside for environmental sampling for Salmonella in currently unidentified industries-CFSAN directed. (7) - Resources for Detroit Laboratory are to conduct Listeria and Salmonella analyses only. Reporting PAC to be determined in sampling assignment to be issued by DFS. Environmental sampling to follow-up on Outbreaks and Emergency Response activities is planned separately (Response to Foodborne Emergencies, NEC: PACs 03R839 and 04R839). District spread of resources is for planning purposes only. 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. Analytical resources are spread based on microbiological servicing laboratories.																	

1. PROGRAM/ASSIGNMENT TITLE Unspecified Foreign Inspections/Assessments			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03						
3. PROGRAM/ASSIGNMENT CODE(S) 03R233		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP EC- TIONS	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (Hours) (1)						
	TOTAL FIELD	48	950						
NE	HEADQUARTERS	(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								
PA	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		30.0							
TOTAL HOURS		1440	950						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		1.52	1.00						
9. REMARKS NO INSPECTIONS ARE TO BE REPORTED UNDER PAC 03R233. Foreign activities per DFI inspection distribution. (1) -Technical Assistance can include, but is not limited to: Training, presentations, speeches, site visits, outreach, workshops, seminars or meetings with partnership groups, trade associations, etc. These resources are set aside for foreign food inspections as yet to be determined. Report accomplishments under the program PAC covered during the inspection. CFSAN will determine the type of inspection and provide relevant information to DFI well in advance of dates required for planning trips.									

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/ Development Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV MICRO (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)						
	TOTAL FIELD	3616	4720						
NE	HEADQUARTERS	(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									
TOTAL HOURS		3616	4720						
CONVERSION FACTOR		1205	1180						
TOTAL OPERATIONAL FTEs		3.00	4.00						
9. REMARKS Workload Sources: Determined by Division of Field Science, ORO									

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response (PPS 03)			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03						
3. PROGRAM/ASSIGNMENT CODE(S) 03R839			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 77.8		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		3 CONSUMER SAFETY OFFICER MICRO (Hours) (1)	7 ANALYSIS MICRO (Hours)					
	TOTAL FIELD		51891	27349					
N E	HEADQUARTERS		(b) (7)(E)						
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
C E	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
S E	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
S W	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
P A	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			51891	27349					
CONVERSION FACTOR			950	1180					
TOTAL OPERATIONAL FTEs			54.62	23.18					
9. REMARKS									
<p>Time to be used for all outbreak and emergency activities related to foodborne biological hazards. District spread is for planning purposes only. 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).</p> <p>(1) - Includes time for districts that could be affected by hurricanes.</p>									

1. PROGRAM/ASSIGNMENT TITLE Contract Management				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) 03R843			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 12.0					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 CONTRACT MANAGE- MENT (Hours)									
	TOTAL FIELD	(1) 11400									
NE	HEADQUARTERS	(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											
TOTAL HOURS			11400								
CONVERSION FACTOR			950								
TOTAL OPERATIONAL FTEs			12.00								
9. REMARKS (1) - Time planned for Contract Management includes resources to conduct audits. Report Foods State Contract Inspection Audit time under operation 13 (Investigation Operations). Note: Non-operational FTEs, i.e. supervisors, should not report contract management time.											

1. PROGRAM/ASSIGNMENT TITLE Food Defense				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03						
3. PROGRAM/ASSIGNMENT CODE(S) 03R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 8.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 CSO DOMESTIC INVESTIGATIONS (Hours)	2 CSO IMPORT INVESTIGATIONS (Hours)	7 DOMESTIC MICRO ANALYTICAL (Hours)	7 DOMESTIC CHEM ANALYTICAL (Hours)	8 IMPORT MICRO ANALYTICAL (Hours)	8 IMPORT CHEM ANALYTICAL (Hours)			
	TOTAL FIELD	2850	2850	590	590	590	590			
	HEADQUARTERS	(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									
	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										
TOTAL HOURS		2850	2850	590	590	590	590			
CONVERSION FACTOR		950	950	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs		3.00	3.00	0.50	0.50	0.50	0.50			
9. REMARKS										
<p>Report Food Defense activities under PAC 03R845. Report Expanded Time under PACs: 04R845, 07R845, 09R845, 21R845.</p> <p>Planned resources are for all special Food Defense related activities over and above operations accomplished under other Project 03 programs.</p> <p>Based on circumstances, resources may be shifted between Import and Domestic. Resources are to be used for CFSAN Food Defense assignments for inspections, sample collections, and analyses including those to support FERN. Total lab time may be used for for maintaining general food defense capabilities.</p> <p>Note: SWID samples collected from TX & NM are to be sent to ARL. SWID samples collected from CA & AZ are to be sent to PRS.</p>										

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04					
3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 04004U, 04R833, 99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 59.5 [34.8]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	3	3	3	3	4	4	7	7
		INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL SURVEILLANCE	DOMESTIC SAMPLE COLL DIOXINS	DOMESTIC SAMPLE COLL SEAFOOD	IMPORT SAMPLE COLL	IMPORT SAMPLE COLL SEAFOOD	DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	DOMESTIC SAMPLES TO BE ANALYZED DIOXINS (3)
TOTAL FIELD		880	1300	100	750	100	3000	300	1400	750
NE	HEADQUARTERS	(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			3.0	3.0	4.0	3.0	1.6	1.6	6.5	20.0
TOTAL HOURS		880	3900	300	3000	300	4800	480	9100	15000
CONVERSION FACTOR		950	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		0.93	4.11	0.32	3.16	0.32	5.05	0.51	7.71	12.71
9. REMARKS CFSAN will issue biannual Dioxin Schedule. DSC Seafoods: See compliance program for collection details. ISC Seafoods: See compliance program for collection details. (1) - Includes time to collect samples for mobile laboratories (2) - Includes time for sample analyses to be conducted by mobile laboratories (3) - Includes analysis of 232 Total Diet Study Sample homogenates.										

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 04004U, 04R833, 99R833, 04R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 59.5 [24.7]
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	8	8	8				
		DOMESTIC SAMPLES TO BE ANALYZED DIOXINS	DOMESTIC SAMPLES TO BE ANALYZED SEAFOOD	IMPORT SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANAL- YZED HIGH THROUGHPUT LAB CHEM	IMPORT SAMPLES TO BE ANALYZED SEAFOOD CHEM				
	TOTAL FIELD	232	100	2244	983	300				
NE	HEADQUARTERS	(b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	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		11.8	6.5	7.8	6.0	7.8				
TOTAL HOURS		2691	650	17503	5896	2340				
CONVERSION FACTOR		1180	1180	1180	1180	1180				
TOTAL OPERATIONAL FTEs		2.28	0.55	14.83	5.00	1.98				

9. REMARKS
 ISAs: Planned numbers based on SWID sending 40% of ISAs to ARL and 60% of ISAs to PRL-SW.
 Sample analyses exceed sample collections because some samples will be collected per unplanned assignments to be issued during the year.

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) 04018			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 32.7 [26.3]		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED NITRO FURANS	7 DOMESTIC SAMPLES TO BE ANALYZED NITRO (1) FURANS	8 IMPORT SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED INDIVIDUAL SUBS	8 IMPORT SAMPLES TO BE ANALYZED COMP- OSITES
	TOTAL FIELD		100	1000	100		30	1000	215
NE	HEADQUARTERS	(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		5.0	2.5	24.0		30.0	24.0		
TOTAL HOURS		500	2500	2400		900	24000		
CONVERSION FACTOR		950	950	1180		1180	1180		
TOTAL OPERATIONAL FTEs		0.53	2.63	2.03		0.76	20.34		

9. REMARKS
 CFSAN spread the number of sample collections per district based on ORADDS line entry data and domestic OEI data. DFS spread the laboratory analyses. Individual sub sample analyses will be for Nitrofurans in shrimp and for all Chloramphenicol samples. All remaining residue analyses will be a composite of 12 subsamples. The analytical module is a Field Wide Average, based on number of total samples planned for individual subsample analysis and for composite analysis. Refer to the FY11 Collection Schedule (when issued) for specific commodities to collect. Import samples can be collected as D/I samples if samples are being collected fresh. The sample collection and analytical numbers are based on all products except for crab being analyzed for two chemo-therapeutic agents.

(b) (7) (E)

(1) - Domestic Samples for Nitrofurans include 20 catfish and 10 shrimp samples. 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.

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04							
3. PROGRAM/ASSIGNMENT CODE(S) 04018		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 32.7 [6.4]					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED NITROFURAN (2)							
	TOTAL FIELD	250							
	HEADQUARTERS	(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	30.0							
	TOTAL HOURS	7500							
	CONVERSION FACTOR	1180							
	TOTAL OPERATIONAL FTEs	6.36							
9. REMARKS (2) - Import Samples for Nitrofurans include 125 Basa/Catfish samples and 125 Shrimp samples.									

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04019A, 04019U	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.6 [12.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	4	7	7	7	8		
		DOMESTIC SAMPLE COLL NON- SEAFOOD	DOMESTIC SAMPLE COLL SEAFOOD	IMPORT SAMPLE COLL NON- SEAFOOD	DOMESTIC SAMPLES TO BE ANALYZED NON SEA- FOOD CHEM	DOMESTIC SAMPLES TO BE ANALYZED SEAFOOD CHEM	DSA _d METHYL MERCURY IN SEAFOOD	IMPORT SAMPLES TO BE ANALYZED NON SEA- FOOD CHEM		
	TOTAL FIELD	25	310	625	25	210	100	625		
NE	HEADQUARTERS	(b) (7) (E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b) (7) (E)								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b) (7) (E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB	(b) (7) (E)								
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT	(b) (7) (E)								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE	(b) (7) (E)								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW	(b) (7) (E)								
	HOURS PER OPERATION	3.5	4.5	1.8	12.0	12.0	12.0	12.0		
	TOTAL HOURS	88	1395	1125	300	2520	1200	7500		
	CONVERSION FACTOR	950	950	950	1180	1180	1180	1180		
	TOTAL OPERATIONAL FTEs	0.09	1.47	1.18	0.25	2.14	1.02	6.36		

9. REMARKS
Both Seafood and Non-Seafood Domestic and Import Sample Collections: CFSAN will issue collection schedule.

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foodware (Domestic and Import)					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04																																																											
3. PROGRAM/ASSIGNMENT CODE(S) 04019B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 19.6 [6.3]																																																										
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	2. IMPORT INVESTIGATIONS (Hours) (1)	3. DOMESTIC SAMPLE COLL HOUSEWARE	4. IMPORT SAMPLE COLL HOUSEWARE	5. FIELD EXAMS/ TESTS	6. IMPORT FIELD EXAM (2)	7. DOMESTIC SAMPLES TO BE ANALYZED CHEM	8. IMPORT SAMPLES TO BE ANALYZED CHEM																																																								
	TOTAL FIELD		684	10	200	25	6406	10	200																																																							
NE	HEADQUARTERS	(b) (7) (E)																																																														
	REGIONAL STAFF																																																															
	NEW ENGLAND																																																															
	NEW YORK																																																															
	REGIONAL LAB																																																															
WEAC																																																																
CE	REGIONAL STAFF								(b) (7) (E)																																																							
	BALTIMORE																																																															
	CHICAGO																																																															
	CINCINNATI																																																															
	DETROIT																																																															
	MINNEAPOLIS																																																															
	NEW JERSEY																																																															
SE	REGIONAL STAFF															(b) (7) (E)																																																
	ATLANTA																																																															
	FLORIDA																																																															
	NEW ORLEANS																																																															
	SAN JUAN																																																															
SW	REGIONAL LAB																						(b) (7) (E)																																									
	REGIONAL STAFF																																																															
	DALLAS																																																															
	DENVER																																																															
	KANSAS CITY																																																															
PA	SOUTHWEST IMPORT DISTRICT																													(b) (7) (E)																																		
	REGIONAL LAB																																																															
	REGIONAL STAFF																																																															
	LOS ANGELES																																																															
	SAN FRANCISCO																																																															
SEATTLE																																					(b) (7) (E)																											
PACIFIC REGIONAL LABORATORY-SW																																												(b) (7) (E)																				
PACIFIC REGIONAL LABORATORY-NW																																																			(b) (7) (E)													
HOURS PER OPERATION																																																											3.5	1.8	0.7	0.5	10.0	10.0
TOTAL HOURS																																																										684	35	360	18	3203	100	2000
CONVERSION FACTOR																																																										950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs																																																										0.72	0.04	0.38	0.02	3.37	0.08	1.69
9. REMARKS																																																																
<p>(1) - Import Investigation Hours are for field exams and any other import operation as required by the District to cover import priorities. Districts should report time under the appropriate operation and PAC for activities performed.</p> <p>(2) - Import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an 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 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 pre-determined "for cause" CT exam, or the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). For districts that are not provided domestic field exam and sample collection resources, district should still collect samples, if necessary.</p>																																																																

1. PROGRAM/ASSIGNMENT TITLE Radionuclides in Foods (Domestic and Import)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04019C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.6 [0.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	5	4	7	8												
		DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED CHEM												
	TOTAL FIELD	18	84	16	84												
NE	HEADQUARTERS	(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										2.5	1.7	15.0	6.0				
TOTAL HOURS										40	143	240	504				
CONVERSION FACTOR										950	950	1180	1180				
TOTAL OPERATIONAL FTEs										0.04	0.15	0.20	0.43				

9. REMARKS
 CFSAN spreads DSCs based on location of nuclear power plants. See compliance program for collection details.

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04									
3. PROGRAM/ASSIGNMENT CODE(S) 04839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 28.6			
REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL (TOTAL) (DIET) (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	7 TOTAL DIET SAMPLE ANALYSIS RADIO- NUCLIDES (3)	7 TOTAL DIET SAMPLE ANALYSIS PERCHLOR- ATES (4)						
	TOTAL FIELD		60	1136	2	1136					
NE	HEADQUARTERS	(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		26.0	20.1	2800.0	3.0						
TOTAL HOURS		1560	22834	5600	3408						
CONVERSION FACTOR		950	1180	1180	1180						
TOTAL OPERATIONAL FTEs		1.64	19.35	4.75	2.89						
9. REMARKS (1) - Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over a five 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. (4) - All TDS foods from each market basket are analyzed for perchlorates.											

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) 04F800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.5			
R E G I O N	8.	3	4	4	4	7	8	8	8	
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL PERCHLOR. IN FOODS	IMPORT SAMPLE COLL CONTAMI- NANTS IN HONEY	IMPORT SAMPLE COLL PERCHLOR. IN FOODS	ISC/DISC PES & TE DIETARY SUPPL.	DOMESTIC SAMPLES TO BE ANALYZED PERCHLOR. IN FOODS	IMPORT SAMPLES TO BE ANA- LYZED CON- TAMINANTS IN HONEY	ISA/DISA PES DIETARY SUPPL. Sub 1	ISA/DISA TE DIETARY SUPPL. Sub 2	IMPORT SAMPLES TO BE ANALYZED PERCHLOR. IN FOODS
	TOTAL FIELD	50	100	50	250	50	100	250	231	50
NE	HEADQUARTERS	(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		3.0	3.0	3.0	3.0	3.0	6.5	6.5	14.5	3.0
TOTAL HOURS		150	300	150	750	150	650	1625	3350	150
CONVERSION FACTOR		950	950	950	950	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.16	0.32	0.16	0.79	0.13	0.55	1.38	2.84	0.13
8. REMARKS Collections for Dietary Supplements will be directed by CFSAN field assignments. Contaminants in honey include chloroamphenicol (See Import Bulletin).										

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04R816	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	9 METHODS VAL/DEV CHEM (Hours)	9 APPLIED TECHN- OLOGY CENTER CHEM (Hours)							
	TOTAL FIELD	2410	5900							
NE	HEADQUARTERS	(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										
TOTAL HOURS		2410	5900							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		2.00	5.00							

9. REMARKS
Workload Source: Determined by Division of Field Science, ORO.

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04								
3. PROGRAM/ASSIGNMENT CODE(S) 04R838			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.0				
R E G I O N	6.	9	9								
	DISTRICT/ SPECIALIZED LABORATORY	FORENSIC SAMPLE ANALYSIS CHEM	FORENSIC EVALUATION								
TOTAL FIELD		1205	13255								
NE	HEADQUARTERS	(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											
TOTAL HOURS		1205	13255								
CONVERSION FACTOR		1205	1205								
TOTAL OPERATIONAL FTEs		1.00	11.00								
9. REMARKS The hours planned above are estimates. Report Forensic activities under the appropriate PAC 04R838; PODS operation code 03, Petition Evaluation, Methods Development, or Forensic Evaluation (Forensic Evaluation added in FY 1999); PODS operation code 41 or 43, domestic or import sample analysis, PAC 04R838 or OCI PAC 04R831. Contact Division of Field Science (HFC-140), ORA, for additional reporting instructions.											

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04					
3. PROGRAM/ASSIGNMENT CODE(S) 04R839, 04R858			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 38.3			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 CSO Hours Total	9 CHEM Analysis Hours Total						
	TOTAL FIELD	25470	13558						
NE	HEADQUARTERS	(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									
TOTAL HOURS		25470	13558						
CONVERSION FACTOR		950	1180						
TOTAL OPERATIONAL FTEs		26.81	11.49						
9. REMARKS Time to be used for all outbreak and emergency activities related to pesticides and chemical contaminants. District spread is for planning purposes only. Report inspections and analyses conducted in response to pesticides and chemical contaminants against the appropriate Foodborne Emergency PAC (e.g. 04R078 Deep Water Horizon Oil Spill Activities, or another PAC to be created in response to a future emergency). Includes time for conducting follow-up to RFR and RCR.									

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin 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	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [5.2]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	3	3	3	4	4	4
		DOMESTIC SAMPLE COLL AFLA- TOXIN	DOMESTIC SAMPLE COLL FUMON- ISON	DOMESTIC SAMPLE COLL DON	DOMESTIC SAMPLE COLL OCHRA TOXIN	DOMESTIC SAMPLE COLL PATULIN	IMPORT SAMPLE COLL AFLA- TOXIN	IMPORT SAMPLE COLL FUMON- ISON	IMPORT SAMPLE COLL DON
	TOTAL FIELD	465	190	145	60	140	284	90	90

(b) (7)(E)

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	4.0	4.0	4.0	4.0	4.0	2.0		2.0	2.0
TOTAL HOURS	1860	760	580	240	560	568		180	180
CONVERSION FACTOR	950	950	950	950	950	950		950	950
TOTAL OPERATIONAL FTEs	1.96	0.80	0.61	0.25	0.59	0.60		0.19	0.19

9. REMARKS

(b) (7)(E)

Report all Domestic and Import Operations under PAC 07001.

(1) - For information only. Subset of Aflatoxin Import Sample Collection.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin 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	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [5.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL OCHRA TOXIN	4 IMPORT SAMPLE COLL PATULIN	4 IMPORT SAMPLE COLL SPECIAL SURVEY	7 ALL DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED #FLA- BIOBII	7 DOMESTIC SAMPLES TO BE ANALYZED FUMON- ISON	7 DOMESTIC SAMPLES TO BE ANALYZED DON	7 DOMESTIC SAMPLES TO BE ANALYZED OGHA TOXIN	7 DOMESTIC SAMPLES TO BE ANALYZED PATERN
	TOTAL FIELD	40	140	20	1000	465	100	145	60	100

(b) (7) (E)

HEADQUARTERS
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	2.0	2.0	2.0	6.0					
TOTAL HOURS	80	280	40	6000					
CONVERSION FACTOR	950	950	950	1180					
TOTAL OPERATIONAL FTEs	0.08	0.29	0.04	5.08					

9. REMARKS

(b) (7)(E)

Report all Domestic and Import Operations under PAC 07001.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin 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	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [3.9]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 ALL IMPORT SAMPLES TO BE ANALYZED	9 IMPORT SAMPLES TO BE ANALYZED APLA- TOWN	10 IMPORT SAMPLES TO BE ANALYZED PIMON- TSON	11 IMPORT SAMPLES TO BE ANALYZED DCM	12 IMPORT SAMPLES TO BE ANALYZED OCHA- TOWN	13 IMPORT SAMPLES TO BE ANALYZED PATUM	14 IMPORT SAMPLES TO BE ANALYZED PACIFIC REGIONAL LABORATORY	15 IMPORT SAMPLES TO BE ANALYZED PACIFIC REGIONAL LABORATORY	16 IMPORT SAMPLES TO BE ANALYZED PACIFIC REGIONAL LABORATORY																											
	TOTAL FIELD	664	224	90	90	40	140																														
NE	HEADQUARTERS	(b) (7)(E)																																			
	REGIONAL STAFF																																				
	NEW ENGLAND																																				
	NEW YORK																																				
	REGIONAL LAB																																				
WEAC																																					
CE	REGIONAL STAFF										(b) (7)(E)																										
	BALTIMORE																																				
	CHICAGO																																				
	CINCINNATI																																				
	DETROIT																																				
	MINNEAPOLIS																																				
	NEW JERSEY																																				
	PHILADELPHIA																																				
	FORENSIC CHEM. CTR																																				
	REGIONAL STAFF																																				
SE	ATLANTA																			(b) (7)(E)																	
	FLORIDA																																				
	NEW ORLEANS																																				
	SAN JUAN																																				
	REGIONAL LAB																																				
SW	REGIONAL STAFF	(b) (7)(E)																																			
	DALLAS																																				
	DENVER																																				
	KANSAS CITY																																				
	SOUTHWEST IMPORT DISTRICT																																				
REGIONAL LAB																																					
PA	REGIONAL STAFF										(b) (7)(E)																										
	LOS ANGELES																																				
	SAN FRANCISCO																																				
	SEATTLE																																				
	PACIFIC REGIONAL LABORATORY-SW																																				
PACIFIC REGIONAL LABORATORY-NW																																					
HOURS PER OPERATION																													7.0								
TOTAL HOURS																													4648								
CONVERSION FACTOR																													1180								
TOTAL OPERATIONAL FTEs																				3.94																	

9. REMARKS

(b) (7)(E)

Report all Domestic and Import Operations under PAC 07001.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program				2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07					
3. PROGRAM/ASSIGNMENT CODE(S) 07R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 METHODS VAL/DEV CHEM (Hours)	8 APPLIED TECHN- OLOGY CENTER CHEM (Hours)	9 APPLIED TECHN- OLOGY CENTER MICRO (Hours)					
	TOTAL FIELD	600	4130	600					
NE	HEADQUARTERS	(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									
TOTAL HOURS		600	4130	600					
CONVERSION FACTOR		1205	1180	1180					
TOTAL OPERATIONAL FTEs		0.50	3.50	0.50					
9. REMARKS Workload Source: Determined by Division of Field Science, ORO.									

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives			2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09															
3. PROGRAM/ASSIGNMENT CODE(S) 09006A (Foods), 09006B (Color)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 15.6												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2	4	4	6	8	8										
			IMPORT INVESTIGATIONS (1)	IMPORT SAMPLE COLL FOOD ADDITIVES	IMPORT SAMPLE COLL COLOR ADDITIVES	IMPORT FIELD EXAMS (2)	IMPORT SAMPLES TO BE ANALYZED FOOD ADDITIVES	IMPORT SAMPLES TO BE ANALYZED COLOR ADDITIVES										
TOTAL FIELD			522	310	865	4804	310	665										
NE	HEADQUARTERS		(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												1.4	1.4	0.5	13.0	10.0		
TOTAL HOURS											522	434	1211	2402	4030	8650		
CONVERSION FACTOR											950	950	950	950	1180	1180		
TOTAL OPERATIONAL FTEs											0.55	0.46	1.27	2.53	3.42	7.33		

9. REMARKS

(b) (7)(E)

Note: Resources for Entry Review and Filer Evaluation are planned under the Import Foods-General Program (PAC 03819).

(1) - Import Investigation Hours are for label reviews of Food and Color Additives as required by Districts to cover program priorities. When repeat violations against manufacturers and importers occur, consider broad-based enforcement in lieu of continued sampling.

(2) - 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 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 an additional exam and time be reported under a 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 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 26.0 [24.2]
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REGION	6. DISTRICT/SPECIALIZED LABORATORY	9 NATIONAL RETAIL FOOD PROG. STANDARDS BASE-LINE SUPP. (1)	9 STANDARDIZATION (ITP,CDC,HS) STATE & LOCAL (2)	9 RE-STANDARDIZATION (ITP,STATE &LOCAL) (3)	9 FDA FOOD BOURNE ILLNESS RISK FACTOR STUDY (4)	9 TEAM LEADER SCI NATIONAL (5)	9 NATIONAL TEAM WORK GROUP (6)	9 REGIONAL SEMINARS (7)	9 TRAINING WORKSHOPS PRE-STANDARDIZATION TRAINING (8)	9 TECHNICAL ASSISTANCE (9)
	TOTAL FIELD	7000	45	59	1170	1200	3640	1560	2600	7802

	HEADQUARTERS	(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		48.0	32.0							
TOTAL HOURS	7000	2160	1888	1170	1200	3640	1560	2600	7802	
CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200	
TOTAL OPERATIONAL FTEs	5.83	1.80	1.57	0.98	1.00	3.03	1.30	2.17	6.50	

9. REMARKS
 Report Counter Terrorism work performed only under 18R845.
 (1) - Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards.
 (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) - Allocation of time to collect data, data entry, quality assurance, and data analysis.
 (5) - Time allocated for team leaders for retail food program planning, development, and coordination.
 (6) - Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards and initiative of National Importance.
 (7) - Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the annual Regional Retail Food Seminars.
 (8) - Includes training pre-standardization workshops, HACCP workshops, and other identified training topics as well as the presentation and training sessions given to stakeholder groups.
 (9) - Includes technical assistance and consultation to enrolled state and local jurisdictions performing self assessments and developing, strategic plans for enhancing the effectiveness of their retail food programs.

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18															
3. PROGRAM/ASSIGNMENT CODE(S) 18002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 26.0 [1.8]													
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 CONFERENCE FOR FOOD PROTECTION ACTIVITIES (10)	9 FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (11)	9 FSS WORK GROUPS (12)															
	TOTAL FIELD	1040	1040	100															
NE	HEADQUARTERS	(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																			
TOTAL HOURS											1040	1040	100						
CONVERSION FACTOR											1200	1200	1200						
TOTAL OPERATIONAL FTEs											0.87	0.87	0.08						
9. REMARKS (10) - Includes all committee work and preliminary work on issues/position paper development for 2008 CFP. (11) - 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. (12) - Provides time for supporting FDA's plan of developing a fully Integrated Food Safety System.																			

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 [17.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 CHECK RATING PLANT (1)	9 CHECK RATING TRANSFER AND RECEIVING (1)	9 CHECK RATING BTU (1)	9 SINGLE SERVICE AUDITS (1)	9 STATE MILK SAMPLING OFFICER INITIAL CONT. (1)	9 STATE MILK SANITATION RATING OFF. INITIAL/CONT. CERTIFICA. (2)	9 STATE PROGRAM EVALUATION (3)	9 NATIONAL STEERING TEAM CONFERENCE CALLS/TEAM (4)	9 TECHNICAL ASSISTANCE HOURS
	TOTAL FIELD	150	36	272	67	46	48	17	32	51
NE	HEADQUARTERS	(b) (7) (E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC	(b) (7) (E)								
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b) (7) (E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB	(b) (7) (E)								
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT	(b) (7) (E)								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE	(b) (7) (E)								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		24.0	12.0	20.0	6.0	24.0	40.0	120.0	40.0	90.0
TOTAL HOURS		3600	432	5440	536	1104	1920	2040	1280	4590
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3.00	0.36	4.53	0.45	0.92	1.60	1.70	1.07	3.83

(1) - Check Ratings of Plants and RS/TS every 3 years, BTUs every 4 years and 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.
 (4) - Activities include the National Steering Team Meetings and conference calls and time for team leader activities (2 RMSs with additional 240 hours each identified).

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 [2.5]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 RMS STANDARDI- ZATION	9 FOOD DEFENSE COORDI- NATION	9 TRAINING GIVEN	9 INTEGRATED FOOD SAFETY SYSTEM	9 NCIMS			
		(5)	(6)	(7)	(8)	(9)			
	TOTAL FIELD	4	20	20	5	20			
	HEADQUARTERS	(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								
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	40.0	20.0	40.0	20.0	80.0			
	TOTAL HOURS	160	400	800	100	1600			
	CONVERSION FACTOR	1200	1200	1200	1200	1200			
	TOTAL OPERATIONAL FTEs	0.13	0.33	0.67	0.08	1.33			
9. REMARKS (5) - Activities include the Re-standardization (Group Field Exercise) of the RMS. (6) - 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. (7) - Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops and RMS Teaching Cadre. (8) - Time is allocated for work related to the development of the National Integrated Food Safety System. (9) - Time is allocated for work related to the National Conference of Interstate Milk Shipments.									

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 14.7 [12.3]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9	9	9	
		GROWING AREA EVALUATION (1)	CONTROL OF HARVEST (2)	VIBRO SPECIES MANAGEMENT (Hours) (3)	TECHNICAL ASSISTANCE (Hours) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	CENTER INTIA- TIVES/LAB (7)	PLANT EVALUATION (8)	STANDARD IZATION & RE-STAN- DARD- IZATION (9)
TOTAL FIELD		187	20	2015	4105	4	2	7	111	14
NE	HEADQUARTERS	(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		20.0	90.0			200.0	180.0	40.0	10.0	40.0
TOTAL HOURS		3740	1800	2015	4105	800	360	280	1110	560
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3.12	1.50	1.68	3.42	0.67	0.30	0.23	0.93	0.47
9. REMARKS										
<p>(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).</p> <p>(2) - Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity Model Ordinance.</p> <p>(3) - Activities include technical assistance, education and evaluation of state shellfish program and management programs.</p> <p>(4) - Includes interpretations and consultation on NSSP MO requirements.</p> <p>(5) - Activities include planning, field evaluations, file reviews and report writing for countries with MOU's with the FDA. Current MOU countries include Canada, Chile, South Korea, Mexico and New Zealand.</p> <p>(6) - Includes time for shellfish program planning, development and coordination.</p> <p>(7) - Time allocated for CFSAN priority assignments in response to national shellfish safety.</p> <p>(8) - Includes time for planning field evaluations of processing plants, file reviews, and final report writing.</p> <p>(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.</p>										

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 14.7 [2.4]								
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 NATIONAL TEAM WORKSHOP (10)	9 TRAINING WORKSHOPS (11)	9 REGIONAL SEMINARS (12)	9 FOOD DEFENSE COORDINATION (13)	9 ISSC COMMITTEE (14)	9 IFSS WORKGROUP (15)							
	TOTAL FIELD	13	14	13	13	13	5							
NE	HEADQUARTERS	(b) (7) (E)												
	REGIONAL STAFF													
	NEW ENGLAND													
	NEW YORK													
	REGIONAL LAB													
WEAC														
CE	REGIONAL STAFF													
	BALTIMORE													
	CHICAGO													
	CINCINNATI													
	DETROIT													
	MINNEAPOLIS													
	NEW JERSEY													
SE	PHILADELPHIA													
	FORENSIC CHEM. CTR													
	REGIONAL STAFF													
	ATLANTA													
	FLORIDA													
SW	NEW ORLEANS													
	SAN JUAN													
	REGIONAL LAB													
	REGIONAL STAFF													
	DALLAS													
PA	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		40.0	30.0	30.0	20.0	90.0	20.0							
TOTAL HOURS		520	420	390	280	1170	100							
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200							
TOTAL OPERATIONAL FTEs		0.43	0.35	0.33	0.22	0.98	0.08							
9. REMARKS (10) - Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, initiatives of national importance. (11) - Includes training workshops coordinated and delivered by the specialists. (12) - Includes time for the Regional Shellfish Specialists to attend regional shellfish conferences. (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. (14) - Time allocated for the specialists to attend the biennial Interstate Shellfish Sanitation Conference to address program related issues and new ISSC proposals. (15) - Time is allocated for participating and or providing information to the developmental workgroups for the Integrated Food Safety System.														

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18						
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 15.8 [14.4]			
REG ION	DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)	1 WATERING POINTS INSPEC- TIONS (2)	1 CATERING POINTS INSPEC- TIONS (3)	1 CONVEYANCE INSPEC- TIONS (C)	1 AIRLINE WATERING PTS. INSPEC- TIONS (D)	2 CONVEY UNDER CONSTRUC- TION (Hours) (4)	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL FOR CAUSE CHEM (5)	3 DOMESTIC SAMPLE COLL SURV MICRO
NE	HEADQUARTERS	(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									
	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	10.5							4.0	4.0	
TOTAL HOURS	11099					935	850	80	720	
CONVERSION FACTOR	950					950	950	950	950	
TOTAL OPERATIONAL FTEs	11.68					0.98	0.89	0.08	0.76	
9. REMARKS										
<p>(1) - Inspections in Columns A-D are included in Column 1. The additional inspections can be used for other establishments under the program.</p> <p>Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B.</p> <p>DSCs should be randomly collected from on-board conveyances water systems outlets ex. faucets, as close to the water holding tank as possible.</p> <p>(2) - all other watering points</p> <p>(3) - Catering Point Insp. (B) is High Risk Priority and some potential Food Allergen firms identified by the District.</p> <p>(4) - Time for Conveyance under Construction- time to be used for plan review, meetings, and final inspections. It includes galleys in DAL, LOS and Aircraft/Vessels in SAN & SEA.</p> <p>(5) - Includes water sample collected from conveyances under construction and major reconstruction to determine compliance with EPA's National Drinking Water Standards (40 CFR 141 & 142) regarding Maximum Contaminant Levels (NCLs) for heavy metals (Pb,Cu,etc.)</p>										

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.8 [1.4]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED FOR CAUSE CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO						
	TOTAL FIELD	20	180						
NE	HEADQUARTERS	(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	12.0	8.0						
	TOTAL HOURS	240	1440						
	CONVERSION FACTOR	1180	1180						
	TOTAL OPERATIONAL FTEs	0.20	1.22						

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21															
3. PROGRAM/ASSIGNMENT CODE(S) 21002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.8												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	2	2	4	7	7	8									
		INSP EC T I O N S	INSP EC T I O N S F O R E I G N C A D R E	D O M E S T I C S A M P L E C O L L	D O M E S T I C S A M P L E C O L L C H E M	D O M E S T I C S A M P L E C O L L M I C R O	I M P O R T S A M P L E C O L L C H E M (1)	D O M E S T I C S A M P L E T O B E A N A L Y Z E D C H E M	D O M E S T I C S A M P L E T O B E A N A L Y Z E D M I C R O	I M P O R T S A M P L E T O B E A N A L Y Z E D C H E M (2)									
TOTAL FIELD		19	2	36	57	18	8	21	15	8									
NE	HEADQUARTERS	(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																		
	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											30.0	30.0	6.0			6.0	100.0	30.0	100.0
TOTAL HOURS											570	60	216			48	2100	450	800
CONVERSION FACTOR											950	950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs											0.60	0.06	0.23			0.05	1.78	0.38	0.68

9. REMARKS
 CFSAN spread inspections and DSCs. CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.
 Time to investigate import entries for admissibility is planned under the Imports Foods General Program (7303.819).
 (1) - Includes samples resulting from import entry review as well as samples collected during foreign inspections.
 (2) - May be used for microbiological analysis.

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Labeling and Economics Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21003	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	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM					
	TOTAL FIELD	950	100	100					
NE	HEADQUARTERS	(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								
	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			4.2	19.0					
TOTAL HOURS		950	420	1900					
CONVERSION FACTOR		950	950	1180					
TOTAL OPERATIONAL FTEs		1.00	0.44	1.61					

9. REMARKS
To be issued as CFSAN Field Assignments.

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program			2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21							
3. PROGRAM/ASSIGNMENT CODE(S) 21005 (includes FPLA)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 11.8 [10.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	3	3	3	4	4	5	6	7
		IMPORT INVESTIGATIONS (Hours) (1)	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL DOCUMENTARY	DOMESTIC SAMPLE COLL PHYSICAL (2)	IMPORT SAMPLE COLL PHYSICAL (OASIS #51) (3)	IMPORT SAMPLE COLL PAPER (OASIS #41) (4)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS (5)	DOMESTIC SAMPLES TO BE ANALYZED CHEM
TOTAL FIELD		522	340	340	100	125	785	2000	8608	100
NE	HEADQUARTERS	(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									
	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			4.2			1.2	1.2	0.4	0.5	19.0
TOTAL HOURS		522	1428			150	942	800	4805	1900
CONVERSION FACTOR		950	950			950	950	950	950	1180
TOTAL OPERATIONAL FTEs		0.55	1.50			0.16	0.99	0.84	5.06	1.61

9. REMARKS

(1) - Hours for field exams and any other import operations as required by the district to cover import priorities. Districts should report time under the appropriate operation and PAC for the activities performed. For Import Field Exams, report time spent reviewing import labels that does not result in Import Sample Collection.

(2) - DSCs (Physical) includes both compliance (for cause) sampling and surveillance sampling. The field should attempt to collect sufficient surveillance samples as well as needed compliance samples to meet their workplan obligations. See compliance programs for details.

(3) - ISCs (Physical) includes time to collect and forward samples to the lab for analysis to support violations.

(4) - ISCs (Paper) includes time spent collecting labels, records or other documentation for submission to Compliance and does not include time spent reviewing the import labels. Time spent reviewing the label will be included as OASIS #27 and reported along with compliance review time as OASIS #43.

Prior to collecting product labels for trans fat and/or allergen contact CFSAN.

(5) - All import field exams are to routinely include: Verification that the imported product is the same as that which was declared (reconciliation exam), an assessment of security concerns related to labeling and source country (including container integrity, sign of intentional adulteration and 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 pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under CT PAC (03R845, 04R845, etc.) See IOM Section 5.4.1.4 for additional information on Food and Cosmetic Security Activities.

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program			2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21							
3. PROGRAM/ASSIGNMENT CODE(S) 21005 (includes FPLA)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 11.8 [1.1]			
R E G I O N	5. DISTRICT/ SPECIALIZED LABORATORY	B IMPORT SAMPLES TO BE ANALYZED CHEM								
	TOTAL FIELD	125								
NE	HEADQUARTERS	(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		10.0								
TOTAL HOURS		1250								
CONVERSION FACTOR		1180								
TOTAL OPERATIONAL FTEs		1.06								
9. REMARKS										

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21006			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.3 [4.0]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	4	5	4	7	7
		INSP EC T I O N S	FOR E I G N I N S P E C T I O N S	IN V E S T I G A T I O N S	DO M E S T I C S A M P L E C O L L	DO M E S T I C S A M P L E C O L L C H E M	DO M E S T I C S A M P L E C O L L M I C R O	IM P O R T S A M P L E C O L L C H E M (1)	DO M E S T I C S A M P L E T O B E A N A L Y Z E D C H E M	DO M E S T I C S A M P L E T O B E A N A L Y Z E D M I C R O
TOTAL FIELD		21	2	200	28	19	5	15	19	9
HEADQUARTERS										
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		42.0	42.0		5.3			5.0	100.0	120.0
TOTAL HOURS		882	84	200	148			75	1900	1080
CONVERSION FACTOR		950	950	950	950			950	1180	1180
TOTAL OPERATIONAL FTEs		0.93	0.09	0.21	0.16			0.08	1.61	0.92
9. REMARKS CFSAN spreads inspections and DSCs, CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. ORA spreads import operations. (1) - Includes samples collected during foreign inspections. Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819).										

(b) (7) (E)

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21008			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 21.1 [16.4]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	3	3	4	4	5	8
		INSPEC- TIONS	DOMESTIC INVESTI- GATIONS (Hours)	IMPORT INVESTI- GATIONS (Hours) (1)	DOMESTIC SAMPLE COLL (2)	HQ INIT DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL PAPER OASIS #41 (3)	IMPORT SAMPLE COLL PHYSICAL (4)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS (5)
	TOTAL FIELD	250	2000	865	200	50	360	70	400	1800
	HEADQUARTERS	(b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	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		40.0			4.2	4.2	1.6	1.6	0.5	0.5
TOTAL HOURS		10000	2000	865	840	210	576	112	200	800
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		10.53	2.11	0.91	0.88	0.22	0.61	0.12	0.21	0.84
9. REMARKS										
Domestic Field Exams and sample collections may be conducted at packers/repackers, distributors, or warehouses if the levels planned cannot be performed during the inspections.										
Domestic Investigational hours are planned primarily for CFSAN directed assignments.										
(1) - Time spent on any other import operations as required by the District to cover import priorities.										
(2) - Half of the planned samples are physical and other half are documentary samples.										
(3) - Time spent collecting labels, records, or other documentation for submission to Compliance. Does not include time spent reviewing the import labels. Field Exam time spent reviewing the label will be included as OASIS # 27 and reported along with compliance review time as OASIS #43.										
(4) - Physical samples collected and forwarded to the laboratory for analyses to support violations. Districts should report time under the appropriate operation and PAC for the activities performed.										
Import Field Exams are time spent reviewing labels that do not result in sample collection.										
(5) - 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, sign of intentional adulteration, etc) and traditional safety concerns. These activities are 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 suspicions are raised conducting routine work requiring follow-up, should be an additional exam and time reported under the CT PAC (03R845, 04R845, etc.) See IOM for additional information on Food and Cosmetic Defense activities.										

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) 21008			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 21.1 [4.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 HQ INT DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED PHYSICAL CHEM					
	TOTAL FIELD	100	50	70					
NE	HEADQUARTERS	(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		25.0	25.0	25.0					
TOTAL HOURS		2500	1250	1750					
CONVERSION FACTOR		1180	1180	1180					
TOTAL OPERATIONAL FTEs		2.12	1.06	1.48					
9. REMARKS									

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrient in Foods Survey - Total Diet	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21839	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (1)							
	TOTAL FIELD	1040							
	HEADQUARTERS	(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	3.8							
	TOTAL HOURS	3952							
	CONVERSION FACTOR	1180							
	TOTAL OPERATIONAL FTEs	3.35							

9. REMARKS
 (1) - Represents total number of TDS foods for all four market baskets to be analyzed for selected nutrients by KAN-DO labs.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.5
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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	600	1180							
NE	HEADQUARTERS	(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										
TOTAL HOURS		600	1180							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		0.50	1.00							

9. REMARKS
Workload Source: Determined by Division of Field Science, ORO.

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports				2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 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 8.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	8	8
		DOMESTIC INSPECT- IONS	IMPORT INVESTI- GATIONS (HOURS) (1)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL 50% CHEM 50% MICRO	IMPORT FIELD EXAMS (2)	DOMESTIC SAMPLES TO BE ANALYZED (Micro)	IMPORT SAMPLES TO BE ANALYZED (Chem)	IMPORT SAMPLES TO BE ANALYZED (Micro)
	TOTAL FIELD	100	1000	60	230	1600	60	115	115
NE	HEADQUARTERS	(b) (7)(E)							
	REGIONAL STAFF								
NE	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		17.0		4.4	1.5	0.5	18.0	16.0	16.0
TOTAL HOURS		1700	1000	264	345	800	1080	1840	1840
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.79	1.05	0.28	0.36	0.84	0.92	1.56	1.56

9. REMARKS

(b) (7)(E)

- (1) - Import Investigation Hours: Resources are for Import Filer Evaluation and Follow-up to refusals.
- (2) - 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.

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2011**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	120.4	4.0	6.6	131.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	35.9		0.1	36.0
42	BLOOD AND BLOOD PRODUCTS	73.8	4.0	3.5	81.3
45	VACCINE AND ALLERGENIC PRODUCTS	10.7		3.0	13.7

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								
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 31.0						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC- TIONS	1 CBER PRIORITY ESTABS	1 FOREIGN INSP EC- TIONS							
	TOTAL FIELD	638	102	2							
NE	HEADQUARTERS	(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							46.0		54.7		
TOTAL HOURS							29348		109		
CONVERSION FACTOR							950		950		
TOTAL OPERATIONAL FTEs							30.89		0.12		

9. REMARKS

* Refer to CBER's memo for inspectional priorities.

C.P. 7341002 - 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:

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 for Inspections of HCT/Ps-361 ALL Other 361 HCT/Ps Products, for product codes: 57J Musculoskeletal Tissue; 57L Ocular Tissue; 57O other Tissue (human skin, pericardium dura mater, heart valves)

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

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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS								
	TOTAL FIELD	53								
NE	HEADQUARTERS	(b)(2)&(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		89.8								
TOTAL HOURS		4759								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		5.01								

9. REMARKS

Resources for PACs 41808, 41809, 41810, and 41811 are planned under PAC 41811 Clinical Investigators.
 Use above resources for Foreign Inspections as needed.
 Inspections are to be conducted only when assignments are received from CBER.
 Report accomplishment hours under appropriate PAC.

PROJECT SUMMARY SHEET

FY 2011

1. PROGRAM CATEGORY Biologics		2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42					
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		73.8	4.0	3.5	81.3	
1	Inspection of Licensed & Unlicensed Blood Banks	42001F,G	48.7		0.6	49.3	42-5
	National Experts		2.6		0.1	2.7	
	Inspection of Donor Centers						
	Inspection of Reference Laboratories						
	Inspection of Blood/Plasma Brokers						
	Inspection of Blood Product Contractors						
	Technical Assistance and Coordination *		2.5			2.5	
2	Inspection of Source Plasma Establishments	42002A,F,G	11.9			11.9	42-6
3	Imported CBER - Regulated Products	42007,42R833, 41R824,42R824 45R824,99R833		4.0		4.0	42-7
4	Inspection of Licensed Viral Marker Test Kits (Team Biologics)	42008,A	1.1		0.9	2.0	42-8
	Field Investigations		0.5			0.5	
5	Bioresearch Monitoring Programs **		4.4			4.4	42-9
	Institutional Review Boards	42809	**				
	Sponsors, Contract Research Organizations, and Monitors	42810	**				
	Clinical Investigators **	42811	(4.0)				
	National Experts	41808-41811 42808-42811 45808-45811	(0.4)				
6	Inspection of Medical Device Manufacturers	42845A,B,C	0.5			0.5	42-10
7	Inspection of Plasma Derivatives of Human Origin (Team Biologics)	42848A,F,G; 42848B,C,D	1.6		1.9	3.5	42-11
	* For BLT-DO to Assist & Coordinate ARC Information.						
	** All Domestic & Foreign Resources 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														
3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 54.5												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	9												
		DOMESTIC INSP CTIONS (1)	FOREIGN INSP CTIONS (2)	DOMESTIC INVEST IGATIONS (Hours) (3)	TECH ASST & COORDIN ATION (Hours) OP CODE 92 (4)												
	TOTAL FIELD	1137	10	2469	2375												
NE	HEADQUARTERS	(b) (7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
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	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										40.7	63.0						
TOTAL HOURS										46276	630	2469	2375				
CONVERSION FACTOR										950	950	950	950				
TOTAL OPERATIONAL FTEs										48.71	0.66	2.60	2.50				

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. 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 DFI.

(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.

1. PROGRAM/ASSIGNMENT TITLE Inspections of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)							
	TOTAL FIELD	219	510							
	HEADQUARTERS	(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	49.4								
	TOTAL HOURS	10819	510							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	11.39	0.54							

9. REMARKS

The above resources are planned under PAC 42002F, use resources as needed to accomplish this compliance program. Resources may be used for Domestic/Foreign/Follow-up Inspections/Investigations, DSCs as needed. Report operations under appropriate PAC and Operation Code. Refer to CBER's memo for inspectional priorities.

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.

Personnel Types required: Investigator, Team Biologics

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Viral Marker Test Kits	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
--	---

3. PROGRAM/ASSIGNMENT CODE(S) 42008, A Domestic & Foreign	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 DOMESTIC INSP EC- TION S	1 FOREIGN INSP EC- TION S	2 DOMESTIC INVEST - GATION S (Hours)				
	TOTAL FIELD	8	5	410				
NE	HEADQUARTERS	(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		135.0	176.7					
TOTAL HOURS		1080	884	410				
CONVERSION FACTOR		950	950	950				
TOTAL OPERATIONAL FTEs		1.14	0.93	0.43				

9. REMARKS

42008 GMP Inspections;
 42008A Pre-License Inspections.
 All inspections will be performed by Team Biologics. Field time is for district support to Team Biologics.
 No separate resources are planned for 42008A, use above resources as needed.
 Report accomplishments under appropriate operation code and PAC.

Field Investigation Hours may be used for any Team Biologics Program.

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)			2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42							
3. PROGRAM/ASSIGNMENT CODE(S) 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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS								
	TOTAL FIELD	45								
	HEADQUARTERS	(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		92.9								
TOTAL HOURS		4181								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.40								

9. REMARKS

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

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	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	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS							
	TOTAL FIELD	12							
	HEADQUARTERS	(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	39.7							
	TOTAL HOURS	476							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	0.50							

9. REMARKS

No Investigation Hours or Foreign Inspections are planned, use above resources as needed.

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

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

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Plasma Derivatives of Human Origin			2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42							
3. PROGRAM/ASSIGNMENT CODE(S) 42848A,F,G; 42848B,C,D Domestic & Foreign			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.5				
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPEC- TIONS	1 FOREIGN LICENSED INSPEC- TIONS							
	TOTAL FIELD	10	10							
NE	HEADQUARTERS	(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			150.0	182.5						
TOTAL HOURS			1500	1825						
CONVERSION FACTOR			950	950						
TOTAL OPERATIONAL FTEs			1.58	1.92						

9. REMARKS
 Team Biologics Compliance Program new in FY05 - Inspection of Biological Drug Products (CBER), (Previously covered by PAC 42006). All Inspections will be performed by Team Biologics.
 42848A Pre-Licensed Inspection - Plasma Derivatives;
 42848F Level 1 CGMP Inspection - Plasma Derivatives;
 42848G Level 2 CGMP Inspection - Plasma Derivatives.

NEW PACs: 42848B Pre-Licensed Inspection - Recombinant Analogues;
42848C Level 1 CGMP Inspection - Recombinant Analogues;
42848D Level 2 CGMP Inspection - Recombinant Analogues.

 No separate resources are planned for Pre-License Inspections, Recombinant Analogues, use above resources as needed.
 All resources are planned under PAC 42848F.

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)			2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45							
3. PROGRAM/ASSIGNMENT CODE(S) 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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S								
	TOTAL FIELD	75								
NE	HEADQUARTERS	(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									
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	FLORIDA									
	NEW ORLEANS									
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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			88.7							
TOTAL HOURS			6653							
CONVERSION FACTOR			950							
TOTAL OPERATIONAL FTEs			7.00							

9. REMARKS

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

Personnel Types required: Investigator

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			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 DOMESTIC INSP EC TIONS	1 FOREIGN INSP EC TIONS								
	TOTAL FIELD	4	2								
NE	HEADQUARTERS	(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										
	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				92.0	150.0						
TOTAL HOURS				368	300						
CONVERSION FACTOR				950	950						
TOTAL OPERATIONAL FTEs				0.39	0.32						

9. REMARKS

New Team Biologics Compliance Program In FY05 - Inspection of Biological Drug Products (CBER)
 (Previously covered by PAC 45001).
 45848A Pre-License Inspection - Allergenic;
 45848F Level 1 CGMP Inspection - Allergenic;
 45848G Level 2 CGMP Inspection - Allergenic.
 All inspections will be performed by Team Biologics.
 Resources are planned under PAC 45848F. Use resources as needed and report under appropriate PAC.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)				2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45									
3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D,H Domestic & Foreign			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.0							
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1										
		DOMESTIC INSP EC- TIONS	FOREIGN INSP EC- TIONS	DOMESTIC INVESTI- GATIONS (Hours)									
TOTAL FIELD		10	13	503									
NE	HEADQUARTERS	(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								260.0	200.0				
TOTAL HOURS								2600	2600	503			
CONVERSION FACTOR								950	950	950			
TOTAL OPERATIONAL FTEs								2.74	2.74	0.53			

9. REMARKS

New Team Biologics Compliance Program in FY05 - Inspection of Biological Drug Products (CBER)
 (Previously covered by PAC 45002).
 45848B Pre-License Inspection - Vaccines;
 45848C Level 1 CGMP Inspection - Vaccines;
 45848D Level 2 CGMP Inspection - Vaccines.
 45848H Off-Year Flu Vaccine: for inspecting the 50% of firm inventory not scheduled for inspection in this year.

All inspections will be performed by Team Biologics.
 Resources are planned under 45848C. Use resources as needed and report under appropriate PAC.
 Field Investigation Hours may be used to assist any Team Biologics Program.

Personnel Types Required: Team Biologics, Investigator

**CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2011**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	231.4	37.9	97.7	367.0
46	NEW DRUG EVALUATION	11.0		14.0	25.0
48	BIORESEARCH MONITORING HUMAN DRUGS	52.0		21.2	73.2
52	GENERIC DRUG EVALUATION	6.0		11.0	17.0
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	10.0		1.0	11.0
56	DRUG QUALITY ASSURANCE	128.9	37.9	50.5	217.3
63	UNAPPROVED AND MISBRANDED DRUGS	11.5			11.5
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							
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 9.5					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 CHEMIST ON INSPECTIONS (Hours) (1)	3 DOMESTIC SAMPLE COLL CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED PROFILE (Hours)				
	TOTAL FIELD	154	703	17	17				
NE	HEADQUARTERS	(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		51.1		6.0	24.0				
TOTAL HOURS		7869	703	102	408				
CONVERSION FACTOR		950	950	950	1180				
TOTAL OPERATIONAL FTEs		8.28	0.74	0.11	0.35				
9. REMARKS (1) - Includes Microbiologists on Inspections.									

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46							
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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1							
		INSPECTIONS (2)	CHEMIST ON INSPECTIONS (Hours) (3)							
	TOTAL FIELD	117	5470							
NE	HEADQUARTERS	(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				58.8						
TOTAL HOURS				6880	5470					
CONVERSION FACTOR				950	950					
TOTAL OPERATIONAL FTEs				7.24	5.76					

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.

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			
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1	1							
		INSPECTIONS Domestic (1)	INSPECTIONS Foreign							
TOTAL FIELD		19	18							
NE	HEADQUARTERS	(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									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		51.1	58.8							
TOTAL HOURS		971	941							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.02	0.99							
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) 46832P		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 0.5					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)								
	TOTAL FIELD	24								
NE	HEADQUARTERS	(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									
	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			20.4							
TOTAL HOURS			490							
CONVERSION FACTOR			950							
TOTAL OPERATIONAL FTEs			0.52							
9. REMARKS (1) - Includes Microbiologists on Inspections. Inspections are to verify that NDA applicant has facilities, equipment, controls, etc. so specified in the application.										

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence - Pre-Approval (PDUFA)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
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 6.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPECTIONS	1 48001A NDA INSPECTIONS						
	TOTAL FIELD	33	47						
NE	HEADQUARTERS	(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		77.3	67.6						
TOTAL HOURS		2551	3177						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		2.69	3.34						

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) 35%, PDUFA 48001A (NDA) 65%.

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA; ANDA - PRE-APPROVAL)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48							
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 5.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPECTIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPECTIONS (PRE-APPVL)							
	TOTAL FIELD	31	29							
NE	HEADQUARTERS	(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		83.8	75.3							
TOTAL HOURS		2598	2184							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.73	2.30							

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.
 We are not planning separate PEPFAR work.

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

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			
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 16.1	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 GLP INSPECTIONS 48808	2 NAT'L EXPERT INVESTI- GATIONS (Hours) 48808 - GLP	3 IRB (1) INSPECTIONS 48809, 48809A (2)	4 SPONSOR, CRO, MONITORS INSPECTIONS 48810 (3)	
	TOTAL FIELD	28	112	121	46	
NE	HEADQUARTERS	(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		98.0		61.0	110.3	
TOTAL HOURS		2744	112	7381	5074	
CONVERSION FACTOR		950	950	950	950	
TOTAL OPERATIONAL FTEs		2.89	0.12	7.77	5.34	
9. REMARKS						
<p>48808: Resources planned for Inspections may also be used for DSCs.</p> <p>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.</p> <p>Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-3).</p> <p>(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</p>						

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)				2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48																																													
3. PROGRAM/ASSIGNMENT CODE(S) 48811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 46.1																																											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS DOMESTIC	2 NAT'L EXPERT INVESTI- GATIONS (Hours)	1 INSPECTIONS FOREIGN																																													
	TOTAL FIELD	283	102	171																																													
NE	HEADQUARTERS	(b) (7)(E)																																															
	REGIONAL STAFF																																																
	NEW ENGLAND																																																
	NEW YORK																																																
	REGIONAL LAB																																																
WEAC																																																	
CE	REGIONAL STAFF									(b) (7)(E)																																							
	BALTIMORE																																																
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	CINCINNATI																																																
	DETROIT																																																
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	NEW JERSEY																																																
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	FORENSIC CHEM. CTR																																																
SE	REGIONAL STAFF																	(b) (7)(E)																															
	ATLANTA																																																
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	NEW ORLEANS																																																
	SAN JUAN																																																
REGIONAL LAB																																																	
SW	REGIONAL STAFF																									(b) (7)(E)																							
	DALLAS																																																
	DENVER																																																
	KANSAS CITY																																																
	SOUTHWEST IMPORT DISTRICT																																																
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PA	REGIONAL STAFF																																	(b) (7)(E)															
	LOS ANGELES																																																
	SAN FRANCISCO																																																
	SEATTLE																																																
	PACIFIC REGIONAL LABORATORY-SW																																																
PACIFIC REGIONAL LABORATORY-NW																																																	
HOURS PER OPERATION																																										100.0		90.0					
TOTAL HOURS																																										28300	102	15390					
CONVERSION FACTOR																																										950	950	950					
TOTAL OPERATIONAL FTEs																																										29.79	0.11	16.20					
9. REMARKS																																																	

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Investigations - Foreign				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52																																																			
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 11.0																																																	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS (1) (Foreign) (2)	1 CHEMIST INSPECTIONS (Hours) (Foreign) (3)	2 INVESTIGA- TIONS (Hours)	4 IMPORT SAMPLE COLL (4)	8 IMPORT SAMPLES ANALYSES PROFILE (Chem) (5)	8 IMPORT SAMPLE ANALYSES BIOTEST (Chem) (5)																																																
	TOTAL FIELD	62	2200	147	203	101	102																																																
NE	HEADQUARTERS	(b) (7) (E)																																																					
	REGIONAL STAFF																																																						
	NEW ENGLAND																																																						
	NEW YORK																																																						
	REGIONAL LAB																																																						
WEAC																																																							
CE	REGIONAL STAFF										(b) (7) (E)																																												
	BALTIMORE																																																						
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	DETROIT																																																						
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SE	REGIONAL STAFF																			(b) (7) (E)																																			
	ATLANTA																																																						
	FLORIDA																																																						
	NEW ORLEANS																																																						
	SAN JUAN																																																						
REGIONAL LAB																																																							
SW	REGIONAL STAFF																												(b) (7) (E)																										
	DALLAS																																																						
	DENVER																																																						
	KANSAS CITY																																																						
	SOUTHWEST IMPORT DISTRICT																																																						
REGIONAL LAB																																																							
PA	REGIONAL STAFF																																					(b) (7) (E)																	
	LOS ANGELES																																																						
	SAN FRANCISCO																																																						
	SEATTLE																																																						
	PACIFIC REGIONAL LABORATORY-SW																																																						
PACIFIC REGIONAL LABORATORY-NW																																																							
HOURS PER OPERATION																																															61.4			3.0	30.0	15.0			
TOTAL HOURS																																															3807	2200	147	609	3030	1530			
CONVERSION FACTOR																																															950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs																																															4.01	2.32	0.15	0.64	2.57	1.30			
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.																																																							

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
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
 1.0

REG I O N	DISTRICT/SPECIALIZED LABORATORY	1 ANDA PET INSPECTIONS (1)							
	TOTAL FIELD	44							
	HEADQUARTERS	(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	21.5							
	TOTAL HOURS	946							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	1.00							

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.

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulation			2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53								
3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS DOMESTIC	1 INSPECTIONS FOREIGN (2)								
	TOTAL FIELD	118	15								
NE	HEADQUARTERS	(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										
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				64.5	64.9						
TOTAL HOURS				7611	974						
CONVERSION FACTOR				950	950						
TOTAL OPERATIONAL FTEs				8.01	1.03						

9. REMARKS

(1) - Report both Domestic and Foreign inspections under 53001A for Center-Initiated and 53001B for District-Initiated.
 (2) - CDER will issue one (1) foreign inspection assignment for the REMS program. Work conducted for the REMS program should be reported to PAC 53001C.

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.

1. PROGRAM/ASSIGNMENT TITLE Risk Evaluation and Mitigation System (REMS)				2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53							
3. PROGRAM/ASSIGNMENT CODE(S) 53001C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1									
	TOTAL FIELD	INSPECTIONS (1)									
NE	HEADQUARTERS	(b) (7)(E)									
	REGIONAL STAFF										
NEW ENGLAND											
NEW YORK											
REGIONAL LAB											
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
SE	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
SW	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
PA	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		66.0									
TOTAL HOURS		1914									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTEs		2.01									
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 Risk Management and Surveillance (HFD-330). This program has one (1) foreign inspection assignment to be issued by CDER using resources from the Adverse Drug Experience Reporting Program (53001A/B). Please note: District inspection allocation may be subject to change as a result of CDER's final site selections.											

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, 56832, 56R359	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 42.0	

R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1	1																																																			
		INSPECTIONS FOREIGN (1)	CHEMIST ON INSPECTIONS FOREIGN (Hours) (2)	FOREIGN CADRE INSPECTIONS																																																			
	TOTAL FIELD	384	6200	250																																																			
NE	HEADQUARTERS	(b) (7)(E)																																																					
	REGIONAL STAFF																																																						
	NEW ENGLAND																																																						
	NEW YORK																																																						
	REGIONAL LAB																																																						
WEAC																																																							
CE	REGIONAL STAFF										(b) (7)(E)																																												
	BALTIMORE																																																						
	CHICAGO																																																						
	CINCINNATI																																																						
	DETROIT																																																						
	MINNEAPOLIS																																																						
	NEW JERSEY																																																						
	PHILADELPHIA																																																						
FORENSIC CHEM. CTR																																																							
SE	REGIONAL STAFF																			(b) (7)(E)																																			
	ATLANTA																																																						
	FLORIDA																																																						
	NEW ORLEANS																																																						
	SAN JUAN																																																						
REGIONAL LAB																																																							
SW	REGIONAL STAFF																												(b) (7)(E)																										
	DALLAS																																																						
	DENVER																																																						
	KANSAS CITY																																																						
	SOUTHWEST IMPORT DISTRICT																																																						
REGIONAL LAB																																																							
PA	REGIONAL STAFF																																					(b) (7)(E)																	
	LOS ANGELES																																																						
	SAN FRANCISCO																																																						
	SEATTLE																																																						
	PACIFIC REGIONAL LABORATORY-SW																																																						
PACIFIC REGIONAL LABORATORY-NW																																																							
HOURS PER OPERATION																																															50.7		57.0						
TOTAL HOURS																																															19469	6200	14250						
CONVERSION FACTOR																																															950	950	950						
TOTAL OPERATIONAL FTEs																																															20.49	6.53	15.00						

9. REMARKS

(1) - Foreign inspections (DPI) are planned under 56002 and should be reported under operation 11 PACs 56002A, B, C, D, E, 56832.

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

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Gas Manufacturers (Domestic)			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3. PROGRAM/ASSIGNMENT CODE(S) 56002E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.0			
R E G I O N	6.	1								
	DISTRICT/ SPECIALIZED LABORATORY	PLANNED INSPECTIONS MEDICAL GAS (1)								
	TOTAL FIELD	285								
	HEADQUARTERS	(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									
	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		30.0								
TOTAL HOURS		8550								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		9.00								

9. REMARKS

(1) - Total number of planned gas inspections in the Program for FY 2011.

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Active Pharmaceutical Ingredients (APIs) - (Domestic and Foreign)		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56				
3. PROGRAM/ASSIGNMENT CODE(S) 56002F		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 13.0	
R E G I O N	b.	1	1			
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPECTIONS	FOREIGN INSPECTIONS			
	TOTAL FIELD	110	108			
NE	HEADQUARTERS	(b) (7)(E)				
	REGIONAL STAFF					
CE	NEW ENGLAND	(b) (7)(E)				
	NEW YORK					
SE	REGIONAL LAB	(b) (7)(E)				
	WEAC					
SW	REGIONAL STAFF	(b) (7)(E)				
	BALTIMORE					
PA	CHICAGO	(b) (7)(E)				
	CINCINNATI					
PA	DETROIT	(b) (7)(E)				
	MINNEAPOLIS					
PA	NEW JERSEY	(b) (7)(E)				
	PHILADELPHIA					
PA	FORENSIC CHEM. CTR	(b) (7)(E)				
	REGIONAL STAFF					
PA	ATLANTA	(b) (7)(E)				
	FLORIDA					
PA	NEW ORLEANS	(b) (7)(E)				
	SAN JUAN					
PA	REGIONAL LAB	(b) (7)(E)				
	REGIONAL STAFF					
PA	DALLAS	(b) (7)(E)				
	DENVER					
PA	KANSAS CITY	(b) (7)(E)				
	SOUTHWEST IMPORT DISTRICT					
PA	REGIONAL LAB	(b) (7)(E)				
	REGIONAL STAFF					
PA	LOS ANGELES	(b) (7)(E)				
	SAN FRANCISCO					
PA	SEATTLE	(b) (7)(E)				
	PACIFIC REGIONAL LABORATORY-SW					
PA	PACIFIC REGIONAL LABORATORY-NW	(b) (7)(E)				
HOURS PER OPERATION		56.1	58.3			
TOTAL HOURS		6171	6180			
CONVERSION FACTOR		950	950			
TOTAL OPERATIONAL FTEs		6.50	6.51			
9. REMARKS						
(b) (7)(E)						

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) 56002P		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	
		5. OPERATIONAL FTE POSITIONS 0.5	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD	1 DOMESTIC INSPECTIONS (1) 20							
NE	HEADQUARTERS	(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	24.0							
	TOTAL HOURS	480							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	0.51							

9. REMARKS

 (1) - Inspections are to evaluate the conditions under which drug products are manufactured, tested, packaged and held. In FY2011, manufacturers are required to adhere to USP <823>; 21 CFR Part 212 becomes effective December 2011.

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			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 18.5 [4.3]												
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI- GATIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM (1)	3 DOMESTIC SAMPLE COLL MICRO (1)	3 DOMESTIC IMPORT SAMPLE COLL (2)	3 DOMESTIC IMPORT SAMPLE COLL CHEM (1)	3 DOMESTIC IMPORT SAMPLE COLL MICRO (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO									
	TOTAL FIELD		700	40	70	10	380	370	370	30	10								
NE	HEADQUARTERS	(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																		
	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												5.5			5.5			37.5	22.0
TOTAL HOURS											700	220			2090			1125	220
CONVERSION FACTOR											950	950			950			1180	1180
TOTAL OPERATIONAL FTEs											0.74	0.23			2.20			0.95	0.19

9. REMARKS

(1) - 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.

(2) - NEW - Reporting Guidance: Report domestic-import sample collections and sample analyses under 56008A.

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			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 18.5 [14.2]		
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	8 METHODS DEVELOP- MENT HOURS CHEM				
	TOTAL FIELD	320	60	3446				
NE	HEADQUARTERS	(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		37.5	22.0					
TOTAL HOURS		12000	1320	3446				
CONVERSION FACTOR		1180	1180	1180				
TOTAL OPERATIONAL FTEs		10.17	1.12	2.92				
9. REMARKS								

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56													
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 37.9										
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	INTERNATIONAL MAIL FACILITY REVIEWS INV HOURS	MAIL COURIER REVIEWS INV HOURS	IMPORT SAMPLE COLL	IMPORT SAMPLES TO BE ANALYZED APIs Chem	IMPORT SAMPLES ANALYZED DOSAGE Chem								
	TOTAL FIELD	11184	3572	6200	12103	1235	202	101	101								
NE	HEADQUARTERS	(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												1.0			2.7	25.0	18.0
TOTAL HOURS										11184	3572	6200	12103	1235	545	2525	1818
CONVERSION FACTOR										1200	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs										9.32	3.76	6.53	12.74	1.30	0.57	2.14	1.54

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.

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/NDA-Field Alert Reporting				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
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			
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	3 DOMESTIC SAMPLE COLL (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED					
	TOTAL FIELD	103	23	23					
NE	HEADQUARTERS	(b) (7)(E)							
	REGIONAL STAFF								
NEW ENGLAND									
NEW YORK									
REGIONAL LAB									
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	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		30.7	5.2	52.8					
TOTAL HOURS		3162	120	1214					
CONVERSION FACTOR		950	950	1180					
TOTAL OPERATIONAL FTEs		3.33	0.13	1.03					

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56								
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						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S	2 I N V E S T I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D						
	TOTAL FIELD		43	294	34	34					
NE	HEADQUARTERS	(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							30.0		2.0	11.0	
TOTAL HOURS							1290	294	68	374	
CONVERSION FACTOR							950	950	950	1180	
TOTAL OPERATIONAL FTEs							1.35	0.31	0.07	0.32	

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Domestic				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 2.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	PLANNED INSPECTIONS						
	TOTAL FIELD	48							
NE	HEADQUARTERS	(b) (7)(E)							
	REGIONAL STAFF								
CE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
SE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
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	40.0							
	TOTAL HOURS	1920							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	2.02							
9. REMARKS									

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - 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 2.0			
R E G I O N	6.	1								
	DISTRICT/ SPECIALIZED LABORATORY	PLANNED INSPECTIONS								
	TOTAL FIELD	48								
	HEADQUARTERS	(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		40.0								
TOTAL HOURS		1920								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		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 5.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	INSPEC- TIONS								
	TOTAL FIELD	58									
NE	HEADQUARTERS	(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		85.0									
TOTAL HOURS		4760									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTEs		5.01									

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

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC CHEM (Hours) FORENSIC EVALUATION								
	TOTAL FIELD	12050								
NE	HEADQUARTERS	(b) (7)(E)								
	REGIONAL STAFF									
	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										
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.

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs		2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63															
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 6.5										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL (1)	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)												
	TOTAL FIELD	133	1300	118	65												
NE	HEADQUARTERS	(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																
PA	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
HOURS PER OPERATION										25.7		5.4	15.3				
TOTAL HOURS										3418	1300	637	995				
CONVERSION FACTOR										950	950	950	1180				
TOTAL OPERATIONAL FTEs										3.60	1.37	0.67	0.84				

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.

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Without Approved NDAs				2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63							
3. PROGRAM/ASSIGNMENT CODE(S) 63002		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.0						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)								
	TOTAL FIELD	88	200								
NE	HEADQUARTERS	(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				51.9							
TOTAL HOURS				4567	200						
CONVERSION FACTOR				950	950						
TOTAL OPERATIONAL FTEs				4.81	0.21						

9. REMARKS

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

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2011**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	108.5	17.3	6.3	132.1
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	5.5		4.2	9.7
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	103.0	17.3	2.1	122.4

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 4.9						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC- TIONS (1)	1 DOMESTIC INSPEC- TIONS (2)	1 CHEMIST ON INSP 850							
	TOTAL FIELD	40	5	850							
NE	HEADQUARTERS	(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							90.0	40.0			
TOTAL HOURS							3600	200	850		
CONVERSION FACTOR							950	950	950		
TOTAL OPERATIONAL FTEs							3.79	0.21	0.89		

(1) - Foreign inspections spread by DFI. 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.

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							
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 4.8					
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)	1 DOMESTIC INSPEC- TIONS 68811				
TOTAL FIELD		2	3	30	44				
NE	HEADQUARTERS	(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		70.0	70.0	63.3	52.0				
TOTAL HOURS		140	210	1899	2288				
CONVERSION FACTOR		950	950	850	950				
TOTAL OPERATIONAL FTEs		0.15	0.22	2.00	2.41				

9. 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.

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 13.0										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	3	4	6	7								
		FOREIGN INSPEC- TIONS (1)	DOMESTIC INSPEC- TIONS (2)	CHEM ON INSPEC (Hours)	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL (3)	DOMESTIC SAMPLES COLL CHEM	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM								
TOTAL FIELD		33	205	600	250	50	20	100	20								
NE	HEADQUARTERS	(b) (7) (E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
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SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
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	REGIONAL STAFF																
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	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										49.0	44.0			7.0		0.8	25.0
TOTAL HOURS										1617	9020	600	250	350		80	500
CONVERSION FACTOR										950	950	950	950	950		950	1180
TOTAL OPERATIONAL FTEs										1.70	9.49	0.63	0.26	0.37		0.08	0.42

9. REMARKS
 (1) - Foreign Inspections spread by Division of Field Investigations, DFI.
 (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: Resource distribution is based on the CVM risk model for ranking firms in this program.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Domestic				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71													
3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-K			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.6 [11.8]										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED Metals 71003B	7 DOMESTIC SAMPLES TO BE ANALYZED Mycro 71003C	7 DOMESTIC SAMPLES TO BE ANALYZED Micro 71003E	7 DOMESTIC SAMPLES TO BE ANALYZED Micro 71003	7 DOMESTIC SAMPLES TO BE ANALYZED Chem 71003A	7 DOMESTIC SAMPLES TO BE ANALYZED Dioxin 71003G	7 DOMESTIC SAMPLES TO BE ANALYZED Antibiotics 71003K									
	TOTAL FIELD	60	395	300	100	290	60	40									
	HEADQUARTERS	(b) (7) (E)															
NE	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
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	NEW JERSEY																
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	FORENSIC CHEM. CTR																
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	ATLANTA																
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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	18.0	11.0	13.0	13.0	6.6	11.7	17.3									
	TOTAL HOURS	1080	4345	3900	1300	1914	702	692									
	CONVERSION FACTOR	1180	1180	1180	1180	1180	1180	1180									
	TOTAL OPERATIONAL FTEs	0.92	3.68	3.31	1.10	1.62	0.59	0.59									
9. REMARKS																	

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Import					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices- 71																																																												
3. PROGRAM/ASSIGNMENT CODE(S) 71003A-K			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 25.6 [6.3]																																																											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL	1 IMPORT SAMPLE COLL Chem	1 IMPORT SAMPLE COLL Micro 71003E	1 IMPORT SAMPLE COLL Antibiotics	8 IMPORT FIELD EXAMS	8 IMPORT SAMPLES TO BE ANALYZED Chem	8 IMPORT SAMPLES TO BE ANALYZED Micro (3)	8 IMPORT SAMPLES TO BE ANALYZED Antibiotics																																																								
	TOTAL FIELD		550	200	200	20	300	250	280	20																																																							
NE	HEADQUARTERS	(b) (7) (E)																																																															
	REGIONAL STAFF																																																																
	NEW ENGLAND																																																																
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SE	FORENSIC CHEM. CTR																	(b) (7) (E)																																															
	REGIONAL STAFF																																																																
	ATLANTA																																																																
	FLORIDA																																																																
	NEW ORLEANS																																																																
SW	SAN JUAN																									(b) (7) (E)																																							
	REGIONAL LAB																																																																
	REGIONAL STAFF																																																																
	DALLAS																																																																
	DENVER																																																																
PA	KANSAS CITY																																	(b) (7) (E)																															
	SOUTHWEST IMPORT DISTRICT																																																																
	REGIONAL LAB																																																																
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	LOS ANGELES																																																																
	SAN FRANCISCO																																									(b) (7) (E)																							
	SEATTLE																																																																
	PACIFIC REGIONAL LABORATORY-SW																																																																
																																																		(b) (7) (E)															
PACIFIC REGIONAL LABORATORY-NW																																																																	
HOURS PER OPERATION																																																										2.5				0.6	7.0	12.0	17.3
TOTAL HOURS																																																										1375				180	1750	3360	346
CONVERSION FACTOR																																																										950				950	1180	1180	1180
TOTAL OPERATIONAL FTEs																																																										1.45				0.19	1.48	2.85	0.29
9. 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.																																																																	
(3) - Import Sample Collections and Analyses: 71003E, sample collections are for pig ears, pet treats, and pet foods as well as other animal feed/ ingredients.																																																																	

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing			2. PPS PROJECT NAME/NUMBER Monitoring of Market Animal Drugs, Feeds and Devices- 71																																																																						
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 5.1																																																																			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC- TIONS	2 DOMESTIC INSPEC- TIONS	3 DOMESTIC SAMPLE COLL	4 DOMESTIC SAMPLE COLL GUIDANCE (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)																																																																			
	TOTAL FIELD	10	141	60	78	15																																																																			
NE	HEADQUARTERS	(b) (7)(E)																																																																							
	REGIONAL STAFF																																																																								
	NEW ENGLAND																																																																								
	NEW YORK																																																																								
	REGIONAL LAB																																																																								
WEAC																																																																									
CE	REGIONAL STAFF									(b) (7)(E)																																																															
	BALTIMORE																																																																								
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	NEW JERSEY																																																																								
	PHILADELPHIA																																																																								
	FORENSIC CHEM. CTR																																																																								
	REGIONAL STAFF																																																																								
SE	ATLANTA																	(b) (7)(E)																																																							
	FLORIDA																																																																								
	NEW ORLEANS																																																																								
	SAN JUAN																																																																								
SW	REGIONAL LAB																									(b) (7)(E)																																															
	REGIONAL STAFF																																																																								
	DALLAS																																																																								
	DENVER																																																																								
	KANSAS CITY																																																																								
PA	SOUTHWEST IMPORT DISTRICT																																	(b) (7)(E)																																							
	REGIONAL LAB																																																																								
	REGIONAL STAFF																																																																								
	LOS ANGELES																																																																								
	SAN FRANCISCO																																																																								
	SEATTLE																																									(b) (7)(E)																															
	PACIFIC REGIONAL LABORATORY-SW																																																	(b) (7)(E)																							
	PACIFIC REGIONAL LABORATORY-NW																																																									(b) (7)(E)															
HOURS PER OPERATION																																																																		40.0	25.0	7.8		39.0			
TOTAL HOURS																																																																		400	3525	468		585			
CONVERSION FACTOR																																																																		950	950	950		1180			
TOTAL OPERATIONAL FTEs																																																																		0.42	3.71	0.49		0.50			
9. 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 363 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. In FY 2009 Voluntary Self Inspection Program (VSIP) resources are cancelled. 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: Resource distribution is based on the CVM risk model for ranking firms in this program.																																																																									

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry				2. PPS PROJECT NAME/NUMBER Monitoring of Market Animal Drugs, Feeds and Devices- 71									
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 38.3							
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	7	9	9						
		DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL MILK (2)	DOMESTIC SAMPLES TO BE ANALYZED MILK (3)	METHODS VALIDA- TION (Hours) (4)	TECH SUPPORT (Hours) (5)						
TOTAL FIELD		400	650	900	900	360	1500						
NE	HEADQUARTERS	(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								39.0	7.0	4.0	15.0		
TOTAL HOURS								15600	4550	3600	13500	360	1500
CONVERSION FACTOR								950	950	950	1180	1180	950
TOTAL OPERATIONAL FTEs								16.42	4.79	3.79	11.44	0.31	1.58

9. 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.

(1) - Documentary samples collected during inspections.

(2) - 900 Milk samples will be collected by the FDA and analyzed by regional laboratories.

(3) - Planned analytical time may be converted to methods validation and methods development (including bridging methods) per CVM's concurrence. Methods validation and methods development work will be assigned by CVM. Report time under OP 3.

(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. 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.

Workload Source: Resource distribution is based on the CVM 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 Market Animal Drugs, Feeds and Devices- 71																																																											
3. PROGRAM/ASSIGNMENT CODE(S) 71009, 71844, 71R843 (99R833, 71R833, 71R824)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 33.1 [30.2]																																																										
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	3	4	6	7	8																																																						
		DOMESTIC INSP CTIONS (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	IMPORT SAMPLE TO BE ANALYZED CHEM																																																						
TOTAL FIELD		1486	1500	7440	2030	640	200	3200	640	200																																																						
NE	HEADQUARTERS	(b) (7) (E)																																																														
	REGIONAL STAFF																																																															
	NEW ENGLAND																																																															
	NEW YORK																																																															
	REGIONAL LAB																																																															
WEAC																																																																
CE	REGIONAL STAFF										(b) (7) (E)																																																					
	BALTIMORE																																																															
	CHICAGO																																																															
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	NEW JERSEY																																																															
	PHILADELPHIA																																																															
	FORENSIC CHEM. CTR																																																															
	REGIONAL STAFF																																																															
SE	ATLANTA																			(b) (7) (E)																																												
	FLORIDA																																																															
	NEW ORLEANS																																																															
	SAN JUAN																																																															
	REGIONAL LAB																																																															
SW	REGIONAL STAFF																												(b) (7) (E)																																			
	DALLAS																																																															
	DENVER																																																															
	KANSAS CITY																																																															
	SOUTHWEST IMPORT DISTRICT																																																															
PA	REGIONAL LAB																																					(b) (7) (E)																										
	REGIONAL STAFF																																																															
	LOS ANGELES																																																															
	SAN FRANCISCO																																																															
	SEATTLE																																																															
PACIFIC REGIONAL LABORATORY-SW																																															(b) (7) (E)																	
PACIFIC REGIONAL LABORATORY-NW																																																																
HOURS PER OPERATION																																																								7.5				4.0	2.5	0.4	6.0	4.3
TOTAL HOURS																																																								11145	1500	7440	2030	2560	500	1280	3840	860
CONVERSION FACTOR																																																								850	950	1200	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs																																																								11.73	1.58	6.20	2.14	2.69	0.53	1.35	3.25	0.73
9. REMARKS																																																																
(b) (7)(E)																																																																
(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.																																																																
(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.																																																																
Workload Distribution: Resource distribution based on the CVM 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 Market Animal Drugs, Feeds and Devices- 71								
3. PROGRAM/ASSIGNMENT CODE(S) PACs 71009, 71844, 71R843 (99R833, 71R833, 71R824)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 33.1 [2.9]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 TECHNICAL SUPPORT (Hours) (5)									
	TOTAL FIELD	2748									
NE	HEADQUARTERS	(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											
TOTAL HOURS			2748								
CONVERSION FACTOR			950								
TOTAL OPERATIONAL FTEs			2.89								

9. REMARKS
 (5) - 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.

CONTINUATION SHEET

<p>1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program</p>	<p>2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs Feeds and Devices - 71</p>
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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. CFR 589.2000 pertains to a variety of firms and animal product operations that involve manufacture, distribution, transportation, and feeding of animal feeds. Although the intent of the rule is to ensure specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily 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. In planning and prioritizing inspections, the following firm/industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- Firms that have a violative history
- Firms handling prohibited materials (Renderers, Protein Blenders, and Feed Mills)
- Rendering operations
- Protein Blenders
- Commercial feed mills (licensed and unlicensed)
- Animal feed distributors/retailers (ruminant feeds involved)
- Pet food/animal feed salvage operations
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Haulers/transporters of animal feeds (ruminant feeds involved)
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feeds involved)
- Haulers/transporters of animal feeds (no ruminant feeds involved)
- On-farm feed mixers (only ruminant or no ruminant animals on farm premises)

1. PROGRAM/ASSIGNMENT TITLE Methods Validation			2. PPS PROJECT NAME/NUMBER Monitoring of Market Animal Drugs, Feeds and Devices- 71				
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		
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) (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		1205	4720				
CONVERSION FACTOR		1205	1180				
TOTAL OPERATIONAL FTEs		1.00	4.00				

9. REMARKS
 Workload Source - Determined by Division of Field Science, ORO

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Monitoring of Market Animal Drugs, Feeds and Devices- 71							
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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	1205								
	HEADQUARTERS	(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									
	LDS 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								

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments			2. PPS PROJECT NAME/NUMBER Monitoring of Market Animal Drugs, Feeds and Devices- 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71V800			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 1.3		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 GRAS AUDIT INSPECTIONS	2 INVESTI- GATIONS (Hours)						
	TOTAL FIELD	5	1020						
NE	HEADQUARTERS	(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								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		40.0							
TOTAL HOURS		200	1020						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		0.21	1.07						
9. REMARKS These resources include time for investigating pet turtle establishments, and to inspect pharmacies compounding animal products and to perform Generally Recognized As Safe (GRAS) inspections. CVM will issue assignments for GRAS inspections based on the need to verify data submitted by the firm. The current distribution of these inspections is subject to change, depending on the location of firms that require verification of their data. 71V800 Workload Source: Based on a pro-rate inventory in Feed Manufacturing, Feed Contaminants and Pre-Approval programs.									

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2011**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	181.9	62.9	29.2	274.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5
82	COMPLIANCE: DEVICES	110.0	54.4	22.6	187.0
83	PRODUCT EVALUATION: DEVICES	30.4		4.6	35.0
84	SCIENCE: DEVICES	5.7			5.7
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.5		0.1	14.6
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	20.8	8.5	1.9	31.2

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up				2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81													
3. PROGRAM/ASSIGNMENT CODE(S) 81010			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.5										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	3	7	7	7								
		INSP CTIONS (1)	INVEST IGATIONS (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		23	40	1	1	1	1	1	1								
NE	HEADQUARTERS	(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										15.6		10.3	10.3	10.3	36.0	20.0	37.0
TOTAL HOURS										359	40	10	10	10	36	20	37
CONVERSION FACTOR										950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs										0.38	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.

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 [43.4]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	4	6	8	8
		ENTRY REVIEW (Hours)	IMPORT INVEST- IGATION HOURS (1)	MAIL COURIER REVIEW	INTERNATIONAL MAIL FACILITY REVIEW	IMPORT SAMPLE COLL (Physical) MICRO (2)	IMPORT SAMPLE COLL (Physical) ENG	IMPORT FIELD EXAMS CONGRES- SIONAL EXPECT'N	IMPORT SAMPLES TO BE ANALYZED MICRO (3)	IMPORT SAMPLES TO BE ANALYZED ENG
TOTAL FIELD		26486	3914	2200	300	120	120	12781	60	150
NE	HEADQUARTERS	(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						2.2	2.2	0.7	25.5	25.5
TOTAL HOURS		26486	3914	2200	300	264	264	8947	1530	3825
CONVERSION FACTOR		1200	950	950	950	950	950	950	1160	1180
TOTAL OPERATIONAL FTEs		22.07	4.12	2.32	0.32	0.28	0.28	9.42	1.30	3.24
9. REMARKS										
<p>(1)-Import investigation hours are for field exams (non-Congressional Target), 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 to meet Congressional Targets are planned in a separate column.</p> <p>(2)-Audit samples for problems other than failure to register or list (eg. special assignment, import alert). Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.</p> <p>(3)-Sterile devices to be tested by USP XX method. Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.</p> <p>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).</p> <p>Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.</p>										

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 [0.6]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D C H E M	30				
	(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	25.5					
	TOTAL HOURS	785					
	CONVERSION FACTOR	1180					
	TOTAL OPERATIONAL FTEs	0.65					
9. REMARKS							

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82															
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 126.3 [118.7]												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	1										
		INSPEC- TIONS LEVEL I DOMESTIC 82845A	INSPEC- TIONS LEVEL II DOMESTIC 82845B	INSPEC- TIONS LEVEL III COMPLIANCE DOMESTIC 82845C	INSPEC- TIONS FOREIGN 82845D	INSPEC- TIONS FOREIGN CADRE 82845E	INSPEC- TIONS FOR CAUSE DOMESTIC 82845G	INSPEC- TIONS FOR CAUSE HIGH RISK DOMESTIC 82845H	INSPEC- TIONS FOR CAUSE HIGH RISK FOREIGN 82845I	INSPEC- TIONS ACCRED PERSONS DOMESTIC 82845P									
TOTAL FIELD		783	529	103	153	180	130	65	20	15									
NE	HEADQUARTERS	(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											39.6	62.5	102.4	65.0	52.8	71.0	100.0	100.0	63.0
TOTAL HOURS											31007	33063	10547	9945	9504	9230	8500	2000	945
CONVERSION FACTOR											950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs											32.64	34.80	11.10	10.47	10.00	9.72	6.84	2.11	0.99

9. REMARKS
 For FY 2011, 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 82845S (sterilization), 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. 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.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82															
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 126.3 [4.1]												
R E G I O N	b. 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	DOMESTIC SAMPLE COLL MORNING	DOMESTIC SAMPLE COLL MORNING	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL MORNING									
TOTAL FIELD		3309	255	42	10	27	12	15	10	10									
NE	HEADQUARTERS	(b) (7) (E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
SE	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR.																		
	REGIONAL STAFF																		
SW	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
	REGIONAL LAB																		
PA	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													6.0				6.0	4.7	
TOTAL HOURS											3309	255	252				72	71	
CONVERSION FACTOR											950	950	950				950	950	
TOTAL OPERATIONAL FTEs											3.48	0.27	0.27				0.08	0.07	
9. REMARKS 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				
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 126.3 [3.5]		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLE SOLL STERILITY TESTING	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		8	10	26	8	12	10
NE	HEADQUARTERS	(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							
PA	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION			80.0	62.0	38.0	66.3	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 and DEN Lab.								
CHEM Sample Analyses: Test Kit or Reagent Testing to support GMP observations at WEAC; Sporidical and Tuberculocidal at WEAC and DEN Lab.								

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82							
3. PROGRAM/ASSIGNMENT CODE(S) 82Z002		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.6						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	4 IMPORT SAMPLE COLL (Physical) CHEM	8 IMPORT SAMPLES TO BE ANALYZED (Physical) CHEM							
	TOTAL FIELD	2	312	312							
NE	HEADQUARTERS	(b) (7)(E)									
	REGIONAL STAFF										
NEW ENGLAND	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		24.0	2.8	10.0							
TOTAL HOURS		48	874	3120							
CONVERSION FACTOR		950	950	1180							
TOTAL OPERATIONAL FTEs		0.05	0.92	2.64							
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											
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 8.8									
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	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	9 OTHER OPERATIONS (Hours) ENG								
	TOTAL FIELD	446	313	446	313	2360								
NE	HEADQUARTERS	(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							2.1	2.1	8.0	8.0				
TOTAL HOURS							937	657	3568	2504	2360			
CONVERSION FACTOR							950	950	1180	1180	1180			
TOTAL OPERATIONAL FTEs							0.99	0.69	3.02	2.12	2.00			
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).														
Other Operations (Hours) are for Private Lab Review Technical Assistance/Coordination at WEAC: 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.														

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82												
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 2.0										
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	9 OTHER OPERATIONS (Hours) METH DEV ENG (5) 82Z800									
	TOTAL FIELD	11	29	5	5	10	550									
	HEADQUARTERS	(b) (7) (E)														
NE	REGIONAL STAFF															
	NEW ENGLAND															
	NEW YORK															
	REGIONAL LAB															
CE	WEAC															
	REGIONAL STAFF															
	BALTIMORE															
	CHICAGO															
	CINCINNATI															
	DETROIT															
	MINNEAPOLIS															
	NEW JERSEY															
SE	PHILADELPHIA															
	FORENSIC CHEM. CTR															
	REGIONAL STAFF															
	ATLANTA															
	FLORIDA															
SW	NEW ORLEANS															
	SAN JUAN															
	REGIONAL LAB															
	REGIONAL STAFF															
	DALLAS															
PA	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	45.0	10.0	15.0	50.0	50.0										
	TOTAL HOURS	495	290	75	250	500	550									
	CONVERSION FACTOR	950	950	1180	1180	1180	1180									
	TOTAL OPERATIONAL FTEs	0.52	0.31	0.06	0.21	0.42	0.47									
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						
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				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9						
		METHODS VAL/DEV CHEM (Hours)	METHODS VAL/DEV MICRO (Hours)						
	TOTAL FIELD	1205	1205						
NE	HEADQUARTERS	(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								
PA	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									

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82									
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			
R E G I O N	8. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC ANALYSIS CHEM (Hours)									
	TOTAL FIELD	360									
	HEADQUARTERS	(b) (7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
SE	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
SW	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
PA	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	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	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							
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 9.7					
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	68	33	48	19				
NE	HEADQUARTERS	(b) (7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF	(b) (7)(E)							
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR	(b) (7)(E)								
REGIONAL STAFF									
ATLANTA									
FLORIDA									
NEW ORLEANS									
SE	SAN JUAN	(b) (7)(E)							
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	SW	DENVER	(b) (7)(E)						
KANSAS CITY									
SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB		(b) (7)(E)							
REGIONAL STAFF									
LOS ANGELES									
SAN FRANCISCO									
PA	SEATTLE	(b) (7)(E)							
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW	(b) (7)(E)							
HOURS PER OPERATION	70.0								
TOTAL HOURS	4760	1610	1968	893					
CONVERSION FACTOR	950	950	950	950					
TOTAL OPERATIONAL FTEs	5.01	1.69	2.07	0.94					
9. REMARKS Report all time used for evaluating compliance with <u>domestic</u> pre-market requirements in PAC 83001, OP CODE 12; report all time used for <u>domestic</u> post-market requirements in PAC 83001A, OP CODE 12. Report all time used for evaluating compliance with <u>foreign</u> pre-market requirements in PAC 83001, OP CODE 11; report all time used for <u>foreign</u> 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		
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 25.3

R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1									
		INSPEC- TIONS DOMESTIC	INSPEC- TIONS FOREIGN									
	TOTAL FIELD	295	25									
NE	HEADQUARTERS	(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		75.1	75.1									
TOTAL HOURS		22155	1878									
CONVERSION FACTOR		950	950									
TOTAL OPERATIONAL FTEs		23.32	1.98									

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 Matthew Tarosky (301-796-5645) with any questions.

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation			2. PPS PROJECT NAME/NUMBER Science: Devices - 84						
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.7		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG						
	TOTAL FIELD	800	3590						
NE	HEADQUARTERS	(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									
TOTAL HOURS		800	3590						
CONVERSION FACTOR		1180	1180						
TOTAL OPERATIONAL FTEs		0.68	3.04						
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									
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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 APPLIED TECHNOLOGY CENTER (Hours) MICRO									
	TOTAL FIELD		2360								
NE	HEADQUARTERS	(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											
TOTAL HOURS		2360									
CONVERSION FACTOR		1180									
TOTAL OPERATIONAL FTEs		2.00									

9. REMARKS
 Workload Source: Determined by Division of Field Science, ORO.

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 [9.2]												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	9	9									
		INSPEC- TIONS 85014 (1)	INSPEC- TIONS FOREIGN 85014 (2)	INSPEC- TIONS 85014 (3)	INSPEC- TIONS 85014 (4)	INSPEC- TIONS 85014F (5)	INSPEC- TIONS 85014F (6)	INVESTI- GATIONS (Hours) 85014A (7)	OTHER OPERA- TIONS (Hours) 85014C (8)	OTHER OPERA- TIONS (Hours) 85014C (8)									
TOTAL FIELD		213	15	118	37	9	9	2299	3948	1200									
NE	HEADQUARTERS	(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											8.0	8.0	8.0	8.0	11.0	11.0			
TOTAL HOURS											1704	120	944	296	99	99	2299	3948	1200
CONVERSION FACTOR											1160	1160	1160	1160	1160	1160	1160	1160	1200
TOTAL OPERATIONAL FTEs											1.47	0.10	0.81	0.26	0.09	0.09	1.98	3.40	1.00

9. 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			
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 [5.4]		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) 85014C (10)	9 OTHER OPERATIONS (Hours) 85014C (11)				
	TOTAL FIELD	8206	59				
NE	HEADQUARTERS	(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							
TOTAL HOURS		8206	59				
CONVERSION FACTOR		1160	1160				
TOTAL OPERATIONAL FTEs		5.35	0.05				
9. REMARKS RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS (10) - Technical Assistance and Coordination Activities: non-RRHRs. (11) - Compliance Activities: Warning Letters.							

PROJECT SUMMARY SHEET

FY 2011

1. PROGRAM CATEGORY Medical Devices and Radiological Health		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
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		20.8	8.5	1.9	31.2	
1	Inspection and Field Testing of Radiation-Emitting Electronic Products:		5.1		0.5	5.6	86-24-25
	Inspection of Manufacturers of Laser Products	86001	(4.3)		(0.5)	(4.8)	
	Field Implementation of the Sunlamp & Sunlamp Products Performance Standard as Amended	86002	(0.3)			(0.3)	
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	(0.5)			(0.5)	
2	Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-Ray Equipment	86003	7.6		1.0	8.6	86-26-31
3	Compliance Testing of Electronic Products at WEAC	86006, A, B, D, E	3.1		0.4	3.5	86-32
4	Imported Electronic Products	86007 *		8.5		8.5	86-33
5	Radiological Health Control Activities:		5.0			5.0	86-34-35
	Medical Device and Radiological Health Use Control and Policy Implementation	86008	(3.0)			(3.0)	
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	
	* In addition to PAC 86007, includes reporting PACs 86R824, 86R833, and 99R833.						

CENTER PROJECT MANAGER/TELEPHONE
Lynne L. Rice 240-276-3209

ORA PLANNER/TELEPHONE
Kristen Kamas 301-796-4391

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 5.6 [4.3]			
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2	2	3	5	5
		INSP CTIONS 86001 (1)	INSP CTIONS FOREIGN 86001 (2)	INSP CTIONS 86002 (3)	INSP CTIONS 86004 (4)	INVEST IGATIONS (Hours) 86001 (5)	INVEST IGATIONS (Hours) 86004	DOMESTIC SAMPLE COLL 86001	FIELD EXAMS/ TESTS 86001 (6)	FIELD EXAMS/ TESTS 86002 (7)
TOTAL FIELD		105	11	3	27	658	31	5	75	20
NE	HEADQUARTERS	(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									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		17.3	54.0	36.0	20.0			3.0	5.0	4.4
TOTAL HOURS		1817	594	108	440	658	31	15	375	132
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		1.91	0.50	0.11	0.46	0.69	0.03	0.02	0.39	0.14

9. 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 5.6 [1.3]						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 OTHER OPERA- TIONS (Hours) 86001 (8)	8 OTHER OPERA- TIONS (Hours) 86002									
	TOTAL FIELD	1197	75									
NE	HEADQUARTERS	(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												
TOTAL HOURS		1197	75									
CONVERSION FACTOR		950	950									
TOTAL OPERATIONAL FTEs		1.26	0.08									
9. REMARKS Laser products (86001): (8) - To include all other activities such as technical assistance, coordination, and training. 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 8.6			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	1	1	1	1	2	2	5	5B	9
		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)	OTHER OPER ATIONS (Hours) (8)
TOTAL FIELD		52	15	5	18	884	1051	345	30	965
NE	HEADQUARTERS	(b) (7) (E)								
	REGIONAL STAFF									
NEW ENGLAND	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		50.0	65.0	50.0	16.0			3.0	4.0	
TOTAL HOURS		2600	975	250	288	884	1051	1035	120	965
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		2.74	1.03	0.26	0.30	0.93	1.11	1.09	0.13	1.02
9. REMARKS										
<p>(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.</p> <p>(2) - Foreign inspections should be joint QSIT and electronic product radiation control inspections if possible.</p> <p>(3) - Directed Inspections based on the OEI of diagnostic x-ray equipment manufacturers.</p> <p>(4) - Inspections based on the OEI of diagnostic x-ray equipment assemblers.</p> <p>(5) - Investigation hours for review and planning of activities under columns 1 (Domestic), 2 (Foreign), and 3 (Directed) Inspections.</p> <p>(6) - Investigation hours for review of 2579 forms (reports of assembly) in preparation for performing field tests and field test follow up activities.</p> <p>(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.</p> <p>(8) - Coordination/technical assistance hours for field test activities.</p>										

ATTACHMENT A - 2011 WORKPLAN INSPECTIONS OF MANUFACTURERS (FOREIGN AND DOMESTIC) AND FIELD COMPLIANCE TESTING OF DIAGNOSTIC X-RAY EQUIPMENT

NEW ENGLAND DISTRICT

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

NEW YORK DISTRICT

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

BALTIMORE DISTRICT

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

CHICAGO DISTRICT

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

CINCINNATI DISTRICT

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

DETROIT DISTRICT

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

MINNEAPOLIS DISTRICT

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

NEW JERSEY DISTRICT

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

PHILADELPHIA DISTRICT

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

ATLANTA DISTRICT

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

FLORIDA DISTRICT

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

NEW ORLEANS DISTRICT

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

SAN JUAN DISTRICT

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

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AR	(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)	(7)	(E)	
NM				
UT				
WY				
Total				

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

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

LOS ANGELES DISTRICT

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

SAN FRANCISCO DISTRICT

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

SEATTLE DISTRICT

	Number Systems Installed	FDA Tests	FDA F/U	Audits
State				
AK	(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																																																																																																												
3. PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.5																																																																																																										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP EC T I O N S P L 9 0 - 6 0 2 S T A N D A R D	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D M I C R O W A V E	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D X - R A Y W H O L E	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D N O N - M E D L A S E R S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D S U N L A M P S																																																																																																									
	TOTAL FIELD	7	80	8	42	10																																																																																																									
NE	HEADQUARTERS	(b) (7)(E)																																																																																																													
	REGIONAL STAFF																																																																																																														
	NEW ENGLAND																																																																																																														
	NEW YORK																																																																																																														
	REGIONAL LAB																																																																																																														
WEAC																																																																																																															
CE	REGIONAL STAFF											(b) (7)(E)																																																																																																			
	BALTIMORE																																																																																																														
	CHICAGO																																																																																																														
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	MINNEAPOLIS																																																																																																														
	NEW JERSEY																																																																																																														
SE	PHILADELPHIA																					(b) (7)(E)																																																																																									
	FORENSIC CHEM. CTR																																																																																																														
	REGIONAL STAFF																																																																																																														
	ATLANTA																																																																																																														
	FLORIDA																																																																																																														
SW	NEW ORLEANS																															(b) (7)(E)																																																																															
	SAN JUAN																																																																																																														
	REGIONAL LAB																																																																																																														
	REGIONAL STAFF																																																																																																														
	DALLAS																																																																																																														
PA	DENVER																																									(b) (7)(E)																																																																					
	KANSAS CITY																																																																																																														
	SOUTHWEST IMPORT DISTRICT																																																																																																														
	REGIONAL LAB																																																																																																														
	REGIONAL STAFF																																																																																																														
	LOS ANGELES																																																			(b) (7)(E)																																																											
	SAN FRANCISCO																																																													(b) (7)(E)																																																	
	SEATTLE																																																																							(b) (7)(E)																																							
	PACIFIC REGIONAL LABORATORY-SW																																																																																	(b) (7)(E)																													
	PACIFIC REGIONAL LABORATORY-NW																																																																																											(b) (7)(E)																			
	HOURS PER OPERATION																																																																																																					68.0	18.0	230.0	15.0	25.0					
	TOTAL HOURS																																																																																																					476	1440	1380	630	250					
	CONVERSION FACTOR																																																																																																					1180	1180	1180	1180	1180					
	TOTAL OPERATIONAL FTEs																																																																																																					0.40	1.22	1.17	0.53	0.21					
9. REMARKS Workplan includes both foreign inspection and laboratory testing activities for electronic products. (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.																																																																																																															

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products			2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86													
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 8.5											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 ENTRY REVIEW (Hours)	2 IMPORT INV (Hours) (1)	4 IMPORT FIELD EXAMS CONGRESS- IONAL TARGET	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED										
	TOTAL FIELD	6877	1400	400	25	25										
NE	HEADQUARTERS	(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										0.7	5.7	40.0				
TOTAL HOURS								6877	1400	280	143	1000				
CONVERSION FACTOR								1200	950	950	950	1180				
TOTAL OPERATIONAL FTEs								5.73	1.47	0.29	0.15	0.85				

9. REMARKS

(1) - Import investigation hours are for field exams (non-Congressional Target), 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 to meet Congressional Targets 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).

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

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

9. 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.

1. PROGRAM/ASSIGNMENT TITLE Tobacco: Domestic and Imports (For Guidance Only)				2. PPS PROJECT NAME/NUMBER Tobacco - 96						
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 2.1				
R E G I O N	6.	2	2	7						
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INVESTIGATION (HOURS)	IMPORT INVESTIGATION (HOURS)	ANALYST HOURS TOTAL						
	TOTAL FIELD	475	1000	700						
NE	HEADQUARTERS	(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										
TOTAL HOURS					475	1000	700			
CONVERSION FACTOR					950	950	1180			
TOTAL OPERATIONAL FTEs					0.50	1.05	0.59			

9. REMARKS
 District and Laboratory allocations are **FOR GUIDANCE ONLY**.

ORA receives funding for Tobacco activities based on reported time therefore all Tobacco work performed by investigators and analysts must be reported under the appropriate PACS.

Guidance on the number of Domestic GMP inspections to be conducted by the Field are under development pending promulgation of regulations and development of the CPG.