



## Memorandum

Date September 8, 2011

From Director, Program Planning and Workforce Management Branch

Subject Final FY 2012 ORA Field Workplan

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

The Final FY 2012 ORA Field Workplan is based primarily on the Centers' compliance program forecasts. The FY 2012 Workplan reflects ORA's planning level of 2,196 operational FTEs, in addition to approximately 18.7 operational FTE for the Tobacco program. There was no increase in operational FTE for the following five program areas: 1) Foods and Cosmetics, 2) Biologics, 3) Human Drugs, 4) Animal Drugs and Feeds, and 5) Devices and Radiological Health. The FY 2012 Field Workplan uses the Centers' and ORA's risk-based approaches for allocating resources within the latter five program areas. The FY 2012 Workplan only includes resources for ORA investigators and analysts; it does not plan operations conducted by States under contract.

**NEW MAJOR MODIFICATION (1):**

The FY 2012 Workplan includes a significant change in the format of the Foods Workplan. Due to the enactment of the Foods Safety and Modernization Act (FSMA), the Foods workplan was reformatted by CFSAN to align with the FSMA frequency goals. This alignment resulted in the consolidation of inspectional resources into two FSMA categories: 1) high-risk inspections, and 2) non-high-risk inspections. The non-inspectional resources are separately consolidated by PPS area. To assist the Field in workplanning, CFSAN provided ORA with the high-risk and non-inventories during the Field Food Workplanners Webinar on 8/3/11. CFSAN also plans to provide the Field with the Sample Collection Operations Plan (SCOP), which will provide details for sample collection and analysis.

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

**NEW MAJOR MODIFICATION (2):**

Another change incorporated in this year's Workplan is the Division of Field Science (DFS) efforts to plan sample analyses in hours, rather than operations. This approach should provide laboratories more flexibility in work planning. DPEM received laboratory allocations from DFS as samples will be distributed by the National Sample Distributor (NSD). The Laboratory Servicing Table is not included in the FY 2012 Workplan. Questions regarding the laboratory sections of this Workplan should be directed to DFS (George Salem).

**Additional Workplan Documents**



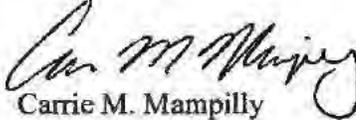
**FY 2012 Workplan Changes:**

The "FY 2012 Workplan Changes" spreadsheets provide a listing of programs compared to the FY 2011 ORA Field Workplan. These documents can be used to identify specific resource shifts and programmatic cuts.

**FY 2012 Workplan CD:**

The FY 2012 Workplan has been published in a CD format. You may make and distribute as many copies of this CD as needed. For further instructions, consult 'A User's Guide – READ ME FIRST' located on the CD. If you have any technical questions, please e-mail Anita McCurdy at [Anita.McCurdy@fda.hhs.gov](mailto: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 2012 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2012
03F810*	Foodborne Biological Hazards	452.6
03F811*	Domestic High-Risk Inspections	248.1
03F812*	Domestic Non-High-Risk Inspections	25.9
03F830*	CFSAN Environmental Sampling Assignments	90.4
03R233*	Foreign Food Inspections	44.2
03R839	Outbreak and Emergency Response	136.8
<b>03</b>	<b>Foodborne Biological Hazards</b>	<b>998.0</b>
04F810*	Pesticides and Chemical Contaminants	117.4
04839	Total Diet Study	28.6
<b>04</b>	<b>Pesticides and Chemical Contaminants</b>	<b>146.0</b>
07001	Mycotoxins in Domestic and Imported Foods	18.9
<b>07</b>	<b>Molecular Biology and Natural Toxins</b>	<b>18.9</b>
09F810*	Food and Color Additives Petition Review	13.2
<b>09</b>	<b>Food and Color Additives Petition Review</b>	<b>13.2</b>
18F810*	Technical Assistance: Food & Cosmetics	3.2
18002	Retail Food Protection- State Program	26.0
18003	(NCIMS) Milk Safety Program	20.0
18004	Molluscan Shellfish Evaluation Program	14.7
<b>18</b>	<b>Technical Assistance: Food &amp; Cosmetics</b>	<b>63.9</b>
21F810*	Food Composition, Standards, Labeling, & Econ	44.8
<b>21</b>	<b>Food Composition, Standards, Labeling, &amp; Econ</b>	<b>44.8</b>
29001	Cosmetics: Domestic and Imports	7.3
<b>29</b>	<b>Colors and Cosmetics Technology</b>	<b>7.3</b>
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>1292.1</b>

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

FY 2012 Foods Workplan consolidates Inspections under Project 03. Remaining operations are planned under the appropriate PPS, therefore FTE distributions cannot be compared to FY 2011. Total FTE level for the Foods and Cosmetics program remained at the FY 2011 level of 1292.

## BIOLOGICS

### FY 2012 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2011	WORKPLAN FTEs FY 2012	FTE DIFFERENCE
41002B,C,D	Inspection of Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Pe)	31.0	31.0	
41808	Good Laboratory Practices	.	.	
41809	Institutional Review Board	.	.	
41810	Sponsors, CROs, Monitors	.	.	
41811	Clinical Investigators	5.0	5.0	
41848A-D,F,G	Licensed Blood Stem Cells, Cell Therapy (CBER Therapeutics)		†	
<b>41</b>	<b>Human Cellular, Tissue, &amp; Gene Therapies</b>	<b>36.0</b>	<b>36.0</b>	
42001F,G	Blood Banks	54.5	54.5	
42002A,F,G	Source Plasma Establishments	11.9	11.9	
42007 <sup>§</sup>	Imported CBER-Regulated Products	4.0	4.0	
42008,A	Licensed Viral Marker Test Kits	2.5	2.5	
42809	Institutional Review Board	.	.	
42810	Sponsors, CROs, Monitors	.	.	
42811	Clinical Investigators	4.4	4.4	
42811	Foreign BIMO Inspection	¶	¶	
42845A,B,C	Medical Device Manufacturers (Biologics)	0.5	0.5	
42848A-D,F,G	Plasma Derivatives of Human Origin, Recombinant Analogues	3.5	3.5	
<b>42</b>	<b>Blood &amp; Blood Products</b>	<b>81.3</b>	<b>81.3</b>	
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,H	Licensed Vaccine Products	6.0	6.0	
<b>45</b>	<b>Vaccines &amp; Allergenic Products</b>	<b>13.7</b>	<b>13.7</b>	
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>131.0</b>	<b>131.0</b>	

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

† For FY 2012, resources for 41848 PACS will continue to be planned with Plasma Derivatives of Human Origin, however some resources have been planned separately under PAC 41848F for these products in anticipation of an increasing inventory.

§ Other PACs include 42R833, 42R824, 41R824, 45R824, 99R833.

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

# HUMAN DRUGS

## FY 2012 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2011	WORKPLAN FTEs FY 2012	FTE DIFFERENCE
46832B,C	NDA Pre-Approval Inspections/Investigations (Domestic)	9.5	9.5	
46832B,C,D	NDA Pre-Approval Inspections/Investigations (Foreign)	13.0	13.0	
46832M	BLA Pre-License/Approval Inspections (Domestic & Foreign)	2.0	2.0	
46832P	Positron Emission Tomography (PET)	0.5	0.5	
<b>46</b>	<b>New Drug Evaluation</b>	<b>25.0</b>	<b>25.0</b>	
48001,A	In Vivo Bioequivalence (Domestic)	6.0	6.0	
48001,A,D,E	Foreign Inspections (In Vivo, GLP, CI)	5.0	5.0	
48808	Good Laboratory Practices	3.0	3.0	
48809,A	Institutional Review Boards	7.8	7.8	
48810	Sponsors, Contract Research Orgs, Monitors	5.3	5.3	
48811,A,B	Clinical investigators (Domestic)	29.9	34.5	4.6
48811,D	Clinical Investigators (Foreign)	16.2	16.2	
<b>48</b>	<b>Bioresearch Monitoring</b>	<b>73.2</b>	<b>77.8</b>	<b>4.6</b>
52832,B,C	ANDA Pre-Approval Inspections/Investigations (Domestic)	5.0	4.0	-1.0
52832,B,C,E	ANDA Pre-Approval Inspections/Investigations (Foreign)	11.0	9.0	-2.0
52832P	Positron Emission Tomography (PET)	1.0	2.4	1.4
<b>52</b>	<b>Generic Drug Evaluation</b>	<b>17.0</b>	<b>15.4</b>	<b>-1.6</b>
53001A	Enforcement of the Adverse Drug. Exp. Rpt. Regul (Center Initiated)	8.0	8.0	
53001B	Enforcement of the Adverse Drug. Exp. Rpt. Regul (Field Initiated)	1.0	1.0	
53001C	Risk Evaluation Mitigation System (REMS)	2.0	2.0	
<b>53</b>	<b>Postmarket Surv. &amp; Epidemiology</b>	<b>11.0</b>	<b>11.0</b>	
56002A,B,D	Drug Process Inspections-Domestic	64.9	54.0	-10.9
56002A-D	Foreign Drug Inspections	42.0	53.0	11.0
56002E	Drug Process Inspections - Gas Manufacturers	9.0	10.0	1.0
56002F	Drug Process Inspections API Manufs (Dom/For)	13.0	9.0	-4.0
56002M	Drug Process Inspections - Biotech Manufacturers	6.0	5.0	-1.0
56002P	Positron Emission Tomography (PET)	0.5	3.0	2.5
56008A	Drug Product Surveillance (Domestic)	18.5	18.5	
56008H	Drug Product Surveillance (Import)	37.9	37.9	
56021A,B	Drug Quality Reporting Systems-DQRS	4.5	4.5	
56022,A	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	2.0	-3.0
56R838	Forensic Evaluation and Sample Analysis	10.0	10.0	
<b>56</b>	<b>Drug Quality Assurance</b>	<b>217.3</b>	<b>212.9</b>	<b>-4.4</b>
63001A	Internet, Health Fraud, & OTC Monographs	6.5	10.4	3.9
63002	New Drugs (Prescription) Not Covered by Approved NDAs	5.0	3.0	-2.0
<b>63</b>	<b>Unapproved &amp; Misbranded Drugs</b>	<b>11.5</b>	<b>13.4</b>	<b>1.9</b>
88--	Shelf Life Extension Projects	12.0	12.0	
<b>88</b>	<b>Interagency Cooperative Activities</b>	<b>12.0</b>	<b>12.0</b>	
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>367.0</b>	<b>367.5</b>	<b>0.5</b>

# ANIMAL DRUGS AND FEEDS

## FY 2012 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2011	WORKPLAN FTEs FY 2012	FTE DIFFERENCE
68001,G	NADA Pre-Approval Inspections	4.9	4.9	
68808,G	(Pre-Market) GLP and Spon/Mon/Com	2.2	2.4	0.2
68810*	Sponsors Contract Research Orgs./Monitors	*	*	
68811,G	(Pre-Market) Clinical Investigators	2.6	2.6	
<b>68</b>	<b>Pre-Approval Eval. of Animal Drugs &amp; Food Additives</b>	<b>9.7</b>	<b>9.9</b>	<b>0.2</b>
71001,A,B†	Animal Drug Manufacturing Inspections	13.0	13.0	
71003A,B,C,E,G-K	Feed Contaminants	25.6	25.6	
71004,A	Feed Manufacturing	5.1	5.4	0.3
71006,M	Illegal Drug Residues in Meat and Poultry	38.3	40.5	2.2
71009, 71R844§	Ruminant Feed Ban Rule (BSE) Program	33.1	30.8	-2.3
71R816	Methods Validation/Development Program	5.0	5.0	
71R838	Forensic Evaluation and Sample Analysis	1.0	1.0	
71V800	Center Initiated Assignments	1.3	1.0	-0.3
<b>71</b>	<b>Monitoring of Marketed Animal Drugs, Feed, &amp; Devices</b>	<b>122.4</b>	<b>122.3</b>	<b>-0.1</b>
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>132.1</b>	<b>132.2</b>	<b>0.1</b>

\* 68810,G planned under 68808

† 71005 / A planned under 71001

§ Includes 71R843, 71R833, 99R833, and 71R824

# MEDICAL DEVICES AND RADIOLOGICAL HEALTH

FY 2012 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2011	WORKPLAN FTEs FY 2012	FTE DIFFERENCE
81010	Med Dev Problem Reporting-MDR/DEN F/U	0.5	1.0	0.5
<b>81</b>	<b>Postmarket Assurance: Devices</b>	<b>0.5</b>	<b>1.0</b>	<b>0.5</b>
82008	Monitoring Device of Foreign Origin-Imports	44.0	43.0	-1.0
82845A,B,C,G,H,S	Inspection of Medical Dev Mfgs: GMP Domestic	100.3	97.3	-3.0
82845B	Inspection of Medical Dev Mfgs: GMP Foreign	22.6	23.9	1.3
82845H	Inspection of Medical Dev Mfgs: Hi-Risk Foreign	2.1	2.1	
82845P	Inspection of Accredited Persons: MDUFMA	1.0	1.0	
82845J	Audits of Accredited Persons	0.3	0.3	
82Z002	Condom Assignment	3.6	3.6	
82Z003	Mfgs & Importers of Surgical/Exam Gloves	8.8	7.5	-1.3
82Z800	Center Initiated Assignments	2.0	4.3	2.3
82R816	Methods Validation/Development Program	2.0	2.0	
82R838	Forensic Evaluation and Sample Analysis	0.3	0.3	
<b>82</b>	<b>Compliance: Devices</b>	<b>187.0</b>	<b>185.3</b>	<b>-1.7</b>
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	23.3	24.0	0.7
83810-11	Bioresearch Monitoring Foreign	2.0	2.5	0.5
<b>83</b>	<b>Project Evaluation: Devices</b>	<b>35.0</b>	<b>36.2</b>	<b>1.2</b>
84Z002	Test Method Development & Evaluation	3.7	3.7	
84R816	Methods Validation/Development Program	2.0	2.0	
<b>84</b>	<b>Science: Devices</b>	<b>5.7</b>	<b>5.7</b>	
85014	Mammography Facilities Insp Program Domestic	14.5	14.5	
85014	Mammography Facilities Insp Program Foreign	0.1	0.1	
<b>85</b>	<b>Mammography Quality Standards Act (MQSA)</b>	<b>14.6</b>	<b>14.6</b>	
86001	Inspection of Mfgs of Laser Products Domestic	4.3	4.3	
86001	Inspection of Mfgs of Laser Products Foreign	0.5	0.9	0.4
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	2.8	-0.3
86006	Compliance Testing of Elec Prod at WEAC Foreign	0.4	0.3	-0.1
86007	Imported Electronic Products	8.5	8.5	
86008	Med Dev & Rad Hlth Use Control & Policy Implementation	3.0	3.0	
86009	Emergency Planning & Response Activities	2.0	2.0	
<b>86</b>	<b>Radiation Control &amp; Health Safety Act (RCHSA)</b>	<b>31.2</b>	<b>31.2</b>	
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>274.0</b>	<b>274.0</b>	<b>0.0</b>

# TOBACCO PRODUCTS

## FY 2012 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2011	WORKPLAN FTEs FY 2012	FTE DIFFERENCE
96R800,96T800*	Regulated Tobacco Products: Domestic and Import	2.1†	18.7	16.6
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>2.1</b>	<b>18.7</b>	<b>16.6</b>

\* Includes 96R824 and 96R833

† FY 11 FTEs were for guidance only

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**RESOURCE SUMMARY BY PROGRAM CATEGORY  
FY 2012**

	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
	DOMESTIC	IMPORT	FOREIGN	
<b>TOTAL ALL PROGRAMS</b>	<b>1415.9</b>	<b>604.8</b>	<b>194.8</b>	<b>2215.5</b>
<b>FOODS AND COSMETICS</b>	<b>772.7</b>	<b>475.2</b>	<b>44.2</b>	<b>1292.1</b>
<b>BIOLOGICS</b>	<b>120.7</b>	<b>4.0</b>	<b>6.3</b>	<b>131.0</b>
<b>HUMAN DRUGS</b>	<b>224.9</b>	<b>37.9</b>	<b>104.7</b>	<b>367.5</b>
<b>ANIMAL DRUGS AND FEEDS</b>	<b>108.2</b>	<b>17.8</b>	<b>6.2</b>	<b>132.2</b>
<b>MEDICAL DEVICES AND RADIOLOGICAL HEALTH</b>	<b>180.0</b>	<b>60.6</b>	<b>33.4</b>	<b>274.0</b>
<b>TOBACCO</b>	<b>9.4</b>	<b>9.3</b>		<b>18.7</b>

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**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
RESOURCE SUMMARY  
FY 2012**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>772.7</b>	<b>475.2</b>	<b>44.2</b>	<b>1292.1</b>
3	FOODBORNE BIOLOGICAL HAZARDS	584.0	369.8	44.2	998.0
4	PESTICIDES AND CHEMICAL CONTAMINANTS	80.3	65.7		146.0
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	12.2	6.7		18.9
9	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		13.2		13.2
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	63.9			63.9
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	29.3	15.5		44.8
28	COLOR AND COSMETICS TECHNOLOGY	3.0	4.3		7.3

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## Compliance Programs and Reporting PACs

### 03 **FOODBORNE BIOLOGICAL HAZARD**

#### **Import Acidified & Low Acid Canned Foods**

**Reporting PACS:** 03003, 03003A

#### **Domestic and Imported Cheese & Cheese Products**

**Reporting PACS:** 03037, 03037B, 03037D

#### **Domestic Food Safety**

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

#### **Domestic Acidified and Low Acid Canned Foods**

**Reporting PACS:** 03803A

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

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

#### **Domestic Fish and Fishery Products Inspection Program**

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

#### **Imported Seafood Products**

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

#### **Juice HACCP Inspection Program**

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

#### **Import & Domestic Micro Assignments**

**Reporting PACS:** 03F098, 03F100

#### **CFSAN Environmental Sampling Assignments**

**Reporting PACS:** 03F830, 03F836, 03F837, 03F838, 03F839, 03F840

#### **Unspecified Foreign Inspections / Assessments**

**Reporting PACS:** 03R233

**Outbreak and Emergency Response**

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

**Food Defense**

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

**04 PESTICIDES & CHEMICAL CONTAMINANTS**

**Pesticides & Industrial Chemicals in Domestic & Imported Foods**

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

**Chemotherapeutics in Seafood**

**Reporting PACS:** 04018

**Toxic Elements in Foods (Domestic and Import)**

**Reporting PACS:** 04019A, 04019U, 04019X

**Toxic Elements in Foodware (Domestic and Import)**

**Reporting PACS:** 04019B

**Radionuclides in Foods (Domestic & Import)**

**Reporting PACS:** 04019C

**Total Diet Study**

**Reporting PACS:** 04839

**Field Assignments for Chemical Contaminants**

**Reporting PACS:** 04F800, 04F106, 04F107

**Forensic Evaluation and Sample Analysis**

**Reporting PACS:** 04R838, 04R831

**07 MOLECULAR BIOLOGY / NATURAL TOXINS: FOOD & COSMETICS**

**Mycotoxins in Domestic & Imported Foods**

**Reporting PACS:** 07001

**09 FOOD & COLOR ADDITIVES PETITION REVIEW & POLICY**

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

**18 TECHNICAL ASSISTANCE: FOOD & COSMETICS**

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

**21 FOOD COMPOSITION, STANDARDS, LABELING & ECONOMICS**

**Medical Foods (Domestic & Import)**  
**Reporting PACS: 21002**

**Domestic Food Labeling and Economics Program**  
**Reporting PACS: 21003**

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

**Infant Formula Program**  
**Reporting PACS: 21006**

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

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

**29 COLORS AND COSMETICS TECHNOLOGY**

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

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1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards					2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03														
3. PROGRAM/ASSIGNMENT CODE(S) Sec Remarks Section				4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 452.6 [107.0]												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	3	3	3	3	3	4									
		IMPORT ENTRY REVIEW (Hours) (1)	IMPORT INTERNATIONAL MAIL FACILITY (Hours)	IMPORT MAIL COURIER REVIEW (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEESE	DOMESTIC SAMPLE COLL SPROUTS	DOMESTIC SAMPLE COLL PRODUCE	DOMESTIC SAMPLE COLL MOBILE LAB	IMPORT SAMPLE COLL									
<b>TOTAL FIELD</b>		58804	950	2850	1228	261	300	1200	200	14530									
HEADQUARTERS		(b)(5)A,(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														6.0	4.0	3.0	3.0	3.0	2.6
TOTAL HOURS											58804	950	2850	7368	1044	900	3600	800	37778
CONVERSION FACTOR											1200	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs											49.00	1.00	3.00	7.76	1.10	0.95	3.79	0.63	39.77
7. REMARKS																			
NOTE: PAC 03F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.																			
(1) - import Entry Review Hours: Resources for these activities cover All Import Food Programs.																			
NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.																			



1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 452.6 [205.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC LAB ANALYST PRODUCE (Hours) MICRO	7 DOMESTIC LAB ANALYST MOBILE LAB (Hours) CHEM	7 DOMESTIC LAB ANALYST MOBILE LAB (Hours) MICRO	8 IMPORT LAB ANALYST (Hours) MICRO	8 IMPORT LAB ANALYST (Hours) CHEM	8 IMPORT LAB ANALYST PRODUCE (Hours) MICRO	8 IMPORT LAB ANALYST MOBILE LAB (Hours) CHEM	8 IMPORT LAB ANALYST MOBILE LAB (Hours) MICRO	9 PRIOR NOTICE REVIEW (Hours) (1)
	<b>TOTAL FIELD</b>	<b>30000</b>	<b>650</b>	<b>4000</b>	<b>95685</b>	<b>39907</b>	<b>37500</b>	<b>1300</b>	<b>2000</b>	<b>32400</b>
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	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		30000	650	4000	95685	39907	37500	1300	2000	32400
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1200
TOTAL OPERATIONAL FTEs		25.42	0.55	3.39	81.09	33.82	31.78	1.10	1.69	27.00

7. REMARKS

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

NOTE: Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 452.6 [25.5]	

R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	9 OP CODE 92 PRIVATE LAB REVIEW IMPORT (Hours) (1)	9 BETTER PROCESSING SCHOOL TRAINING (Hours) (2)	9 CONTRACT MANAGE- MENT (Hours) (3)	9 LEVEL II AUDITORS CERTI- FICATION (Hours) (4)	9 APPLIED TECH CENTER MICRO 03R816 (Hours)	9 METHODS VAL/DEV MICRO 03R816 (Hours)												
	<b>TOTAL FIELD</b>	4720	780	11400	1600	4720	3615												
NE	HEADQUARTERS	(b)(5)(D)(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																			
TOTAL HOURS											4720	780	11400	1600	4720	3615			
CONVERSION FACTOR											1.180	950	950	950	1.180	1.205			
TOTAL OPERATIONAL FTEs											4.00	0.80	12.00	1.68	4.00	3.00			

7. REMARKS

(1) - Private Laboratory Review Time is for NRL, SRL, DEN, 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.

(2) - Resources are for the attendance at Better Processing Schools (BPS).

(3) - 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 FTE's, i.e. supervisors, should not report contract management time.

(4) - 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: Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE <b>Domestic High Risk Inspections</b>	2. PPS PROJECT NAME/NUMBER <b>Foodborne Biological Hazards</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>See Remarks Section</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>248.1</b>
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	FOOD FARM INSPECTIONS GUIDANCE ONLY (1)	PRODUCE FARM POINTS GUIDANCE ONLY (2)	INTERSTATE TRAVEL WATERBORN FOOD INSPECTIONS GUIDANCE ONLY (3)	IMPORT FORMULA MEDICAL FOODS FIRMS GUIDANCE ONLY (4)					
		FDA HIGH RISK INSPECTIONS (1)	(1)	(2)	(3)	(4)					
	<b>TOTAL FIELD</b>	<b>6735</b>	<b>500</b>	<b>300</b>	<b>550</b>	<b>41</b>					
	HEADQUARTERS	(b)(5)A, (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	36.0									
	TOTAL HOURS	235725									
	CONVERSION FACTOR	950									
	TOTAL OPERATIONAL FTEs	248.13									

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

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

NOTE: Hours per operation module is for guidance only. Report actual time spent on operations.

1. PROGRAM/ASSIGNMENT TITLE Domestic Non-High Risk Inspections	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.9
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 FDA NON-HIGH RISK INSPECTIONS (1)	1 PROJECTED FDA FOLLOW-UP OAI INSPECTIONS (2)	ITP NON-ASPRE WATERBNC POINT INSPECTIONS SUPPORT ONLY					
	<b>TOTAL FIELD</b>	1576	32	299					
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR.								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	15.0	30.0						
	TOTAL HOURS	23840	960						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	24.88	1.01						

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

(b)(5)&(b)(7)(E)

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

1. PROGRAM/ASSIGNMENT TITLE <b>CFSAN Environmental Sampling Assignments</b>	2. PPS PROJECT NAME/NUMBER <b>Foodborne Biological Hazards</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>See Remarks Section</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>90.4</b>
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	Environmental SAMPLE CSO HOURS EGG RULE INSPECTIONS	Environmental SAMPLE CSO HOURS DRIED SPICES AND HERBS	Environmental SAMPLE CSO HOURS SOFT CHEESE	Environmental SAMPLE CSO HOURS RTE COLD CUT SANDWICH	Environmental DOMESTIC LAB ANALYST (Hours) MICRO								
		(1)	(2)	(3)	(4)									
	<b>TOTAL FIELD</b>	50000	3500	8700	10000	18958								
	HEADQUARTERS	(b) (5) & (b) (7) (E)												
	REGIONAL STAFF													
NE	NEW ENGLAND													
	NEW YORK													
	REGIONAL LAB													
	WEAC													
CE	REGIONAL STAFF													
	BALTIMORE													
	CHICAGO													
	CINCINNATI													
	DETROIT													
	MINNEAPOLIS													
	NEW JERSEY													
	PHILADELPHIA													
	FORENSIC CHEM. CTR													
	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													
<b>HOURS PER OPERATION</b>														
TOTAL HOURS		50000	3500	8700	10000	18958								
CONVERSION FACTOR		950	950	950	950	1180								
TOTAL OPERATIONAL FTEs		52.63	3.68	9.16	10.53	14.37								

**7. REMARKS**  
 NOTE: PAC 03F830 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.  
 CSO time to include inspections and sample collections. Report hours utilized under the appropriate operation code.  
 (1) - Estimated  firms  
 (2) - Estimated  firms  
 (3) - Estimated  firms  
 (4) - Estimated  firms  
 Hours based on estimated 75 hours per inspection and 25 hours per sample collection. Additional time for inspections is included under the High Risk Inspections planned separately. **District spread of resources are for planning purposes only.** Above numbers are estimates only – assignment parameters will dictate the final number of firms to be covered.  
 Environmental sampling to follow-up on Outbreaks and Emergency Response activities is planned separately (Response to Foodborne Emergencies).  
 Report inspections and analyses conducted in response to an outbreak and emergency against the appropriate Foodborne Emergency PAC (e.g. 03R855) Salmonella in Peanut Butter Emergency/Recall - Human Food Use, 03R266 Listeria Emergency, or another PAC to be created in response to a future emergency. Assignments and district inventories will determine resource usage.  
 NOTE: Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Foreign Foods Inspections	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 44.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	HIGH RISK Foreign Inspections	Foreign Food Cadre Inspections						
	<b>TOTAL FIELD</b>	749	451						
NE	HEADQUARTERS	(b)(5)/(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
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		35.0	35.0						
TOTAL HOURS		26215	15785						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		27.59	16.62						

7. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response	2. PFS PROJECT NAME/NUMBER Foodborne Biological Hazards
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 136.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 DOMESTIC INVESTIGATION  (Hours) (1)	2 IMPORT INVESTIGATION  (Hours) (1)	3 CONSUMER SAFETY OFFICER  (Hours) (2)	7 DOMESTIC LAB ANALYST  (Hours) MICRO	7 DOMESTIC LAB ANALYST  (Hours) CHEM																																																
		<b>TOTAL FIELD</b>	10000	10000	62605	28272	30479																																															
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)																																																				
	REGIONAL STAFF																																																					
	NEW ENGLAND																																																					
	NEW YORK																																																					
	REGIONAL LAB																																																					
WEAC																																																						
CE	REGIONAL STAFF																																																					
	BALTIMORE																																																					
	CHICAGO																																																					
	CINCINNATI																																																					
	DETROIT																																																					
	MINNEAPOLIS																																																					
	NEW JERSEY																																																					
	PHILADELPHIA																																																					
	FORENSIC CHEM. CTR																																																					
	REGIONAL STAFF																																																					
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																																															10000	10000	62605	28272	30479			
CONVERSION FACTOR																																															950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs																																															10.53	10.53	66.90	23.96	25.83			

**7. REMARKS**  
 NOTE: PAC 03R839 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.

Time to be used for all outbreak and emergency activities related to food and cosmetics. 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).

(1) - Includes investigational hours for all domestic and import investigations.  
 (2) - Planned time includes CSO time for follow-up to RFR-RCR and Food Defense Assignments.

NOTE: Laboratory allocations were planned by DFS.

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1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 117.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	4	5	6	7	8	9	9	9
		DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAM/ TESTS	IMPORT FIELD EXAMS (1)	DOMESTIC LAB ANALYST (Hours) CHEM	IMPORT LAB ANALYST (Hours) CHEM	FORENSICS  (Hours)	APPLIED TECH- NOLOGY CENTER CHEM (Hours)	METHODS VAL/DEV CHEM (Hours)
	<b>TOTAL FIELD</b>	2661	5609	25	6406	26966	56192	14460	5900	2410
	HEADQUARTERS									
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	3.5	2.5	0.7	0.5					
	TOTAL HOURS	9314	14023	18	3203	26966	56192	14460	5900	2410
	CONVERSION FACTOR	950	950	950	950	1180	1180	1205	1180	1205
	TOTAL OPERATIONAL FTEs	9.80	14.76	0.02	3.37	22.85	47.62	12.00	5.00	2.00

7. REMARKS

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

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

Laboratory allocations were planned by DFS.

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

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04839	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 28.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	7	7	7				
		DOMESTIC SAMPLE COLL (TOTAL) (DIET) (1)	DOMESTIC LAB ANALYST (Hours) CHEM (2)	TDS ANALYSIS (Hours) RADIO- NUCLIDES (3)	TDS ANALYSIS (Hours) PERCHLOR- ATES (4)				
	TOTAL FIELD	60	22834	5600	3408				
NE	HEADQUARTERS	(1)(5)(16)(7)(1E)							
	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								
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		26.0							
TOTAL HOURS		1500	22834	5600	3408				
CONVERSION FACTOR		950	1180	1180	1180				
TOTAL OPERATIONAL FTEs		1.64	19.35	4.75	2.89				

7. 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.

Laboratory allocations were planned by DFS.

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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) 07001,07R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 18.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3. DOMESTIC SAMPLE COLL	4. IMPORT SAMPLE COLL	7. DOMESTIC LAB ANALYST CHEM (Hours)	8. IMPORT LAB ANALYST CHEM (Hours)	9. METHOD VAL/DEV CHEM (Hours) 07R816	9. APPLIED TECHN- OLOGY CTR. MICRO (Hours) 07R816	9. APPLIED TECHN- OLOGY CTR. CHEM (Hours) 07R816											
	<b>TOTAL FIELD</b>	832	832	4992	5824	603	600	4130											
	HEADQUARTERS	(b)(5)&(b)(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
SW	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
PA	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY-SW																		
	PACIFIC REGIONAL LABORATORY-NW																		
	HOURS PER OPERATION										4.0	2.0							
	TOTAL HOURS										3328	1664	4992	5824	603	600	4130		
	CONVERSION FACTOR										950	950	1180	1180	1205	1180	1180		
	TOTAL OPERATIONAL FTEs										3.50	1.75	4.23	4.94	0.50	0.51	3.50		

7. REMARKS

NOTE: Laboratory allocations were planned by DFS.

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1. PROGRAM/ASSIGNMENT TITLE <b>Food &amp; Color Additive Petition Review &amp; Development</b>	2. PPS PROJECT NAME/NUMBER <b>Food &amp; Color Additive Petition Review &amp; Policy Development - 09</b>
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.2
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R E C I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL	6 IMPORT FIELD EXAMS (1)	8 IMPORT LAB ANALYST (Hours) CHEM				
	TOTAL FIELD	1175	4804	10575				
	HEADQUARTERS	(b) (5)/(b) (7) (E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
SE	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
PA	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION		1.4	0.5					
TOTAL HOURS		1645	2402	10575				
CONVERSION FACTOR		950	950	1180				
TOTAL OPERATIONAL FTEs		1.73	2.53	8.96				

7. REMARKS

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

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

(1) - 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 (Reconciliation Exams); an assessment of security concerns related to labeling and source country (including container integrity, 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.

Laboratory allocations were planned by DFS.

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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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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 NATIONAL RETAIL FOOD PROG. STAND- ARDS BASE- LINE SUPP. (1)	9 STANDARD- IZATION (ITP, CDC, HS, STATE & LOCAL) (2)	9 RE-STANDARD- IZATION (ITP, STATE & LOCAL) (3)	9 FDA FOODBORNE ILLNESS RISK FACTOR STUDY (4)	9 TEAM LEADER SC/ NATIONAL (5)	9 NATIONAL TEAM WORK GROUP (6)	9 REGIONAL SEMINARS (7)	9 TRAINING WORKSHOPS PRE-STAND- ARDIZATION TRAINING (8)	9 TECHNICAL ASSISTANCE (9)
	<b>TOTAL FIELD</b>	7000	45	59	1170	1200	3640	1560	2600	7802
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	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		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	

7. 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 initiatives 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]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 CONFERENCE FOR FOOD PROTECTION ACTIVITIES (10)	9 FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (11)	9 IFSS WORK GROUPS (12)					
	TOTAL FIELD	1040	1040	100					
	HEADQUARTERS	(10) (11) (12)							
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									
TOTAL HOURS		1040	1040	100					
CONVERSION FACTOR		1200	1200	1200					
TOTAL OPERATIONAL FTEs		0.87	0.87	0.08					

7. 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]
--	--	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9	9	9	9
		CHECK RATING PLANT (1)	CHECK RATING TRANSFER AND RECEIVING (1)	CHECK RATING BTU (1)	SINGLE SERVICE AUDITS (1)	STATE MILK SAMPLING OFFICER INITIAL CONT. (1)	STATE MILK SANITATION RATING OFF. INITIAL/CONT. CERTIFICA. (2)	STATE PROGRAM EVALUATION (3)	NATIONAL STEERING TEAM CONFERENCE CALLS/TEAM (4)	TECHNICAL ASSISTANCE HOURS
	TOTAL FIELD	150	36	272	87	46	48	17	32	91
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	NEW ENGLAND	(b)(5)&(b)(7)(E)								
	NEW YORK	(b)(5)&(b)(7)(E)								
	REGIONAL LAB	(b)(5)&(b)(7)(E)								
	WEAC	(b)(5)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	BALTIMORE	(b)(5)&(b)(7)(E)								
	CHICAGO	(b)(5)&(b)(7)(E)								
	CINCINNATI	(b)(5)&(b)(7)(E)								
	DETROIT	(b)(5)&(b)(7)(E)								
	MINNEAPOLIS	(b)(5)&(b)(7)(E)								
	NEW JERSEY	(b)(5)&(b)(7)(E)								
	PHILADELPHIA	(b)(5)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(5)&(b)(7)(E)								
SE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	ATLANTA	(b)(5)&(b)(7)(E)								
	FLORIDA	(b)(5)&(b)(7)(E)								
	NEW ORLEANS	(b)(5)&(b)(7)(E)								
	SAN JUAN	(b)(5)&(b)(7)(E)								
SW	REGIONAL LAB	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	DALLAS	(b)(5)&(b)(7)(E)								
	DENVER	(b)(5)&(b)(7)(E)								
	KANSAS CITY	(b)(5)&(b)(7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b)(5)&(b)(7)(E)								
	REGIONAL LAB	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	LOS ANGELES	(b)(5)&(b)(7)(E)								
	SAN FRANCISCO	(b)(5)&(b)(7)(E)								
	SEATTLE	(b)(5)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-SW	(b)(5)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-NW	(b)(5)&(b)(7)(E)								
	HOURS PER OPERATION	24.0	12.0	20.0	8.0	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

7. REMARKS  
 (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
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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    [2.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 RMS STANDARDI- ZATION (5)	9 FOOD DEFENSE COORDI- NATION (6)	9 TRAINING GIVEN (7)	9 INTEGRATED FOOD SAFETY SYSTEM (8)	9 NCIMS											
	<b>TOTAL FIELD</b>	4	20	20	5	20											
	HEADQUARTERS	(b) (5) / (b) (7) (E)															
NE	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
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			

7. 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
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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]
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R E G I O N	8. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9	9	9	9
		GROWING AREA EVALUATION (1)	CONTROL OF HARVEST (2)	VIBRIO SPECIES MANAGEMENT (Hours) (3)	TECHNICAL ASSISTANCE (Hours) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	CENTER INITIA- TIVES/LAB (7)	PLANT EVALUATION (8)	STANDARD IZATION & RE-STAN- DARD IZATION (9)
	TOTAL FIELD	187	20	2015	4105	4	2	7	111	14
	HEADQUARTERS	DISBUDGETED								
NE	REGIONAL STAFF	DISBUDGETED								
	NEW ENGLAND	DISBUDGETED								
	NEW YORK	DISBUDGETED								
	REGIONAL LAB	DISBUDGETED								
	WEAC	DISBUDGETED								
CE	REGIONAL STAFF	DISBUDGETED								
	BALTIMORE	DISBUDGETED								
	CHICAGO	DISBUDGETED								
	CINCINNATI	DISBUDGETED								
	DETROIT	DISBUDGETED								
	MINNEAPOLIS	DISBUDGETED								
	NEW JERSEY	DISBUDGETED								
	PHILADELPHIA	DISBUDGETED								
	FORENSIC CHEM. CTR.	DISBUDGETED								
	REGIONAL STAFF	DISBUDGETED								
SE	ATLANTA	DISBUDGETED								
	FLORIDA	DISBUDGETED								
	NEW ORLEANS	DISBUDGETED								
	SAN JUAN	DISBUDGETED								
	REGIONAL LAB	DISBUDGETED								
SW	REGIONAL STAFF	DISBUDGETED								
	DALLAS	DISBUDGETED								
	DENVER	DISBUDGETED								
	KANSAS CITY	DISBUDGETED								
	SOUTHWEST IMPORT DISTRICT	DISBUDGETED								
PA	REGIONAL LAB	DISBUDGETED								
	REGIONAL STAFF	DISBUDGETED								
	LOS ANGELES	DISBUDGETED								
	SAN FRANCISCO	DISBUDGETED								
	SEATTLE	DISBUDGETED								
	PACIFIC REGIONAL LABORATORY-SW	DISBUDGETED								
	PACIFIC REGIONAL LABORATORY-NW	DISBUDGETED								

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

7. REMARKS

(1) - Time is allocated for planning, field evaluations, file reviews to determine state program conformity to the requirements of National Shellfish Sanitation Program (NSSP) Model Ordinance (MO).

(2) - Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity Model Ordinance.

(3) - Activities include technical assistance, education and evaluation of state shellfish program and management programs.

(4) - Includes interpretations and consultation on NSSP MO requirements.

(5) - Activities include planning, field evaluations, file reviews and report writing for countries with MOU's with the FDA. Current MOU's include Canada, Chile, South Korea, Mexico and New Zealand.

(6) - Includes time for shellfish program planning, development and coordination.

(7) - Time allocated for CFSAN priority assignments in response to national shellfish safety.

(8) - Includes time for planning field evaluations of processing plants, file reviews, and final report writing.

(9) - Standardization conducted every 5 years for all FDA and state standardization officers. Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs.

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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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]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9										
		NATIONAL TEAM WORKSHOP (10)	TRAINING WORKSHOPS (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE COORDINATION (13)	ISSC COMMITTEE (14)	IFSS WORKGROUP (15)										
	TOTAL FIELD	13	14	13	13	13	5										
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
PA	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	260	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			

7. 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.

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1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 44.8 [43.3]
--	---	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	4	5	6	7	7	7	7	7
		DOMESTIC SAMPLE COLL.	IMPORT SAMPLE COLL.	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC LAB ANALYST (Hours) CHEM	DOMESTIC LAB ANALYST (Hours) MICRO	DOMESTIC LAB ANALYST (Hours) CHEM	IMPORT LAB ANALYST (Hours) CHEM	IMPORT LAB ANALYST (Hours) CHEM
	TOTAL FIELD	754	1363	2400	11208 (1)	21890	1800	4000 21002/21006	3780	800 21002/21006

	HEADQUARTERS	(B) 21215 (1) (C)								
NE	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									
	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	4.0	0.4	0.5						
TOTAL HOURS	3167	5452	960	5805	21890	1800	4000	3780	800	
CONVERSION FACTOR	950	950	950	950	1180	1180	1180	1180	1180	
TOTAL OPERATIONAL FTEs	3.33	5.74	1.01	5.90	18.55	1.53	3.39	3.20	0.68	

7. REMARKS  
 NOTE: PAC 21F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for listing of compliance program and corresponding reporting PACs.  
 Hours per operation modules are for guidance only. Report actual time spent on operations.  
  
 Laboratory allocations were planned by DFS.  
  
 For Pac 21008  
 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.  
 Import Field Exams are time spent reviewing labels that do not result in sample collection.  
  
 (1) - All import field exams are to routinely include verification that the imported product is the same as that which was declared (reconciliation exams); and assessment of security concerns related to labeling and source country (including container integrity, sign of intentional adulteration, etc) and traditional safety concerns. These activities are reported as a single import field exam under 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.



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1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29
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3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.3
--	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECT- IONS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	6 IMPORT FIELD EXAMS  (1)	7 DOMESTIC LAB ANALYST (Hours) MICRO	8 IMPORT LAB ANALYST (Hours) CHEM	8 IMPORT LAB ANALYST (Hours) MICRO		
	TOTAL FIELD	100	60	230	1600	1080	1840	1840		
	HEADQUARTERS	(b) (5) / (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		17.0	4.4	1.5	0.5					
TOTAL HOURS		1700	264	345	800	1080	1840	1840		
CONVERSION FACTOR		950	950	950	950	1180	1180	1180		
TOTAL OPERATIONAL FTEs		1.79	0.28	0.36	0.84	0.92	1.56	1.56		

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

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

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

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

NOTE: Laboratory allocations were planned by DFS.

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**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2012**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>120.7</b>	<b>4.0</b>	<b>6.3</b>	<b>131.0</b>
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	36.0			36.0
42	BLOOD AND BLOOD PRODUCTS	74.0	4.0	3.3	81.3
45	VACCINE AND ALLERGENIC PRODUCTS	10.7		3.0	13.7

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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	6. OPERATIONAL FTE POSITIONS 31.0
---	--	--------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP ECTIONS (1)	1 CBER PRIORITY ESTABS (2)						
	<b>TOTAL FIELD</b>	<b>606</b>	<b>84</b>						
NE	HEADQUARTERS	(b) (5)&(b) (7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
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		49.1							
TOTAL HOURS		29460							
CONVERSION FACTOR		960							
TOTAL OPERATIONAL FTEs		31.01							

9. REMARKS

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

(2) - Refer to CBER's memo for inspectional priorities.

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 created in FY11:**

**PAC 41002B** Inspection of HCT/Ps-361 Reproductive, for product codes: 57K Reproductive Tissue

**PAC 41002C** Inspection of HCT/Ps-361 Hematopoietic Stem Cells, for product codes: 57M Hematopoietic Stem Cells

**PAC 41002D** Inspections of HCT/Ps-361 ALL Other 361 HCT/Ps Products, for product codes: 57J Musculoskeletal Tissue; 57L Ocular Tissue; 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
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3. PROGRAM/ASSIGNMENT CODE(S) 41808-GLPs, 41809-IRBs, 41810-Spon/Mon/CROs, 41811 Clinical Investigators	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S (1)							
	<b>TOTAL FIELD</b>	<b>53</b>							
	HEADQUARTERS	(0)							
NE	REGIONAL STAFF	5/3(b)							
	NEW ENGLAND	(7NE)							
	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	89.8							
	TOTAL HOURS	4759							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	5.01							

9. REMARKS

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

Personnel Types required: Investigator

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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
---	--	--------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S (1)										
	<b>TOTAL FIELD</b>	<b>106</b>										
	HEADQUARTERS	(d)										
NE	REGIONAL STAFF	(5)&(b)										
	NEW ENGLAND	(7)(E)										
	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	57.7										
	TOTAL HOURS	11309										
	CONVERSION FACTOR	960										
	TOTAL OPERATIONAL FTEs	11.90										

9. REMARKS

(1) - Resources may be used for Domestic/Foreign/Follow-up Inspections/Investigations, DSCs as needed. The above resources are planned under PAC 42002F, use resources as needed to accomplish this compliance program. 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.

1. PROGRAM/ASSIGNMENT TITLE Imported CBER-Regulated Products	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42	
3. PROGRAM/ASSIGNMENT CODE(S) 42007, 42R833, 42R824, 99R833, 41R824, 45R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT INVESTI- GATION HOURS (1)							
	<b>TOTAL FIELD</b>	<b>3800</b>							
NE	HEADQUARTERS	(5)							
	REGIONAL STAFF	(5)&(6)							
	NEW ENGLAND	(7)(E)							
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
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		3800							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		4.00							

9. REMARKS

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

Report accomplishments under appropriate PAC and Operation Code.

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

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 (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.5
--	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2							
		DOMESTIC INSP CTIONS	FOREIGN INSP CTIONS	DOMESTIC INVEST IGATIONS (Hours) (2)							
	TOTAL FIELD	0	4	421							
	HEADQUARTERS	(b)(5)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		141.0	174.0								
TOTAL HOURS		1269	696	421							
CONVERSION FACTOR		950	950	950							
TOTAL OPERATIONAL FTEs		1.34	0.73	0.44							

9. REMARKS

(1) - No separate resources are planned for Pre-License Inspections, use above resources as needed.  
42008 GMP Inspections; 42008A Pre-License Inspections.

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

Report accomplishments under appropriate PAC and Operation Code.  
All Inspections will be performed by Team Biologics.

1. PROGRAM/ASSIGNMENT TITLE GLPs, 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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S (1)								
	<b>TOTAL FIELD</b>	<b>45</b>								
NE	HEADQUARTERS	(b)								
	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	7(E)								
	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									
PA	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

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

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
---	---

3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1								
		DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS								
	<b>TOTAL FIELD</b>	<b>7</b>	<b>5</b>								
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
SW	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
PA	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		40.0	40.0								
TOTAL HOURS		280	200								
CONVERSION FACTOR		950	950								
TOTAL OPERATIONAL FTEs		0.28	0.21								

9. REMARKS

(1) - All Resources are planned under PAC 42845A. Use resources as needed and report under appropriate PAC and Operation Code. Foreign Inspections were planned by DFFI.

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.



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1. PROGRAM/ASSIGNMENT TITLE GLPs, 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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S (1)								
	<b>TOTAL FIELD</b>	<b>68</b>								
	HEADQUARTERS	(0)								
NE	REGIONAL STAFF	(5)(A)								
	NEW ENGLAND	(7)(E)								
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
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		97.8								
TOTAL HOURS		6650								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		7.00								

9. REMARKS

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

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 (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1						
		DOMESTIC INSP EC T I O N S	FOREIGN INSP EC T I O N S						
	TOTAL FIELD	5	1						
NE	HEADQUARTERS	(b)(5)(3)(b)(7)(E)	(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		103.0	150.0						
TOTAL HOURS		515	150						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		0.54	0.16						

9. REMARKS

(1) - Resources are planned under PAC 45848F. Use resources as needed and report under appropriate PAC and Operation Code. Report Foreign Inspections under Operation Code 11.  
 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.

New Core Team Compliance Program In FY05 - Inspection of Biological Drug Products (CBER) (Previously covered by PAC 45001).

Personnel Types Required: Team Biologics

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 (1)	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 DOMESTIC INSP EC- TIONS	1 FOREIGN INSP EC- TIONS	2 DOMESTIC INVESTI- GATIONS (Hours)					
	<b>TOTAL FIELD</b>	11	13	503					
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	<b>HOURS PER OPERATION</b>	230.0	206.5						
	<b>TOTAL HOURS</b>	2530	2685	503					
	<b>CONVERSION FACTOR</b>	950	950	950					
	<b>TOTAL OPERATIONAL FTEs</b>	2.66	2.83	0.53					

9. REMARKS

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

45848B Pre-License Inspection - Vaccines;  
 45848C Level 1 CGMP Inspection - Vaccines;  
 45848D Level 2 CGMP Inspection - Vaccines.  
 45848H Off-Year Flu Vaccine: for inspecting the 50% of firm inventory not scheduled for inspection in this year.

Field Investigation Hours may be used to assist any Team Biologics Program.

New Team Biologics Compliance Program in FY05 - Inspection of Biological Drug Products (CBER): (Previously covered by PAC 45002).

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**CENTER FOR DRUG EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2012**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>224.9</b>	<b>37.9</b>	<b>104.7</b>	<b>367.5</b>
46	NEW DRUG EVALUATION	11.0		14.0	25.0
48	BIORESEARCH MONITORING HUMAN DRUGS	56.6		21.2	77.8
52	GENERIC DRUG EVALUATION	6.4		9.0	15.4
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	10.0		1.0	11.0
56	DRUG QUALITY ASSURANCE	115.5	37.9	59.5	212.9
63	UNAPPROVED AND MISBRANDED DRUGS	13.4			13.4
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0

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1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.5
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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 LAB ANALYST PROFILE (Hours) CHEM				
	<b>TOTAL FIELD</b>	<b>164</b>	<b>703</b>	<b>17</b>	<b>413</b>				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	51.1		6.0					
	TOTAL HOURS	7869	703	102	413				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	8.28	0.74	0.11	0.35				

9. REMARKS

(1) - Includes Microbiologists on inspections.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) (1) 46832, 46832B, 46832C, 46832D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.0
--	--	--------------------------------------

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)(5)(3)(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		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.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Pre-Licensed Biotech (BLA) Inspections/Investigations - Domestic and Foreign (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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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
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)	1 INSPECTIONS Foreign						
	<b>TOTAL FIELD</b>	<b>19</b>	<b>16</b>						
	HEADQUARTERS	(1) (5) (5) (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	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
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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)							
	<b>TOTAL FIELD</b>	<b>24</b>							
	HEADQUARTERS	(b)							
NE	REGIONAL STAFF	5)&(b)							
	NEW ENGLAND	7)(E)							
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	20.4							
	TOTAL HOURS	490							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	0.51							

9. REMARKS

(1) - Includes Microbiologists on Inspections. Inspections are to verify that NDA applicant has facilities, equipment, controls, etc. so specified in the application.

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1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence - Pre-Approval (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs), 48001A (NDAs)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0
---	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPECTIONS	1 48001A NDA INSPECTIONS							
	<b>TOTAL FIELD</b>	<b>33</b>	<b>47</b>							
	HEADQUARTERS	(b) (5) & (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		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) 48001A; 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	B. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPECTIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPECTIONS (PRE-APPVL)					
	TOTAL FIELD	31	29					
	HEADQUARTERS	(b)(5)&(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	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: 48001A 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 INSP- CTIONS 48808	2 NAT'L EXPERT INVESTI- GATIONS (Hours) 48808 - GLP	1 IRB (1) INSP- CTIONS 48809, 48809A (2)	1 SPONSOR, CRD, MONITORS INSP- CTIONS 48810 (3)				
	<b>TOTAL FIELD</b>	28	112	121	46				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	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

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

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

Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-3).

(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

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48811, A, B	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 50.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC T I O N S	2 NAT'L EXPERT INVEST I G A T I O N S (Hours)	1 FOREIGN INSP EC T I O N S	1 FOREIGN CADRE INSP EC T I O N S	2 DOMESTIC Follow-Up & Complaints INVEST I G A T I O N S (1)					
	TOTAL FIELD	178	102	153	16	14820					
	HEADQUARTERS	(b) (5) & (b) (7) (E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
SW	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
PA	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		100.0		90.0	90.0						
TOTAL HOURS		17800	102	13770	1620	14820					
CONVERSION FACTOR		950	950	950	950	950					
TOTAL OPERATIONAL FTEs		18.74	0.11	14.49	1.71	15.60					

9. REMARKS

(1) - NEW - Reporting Guidance: Report domestic follow-up and complaints investigations under 48811B.

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1. PROGRAM/ASSIGNMENT TITLE Positron Emission Tomography (PET) Pre-Approval Inspections/Investigations	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832P	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 AND PET INSP EC T I O N S (1)								
	<b>TOTAL FIELD</b>	<b>106</b>								
NE	HEADQUARTERS	(b)								
	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	(7)(E)								
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		21.5								
TOTAL HOURS		2279								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		2.40								

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.

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1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulation	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1							
		DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS (2)							
	TOTAL FIELD	118	15							
	HEADQUARTERS	(b)(5)&(6)(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			64.5	64.8					
	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 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 INSPEC- TIONS (1)								
	<b>TOTAL FIELD</b>	29								
NE	HEADQUARTERS	0								
	REGIONAL STAFF	5								
	NEW ENGLAND	7								
	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		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 Safety Compliance (CDER/OC/OS!).

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

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1. PROGRAM/ASSIGNMENT TITLE <b>Drug Process Inspections - Domestic</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>56002, A-D, 56832, 56R359</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>54.0</b>
---	--	---

REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	1	1	3	3	3	7	7
		INSP CTIONS	CERTI FICA TION AUDITS <small>(EIV Hours) (1)</small>	CHEMIST ON INSP CTIONS <small>(Hours)</small>	MICRO ON INSP CTIONS <small>(Hours)</small>	DOMESTIC SAMPLE COLL <small>(2)</small>	DOMESTIC SAMPLE COLL <small>(CHEM) (3)</small>	DOMESTIC SAMPLE COLL <small>(MICRO) (3)</small>	DOMESTIC LAB ANALYST <small>(Hours) CHEM</small>	DOMESTIC LAB ANALYST <small>(Hours) MICRO</small>
	<b>TOTAL FIELD</b>	<b>898</b>	<b>1900</b>	<b>2499</b>	<b>1200</b>	<b>310</b>	<b>227</b>	<b>40</b>	<b>5743</b>	<b>720</b>
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
	<b>HOURS PER OPERATION</b>	<b>56.0</b>				<b>5.0</b>				
	<b>TOTAL HOURS</b>	<b>38976</b>	<b>1900</b>	<b>2499</b>	<b>1200</b>	<b>1550</b>			<b>5743</b>	<b>720</b>
	<b>CONVERSION FACTOR</b>	<b>950</b>	<b>950</b>	<b>950</b>	<b>950</b>	<b>950</b>			<b>1180</b>	<b>1180</b>
	<b>TOTAL OPERATIONAL FTEs</b>	<b>41.03</b>	<b>2.00</b>	<b>2.63</b>	<b>1.26</b>	<b>1.63</b>			<b>4.87</b>	<b>0.61</b>

9. REMARKS

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

(2) - DSCs not analyzed are documentary samples. District offices should be prepared to collect an increased number of samples for testing.

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

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, 56832, 56R359	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 53.0
---	--	--------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP EC T I O N  (1)	1 CHEMIST ON INSP EC T I O N S F O R E I G N  (Hours) (2)	1 FOREIGN CADRE INSP EC T I O N S						
	TOTAL FIELD	382	7200	252						
NE	HEADQUARTERS									
	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									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		80.0		50.1						
TOTAL HOURS		30560	7200	12625						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		32.17	7.58	13.29						

9. REMARKS

(1) - Report time under appropriate PAC (56002, A, B, C, D, 56832, 56R359) and operation 11. Module includes time for inspection preparation and actual time on inspections.

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

Laboratory allocations were planned by DFS.

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 10.0
---	--	--------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS MEDICAL GAS (1)								
	<b>TOTAL FIELD</b>	<b>317</b>								
	HEADQUARTERS	(b)								
	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	(7)(E)								
	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	30.0								
	TOTAL HOURS	9510								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	10.01								

9. REMARKS

(1) - Total number of planned gas inspections in the Program for FY 2012.

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 9.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1						
		DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS						
	<b>TOTAL FIELD</b>	143	106						
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
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	30.0	40.0						
	TOTAL HOURS	4290	4240						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	4.52	4.48						

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Positron Emission Tomography (PET) Inspections/Investigations		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3. PROGRAM/ASSIGNMENT CODE(S) 56002P			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1  INSP EC T I O N S  (1)							
	<b>TOTAL FIELD</b>	<b>119</b>							
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		24.0							
TOTAL HOURS		2856							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		3.01							

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 <b>Drug Quality Sampling and Testing Program</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>56008A, L (1)</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>18.5 [4.2]</b>
---	---	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	3	3	3	7	7			
		INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (NEW)	DOMESTIC SAMPLE COLL (SWTH)	DOMESTIC IMPORT SAMPLE COLL 56008L (2)	DOMESTIC IMPORT SAMPLE COLL (NEW)	DOMESTIC IMPORT SAMPLE COLL (SWTH)	DOMESTIC LAB ANALYST (Hours) CHEM	DOMESTIC LAB ANALYST (Hours) MICRO
	<b>TOTAL FIELD</b>	<b>700</b>	<b>40</b>	<b>56</b>	<b>117</b>	<b>380</b>	<b>120</b>	<b>49</b>	<b>1020</b>	<b>220</b>
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
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									
<b>HOURS PER OPERATION</b>			<b>5.5</b>			<b>5.5</b>				
<b>TOTAL HOURS</b>		<b>700</b>	<b>220</b>			<b>2090</b>			<b>1020</b>	<b>220</b>
<b>CONVERSION FACTOR</b>		<b>950</b>	<b>950</b>			<b>950</b>			<b>1180</b>	<b>1180</b>
<b>TOTAL OPERATIONAL FTEs</b>		<b>0.74</b>	<b>0.23</b>			<b>2.20</b>			<b>0.86</b>	<b>0.19</b>

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.

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

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Sampling and Testing Program	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008A, L (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 18.5 [14.3]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7. DOMESTIC IMPORT LAB ANALYST (Hours) CHEM	7. DOMESTIC IMPORT LAB ANALYST (Hours) MICRO	9. METHODS VAL/DEV (Hours) CHEM (2)						
	<b>TOTAL FIELD</b>	10880	1320	4661						
	HEADQUARTERS	(b) (5) & (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		10880	1320	4661						
CONVERSION FACTOR		1180	1180	1180						
TOTAL OPERATIONAL FTEs		9.22	1.12	3.95						

9. REMARKS

(2) - Methods Validation/Development hours include resources for development activities (Pharmacy Compounding, FDA-USP activities, etc.

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 37.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	5	2	2	4	8	8								
		IMPORT ENTRY REVIEW HOURS	IMPORT INVESTIGA- TIONS HOURS (1)	IMPORT FIELD EXAM HOURS	INTERNATIONAL MAIL FACILITY REVIEWS INV HOURS	MAIL COURIER REVIEWS INV HOURS	IMPORT SAMPLE COLL	IMPORT LAB ANALYST APIs (Hours) CHEM	IMPORT LAB ANALYST FIN-DOSEAGE (Hours) CHEM								
	TOTAL FIELD	11187	3574	6200	12103	1235	202	2525	1818								
NE	HEADQUARTERS	(b) (5) - DPP															
	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		
TOTAL HOURS										11187	3574	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.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	7				
		INSPECTIONS	DQRS FARS INVESTI- GATIONS (Hours)	DOMESTIC SAMPLES CDLL (Hours)	DOMESTIC LAB ANALYST (Hours) CHEM				
	TOTAL FIELD	57	1425	23	1213				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	30.7		5.2					
	TOTAL HOURS	1750	1425	120	1213				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	1.84	1.50	0.13	1.03				

9. REMARKS

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56022, 56022A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
--	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	7				
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLES COLL (Hours)	DOMESTIC LAB ANALYST (Hours) CHEM				
	TOTAL FIELD	43	294	34	378				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	NEW ENGLAND	(b)(5)&(b)(7)(E)							
	NEW YORK	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	WEAC	(b)(5)&(b)(7)(E)							
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	BALTIMORE	(b)(5)&(b)(7)(E)							
	CHICAGO	(b)(5)&(b)(7)(E)							
	CINCINNATI	(b)(5)&(b)(7)(E)							
	DETROIT	(b)(5)&(b)(7)(E)							
	MINNEAPOLIS	(b)(5)&(b)(7)(E)							
	NEW JERSEY	(b)(5)&(b)(7)(E)							
	PHILADELPHIA	(b)(5)&(b)(7)(E)							
FORENSIC CHEM. CTR	(b)(5)&(b)(7)(E)								
SE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	ATLANTA	(b)(5)&(b)(7)(E)							
	FLORIDA	(b)(5)&(b)(7)(E)							
	NEW ORLEANS	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
SW	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	DALLAS	(b)(5)&(b)(7)(E)							
	DENVER	(b)(5)&(b)(7)(E)							
	KANSAS CITY	(b)(5)&(b)(7)(E)							
	SOUTHWEST IMPORT DISTRICT	(b)(5)&(b)(7)(E)							
PA	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	LOS ANGELES	(b)(5)&(b)(7)(E)							
	SAN FRANCISCO	(b)(5)&(b)(7)(E)							
	SEATTLE	(b)(5)&(b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-SW	(b)(5)&(b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-NW	(b)(5)&(b)(7)(E)							
	HOURS PER OPERATION	30.0		2.0					
	TOTAL HOURS	1290	294	68	378				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	1.35	0.31	0.07	0.32				

9. REMARKS

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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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	7 INSPEC- TIONS							
	<b>TOTAL FIELD</b>	<b>48</b>							
	HEADQUARTERS	(b)							
NE	REGIONAL STAFF	(5)&(b)							
	NEW ENGLAND	(7)(E)							
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
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	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
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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 INSPEC- TIONS							
	<b>TOTAL FIELD</b>	<b>48</b>							
	HEADQUARTERS	(0)							
NE	REGIONAL STAFF	54.00							
	NEW ENGLAND	(7.1E)							
	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
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3. PROGRAM/ASSIGNMENT CODE(S) 56D015	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S							
	<b>TOTAL FIELD</b>	<b>22</b>							
	HEADQUARTERS	(b)							
NE	REGIONAL STAFF	(5)&(b)							
	NEW ENGLAND	(7)(E)							
	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	85.0							
	TOTAL HOURS	1870							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	1.97							

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

1. PROGRAM/ASSIGNMENT TITLE 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				
	<b>TOTAL FIELD</b>	<b>12050</b>				
NE	HEADQUARTERS	(b)				
	REGIONAL STAFF	(5)&(b)				
	NEW ENGLAND	(7)(E)				
	NEW YORK					
	REGIONAL LAB					
CE	WEAC					
	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
	PHILADELPHIA					
SE	FORENSIC CHEM. CTR					
	REGIONAL STAFF					
	ATLANTA					
	FLORIDA					
	NEW ORLEANS					
SW	SAN JUAN					
	REGIONAL LAB					
	REGIONAL STAFF					
	DALLAS					
	DENVER					
	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.

Laboratory allocations were planned by DFS.

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1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	7					
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL (1)	DOMESTIC LAB ANALYST (Hours) CHEM					
	<b>TOTAL FIELD</b>	133	1300	274	4520					
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION			25.7		5.4					
TOTAL HOURS			3418	1300	1480	4529				
CONVERSION FACTOR			950	950	950	1180				
TOTAL OPERATIONAL FTEs			3.60	1.37	1.56	3.84				

9. REMARKS

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

Please note that at least 225 samples should be sent to labs for analyses.

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

Laboratory allocations were planned by DFS.

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	6. OPERATIONAL FTE POSITIONS 3.0
--	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2						
		INSPEC- TIONS	INVESTI- GATIONS (Hours)						
	<b>TOTAL FIELD</b>	51	200						
	HEADQUARTERS	(b)(5)&(d)(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		51.9							
TOTAL HOURS		2647	200						
CONVERSION FACTOR		960	950						
TOTAL OPERATIONAL FTEs		2.79	0.21						

9. REMARKS

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

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1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects			2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88						
3. PROGRAM/ASSIGNMENT CODE(S) All Appropriate PACs			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7. DOMESTIC LAB ANALYST (Hours) CHEM							
	TOTAL FIELD	14160							
NE	HEADQUARTERS	(b)							
	REGIONAL STAFF	518(b)							
	NEW ENGLAND	(7)(E)							
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		14160							
CONVERSION FACTOR		1180							
TOTAL OPERATIONAL FTEs		12.00							

9. REMARKS

Five FTEs are assigned to this Program using dollars reimbursed by DOD.  
Seven additional FTEs are assigned to this Program using dollars reimbursed by the Department of Homeland Security.

Laboratory allocations were planned by DFS.

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**CENTER FOR VETERINARY MEDICINE  
RESOURCE SUMMARY  
FY 2012**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>108.2</b>	<b>17.8</b>	<b>6.2</b>	<b>132.2</b>
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	5.7		4.2	9.9
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	102.5	17.8	2.0	122.3

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1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives-68
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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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP CTIONS  (1)	1 DOMESTIC INSP CTIONS  (2)	1 CHEMIST ON INSP					
	TOTAL FIELD	40	5	850					
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	REGIONAL LAB								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL STAFF								
	DALLAS								
	REGIONAL LAB								
PA	SEATTLE								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	90.0	50.0						
	TOTAL HOURS	3600	250	850					
	CONVERSION FACTOR	950	950	950					
	TOTAL OPERATIONAL FTEs	3.79	0.26	0.89					

7. REMARKS

(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.

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

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

1. PROGRAM/ASSIGNMENT TITLE GLPs Sponsor-Monitors, Clinical Investigators (Pre-Market)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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3. PROGRAM/ASSIGNMENT CODE(S) PACs 68808, G, 68810, G, 68811, G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC- TIONS 68810	1 FOREIGN INSPEC- TIONS 68811	1 DOMESTIC INSPEC- TIONS 68808 (1)	1 DOMESTIC INSPEC- TIONS 68811				
	<b>TOTAL FIELD</b>	2	3	30	44				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	70.0	70.0	70.0	52.0				
	TOTAL HOURS	140	210	2100	2288				
	CONVERSION FACTOR	950	950	950	950				
	TOTAL OPERATIONAL FTEs	0.15	0.22	2.21	2.41				

7. REMARKS

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

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

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

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

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

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

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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
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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
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R E G I O N	5. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	3	7	6	7								
		FOREIGN INSP CTIONS	DOMESTIC INSP CTIONS	CHEM ON INSP C	INVESTI- GATIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (ORA)	IMPORT FIELD EXAMS	DOMESTIC LAB ANALYST (Hours) CHEM								
TOTAL FIELD		(1)	(2)	(Hours)	(Hours)	(3)	ORA		CHEM								
	HEADQUARTERS	33	205	600	250	50	30	100	500								
NE	REGIONAL STAFF	(b) (5) (1) (6) (7) (E)															
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
REGIONAL STAFF																	
CE	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
REGIONAL LAB																	
SW	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
REGIONAL LAB																	
PA	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										49.0	44.0			7.0		0.8	
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

7. 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.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Domestic	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.6    [7.5]
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R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1	3	1	1	1	1	1	1	1
		INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL FOLL WUP FINDS	DOMESTIC SAMPLE COLL FOLL FINDS	DOMESTIC SAMPLE COLL FOLL FINDS	DOMESTIC SAMPLE COLL FOLL FINDS	DOMESTIC SAMPLE COLL FOLL FINDS	DOMESTIC SAMPLE COLL FOLL FINDS	DOMESTIC SAMPLE COLL FOLL FINDS
TOTAL FIELD		25	1545	60	285	540	190	290	80	40
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										

HOURS PER OPERATION	25.0	4.2							
TOTAL HOURS	625	6489							
CONVERSION FACTOR	950	950							
TOTAL OPERATIONAL FTEs	0.86	6.83							

7. REMARKS

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

The shaded area serves as a guide for the districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis. Districts, where samples are not planned or insufficiently planned, may still need to collect samples for specific contaminants for F/U, "for cause", or unexpected reasons.

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

EXPECT TWO CENTER ASSIGNMENTS:

- Continuation of the assignment for collecting Direct Human Contact Feeds and analyzing for Salmonella. For more details please see the assignment.
- A second micro assignment under 71003E will cover feeds/ingredients, or targeted animal feeds/ingredients for farm use, analyzing for salmonella.

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

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

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Domestic	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	6. OPERATIONAL FTE POSITIONS 25.6    [11.8]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	7	7	7	7	7	7	
		DOMESTIC LAB ANALYST (Hours) Metals 71003B	DOMESTIC LAB ANALYST (Hours) Myc 71003C	DOMESTIC LAB ANALYST (Hours) Micro 71003E	DOMESTIC LAB ANALYST (Hours) Micro 71003E	DOMESTIC LAB ANALYST (Hours) Chem 71003A	DOMESTIC LAB ANALYST (Hours) Dioxin 71003G	DOMESTIC LAB ANALYST (Hours) Antibiotics 71003K		
	<b>TOTAL FIELD</b>	<b>1080</b>	<b>4345</b>	<b>3900</b>	<b>1300</b>	<b>1915</b>	<b>702</b>	<b>692</b>		
	HEADQUARTERS	(b) (5) & (b) (7) (E)								
NE	REGIONAL STAFF	(b) (5) & (b) (7) (E)								
	NEW ENGLAND	(b) (5) & (b) (7) (E)								
	NEW YORK	(b) (5) & (b) (7) (E)								
	REGIONAL LAB	(b) (5) & (b) (7) (E)								
	WEAC	(b) (5) & (b) (7) (E)								
CE	REGIONAL STAFF	(b) (5) & (b) (7) (E)								
	BALTIMORE	(b) (5) & (b) (7) (E)								
	CHICAGO	(b) (5) & (b) (7) (E)								
	CINCINNATI	(b) (5) & (b) (7) (E)								
	DETROIT	(b) (5) & (b) (7) (E)								
	MINNEAPOLIS	(b) (5) & (b) (7) (E)								
	NEW JERSEY	(b) (5) & (b) (7) (E)								
SE	PHILADELPHIA	(b) (5) & (b) (7) (E)								
	FORENSIC CHEM. CTR	(b) (5) & (b) (7) (E)								
	REGIONAL STAFF	(b) (5) & (b) (7) (E)								
	ATLANTA	(b) (5) & (b) (7) (E)								
	FLORIDA	(b) (5) & (b) (7) (E)								
SW	NEW ORLEANS	(b) (5) & (b) (7) (E)								
	SAN JUAN	(b) (5) & (b) (7) (E)								
	REGIONAL LAB	(b) (5) & (b) (7) (E)								
	REGIONAL STAFF	(b) (5) & (b) (7) (E)								
	DALLAS	(b) (5) & (b) (7) (E)								
PA	DENVER	(b) (5) & (b) (7) (E)								
	KANSAS CITY	(b) (5) & (b) (7) (E)								
	SOUTHWEST IMPORT DISTRICT	(b) (5) & (b) (7) (E)								
	REGIONAL LAB	(b) (5) & (b) (7) (E)								
	REGIONAL STAFF	(b) (5) & (b) (7) (E)								
	LOS ANGELES	(b) (5) & (b) (7) (E)								
	SAN FRANCISCO	(b) (5) & (b) (7) (E)								
	SEATTLE	(b) (5) & (b) (7) (E)								
	PACIFIC REGIONAL LABORATORY-SW	(b) (5) & (b) (7) (E)								
	PACIFIC REGIONAL LABORATORY-NW	(b) (5) & (b) (7) (E)								
<b>HOURS PER OPERATION</b>										
TOTAL HOURS		1080	4345	3900	1300	1915	702	692		
CONVERSION FACTOR		1.180	1.180	1.180	1.180	1.180	1.180	1.180		
TOTAL OPERATIONAL FTEs		0.92	3.68	3.31	1.10	1.62	0.59	0.59		

7. REMARKS

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Import	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices- 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.6 [6.3]
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R E G I O N	C. DISTRICT/ SPECIALIZED LABORATORY	4	5	5	5	6	8	8	8
		IMPORT SAMPLE COLL (3)	IMPORT SAMPLE COLL Chem	IMPORT SAMPLE COLL Micro	IMPORT SAMPLE COLL Antibiotics	IMPORT FIELD EXAMS	IMPORT LAB ANALYST (Hours) Chem	IMPORT LAB ANALYST (Hours) Micro	IMPORT LAB ANALYST (Hours) Antibiotics
	TOTAL FIELD	550	230	280	70	300	1750	3360	346
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	2.5				0.6			
	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

7. REMARKS

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

(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.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing	2. PPS PROJECT NAME/NUMBER Monitoring of Market Animal Drugs, Feeds and Devices- 71
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3. PROGRAM/ASSIGNMENT CODE(S) PACs 71004, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.4
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REGION	DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	7							
		FOREIGN INSPEC- TIONS	DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE CALL SUPPORT (CHRM)	DOMESTIC LAB ANALYST (Hours) CHEM							
	TOTAL FIELD	71	141	60	15	585							
	HEADQUARTERS	(b) (5) & (b) (7) (E)											
	REGIONAL STAFF												
NE	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB												
	WEAC												
CE	REGIONAL STAFF												
	BALTIMORE												
	CHICAGO												
	CINCINNATI												
	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA												
	FORENSIC CHEM. CTR												
SE	REGIONAL STAFF												
	ATLANTA												
	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
SW	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
	DENVER												
	KANSAS CITY												
PA	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LABORATORY-SW												
	PACIFIC REGIONAL LABORATORY-NW												
	HOURS PER OPERATION	40.0	28.0	7.8									
	TOTAL HOURS	280	3948	466		585							
	CONVERSION FACTOR	950	950	950		1180							
	TOTAL OPERATIONAL FTEs	0.29	4.16	0.49		0.50							

7. REMARKS

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

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

There are 336 State Contract inspections. Charge inspectional time for these contracts under 71S004.

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

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

Workload Source: Resource distribution is based on the CVM risk model for ranking firms in this program.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE <b>Illegal Residues in Meat &amp; Poultry</b>	2. PPS PROJECT NAME/NUMBER <b>Monitoring of Market Animal Drugs, Feeds and Devices- 71</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>71006</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>40.5</b>
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	7	9	8			
		DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC LAB ANALYST (Hours) CHEM (3)	METHODS VAL/DEV CHEM (Hours) (4)	TECH SUPPORT (Hours) (5)			
	<b>TOTAL FIELD</b>	<b>440</b>	<b>728</b>	<b>1440</b>	<b>13500</b>	<b>360</b>	<b>1500</b>			
	HEADQUARTERS	(b) (5) (6) (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		39.0	7.0	2.5						
TOTAL HOURS		17160	5096	3600	13500	360	1500			
CONVERSION FACTOR		950	950	950	1180	1180	950			
TOTAL OPERATIONAL FTEs		18.06	5.36	3.79	11.44	0.31	1.58			

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

(1) - Documentary samples collected during inspections.

(2) - 1440 Milk samples will be collected by the FDA at state certified labs and analyzed by regional laboratories. See CVM's milk assignment for more details.

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

(4) - Additional time for methods validation and methods development studies. Report time under OP 3.

(5) - Tech support hours include supporting state activities under Illegal Residues in Meat & Poultry and time for Tissue Residue Monitors. Laboratory allocations were planned by DFS.

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
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3. PROGRAM/ASSIGNMENT CODE(S) 71009, 71R844, 71R843 (99R833, 71R833, 71R824)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 30.8 [27.2]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	3	4	6	7	7									
		DOMESTIC INSPEC- TIONS (1)	DOMESTIC INVESTI- GATIONS (Hours) (2)	IMPORT ENTRY REVIEW (Hours) (3)	IMPORT INVESTI- GATIONS (Hours) (4)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS	DOMESTIC LAB ANALYST (Hours) CHEM (5)	DOMESTIC LAB ANALYST (Hours) MICRO (5)									
	TOTAL FIELD	1205	1000	7940	2030	640	200	3200	2560	1280									
NE	HEADQUARTERS	(b) (5) / (b) (7) (C)																	
	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										7.6				4.0	2.5	0.4		
	TOTAL HOURS										9038	1000	7940	2030	2560	500	1280	2560	1280
	CONVERSION FACTOR										950	950	1200	950	950	950	950	1180	1180
	TOTAL OPERATIONAL FTEs										9.51	1.05	6.62	2.14	2.69	0.53	1.35	2.17	1.08

7. REMARKS

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

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

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

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

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

Workload Distribution: Resource distribution based on the CVM risk model for ranking firms in this program.

1. PROGRAM/ASSIGNMENT TITLE <b>Ruminant Feed Ban Rule/BSE Program</b>	2. PPS PROJECT NAME/NUMBER <b>Monitoring of Market Animal Drugs, Feeds and Devices- 71</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>PACs 71009, 71R844, 71R843 (99R833, 71R833, 71R824)</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>30.8    [3.6]</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT LAB ANALYST (Hours) CHEM	9 TECHNICAL SUPPORT  (Hours) (6)						
	<b>TOTAL FIELD</b>	<b>860</b>	<b>2748</b>						
	HEADQUARTERS								
NE	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								
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		860	2748						
CONVERSION FACTOR		1.180	950						
TOTAL OPERATIONAL FTEs		0.73	2.89						

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

Laboratory allocations were planned by DFS.

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

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

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

7. 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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM  (Hours)								
	<b>TOTAL FIELD</b>	<b>1205</b>								
	HEADQUARTERS	(b)								
NE	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	(7)(E)								
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		1205								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		1.00								

7. REMARKS



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**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
RESOURCE SUMMARY  
FY 2012**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>180.0</b>	<b>60.6</b>	<b>33.4</b>	<b>274.0</b>
81	POSTMARKET ASSURANCE: DEVICES	1.0			1.0
82	COMPLIANCE: DEVICES	107.2	52.1	26.0	185.3
83	PRODUCT EVALUATION: DEVICES	31.1		5.1	36.2
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	20.5	8.5	2.2	31.2

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1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM/ASSIGNMENT CODE(S) 81010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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REG ION	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 LAB ANALYST (Hours) CHEM (3)	DOMESTIC LAB ANALYST (Hours) STER (4)	DOMESTIC LAB ANALYST (Hours) ENG (5)								
	<b>TOTAL FIELD</b>	40	60	1	1	1	36	20	37								
NE	HEADQUARTERS	(b) (5) & (b) (7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
HOURS PER OPERATION										20.0		10.3	10.3	10.3			
TOTAL HOURS										800	60	10	10	10	36	20	37
CONVERSION FACTOR										950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs										0.84	0.06	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.

Laboratory allocations were planned by DFS.

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1. PROGRAM/ASSIGNMENT TITLE <b>Monitoring Devices of Foreign Origin - Import</b>	2. PPS PROJECT NAME/NUMBER <b>Compliance: Devices - 82</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>82008, 82R824, 82R833, 99R833</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>43.0 [42.4]</b>
---	--	--

R E C O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	4	6	6	8
		IMPORT ENTRY REVIEW (Hours)	IMPORT INVESTI- GATIONS (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 LAB ANALYST (Hours) MICRO (3)	IMPORT LAB ANALYST (Hours) ENG
	<b>TOTAL FIELD</b>	<b>26065</b>	<b>3912</b>	<b>2200</b>	<b>300</b>	<b>120</b>	<b>120</b>	<b>13935</b>	<b>1530</b>	<b>3825</b>
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										

HOURS PER OPERATION						2.2	2.2	0.6		
TOTAL HOURS	26065	3912	2200	300		264	264	8361	1530	3825
CONVERSION FACTOR	1200	950	950	950		950	950	950	1180	1180
TOTAL OPERATIONAL FTEs	21.72	4.12	2.32	0.32		0.28	0.28	8.80	1.30	3.24

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.

(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.

(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.

Reporting Guidance:

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

Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE <b>Monitoring Devices of Foreign Origin - Import</b>	2. PPS PROJECT NAME/NUMBER <b>Compliance: Devices - 82</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 43.0 [0.6]
--	--	--

R E G I O N	8 DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT LAB ANALYST (Hours) CHEM																		
	<b>TOTAL FIELD</b>	765																		
NE	HEADQUARTERS	(b)																		
	REGIONAL STAFF	(5)&(b)																		
	NEW ENGLAND	(7)(E)																		
	NEW YORK																			
	REGIONAL LAB																			
WEAC	REGIONAL STAFF																			
	BALTIMORE																			
	CHICAGO																			
	CINCINNATI																			
	DETROIT																			
CE	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	765																		
	CONVERSION FACTOR	1180																		
	TOTAL OPERATIONAL FTEs	0.65																		

9. REMARKS  
 Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,H,J,K,P,S,81845R,T,81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> DRA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 124.6 [117.3]
--	--	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	1	1
		INSP EC T I O N S L E V E L I D O M E S T I C	INSP EC T I O N S L E V E L II D O M E S T I C	INSP EC T I O N S L E V E L III C O M P L I A N C E D O M E S T I C	INSP EC T I O N S F O R E I G N	INSP EC T I O N S F O R E I G N C A D R E	INSP EC T I O N S F O R C A U S E D O M E S T I C	INSP EC T I O N S F O R C A U S E H I G H R I S K D O M E S T I C	INSP EC T I O N S F O R C A U S E H I G H R I S K F O R E I G N	INSP EC T I O N S A C C R E D P E R S O N S D O M E S T I C
	TOTAL FIELD	782	530	103	180	180	99	38	20	15

	HEADQUARTERS									
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									
PA	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION	39.6	63.1	102.4	65.0	60.9	71.0	101.0	100.0	63.0
TOTAL HOURS	30967	33443	10547	11700	10962	7029	3838	2000	945
CONVERSION FACTOR	950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs	32.60	35.20	11.10	12.32	11.54	7.40	4.04	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 124.6 [3.8]
--	--	---

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	3	3	3	3	3	3	3
		INVESTIGATIONS (Hours) 82845B	INVESTIGATIONS (Hours) A.P. AUDITS MDUFMA 82845J	DOMESTIC SAMPLE COLL 82845C	DOMESTIC SAMPLE COLL EVAL 82845C	DOMESTIC SAMPLE COLL EVAL 82845C	DOMESTIC SAMPLE COLL 82845H	DOMESTIC SAMPLE COLL 82845S	DOMESTIC SAMPLE COLL 82845S	DOMESTIC SAMPLE COLL 82845S
	<b>TOTAL FIELD</b>	<b>2976</b>	<b>255</b>	<b>42</b>					<b>12</b>	<b>16</b>
NE	HEADQUARTERS									
	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									
PA	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

HOURS PER OPERATION			6.0				6.0	4.7
TOTAL HOURS	2976	255	252				72	71
CONVERSION FACTOR	950	950	950				950	950
TOTAL OPERATIONAL FTEs	3.13	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 124.6    [3.5]
--	--	--

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	7	7	7	7	7	7
		DOMESTIC SAMPLE COLL STERILITY 82845S	DOMESTIC LAB ANALYST (Hours) ENG 82845C	DOMESTIC LAB ANALYST (Hours) MICRO 82845C	DOMESTIC LAB ANALYST (Hours) CHEM 82845C	DOMESTIC LAB ANALYST (Hours) ENG 82845H	DOMESTIC LAB ANALYST (Hours) BIOBURDEN 82845S	DOMESTIC LAB ANALYST (Hours) STERILITY 82845S	
	<b>TOTAL FIELD</b>	5	800	1612	228	1060	250	148	
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
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			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	

**B. 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; Sporicidal and Tuberculocidal at WEAC and DEN Lab.

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 822002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.6
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REG I GN	6. DISTRICT/SPECIALIZED LABORATORY	1. INSPEC-TIONS	4. IMPORT SAMPLE COLL (Physical) CHEM	4. IMPORT SAMPLE COLL (Physical) ENG	8. IMPORT LAB ANALYST (Hours) (Physical) CHEM	8. IMPORT LAB ANALYST (Hours) (Physical) ENG								
							TOTAL FIELD							
	HEADQUARTERS	(b)(5)(8)(6)(7)(E)	187	121	1870	1210								
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		24.0	2.9	2.9										
TOTAL HOURS		48	542	351	1870	1210								
CONVERSION FACTOR		950	950	950	1180	1180								
TOTAL OPERATIONAL FTEs		0.05	0.57	0.37	1.58	1.03								

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).

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.5
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	4	4	8	8	9								
		IMPORT SAMPLE COLL (Physical) CHEM	IMPORT SAMPLE COLL (Physical) ENG	IMPORT LAB ANALYST (Hours) (Physical) CHEM	IMPORT LAB ANALYST (Hours) (Physical) ENG	OTHER OPERATIONS (Hours) ENG								
	<b>TOTAL FIELD</b>	349	413	2094	2478	2360								
	HEADQUARTERS													
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	2.0	2.0											
	TOTAL HOURS	698	826	2094	2478	2360								
	CONVERSION FACTOR	950	950	1180	1180	1180								
	TOTAL OPERATIONAL FTEs	0.73	0.87	1.77	2.10	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.

Laboratory allocations were planned by DFS.



1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
---	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 METHODS VAL/DEV CHEM (Hours)	9 METHODS VAL/DEV MICRO (Hours)						
	<b>TOTAL FIELD</b>	1205	1205						
	HEADQUARTERS	(b) (5) & (b) (7) (E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		1205	1205						
CONVERSION FACTOR		1205	1205						
TOTAL OPERATIONAL FTEs		1.00	1.00						

9. REMARKS

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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC ANALYSIS CHEM (Hours)							
	<b>TOTAL FIELD</b>	<b>360</b>							
	HEADQUARTERS	(b)							
NE	REGIONAL STAFF	(5)&(b)							
	NEW ENGLAND	(7)(E)							
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		360							
CONVERSION FACTOR		1206							
TOTAL OPERATIONAL FTEs		0.30							

9. REMARKS

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1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83001, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS MDUFMA USER FEE 83001	1 FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	1 INSPEC- TIONS POST- APPROVAL 83001A	1 FOREIGN INSPEC- TIONS POST- APPROVAL 83001A				
	<b>TOTAL FIELD</b>	<b>68</b>	<b>33</b>	<b>46</b>	<b>19</b>				
	HEADQUARTERS	(015) (017) (E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		70.0	49.0	43.3	45.0				
TOTAL HOURS		4760	1617	1992	855				
CONVERSION FACTOR		950	950	950	950				
TOTAL OPERATIONAL FTEs		5.01	1.70	2.10	0.90				

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 26.5
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN						
	TOTAL FIELD	302	31						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	75.5	75.5						
	TOTAL HOURS	22801	2341						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	24.00	2.46						

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.

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<b>1. PROGRAM/ASSIGNMENT TITLE</b> Test Method Development and Evaluation	<b>2. PPS PROJECT NAME/NUMBER</b> Science: Devices - 84
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 84Z002	<b>4. WORK ALLOCATION PLANNED BY</b> <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 3.7
--	---	--

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) METH DEV ENG								
	<b>TOTAL FIELD</b>	<b>4390</b>								
	HEADQUARTERS	(0)								
NE	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	(7)(E)								
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
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									
<b>HOURS PER OPERATION</b>										
<b>TOTAL HOURS</b>		4390								
<b>CONVERSION FACTOR</b>		1180								
<b>TOTAL OPERATIONAL FTEs</b>		3.72								

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

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 APPLIED TECHNOLOGY CENTER (Hours) MICRO								
	<b>TOTAL FIELD</b>	<b>2360</b>								
	HEADQUARTERS	(b)								
NE	REGIONAL STAFF	(5)(b)								
	NEW ENGLAND	(7)(E)								
	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										
TOTAL HOURS		2360								
CONVERSION FACTOR		1180								
TOTAL OPERATIONAL FTEs		2.00								

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

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1. PROGRAM/ASSIGNMENT TITLE <b>Mammography Facilities Inspection Program</b>	2. PPS PROJECT NAME/NUMBER <b>Mammography Quality Standards Act (MQSA) Authority - 85</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6    [10.2]
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	9	9
		INSP CTIONS 85014 (1)	INSP CTIONS FOREIGN 85014 (2)	INSP CTIONS 85014 (3)	INSP CTIONS 85014 (4)	INSP CTIONS 85014F (5)	INSP CTIONS 85014F (6)	INVESTI GATIONS (Hours) 85014A (7)	OTHER OPERA TIONS (Hours) 85014C (8)	OTHER OPERA TIONS (Hours) 85014C (9)
	<b>TOTAL FIELD</b>	<b>415</b>	<b>15</b>	<b>116</b>	<b>43</b>	<b>9</b>	<b>9</b>	<b>2398</b>	<b>3381</b>	<b>1200</b>
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.0	8.0	8.0	8.0	11.0	11.0			
TOTAL HOURS		3320	120	928	344	99	99	2398	3381	1200
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1200
TOTAL OPERATIONAL FTEs		2.86	0.10	0.80	0.30	0.09	0.09	2.07	2.91	1.00

9. REMARKS  
 RRRRs 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: RRRRs.

1. PROGRAM/ASSIGNMENT TITLE <b>Mammography Facilities Inspection Program</b>	2. PPS PROJECT NAME/NUMBER <b>Mammography Quality Standards Act (MQSA) Authority - 85</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [4.4]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPER- ATIONS (Hours) 85014C (10)	9 OTHER OPER- ATIONS (Hours) 85014C (11)							
	<b>TOTAL FIELD</b>	5025	59							
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		5025	59							
CONVERSION FACTOR		1100	1100							
TOTAL OPERATIONAL FTEs		4.33	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.

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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
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3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0 [4.7]
--	--	---

R E G I O N	6. 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 (5)	DOMESTIC SAMPLE COLL 86001	FIELD EXAMS/ TESTS 86001 (6)	FIELD EXAMS/ TESTS 86002 (7)
	<b>TOTAL FIELD</b>	<b>105</b>	<b>29</b>	<b>3</b>	<b>22</b>	<b>658</b>	<b>31</b>	<b>5</b>	<b>75</b>	<b>30</b>

	HEADQUARTERS									
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									
	REGIONAL LAB									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL STAFF									
	DALLAS									
	REGIONAL LAB									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL STAFF									
	LOS ANGELES									
	REGIONAL LAB									
	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	1080	108	440	658	31	15	375	132	
CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs	1.91	0.92	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 manufacturers 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.

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspection and Field Testing of Radiation-Emitting Electronic Products	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 86001, 86002, 86004	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 6.0 [1.3]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 O T H E R O P E R A T I O N S (Hours) 86001 (8)	9 O T H E R O P E R A T I O N S (Hours) 86002						
	<b>TOTAL FIELD</b>	1197	75						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	NEW ENGLAND	(b)(5)&(b)(7)(E)							
	NEW YORK	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	WEAC	(b)(5)&(b)(7)(E)							
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	BALTIMORE	(b)(5)&(b)(7)(E)							
	CHICAGO	(b)(5)&(b)(7)(E)							
	CINCINNATI	(b)(5)&(b)(7)(E)							
	DETROIT	(b)(5)&(b)(7)(E)							
	MINNEAPOLIS	(b)(5)&(b)(7)(E)							
	NEW JERSEY	(b)(5)&(b)(7)(E)							
	PHILADELPHIA	(b)(5)&(b)(7)(E)							
	FORENSIC CHEM. CTR	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
SE	ATLANTA	(b)(5)&(b)(7)(E)							
	FLORIDA	(b)(5)&(b)(7)(E)							
	NEW ORLEANS	(b)(5)&(b)(7)(E)							
	SAN JUAN	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
SW	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	DALLAS	(b)(5)&(b)(7)(E)							
	DENVER	(b)(5)&(b)(7)(E)							
	KANSAS CITY	(b)(5)&(b)(7)(E)							
	SOUTHWEST IMPORT DISTRICT	(b)(5)&(b)(7)(E)							
PA	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	LOS ANGELES	(b)(5)&(b)(7)(E)							
	SAN FRANCISCO	(b)(5)&(b)(7)(E)							
	SEATTLE	(b)(5)&(b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-SW	(b)(5)&(b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-NW	(b)(5)&(b)(7)(E)							
	HOURS PER OPERATION								
	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 EC T I O N S D O M E S T I C	INSP EC T I O N S F O R E I G N	INSP EC T I O N S D I R E C T E D	INSP EC T I O N S	INVE S T I G A T I O N S (Hours)	INVE S T I G A T I O N S (Hours)	FI E L D E X A M S/ T E S T S	A U D I T S	O T H E R O P E R A T I O N S (Hours)
TOTAL FIELD		52	15	5	18	884	1051	345	30	965
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		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

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

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

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

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

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

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

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

(8) - Coordination/technical assistance hours for field test activities.

**ATTACHMENT A - 2012 WORKPLAN  
INSPECTIONS OF MANUFACTURERS (FOREIGN AND  
DOMESTIC) AND FIELD COMPLIANCE TESTING  
OF DIAGNOSTIC X-RAY EQUIPMENT**

**NEW ENGLAND DISTRICT**

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

**NEW YORK DISTRICT**

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

**BALTIMORE DISTRICT**

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

**CHICAGO DISTRICT**

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

**CINCINNATI DISTRICT**

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

**DETROIT DISTRICT**

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

**MINNEAPOLIS DISTRICT**

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

**NEW JERSEY DISTRICT**

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

**PHILADELPHIA DISTRICT**

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

**ATLANTA DISTRICT**

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

**FLORIDA DISTRICT**

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

**NEW ORLEANS DISTRICT**

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

**SAN JUAN DISTRICT**

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

**SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)**

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

**SW REGIONAL STAFF (STATES IN DENVER DISTRICT)**

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

**SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)**

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

**LOS ANGELES DISTRICT**

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

**SAN FRANCISCO DISTRICT**

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

**SEATTLE DISTRICT**

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Compliance Testing of Electronic Products at WEAC	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
---	--

<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 86006 A,D,E	<b>4. WORK ALLOCATION PLANNED BY</b> <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 3.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP CTIONS PL 88- 802 STANDARD	7 DOMESTIC LAB ANALYST (Hours) ENG						
	<b>TOTAL FIELD</b>	5	3356						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	<b>HOURS PER OPERATION</b>	68.0							
	<b>TOTAL HOURS</b>	340	3356						
	<b>CONVERSION FACTOR</b>	1180	1180						
	<b>TOTAL OPERATIONAL FTEs</b>	0.29	2.84						

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

(b)(5)&(b)(7)(E)

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

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

Laboratory allocations were planned by DFS.

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 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INV (Hours) (1)	4 IMPORT FIELD EXAMS CONGRESS- IONAL TARGET	4 IMPORT SAMPLE COLL	8 IMPORT LAB ANALYST (Hours) ENG										
	<b>TOTAL FIELD</b>	6877	1400	400	25	1000										
	HEADQUARTERS	(b)(5)&(b)(7)(E)														
NE	REGIONAL STAFF															
	NEW ENGLAND															
	NEW YORK															
	REGIONAL LAB															
	WEAC															
CE	REGIONAL STAFF															
	BALTIMORE															
	CHICAGO															
	CINCINNATI															
	DETROIT															
	MINNEAPOLIS															
	NEW JERSEY															
	PHILADELPHIA															
	FORENSIC CHEM. CTR															
	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												0.7	5.7			
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).

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities			2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86							
3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.0			
R E G I O N	8. DISTRICT/ SPECIALIZED LABORATORY	9 MISC (Hours) RRHR 86008 (1)	9 TECHNICAL ASSISTANCE (Hours) RRHR 86008							
	TOTAL FIELD	3600	2400							
NE	HEADQUARTERS	(6)(5)(8)(7)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAG									
	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										
TOTAL HOURS		3600	2400							
CONVERSION FACTOR		1200	1200							
TOTAL OPERATIONAL FTEs		3.00	2.00							

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

## CONTINUATION SHEET

## 1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

## 2. PPS PROJECT NAME/NUMBER

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

## 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.

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**CENTER FOR TOBACCO  
RESOURCE SUMMARY  
FY 2012**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	9.4	9.3		18.7
06	REGULATED TOBACCO PRODUCTS: DOMESTIC AND IMPORT	9.4	9.3		18.7

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1. PROGRAM/ASSIGNMENT TITLE <b>Regulated Tobacco Products: Domestic and Import</b>	2. PPS PROJECT NAME/NUMBER <b>Tobacco - 96</b>
---	---

3. PROGRAM/ASSIGNMENT CODE(S) <b>96R800, 96T800, 96R824, 96R833</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>18.7 [13.1]</b>
--	--	--

R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 PRE- APPROVAL INSP EC- TIONS DOMESTIC	1 INSP EC- TIONS DOMESTIC (1)	1 INSP EC- TIONS ASSIGN- MENTS DOMESTIC (2)	2 INVEST- GATIONS (Hours)	2 IMP ORT INVEST- GATIONS (Hours)	2 IMP ORT ENTR Y REVIEW (Hours)	3 DOMESTIC SAMPLE COLL. (3)	3 DOMESTIC SAMPLE COLL ASSIGN- MENTS (2)	4 IMP ORT SAMPLE COLL
	<b>TOTAL FIELD</b>	<b>10</b>	<b>42</b>	<b>8</b>	<b>950</b>	<b>4000</b>	<b>5000</b>	<b>60</b>	<b>60</b>	<b>60</b>

	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	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									
	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	40.0	40.0					6.0	6.0	6.0
TOTAL HOURS	400	1680	320	950	4000	5000	360	360	360	
CONVERSION FACTOR	850	950	950	950	950	1200	950	950	950	
TOTAL OPERATIONAL FTEs	0.42	1.77	0.34	1.00	4.21	4.17	0.38	0.38	0.38	

7. REMARKS

(1) - Represents half of the manufacturing facilities registered with FDA. By statute, FDA is required to inspect tobacco product manufacturing facilities once every two years.

(2) - CTP will issue Inspection, Collection, and Analysis assignments during the year; operations include Inspections, DSC, and Lab Analyst Hours noted by "Assignments."

(3) - DSC and Lab Analyst Hours are linked to Inspections noted in (1).





# OPERATIONS



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Date: 13-SEP-2011  
Time 10:09:24 AM

**WORKPLAN SUMMARY / COMBINED OPERATIONS**  
**Workplan 0 - 2012 (2012 WORKPLAN)**

Report: FWF118C  
Page 22 of 120

Report Type: Complete

Region: NE REGN

	1		2		3		4		5	
	DOMESTIC INSPECTIONS OPRNS	OPR FTE'S	INVESTIGATIONS OPRNS	OPR FTE'S	DOM SAMPL COLL OPRNS	OPR FTE'S	IMP SAMPL COLL OPRNS	OPR FTE'S	FIELD EXAM/TESTS OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>1926</b>	<b>85.20</b>	<b>0</b>	<b>46.69</b>	<b>1286</b>	<b>7.56</b>	<b>7505</b>	<b>20.30</b>	<b>492</b>	<b>0.47</b>
<b>FOOD SAFETY/COS</b>	<b>897</b>	<b>34.53</b>	<b>0</b>	<b>23.39</b>	<b>767</b>	<b>5.04</b>	<b>6886</b>	<b>18.64</b>	<b>442</b>	<b>0.29</b>
03	884	34.30	0	23.23	270	2.96	3855	10.69	154	0.16
04	0	0.00	0	0.00	295	1.21	1960	5.16	10	0.01
07	0	0.00	0	0.00	84	0.35	220	0.46	0	0.00
09	0	0.00	0	0.00	0	0.00	347	0.51	0	0.00
18	0	0.00	0	0.16	20	0.08	0	0.00	0	0.00
21	0	0.00	0	0.00	90	0.40	386	1.63	278	0.12
29	13	0.23	0	0.00	8	0.04	118	0.19	0	0.00
<b>BIOLOGICS</b>	<b>181</b>	<b>9.47</b>	<b>0</b>	<b>0.88</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	61	3.32	0	0.00	0	0.00	0	0.00	0	0.00
42	114	5.53	0	0.70	0	0.00	0	0.00	0	0.00
45	6	0.62	0	0.17	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>336</b>	<b>18.33</b>	<b>0</b>	<b>10.50</b>	<b>138</b>	<b>0.76</b>	<b>67</b>	<b>0.20</b>	<b>0</b>	<b>0.00</b>
46	29	1.46	0	0.00	1	0.01	0	0.00	0	0.00
48	54	4.73	0	1.23	0	0.00	0	0.00	0	0.00
52	24	0.78	0	0.02	6	0.04	18	0.06	0	0.00
53	23	1.57	0	0.00	0	0.00	0	0.00	0	0.00
56	182	8.88	0	9.07	101	0.54	49	0.14	0	0.00
63	24	0.90	0	0.19	30	0.17	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>124</b>	<b>3.95</b>	<b>0</b>	<b>3.65</b>	<b>352</b>	<b>1.58</b>	<b>295</b>	<b>0.78</b>	<b>0</b>	<b>0.00</b>
68	6	0.37	0	0.00	0	0.00	0	0.00	0	0.00
71	118	3.59	0	3.65	352	1.58	295	0.78	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>382</b>	<b>18.67</b>	<b>0</b>	<b>4.83</b>	<b>19</b>	<b>0.13</b>	<b>234</b>	<b>0.55</b>	<b>45</b>	<b>0.17</b>
81	13	0.27	0	0.00	3	0.03	0	0.00	0	0.00
82	232	12.96	0	2.91	15	0.10	232	0.54	0	0.00
83	56	4.15	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	52	0.37	0	0.75	0	0.00	0	0.00	0	0.00
86	29	0.92	0	1.16	1	0.00	2	0.01	45	0.17
<b>TOBACCO PROD</b>	<b>6</b>	<b>0.25</b>	<b>0</b>	<b>3.45</b>	<b>10</b>	<b>0.06</b>	<b>23</b>	<b>0.15</b>	<b>5</b>	<b>0.01</b>
96	6	0.25	0	3.45	10	0.06	23	0.15	5	0.01

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**WORKPLAN SUMMARY / COMBINED OPERATIONS**  
**Workplan 0 - 2012 (2012 WORKPLAN)**

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Report Type: Complete

Region: NE REGN

	6		7		8		9		10	
	IMPORT FIELD EXAMS OPRNS	OPR FTE'S	DOM SAMPL ANALYSIS OPRNS	OPR FTE'S	IMP SAMPL ANALYSIS OPRNS	OPR FTE'S	MISC OPRNS	OPR FTE'S	FOREIGN INSPECTIONS OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>50174</b>	<b>27.36</b>	<b>25</b>	<b>57.68</b>	<b>0</b>	<b>71.47</b>	<b>224</b>	<b>27.94</b>	<b>297</b>	<b>17.44</b>
<b>FOOD SAFETY/COS</b>	<b>44986</b>	<b>23.68</b>	<b>0</b>	<b>38.45</b>	<b>0</b>	<b>55.97</b>	<b>224</b>	<b>14.02</b>	<b>102</b>	<b>3.76</b>
03	37516	19.75	0	27.30	0	40.69	0	3.44	102	3.76
04	2237	1.18	0	7.19	0	9.03	0	0.50	0	0.00
07	0	0.00	0	0.70	0	1.89	0	0.08	0	0.00
09	1413	0.74	0	0.00	0	2.91	0	0.00	0	0.00
18	0	0.00	0	0.14	0	0.00	224	10.00	0	0.00
21	3005	1.58	0	3.00	0	0.00	0	0.00	0	0.00
29	815	0.43	0	0.12	0	1.45	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>2</b>	<b>0.08</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	0.00	2	0.08
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>1511</b>	<b>1.59</b>	<b>0</b>	<b>9.23</b>	<b>0</b>	<b>3.55</b>	<b>0</b>	<b>0.79</b>	<b>128</b>	<b>9.37</b>
46	0	0.00	0	1.00	0	0.00	0	0.00	21	1.30
48	0	0.00	0	0.00	0	0.00	0	0.00	28	2.57
52	0	0.00	0	1.48	0	2.07	0	0.00	7	0.45
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.21
56	1511	1.59	0	5.94	0	1.48	0	0.79	69	4.84
63	0	0.00	0	0.80	0	0.00	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>1286</b>	<b>0.58</b>	<b>0</b>	<b>1.37</b>	<b>0</b>	<b>1.76</b>	<b>0</b>	<b>0.77</b>	<b>13</b>	<b>0.92</b>
68	0	0.00	0	0.08	0	0.00	0	0.00	6	0.57
71	1286	0.58	0	1.29	0	1.76	0	0.77	7	0.35
<b>DEVICES &amp; RAD H</b>	<b>2391</b>	<b>1.51</b>	<b>25</b>	<b>8.64</b>	<b>0</b>	<b>10.18</b>	<b>0</b>	<b>12.36</b>	<b>52</b>	<b>3.31</b>
81	0	0.00	0	0.08	0	0.00	0	0.00	0	0.00
82	2362	1.49	0	4.51	0	9.34	0	4.84	33	2.37
83	0	0.00	0	0.00	0	0.00	0	0.00	11	0.70
84	0	0.00	0	0.00	0	0.00	0	5.72	0	0.00
85	0	0.00	0	0.00	0	0.00	0	0.77	5	0.03
86	29	0.02	25	4.05	0	0.85	0	1.04	3	0.21
<b>TOBACCO PROD</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
96	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

Report Type: Complete

Region: NE REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	362.11	384797.40
FOOD SAFETY/COS	217.75	234695.80
03	166.27	177062.60
04	24.27	26913.50
07	3.48	3924.00
09	4.17	4630.30
18	10.38	12393.00
21	6.72	7075.70
29	2.46	2696.70
BIOLOGICS	10.43	9908.60
41	3.32	3157.90
42	6.32	5999.90
45	0.79	750.80
HUMAN DRUGS	54.30	54587.50
46	3.77	3580.60
48	8.53	8101.40
52	4.90	5384.60
53	1.78	1688.70
56	33.28	33697.60
63	2.05	2134.60
88	0.00	0.00
ANIMAL D & F	15.35	16109.70
68	1.01	963.00
71	14.34	15146.70
DEVICES & RAD H	60.35	65351.80
81	0.39	383.90
82	39.05	41910.40
83	4.85	4605.60
84	5.72	6750.00
85	1.93	2242.00
86	8.42	9459.90
TOBACCO PROD	3.92	4144.00
96	3.92	4144.00























































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WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)

Report: FWF118C  
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Report Type: Complete

Region: CE REGN

	1		2		3		4		5	
	DOMESTIC INSPECTIONS		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>5968</b>	<b>252.74</b>	<b>0</b>	<b>67.96</b>	<b>4367</b>	<b>28.42</b>	<b>5240</b>	<b>14.27</b>	<b>1368</b>	<b>1.39</b>
<b>FOOD SAFETY/COS</b>	<b>2593</b>	<b>109.92</b>	<b>0</b>	<b>41.25</b>	<b>2257</b>	<b>18.65</b>	<b>4744</b>	<b>12.91</b>	<b>1199</b>	<b>0.81</b>
03	2561	109.34	0	40.98	941	12.93	3186	8.84	483	0.51
04	0	0.00	0	0.00	678	2.97	923	2.43	0	0.00
07	0	0.00	0	0.00	328	1.38	175	0.37	0	0.00
09	0	0.00	0	0.00	0	0.00	200	0.29	0	0.00
18	0	0.00	0	0.26	44	0.18	0	0.00	0	0.00
21	0	0.00	0	0.00	247	1.09	214	0.90	716	0.30
29	32	0.57	0	0.00	19	0.09	46	0.07	0	0.00
<b>BIOLOGICS</b>	<b>642</b>	<b>34.11</b>	<b>0</b>	<b>1.21</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	198	11.09	0	0.00	0	0.00	0	0.00	0	0.00
42	423	20.86	0	0.99	0	0.00	0	0.00	0	0.00
45	21	2.16	0	0.23	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>873</b>	<b>47.49</b>	<b>0</b>	<b>13.31</b>	<b>348</b>	<b>1.92</b>	<b>127</b>	<b>0.38</b>	<b>0</b>	<b>0.00</b>
46	88	4.44	0	0.00	13	0.08	0	0.00	0	0.00
48	139	12.45	0	3.42	0	0.00	0	0.00	0	0.00
52	62	2.01	0	0.06	16	0.10	57	0.18	0	0.00
53	59	4.02	0	0.00	0	0.00	0	0.00	0	0.00
56	499	23.34	0	9.69	306	1.66	70	0.20	0	0.00
63	26	1.23	0	0.15	13	0.07	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>833</b>	<b>18.10</b>	<b>0</b>	<b>2.95</b>	<b>1679</b>	<b>7.28</b>	<b>204</b>	<b>0.54</b>	<b>0</b>	<b>0.00</b>
68	26	1.67	0	0.00	0	0.00	0	0.00	0	0.00
71	807	16.44	0	2.95	1679	7.28	204	0.54	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>1009</b>	<b>42.35</b>	<b>0</b>	<b>7.23</b>	<b>45</b>	<b>0.34</b>	<b>152</b>	<b>0.37</b>	<b>150</b>	<b>0.54</b>
81	3	0.06	0	0.06	0	0.00	0	0.00	0	0.00
82	487	28.04	0	2.83	44	0.33	145	0.32	0	0.00
83	137	10.34	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	324	2.25	0	1.54	0	0.00	0	0.00	0	0.00
86	58	1.66	0	2.81	1	0.00	7	0.04	150	0.54
<b>TOBACCO PROD</b>	<b>18</b>	<b>0.76</b>	<b>0</b>	<b>2.01</b>	<b>38</b>	<b>0.24</b>	<b>13</b>	<b>0.08</b>	<b>19</b>	<b>0.04</b>
96	18	0.76	0	2.01	38	0.24	13	0.08	19	0.04

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**WORKPLAN SUMMARY / COMBINED OPERATIONS**  
**Workplan 0 - 2012 (2012 WORKPLAN)**

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Report Type: Complete

Region: CE REGN

	6		7		8		9		10	
	IMPORT FIELD EXAMS OPRNS	OPR FTE'S	DOM SAMPL ANALYSIS OPRNS	OPR FTE'S	IMP SAMPL ANALYSIS OPRNS	OPR FTE'S	MISC OPRNS	OPR FTE'S	FOREIGN INSPECTIONS OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>35687</b>	<b>19.97</b>	<b>0</b>	<b>46.16</b>	<b>0</b>	<b>1.99</b>	<b>458</b>	<b>31.82</b>	<b>725</b>	<b>43.24</b>
<b>FOOD SAFETY/COS</b>	<b>31315</b>	<b>16.48</b>	<b>0</b>	<b>14.98</b>	<b>0</b>	<b>1.26</b>	<b>458</b>	<b>20.88</b>	<b>273</b>	<b>10.06</b>
03	27008	14.21	0	2.98	0	0.17	0	4.70	273	10.06
04	1054	0.55	0	12.00	0	0.00	0	0.00	0	0.00
07	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
09	820	0.43	0	0.00	0	0.92	0	0.00	0	0.00
18	0	0.00	0	0.00	0	0.00	458	16.19	0	0.00
21	2111	1.11	0	0.00	0	0.00	0	0.00	0	0.00
29	322	0.17	0	0.00	0	0.18	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>2.50</b>	<b>6</b>	<b>0.34</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	2.50	6	0.34
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>2284</b>	<b>2.40</b>	<b>0</b>	<b>29.88</b>	<b>0</b>	<b>0.74</b>	<b>0</b>	<b>1.66</b>	<b>301</b>	<b>22.80</b>
46	0	0.00	0	1.81	0	0.00	0	0.00	33	2.04
48	0	0.00	0	0.00	0	0.00	0	0.00	68	6.22
52	0	0.00	0	0.45	0	0.00	0	0.00	21	1.36
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.21
56	2284	2.40	0	17.17	0	0.74	0	1.66	176	12.97
63	0	0.00	0	1.45	0	0.00	0	0.00	0	0.00
88	0	0.00	0	9.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>1251</b>	<b>0.56</b>	<b>0</b>	<b>1.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>1.58</b>	<b>36</b>	<b>2.57</b>
68	0	0.00	0	0.00	0	0.00	0	0.00	18	1.66
71	1251	0.56	0	1.00	0	0.00	0	1.58	18	0.91
<b>DEVICES &amp; RAD H</b>	<b>837</b>	<b>0.54</b>	<b>0</b>	<b>0.30</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>4.19</b>	<b>109</b>	<b>7.48</b>
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	775	0.49	0	0.30	0	0.00	0	0.00	79	5.66
83	0	0.00	0	0.00	0	0.00	0	0.00	27	1.61
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	0	0.00	0	0.00	0	0.00	0	1.86	0	0.00
86	62	0.05	0	0.00	0	0.00	0	2.34	3	0.21
<b>TOBACCO PROD</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>1.00</b>	<b>0</b>	<b>0.00</b>
96	0	0.00	0	0.00	0	0.00	0	1.00	0	0.00

Report Type: Complete

Region: CE REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	507.97	504507.70
FOOD SAFETY/COS	247.19	245356.00
03	204.73	197657.60
04	17.95	20117.50
07	1.75	1662.00
09	1.64	1770.00
18	16.63	19848.00
21	3.41	3235.30
29	1.08	1065.60
BIOLOGICS	38.16	36254.10
41	11.09	10535.80
42	24.68	23450.50
45	2.39	2267.80
HUMAN DRUGS	120.58	122270.30
46	8.38	8039.90
48	22.09	20980.90
52	4.15	3949.40
53	4.23	4015.20
56	69.83	71579.70
63	2.90	3085.20
88	9.00	10620.00
ANIMAL D & F	34.58	33541.90
68	3.33	3162.00
71	31.26	30379.90
DEVICES & RAD H	63.34	62700.40
81	0.12	115.00
82	37.98	36562.40
83	11.95	11353.90
84	0.00	0.00
85	5.64	6555.00
86	7.65	8114.10
TOBACCO PROD	4.13	4385.00
96	4.13	4385.00





































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WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)

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Report Type: Complete

Region: SE REGN

	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>2887</b>	<b>128.97</b>	<b>0</b>	<b>43.74</b>	<b>2082</b>	<b>12.37</b>	<b>2266</b>	<b>6.25</b>	<b>697</b>	<b>0.80</b>
<b>FOOD SAFETY/COS</b>	<b>1225</b>	<b>48.21</b>	<b>0</b>	<b>21.54</b>	<b>1298</b>	<b>8.40</b>	<b>1855</b>	<b>5.09</b>	<b>565</b>	<b>0.38</b>
03	1206	47.87	0	21.38	498	4.94	1290	3.59	224	0.24
04	0	0.00	0	0.00	540	2.35	335	0.88	0	0.00
07	0	0.00	0	0.00	96	0.41	65	0.14	0	0.00
09	0	0.00	0	0.00	0	0.00	63	0.09	0	0.00
18	0	0.00	0	0.16	51	0.22	0	0.00	0	0.00
21	0	0.00	0	0.00	102	0.45	87	0.37	341	0.14
29	19	0.34	0	0.00	11	0.05	15	0.02	0	0.00
<b>BIOLOGICS</b>	<b>454</b>	<b>23.37</b>	<b>0</b>	<b>1.25</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	124	6.84	0	0.00	0	0.00	0	0.00	0	0.00
42	318	15.30	0	1.20	0	0.00	0	0.00	0	0.00
45	12	1.24	0	0.05	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>562</b>	<b>29.57</b>	<b>0</b>	<b>12.64</b>	<b>267</b>	<b>1.47</b>	<b>68</b>	<b>0.20</b>	<b>0</b>	<b>0.00</b>
46	31	1.51	0	0.00	3	0.02	0	0.00	0	0.00
48	90	8.16	0	4.12	0	0.00	0	0.00	0	0.00
52	20	0.66	0	0.03	5	0.03	30	0.09	0	0.00
53	28	1.91	0	0.00	0	0.00	0	0.00	0	0.00
56	334	15.36	0	7.97	165	0.89	38	0.11	0	0.00
63	59	1.98	0	0.52	94	0.54	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>210</b>	<b>4.63</b>	<b>0</b>	<b>0.75</b>	<b>441</b>	<b>2.02</b>	<b>21</b>	<b>0.06</b>	<b>0</b>	<b>0.00</b>
68	17	0.99	0	0.00	0	0.00	0	0.00	0	0.00
71	193	3.64	0	0.75	441	2.02	21	0.06	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>407</b>	<b>21.97</b>	<b>0</b>	<b>5.64</b>	<b>14</b>	<b>0.08</b>	<b>311</b>	<b>0.83</b>	<b>101</b>	<b>0.35</b>
81	5	0.11	0	0.00	0	0.00	0	0.00	0	0.00
82	256	15.41	0	3.24	13	0.08	309	0.82	0	0.00
83	68	5.15	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	43	0.31	0	1.06	0	0.00	0	0.00	0	0.00
86	35	0.99	0	1.34	1	0.00	2	0.01	101	0.35
<b>TOBACCO PROD</b>	<b>29</b>	<b>1.22</b>	<b>0</b>	<b>1.92</b>	<b>62</b>	<b>0.39</b>	<b>11</b>	<b>0.07</b>	<b>31</b>	<b>0.07</b>
96	29	1.22	0	1.92	62	0.39	11	0.07	31	0.07

WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)

Report Type: Complete

Region: SE REGN	6		7		8		9		10	
	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>16935</b>	<b>9.66</b>	<b>0</b>	<b>65.41</b>	<b>0</b>	<b>37.24</b>	<b>196</b>	<b>27.69</b>	<b>394</b>	<b>23.79</b>
<b>FOOD SAFETY/COS</b>	<b>14487</b>	<b>7.62</b>	<b>0</b>	<b>42.86</b>	<b>0</b>	<b>34.97</b>	<b>196</b>	<b>20.24</b>	<b>130</b>	<b>4.79</b>
03	12816	6.75	0	20.56	0	21.90	0	4.75	130	4.79
04	383	0.20	0	3.67	0	7.56	0	0.17	0	0.00
07	0	0.00	0	1.33	0	0.84	0	3.09	0	0.00
09	260	0.14	0	0.00	0	0.42	0	0.00	0	0.00
18	0	0.00	0	0.50	0	0.00	196	11.75	0	0.00
21	917	0.48	0	16.47	0	3.88	0	0.50	0	0.00
29	111	0.06	0	0.34	0	0.37	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>3</b>	<b>0.21</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	0.00	3	0.21
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>1218</b>	<b>1.28</b>	<b>0</b>	<b>14.38</b>	<b>0</b>	<b>0.80</b>	<b>0</b>	<b>0.99</b>	<b>195</b>	<b>14.38</b>
46	0	0.00	0	1.53	0	0.00	0	0.00	30	1.86
48	0	0.00	0	0.00	0	0.00	0	0.00	38	3.48
52	0	0.00	0	0.71	0	0.00	0	0.00	11	0.71
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.21
56	1218	1.28	0	7.87	0	0.80	0	0.99	113	8.13
63	0	0.00	0	1.28	0	0.00	0	0.00	0	0.00
88	0	0.00	0	3.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>167</b>	<b>0.08</b>	<b>0</b>	<b>7.18</b>	<b>0</b>	<b>0.97</b>	<b>0</b>	<b>0.92</b>	<b>15</b>	<b>1.22</b>
68	0	0.00	0	0.15	0	0.00	0	0.00	11	1.02
71	167	0.08	0	7.03	0	0.97	0	0.92	4	0.20
<b>DEVICES &amp; RAD H</b>	<b>1063</b>	<b>0.68</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>2.53</b>	<b>51</b>	<b>3.20</b>
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	1037	0.66	0	0.00	0	0.00	0	0.00	30	2.16
83	0	0.00	0	0.00	0	0.00	0	0.00	13	0.79
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	0	0.00	0	0.00	0	0.00	0	1.24	5	0.03
86	26	0.02	0	0.00	0	0.00	0	1.30	3	0.21
<b>TOBACCO PROD</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>1.00</b>	<b>0</b>	<b>0.50</b>	<b>0</b>	<b>3.00</b>	<b>0</b>	<b>0.00</b>
96	0	0.00	0	1.00	0	0.50	0	3.00	0	0.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)

Report: FWF118C  
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Report Type: Complete

Region: SE REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	355.92	368555.40
FOOD SAFETY/COS	194.10	207434.40
03	136.74	140990.00
04	14.83	16708.50
07	5.80	6725.00
09	0.65	713.20
18	12.62	15036.00
21	22.29	25984.30
29	1.18	1277.40
BIOLOGICS	24.83	23591.60
41	6.84	6495.40
42	16.71	15872.60
45	1.29	1223.60
HUMAN DRUGS	75.71	74834.40
46	4.91	4661.60
48	15.76	14972.80
52	2.23	2122.10
53	2.11	2008.20
56	43.39	43141.00
63	4.31	4388.70
88	3.00	3540.00
ANIMAL D & F	17.82	18800.60
68	2.16	2048.00
71	15.66	16752.60
DEVICES & RAD H	35.29	34854.40
81	0.11	103.00
82	22.37	21673.20
83	5.94	5644.80
84	0.00	0.00
85	2.64	3074.00
86	4.22	4359.40
TOBACCO PROD	8.17	9040.00
96	8.17	9040.00





































**WORKPLAN SUMMARY / COMBINED OPERATIONS**  
**Workplan 0 - 2012 (2012 WORKPLAN)**

**Report Type: Complete**

Region: SW REGN

	1		2		3		4		5	
	DOMESTIC INSPECTIONS		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>3138</b>	<b>125.08</b>	<b>0</b>	<b>59.57</b>	<b>2222</b>	<b>13.41</b>	<b>7282</b>	<b>20.02</b>	<b>739</b>	<b>0.78</b>
<b>FOOD SAFETY/COS</b>	<b>1420</b>	<b>55.85</b>	<b>0</b>	<b>31.08</b>	<b>1163</b>	<b>8.48</b>	<b>6912</b>	<b>19.08</b>	<b>639</b>	<b>0.44</b>
03	1406	55.60	0	31.08	435	5.37	5513	15.48	267	0.28
04	0	0.00	0	0.00	426	1.81	583	1.53	7	0.01
07	0	0.00	0	0.00	140	0.59	153	0.32	0	0.00
09	0	0.00	0	0.00	0	0.00	375	0.55	0	0.00
18	0	0.00	0	0.00	28	0.12	0	0.00	0	0.00
21	0	0.00	0	0.00	125	0.55	282	1.19	365	0.15
29	14	0.25	0	0.00	9	0.04	6	0.01	0	0.00
<b>BIOLOGICS</b>	<b>402</b>	<b>21.82</b>	<b>0</b>	<b>0.58</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	131	7.07	0	0.00	0	0.00	0	0.00	0	0.00
42	254	13.00	0	0.55	0	0.00	0	0.00	0	0.00
45	17	1.75	0	0.03	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>363</b>	<b>20.07</b>	<b>0</b>	<b>5.43</b>	<b>127</b>	<b>0.70</b>	<b>51</b>	<b>0.15</b>	<b>0</b>	<b>0.00</b>
46	17	0.82	0	0.00	0	0.00	0	0.00	0	0.00
48	84	7.41	0	2.98	0	0.00	0	0.00	0	0.00
52	15	0.48	0	0.02	4	0.03	23	0.07	0	0.00
53	14	0.96	0	0.00	0	0.00	0	0.00	0	0.00
56	222	9.95	0	2.35	113	0.62	28	0.08	0	0.00
63	11	0.46	0	0.08	10	0.06	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>552</b>	<b>10.43</b>	<b>0</b>	<b>1.14</b>	<b>914</b>	<b>4.13</b>	<b>39</b>	<b>0.10</b>	<b>0</b>	<b>0.00</b>
68	21	1.36	0	0.00	0	0.00	0	0.00	0	0.00
71	531	9.07	0	1.14	914	4.13	39	0.10	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>395</b>	<b>16.66</b>	<b>0</b>	<b>20.61</b>	<b>10</b>	<b>0.06</b>	<b>276</b>	<b>0.66</b>	<b>96</b>	<b>0.34</b>
81	7	0.15	0	0.00	0	0.00	0	0.00	0	0.00
82	186	10.76	0	17.69	9	0.06	269	0.62	0	0.00
83	57	4.32	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	122	0.85	0	0.62	0	0.00	0	0.00	0	0.00
86	23	0.59	0	2.29	1	0.00	7	0.04	96	0.34
<b>TOBACCO PROD</b>	<b>6</b>	<b>0.25</b>	<b>0</b>	<b>0.75</b>	<b>8</b>	<b>0.05</b>	<b>4</b>	<b>0.03</b>	<b>4</b>	<b>0.01</b>
96	6	0.25	0	0.75	8	0.05	4	0.03	4	0.01

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**WORKPLAN SUMMARY / COMBINED OPERATIONS**  
Workplan 0 - 2012 (2012 WORKPLAN)

Report: FWF118C  
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Report Type: Complete

Region: SW REGN

	6		7		8		9		10	
	IMPORT FIELD EXAMS OPRNS	OPR FTE'S	DOM SAMPL ANALYSIS OPRNS	OPR FTE'S	IMP SAMPL ANALYSIS OPRNS	OPR FTE'S	MISC OPRNS	OPR FTE'S	FOREIGN INSPECTIONS OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>63759</b>	<b>34.90</b>	<b>0</b>	<b>95.96</b>	<b>0</b>	<b>59.45</b>	<b>211</b>	<b>27.56</b>	<b>319</b>	<b>19.47</b>
<b>FOOD SAFETY/COS</b>	<b>54132</b>	<b>28.49</b>	<b>0</b>	<b>71.61</b>	<b>0</b>	<b>58.14</b>	<b>211</b>	<b>20.46</b>	<b>108</b>	<b>3.98</b>
03	48768	25.67	0	31.69	0	37.83	0	4.10	108	3.98
04	666	0.35	0	35.26	0	18.25	0	5.76	0	0.00
07	0	0.00	0	1.02	0	1.15	0	0.25	0	0.00
09	1532	0.81	0	0.00	0	0.37	0	0.00	0	0.00
18	0	0.00	0	0.38	0	0.00	211	10.36	0	0.00
21	3126	1.65	0	3.00	0	0.00	0	0.00	0	0.00
29	40	0.02	0	0.26	0	0.56	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>806</b>	<b>0.85</b>	<b>0</b>	<b>5.37</b>	<b>0</b>	<b>0.11</b>	<b>0</b>	<b>0.32</b>	<b>163</b>	<b>12.21</b>
46	0	0.00	0	1.61	0	0.00	0	0.00	21	1.30
48	0	0.00	0	0.00	0	0.00	0	0.00	42	3.88
52	0	0.00	0	0.39	0	0.00	0	0.00	8	0.52
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.21
56	806	0.85	0	3.37	0	0.11	0	0.32	89	6.32
63	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>161</b>	<b>0.08</b>	<b>0</b>	<b>18.39</b>	<b>0</b>	<b>1.20</b>	<b>0</b>	<b>5.00</b>	<b>10</b>	<b>0.67</b>
68	0	0.00	0	0.57	0	0.00	0	0.00	5	0.43
71	161	0.08	0	17.81	0	1.20	0	5.00	5	0.24
<b>DEVICES &amp; RAD H</b>	<b>8660</b>	<b>5.48</b>	<b>0</b>	<b>0.59</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>1.79</b>	<b>38</b>	<b>2.61</b>
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	8538	5.39	0	0.59	0	0.00	0	0.00	23	1.69
83	0	0.00	0	0.00	0	0.00	0	0.00	12	0.72
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	0	0.00	0	0.00	0	0.00	0	0.56	0	0.00
86	122	0.09	0	0.00	0	0.00	0	1.23	3	0.21
<b>TOBACCO PROD</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
96	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

Report Type: Complete

Region: SW REGN

	Total	
	OPR FTE'S	PERSNHRS
<b>REGION TOTAL</b>	<b>456.21</b>	<b>482288.60</b>
<b>FOOD SAFETY/COS</b>	<b>297.60</b>	<b>320670.40</b>
03	211.06	220604.40
04	62.96	73462.40
07	3.33	3723.00
09	1.73	1723.00
18	10.85	12987.00
21	6.54	6902.00
29	1.14	1268.60
<b>BIOLOGICS</b>	<b>22.39</b>	<b>21274.10</b>
41	7.07	6717.00
42	13.55	12869.50
45	1.78	1687.60
<b>HUMAN DRUGS</b>	<b>45.21</b>	<b>43528.10</b>
46	3.72	3539.40
48	14.27	13553.60
52	1.51	1431.10
53	1.16	1102.20
56	23.96	23335.90
63	0.60	565.90
88	0.00	0.00
<b>ANIMAL D &amp; F</b>	<b>41.12</b>	<b>44331.60</b>
68	2.36	2241.00
71	38.76	42090.60
<b>DEVICES &amp; RAD H</b>	<b>48.80</b>	<b>51369.40</b>
81	0.15	140.00
82	36.79	38924.20
83	5.04	4786.00
84	0.00	0.00
85	2.03	2357.00
86	4.79	5162.20
<b>TOBACCO PROD</b>	<b>1.08</b>	<b>1115.00</b>
96	1.08	1115.00





































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WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)

Report: FWF118C  
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Report Type: Complete

Region: PA REGN

	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>4096</b>	<b>170.66</b>	<b>0</b>	<b>41.32</b>	<b>3618</b>	<b>18.14</b>	<b>5836</b>	<b>15.89</b>	<b>1189</b>	<b>1.06</b>
<b>FOOD SAFETY/COS</b>	<b>2200</b>	<b>80.33</b>	<b>0</b>	<b>23.60</b>	<b>2271</b>	<b>12.06</b>	<b>5234</b>	<b>14.37</b>	<b>1100</b>	<b>0.72</b>
03	2178	79.94	0	23.28	1045	7.03	2586	7.17	392	0.41
04	0	0.00	0	0.00	782	3.12	1808	4.76	8	0.01
07	0	0.00	0	0.00	184	0.78	219	0.46	0	0.00
09	0	0.00	0	0.00	0	0.00	190	0.28	0	0.00
18	0	0.00	0	0.32	57	0.24	0	0.00	0	0.00
21	0	0.00	0	0.00	190	0.84	386	1.63	700	0.30
29	22	0.39	0	0.00	13	0.06	45	0.07	0	0.00
<b>BIOLOGICS</b>	<b>366</b>	<b>19.45</b>	<b>0</b>	<b>1.06</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	139	7.70	0	0.00	0	0.00	0	0.00	0	0.00
42	215	10.52	0	1.01	0	0.00	0	0.00	0	0.00
45	12	1.24	0	0.05	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>491</b>	<b>26.08</b>	<b>0</b>	<b>6.86</b>	<b>239</b>	<b>1.34</b>	<b>40</b>	<b>0.12</b>	<b>0</b>	<b>0.00</b>
46	32	1.59	0	0.00	0	0.00	0	0.00	0	0.00
48	86	8.02	0	3.86	0	0.00	0	0.00	0	0.00
52	28	0.91	0	0.02	10	0.06	23	0.07	0	0.00
53	23	1.57	0	0.00	0	0.00	0	0.00	0	0.00
56	258	12.18	0	2.33	102	0.55	17	0.05	0	0.00
63	64	1.81	0	0.65	127	0.72	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>376</b>	<b>9.65</b>	<b>0</b>	<b>2.60</b>	<b>1077</b>	<b>4.54</b>	<b>191</b>	<b>0.50</b>	<b>0</b>	<b>0.00</b>
68	9	0.51	0	0.00	0	0.00	0	0.00	0	0.00
71	367	9.14	0	2.60	1077	4.54	191	0.50	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>662</b>	<b>35.11</b>	<b>0</b>	<b>5.95</b>	<b>29</b>	<b>0.19</b>	<b>362</b>	<b>0.84</b>	<b>88</b>	<b>0.35</b>
81	12	0.25	0	0.00	0	0.00	0	0.00	0	0.00
82	441	25.72	0	2.57	28	0.19	355	0.80	0	0.00
83	98	7.15	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	51	0.36	0	1.01	0	0.00	0	0.00	0	0.00
86	60	1.63	0	2.37	1	0.00	7	0.04	88	0.35
<b>TOBACCO PROD</b>	<b>1</b>	<b>0.04</b>	<b>0</b>	<b>1.26</b>	<b>2</b>	<b>0.01</b>	<b>9</b>	<b>0.06</b>	<b>1</b>	<b>0.00</b>
96	1	0.04	0	1.26	2	0.01	9	0.06	1	0.00

Report Type: Complete

Region: PA REGN

	6		7		8		9		10	
	IMPORT FIELD EXAMS OPRNS	OPR FTE'S	DOM SAMPL ANALYSIS OPRNS	OPR FTE'S	IMP SAMPL ANALYSIS OPRNS	OPR FTE'S	MISC OPRNS	OPR FTE'S	FOREIGN INSPECTIONS OPRNS	OPR FTE'S
<b>REGION TOTAL</b>	<b>33738</b>	<b>18.07</b>	<b>0</b>	<b>53.15</b>	<b>0</b>	<b>71.97</b>	<b>219</b>	<b>27.53</b>	<b>309</b>	<b>17.05</b>
<b>FOOD SAFETY/COS</b>	<b>31238</b>	<b>16.44</b>	<b>0</b>	<b>44.19</b>	<b>0</b>	<b>67.66</b>	<b>219</b>	<b>23.42</b>	<b>136</b>	<b>5.01</b>
03	26031	13.70	0	37.69	0	48.90	0	8.34	136	5.01
04	2066	1.09	0	3.72	0	12.78	0	0.58	0	0.00
07	0	0.00	0	1.18	0	1.06	0	1.09	0	0.00
09	779	0.41	0	0.00	0	4.35	0	0.00	0	0.00
18	0	0.00	0	0.40	0	0.00	219	12.41	0	0.00
21	2050	1.08	0	1.00	0	0.00	0	1.00	0	0.00
29	312	0.16	0	0.20	0	0.57	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>381</b>	<b>0.40</b>	<b>0</b>	<b>6.93</b>	<b>0</b>	<b>0.55</b>	<b>0</b>	<b>0.20</b>	<b>120</b>	<b>8.61</b>
46	0	0.00	0	0.90	0	0.00	0	0.00	17	1.05
48	0	0.00	0	0.00	0	0.00	0	0.00	29	2.64
52	0	0.00	0	0.38	0	0.00	0	0.00	9	0.58
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.21
56	381	0.40	0	5.33	0	0.55	0	0.20	62	4.13
63	0	0.00	0	0.32	0	0.00	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>735</b>	<b>0.33</b>	<b>0</b>	<b>2.02</b>	<b>0</b>	<b>1.43</b>	<b>0</b>	<b>1.50</b>	<b>11</b>	<b>0.77</b>
68	0	0.00	0	0.10	0	0.00	0	0.00	5	0.47
71	735	0.33	0	1.93	0	1.43	0	1.50	6	0.30
<b>DEVICES &amp; RAD H</b>	<b>1384</b>	<b>0.89</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>2.33</b>	<b>0</b>	<b>2.41</b>	<b>42</b>	<b>2.66</b>
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	1223	0.77	0	0.00	0	2.33	0	0.00	23	1.72
83	0	0.00	0	0.00	0	0.00	0	0.00	11	0.69
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	0	0.00	0	0.00	0	0.00	0	0.96	5	0.03
86	161	0.12	0	0.00	0	0.00	0	1.45	3	0.21
<b>TOBACCO PROD</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
96	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)  
Report Type: Complete

Report: FWF118C  
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Region: PA REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	434.84	450525.20
FOOD SAFETY/COS	287.80	306383.70
03	231.48	243340.90
04	26.05	28684.60
07	4.57	5107.00
09	5.04	5785.50
18	13.37	15898.00
21	5.84	6007.00
29	1.46	1560.70
BIOLOGICS	20.51	19484.30
41	7.70	7313.30
42	11.52	10947.40
45	1.29	1223.60
HUMAN DRUGS	51.09	49612.10
46	3.55	3370.00
48	14.52	13794.50
52	2.02	1922.20
53	1.77	1684.20
56	25.72	25442.00
63	3.50	3399.20
88	0.00	0.00
ANIMAL D & F	23.34	23517.70
68	1.08	1024.00
71	22.27	22493.70
DEVICES & RAD H	50.73	50068.40
81	0.25	242.00
82	34.11	33231.50
83	7.85	7454.50
84	0.00	0.00
85	2.36	2745.00
86	6.16	6395.40
TOBACCO PROD	1.37	1459.00
96	1.37	1459.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS  
Workplan 0 - 2012 (2012 WORKPLAN)

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TOTAL FIELD	1 DOMESTIC INSPECTIONS		2 INVESTIGATIONS		3 DOM SAMPL COLL		4 IMP SAMPL COLL		5 FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>GRAND TOTAL</b>	<b>18181</b>	<b>774.41</b>	<b>0</b>	<b>291.91</b>	<b>13575</b>	<b>79.90</b>	<b>28137</b>	<b>76.77</b>	<b>4485</b>	<b>4.51</b>
<b>FOOD SAFETY/COS</b>	<b>8443</b>	<b>332.81</b>	<b>0</b>	<b>167.85</b>	<b>7756</b>	<b>52.63</b>	<b>25639</b>	<b>70.11</b>	<b>3945</b>	<b>2.63</b>
03	8343	331.03	0	166.96	3189	33.22	16430	45.77	1520	1.60
04	0	0.00	0	0.00	2721	11.45	5609	14.76	25	0.02
07	0	0.00	0	0.00	832	3.50	832	1.75	0	0.00
09	0	0.00	0	0.00	0	0.00	1175	1.73	0	0.00
18	0	0.00	0	0.90	200	0.84	0	0.00	0	0.00
21	0	0.00	0	0.00	754	3.34	1363	5.74	2400	1.01
29	100	1.79	0	0.00	60	0.28	230	0.36	0	0.00
<b>BIOLOGICS</b>	<b>2084</b>	<b>114.53</b>	<b>0</b>	<b>7.71</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	653	36.02	0	0.00	0	0.00	0	0.00	0	0.00
42	1347	68.30	0	7.18	0	0.00	0	0.00	0	0.00
45	84	10.21	0	0.53	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>2644</b>	<b>143.01</b>	<b>0</b>	<b>49.00</b>	<b>1119</b>	<b>6.18</b>	<b>353</b>	<b>1.05</b>	<b>0</b>	<b>0.00</b>
46	197	9.82	0	0.00	17	0.11	0	0.00	0	0.00
48	453	40.99	0	15.60	0	0.00	0	0.00	0	0.00
52	153	5.05	0	0.15	41	0.26	151	0.48	0	0.00
53	147	10.03	0	0.00	0	0.00	0	0.00	0	0.00
56	1510	70.74	0	31.67	787	4.26	202	0.58	0	0.00
63	184	6.38	0	1.58	274	1.56	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>2095</b>	<b>46.76</b>	<b>0</b>	<b>11.09</b>	<b>4463</b>	<b>19.54</b>	<b>750</b>	<b>1.97</b>	<b>0</b>	<b>0.00</b>
68	79	4.88	0	0.00	0	0.00	0	0.00	0	0.00
71	2016	41.88	0	11.09	4463	19.54	750	1.97	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>2855</b>	<b>134.76</b>	<b>0</b>	<b>46.89</b>	<b>117</b>	<b>0.80</b>	<b>1335</b>	<b>3.25</b>	<b>480</b>	<b>1.75</b>
81	40	0.84	0	0.06	3	0.03	0	0.00	0	0.00
82	1602	92.89	0	31.87	109	0.75	1310	3.10	0	0.00
83	416	31.11	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	592	4.13	0	4.98	0	0.00	0	0.00	0	0.00
86	205	5.79	0	9.97	5	0.02	25	0.15	480	1.75
<b>TOBACCO PROD</b>	<b>60</b>	<b>2.53</b>	<b>0</b>	<b>9.38</b>	<b>120</b>	<b>0.76</b>	<b>60</b>	<b>0.38</b>	<b>60</b>	<b>0.13</b>
96	60	2.53	0	9.38	120	0.76	60	0.38	60	0.13

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WORKPLAN SUMMARY / COMBINED OPERATIONS  
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TOTAL FIELD	6 IMPORT FIELD EXAMS		7 DOM SAMPL ANALYSIS		8 IMP SAMPL ANALYSIS		9 MISC		10 FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>GRAND TOTAL</b>	<b>200293</b>	<b>109.96</b>	<b>25</b>	<b>318.36</b>	<b>0</b>	<b>242.12</b>	<b>1308</b>	<b>142.70</b>	<b>3047</b>	<b>175.30</b>
<b>FOOD SAFETY/COS</b>	<b>176158</b>	<b>92.72</b>	<b>0</b>	<b>212.09</b>	<b>0</b>	<b>218.00</b>	<b>1308</b>	<b>99.19</b>	<b>1200</b>	<b>44.21</b>
03	152139	80.07	0	120.22	0	149.49	0	25.49	1200	44.21
04	6406	3.37	0	61.84	0	47.62	0	7.00	0	0.00
07	0	0.00	0	4.23	0	4.94	0	4.51	0	0.00
09	4804	2.53	0	0.00	0	8.96	0	0.00	0	0.00
18	0	0.00	0	1.42	0	0.00	1308	60.69	0	0.00
21	11209	5.90	0	23.47	0	3.88	0	1.50	0	0.00
29	1600	0.84	0	0.92	0	3.12	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>2.50</b>	<b>40</b>	<b>6.35</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	2.50	26	3.36
45	0	0.00	0	0.00	0	0.00	0	0.00	14	2.98
<b>HUMAN DRUGS</b>	<b>6200</b>	<b>6.53</b>	<b>0</b>	<b>65.79</b>	<b>0</b>	<b>5.75</b>	<b>0</b>	<b>3.95</b>	<b>1229</b>	<b>86.44</b>
46	0	0.00	0	6.85	0	0.00	0	0.00	133	8.23
48	0	0.00	0	0.00	0	0.00	0	0.00	231	21.23
52	0	0.00	0	3.42	0	2.07	0	0.00	62	4.01
53	0	0.00	0	0.00	0	0.00	0	0.00	15	1.03
56	6200	6.53	0	39.69	0	3.68	0	3.95	788	51.94
63	0	0.00	0	3.84	0	0.00	0	0.00	0	0.00
88	0	0.00	0	12.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>3600</b>	<b>1.62</b>	<b>0</b>	<b>29.95</b>	<b>0</b>	<b>5.35</b>	<b>0</b>	<b>9.77</b>	<b>85</b>	<b>6.15</b>
68	0	0.00	0	0.90	0	0.00	0	0.00	45	4.16
71	3600	1.62	0	29.05	0	5.35	0	9.77	40	2.00
<b>DEVICES &amp; RAD H</b>	<b>14335</b>	<b>9.10</b>	<b>25</b>	<b>9.53</b>	<b>0</b>	<b>12.52</b>	<b>0</b>	<b>23.29</b>	<b>493</b>	<b>32.16</b>
81	0	0.00	0	0.08	0	0.00	0	0.00	0	0.00
82	13935	8.80	0	5.40	0	11.67	0	4.84	380	25.96
83	0	0.00	0	0.00	0	0.00	0	0.00	83	5.07
84	0	0.00	0	0.00	0	0.00	0	5.72	0	0.00
85	0	0.00	0	0.00	0	0.00	0	5.38	15	0.10
86	400	0.30	25	4.05	0	0.85	0	7.35	15	1.03
<b>TOBACCO PROD</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>1.00</b>	<b>0</b>	<b>0.50</b>	<b>0</b>	<b>4.00</b>	<b>0</b>	<b>0.00</b>
96	0	0.00	0	1.00	0	0.50	0	4.00	0	0.00

TOTAL FIELD

	Total	
	OPR FTE'S	PERSNHRS
GRAND TOTAL	2215.94	2291373.80
FOOD SAFETY/COS	1292.23	1366692.30
03	998.04	1031775.50
04	146.05	165886.50
07	18.93	21141.00
09	13.22	14622.00
18	63.85	76162.00
21	44.83	49236.30
29	7.31	7869.00
BIOLOGICS	131.09	124529.10
41	36.02	34219.40
42	81.34	77276.80
45	13.72	13032.90
HUMAN DRUGS	367.70	364599.00
46	25.01	23838.30
48	77.83	73932.40
52	15.43	15392.60
53	11.05	10498.50
56	213.02	213203.60
63	13.36	13573.60
88	12.00	14160.00
ANIMAL D & F	132.21	136301.50
68	9.93	9438.00
71	122.28	126863.50
DEVICES & RAD H	274.04	279108.90
81	1.02	983.90
82	185.29	186545.70
83	36.17	34365.30
84	5.72	6750.00
85	14.60	16973.00
86	31.24	33491.00
TOBACCO PROD	18.67	20143.00
96	18.67	20143.00

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# **POSITION CLASS**

**SEPARATE LAB RESOURCES**

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Output Reflects: OPR FTE'S (Complete)

REGION: NE REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
REGION TOTAL	218.66	60.16	56.98	20.36	3.95	2.00	362.11	384797.40
FOOD SAFETY/COS	120.67	43.99	51.43	0.00	1.66	0.00	217.75	234695.80
03	96.20	18.58	50.41	0.00	1.08	0.00	166.27	177062.60
04	7.55	16.22	0.00	0.00	0.50	0.00	24.27	26913.50
07	0.82	2.58	0.00	0.00	0.08	0.00	3.48	3924.00
09	1.26	2.91	0.00	0.00	0.00	0.00	4.17	4630.30
18	10.24	0.02	0.12	0.00	0.00	0.00	10.38	12393.00
21	3.72	3.00	0.00	0.00	0.00	0.00	6.72	7075.70
29	0.89	0.68	0.90	0.00	0.00	0.00	2.46	2696.70
BIOLOGICS	10.43	0.00	0.00	0.00	0.00	0.00	10.43	9908.60
41	3.32	0.00	0.00	0.00	0.00	0.00	3.32	3157.90
42	6.32	0.00	0.00	0.00	0.00	0.00	6.32	5999.90
45	0.79	0.00	0.00	0.00	0.00	0.00	0.79	750.80
HUMAN DRUGS	40.74	12.60	0.97	0.00	0.00	0.00	54.31	54587.50
46	2.77	1.00	0.00	0.00	0.00	0.00	3.77	3580.60
48	8.53	0.00	0.00	0.00	0.00	0.00	8.53	8101.40
52	1.35	3.56	0.00	0.00	0.00	0.00	4.90	5384.60
53	1.78	0.00	0.00	0.00	0.00	0.00	1.78	1688.70
56	25.06	7.25	0.97	0.00	0.00	0.00	33.28	33697.60
63	1.26	0.80	0.00	0.00	0.00	0.00	2.05	2134.60
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	11.93	1.67	1.46	0.00	0.29	0.00	15.35	16109.70
68	0.94	0.08	0.00	0.00	0.00	0.00	1.01	963.00
71	11.00	1.59	1.46	0.00	0.29	0.00	14.34	15146.70
DEVICES & RAD H	30.97	1.90	3.13	20.36	2.00	2.00	60.35	65351.80
81	0.31	0.03	0.02	0.03	0.00	0.00	0.39	383.90
82	20.37	1.87	3.11	11.71	2.00	0.00	39.05	41910.40
83	4.85	0.00	0.00	0.00	0.00	0.00	4.85	4605.60
84	0.00	0.00	0.00	3.72	0.00	2.00	5.72	6750.00
85	1.93	0.00	0.00	0.00	0.00	0.00	1.93	2242.00
86	3.53	0.00	0.00	4.90	0.00	0.00	8.42	9459.90
TOBACCO PROD	3.92	0.00	0.00	0.00	0.00	0.00	3.92	4144.00
96	3.92	0.00	0.00	0.00	0.00	0.00	3.92	4144.00



















REGION: CE REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
<b>REGION TOTAL</b>	457.17	46.92	2.90	0.00	1.00	0.00	507.99	504507.70
<b>FOOD SAFETY/COS</b>	230.96	13.34	2.90	0.00	0.00	0.00	247.19	245356.00
03	201.58	0.25	2.90	0.00	0.00	0.00	204.73	197657.60
04	5.96	12.00	0.00	0.00	0.00	0.00	17.96	20117.50
07	1.75	0.00	0.00	0.00	0.00	0.00	1.75	1662.00
09	0.73	0.92	0.00	0.00	0.00	0.00	1.64	1770.00
18	16.63	0.00	0.00	0.00	0.00	0.00	16.63	19848.00
21	3.41	0.00	0.00	0.00	0.00	0.00	3.41	3235.30
29	0.90	0.18	0.00	0.00	0.00	0.00	1.08	1065.60
<b>BIOLOGICS</b>	38.16	0.00	0.00	0.00	0.00	0.00	38.16	36254.10
41	11.09	0.00	0.00	0.00	0.00	0.00	11.09	10535.80
42	24.69	0.00	0.00	0.00	0.00	0.00	24.69	23450.50
45	2.39	0.00	0.00	0.00	0.00	0.00	2.39	2267.80
<b>HUMAN DRUGS</b>	88.30	32.28	0.00	0.00	0.00	0.00	120.58	122270.30
46	6.57	1.81	0.00	0.00	0.00	0.00	8.38	8039.90
48	22.09	0.00	0.00	0.00	0.00	0.00	22.09	20980.90
52	3.71	0.45	0.00	0.00	0.00	0.00	4.16	3949.40
53	4.23	0.00	0.00	0.00	0.00	0.00	4.23	4015.20
56	50.27	19.57	0.00	0.00	0.00	0.00	69.84	71579.70
63	1.45	1.45	0.00	0.00	0.00	0.00	2.90	3085.20
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
<b>ANIMAL D &amp; F</b>	33.59	1.00	0.00	0.00	0.00	0.00	34.59	33541.90
68	3.33	0.00	0.00	0.00	0.00	0.00	3.33	3162.00
71	30.26	1.00	0.00	0.00	0.00	0.00	31.26	30379.90
<b>DEVICES &amp; RAD H</b>	63.04	0.30	0.00	0.00	0.00	0.00	63.34	62700.40
81	0.12	0.00	0.00	0.00	0.00	0.00	0.12	115.00
82	37.68	0.30	0.00	0.00	0.00	0.00	37.98	36562.40
83	11.95	0.00	0.00	0.00	0.00	0.00	11.95	11353.90
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	5.64	0.00	0.00	0.00	0.00	0.00	5.64	6555.00
86	7.65	0.00	0.00	0.00	0.00	0.00	7.65	8114.10
<b>TOBACCO PROD</b>	3.13	0.00	0.00	0.00	1.00	0.00	4.13	4385.00
96	3.13	0.00	0.00	0.00	1.00	0.00	4.13	4385.00













Output Reflects: OPR FTE'S (Complete)

REGION: SE REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	CHEM	MICRO	ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
<b>REGION TOTAL</b>	<b>243.81</b>	<b>62.23</b>	<b>42.42</b>	<b>0.00</b>	<b>4.46</b>	<b>3.00</b>	<b>355.91</b>	<b>368555.40</b>
<b>FOOD SAFETY/COS</b>	<b>111.10</b>	<b>39.70</b>	<b>39.13</b>	<b>0.00</b>	<b>1.17</b>	<b>3.00</b>	<b>194.10</b>	<b>207434.40</b>
03	92.87	6.90	36.56	0.00	0.42	0.00	136.75	140990.00
04	3.43	11.23	0.00	0.00	0.17	0.00	14.82	16708.50
07	0.54	2.18	0.00	0.00	0.09	3.00	5.80	6725.00
09	0.23	0.42	0.00	0.00	0.00	0.00	0.65	713.20
18	12.12	0.03	0.47	0.00	0.00	0.00	12.62	15036.00
21	1.44	18.82	1.53	0.00	0.50	0.00	22.29	25984.30
29	0.47	0.12	0.58	0.00	0.00	0.00	1.17	1277.40
<b>BIOLOGICS</b>	<b>24.83</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>24.83</b>	<b>23591.60</b>
41	6.84	0.00	0.00	0.00	0.00	0.00	6.84	6495.40
42	16.71	0.00	0.00	0.00	0.00	0.00	16.71	15872.60
45	1.29	0.00	0.00	0.00	0.00	0.00	1.29	1223.60
<b>HUMAN DRUGS</b>	<b>59.55</b>	<b>15.31</b>	<b>0.86</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>75.71</b>	<b>74834.40</b>
46	3.38	1.53	0.00	0.00	0.00	0.00	4.91	4661.60
48	15.76	0.00	0.00	0.00	0.00	0.00	15.76	14972.80
52	1.52	0.71	0.00	0.00	0.00	0.00	2.23	2122.10
53	2.11	0.00	0.00	0.00	0.00	0.00	2.11	2008.20
56	33.73	8.80	0.86	0.00	0.00	0.00	43.39	43141.00
63	3.04	1.28	0.00	0.00	0.00	0.00	4.31	4388.70
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
<b>ANIMAL D &amp; F</b>	<b>9.38</b>	<b>5.72</b>	<b>2.42</b>	<b>0.00</b>	<b>0.29</b>	<b>0.00</b>	<b>17.82</b>	<b>18800.60</b>
68	2.01	0.15	0.00	0.00	0.00	0.00	2.15	2048.00
71	7.38	5.57	2.42	0.00	0.29	0.00	15.66	16752.60
<b>DEVICES &amp; RAD II</b>	<b>35.29</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>35.29</b>	<b>34854.40</b>
81	0.11	0.00	0.00	0.00	0.00	0.00	0.11	103.00
82	22.37	0.00	0.00	0.00	0.00	0.00	22.37	21673.20
83	5.94	0.00	0.00	0.00	0.00	0.00	5.94	5644.80
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.64	0.00	0.00	0.00	0.00	0.00	2.64	3074.00
86	4.23	0.00	0.00	0.00	0.00	0.00	4.23	4359.40
<b>TOBACCO PROD</b>	<b>3.66</b>	<b>1.50</b>	<b>0.00</b>	<b>0.00</b>	<b>3.00</b>	<b>0.00</b>	<b>8.17</b>	<b>9040.00</b>
96	3.66	1.50	0.00	0.00	3.00	0.00	8.17	9040.00













REGION: SW REGN

	1	2	3	4	5	6			
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRS	
<b>REGION TOTAL</b>	<b>289.44</b>	<b>101.89</b>	<b>55.14</b>	<b>0.00</b>	<b>1.25</b>	<b>8.50</b>	<b>456.22</b>	<b>482288.60</b>	
<b>FOOD SAFETY/COS</b>	<b>160.85</b>	<b>79.53</b>	<b>51.22</b>	<b>0.00</b>	<b>1.00</b>	<b>5.00</b>	<b>297.61</b>	<b>320670.40</b>	
03	140.55	20.09	50.43	0.00	0.00	0.00	211.07	220604.40	
04	3.70	53.51	0.00	0.00	0.76	5.00	62.96	73462.40	
07	0.91	2.17	0.00	0.00	0.25	0.00	3.33	3723.00	
09	1.36	0.37	0.00	0.00	0.00	0.00	1.73	1723.00	
18	10.47	0.10	0.28	0.00	0.00	0.00	10.85	12987.00	
21	3.54	3.00	0.00	0.00	0.00	0.00	6.54	6902.00	
29	0.32	0.30	0.52	0.00	0.00	0.00	1.14	1268.60	
<b>BIOLOGICS</b>	<b>22.39</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>22.39</b>	<b>21274.10</b>	
41	7.07	0.00	0.00	0.00	0.00	0.00	7.07	6717.00	
42	13.55	0.00	0.00	0.00	0.00	0.00	13.55	12869.50	
45	1.78	0.00	0.00	0.00	0.00	0.00	1.78	1687.60	
<b>HUMAN DRUGS</b>	<b>39.42</b>	<b>5.31</b>	<b>0.49</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>45.21</b>	<b>43528.10</b>	
46	2.12	1.61	0.00	0.00	0.00	0.00	3.73	3539.40	
48	14.27	0.00	0.00	0.00	0.00	0.00	14.27	13553.60	
52	1.11	0.39	0.00	0.00	0.00	0.00	1.51	1431.10	
53	1.16	0.00	0.00	0.00	0.00	0.00	1.16	1102.20	
56	20.16	3.30	0.49	0.00	0.00	0.00	23.96	23335.90	
63	0.60	0.00	0.00	0.00	0.00	0.00	0.60	565.90	
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
<b>ANIMAL D &amp; F</b>	<b>17.49</b>	<b>16.99</b>	<b>2.90</b>	<b>0.00</b>	<b>0.25</b>	<b>3.50</b>	<b>41.12</b>	<b>44331.60</b>	
68	1.79	0.57	0.00	0.00	0.00	0.00	2.36	2241.00	
71	15.70	16.42	2.90	0.00	0.25	3.50	38.76	42090.60	
<b>DEVICES &amp; RAD H</b>	<b>48.20</b>	<b>0.06</b>	<b>0.53</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>48.79</b>	<b>51369.40</b>	
81	0.15	0.00	0.00	0.00	0.00	0.00	0.15	140.00	
82	36.20	0.06	0.53	0.00	0.00	0.00	36.79	38924.20	
83	5.04	0.00	0.00	0.00	0.00	0.00	5.04	4786.00	
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
85	2.03	0.00	0.00	0.00	0.00	0.00	2.03	2357.00	
86	4.79	0.00	0.00	0.00	0.00	0.00	4.79	5162.20	
<b>TOBACCO PROD</b>	<b>1.09</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>1.09</b>	<b>1115.00</b>	
96	1.09	0.00	0.00	0.00	0.00	0.00	1.09	1115.00	













Output Reflects: OPR FTE'S (Complete)

REGION: PA REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
<b>REGION TOTAL</b>	299.67	55.52	70.80	0.00	2.33	6.51	434.83	450525.20
<b>FOOD SAFETY/COS</b>	166.77	44.47	68.38	0.00	2.16	6.01	287.79	306383.70
03	138.38	20.05	67.55	0.00	1.50	4.00	231.48	243340.90
04	8.97	16.49	0.00	0.00	0.58	0.00	26.04	28684.60
07	1.24	2.24	0.00	0.00	0.08	1.01	4.57	5107.00
09	0.69	4.35	0.00	0.00	0.00	0.00	5.04	5785.50
18	12.97	0.05	0.35	0.00	0.00	0.00	13.37	15898.00
21	3.84	1.00	0.00	0.00	0.00	1.00	5.84	6007.00
29	0.69	0.29	0.48	0.00	0.00	0.00	1.46	1560.70
<b>BIOLOGICS</b>	20.51	0.00	0.00	0.00	0.00	0.00	20.51	19484.30
41	7.70	0.00	0.00	0.00	0.00	0.00	7.70	7313.30
42	11.52	0.00	0.00	0.00	0.00	0.00	11.52	10947.40
45	1.29	0.00	0.00	0.00	0.00	0.00	1.29	1223.60
<b>HUMAN DRUGS</b>	43.40	6.82	0.86	0.00	0.00	0.00	51.09	49612.10
46	2.64	0.90	0.00	0.00	0.00	0.00	3.55	3370.00
48	14.52	0.00	0.00	0.00	0.00	0.00	14.52	13794.50
52	1.64	0.38	0.00	0.00	0.00	0.00	2.02	1922.20
53	1.77	0.00	0.00	0.00	0.00	0.00	1.77	1684.20
56	19.64	5.22	0.86	0.00	0.00	0.00	25.72	25442.00
63	3.18	0.32	0.00	0.00	0.00	0.00	3.50	3399.20
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>ANIMAL D &amp; F</b>	19.22	1.89	1.56	0.00	0.17	0.50	23.34	23517.70
68	0.98	0.10	0.00	0.00	0.00	0.00	1.08	1024.00
71	18.24	1.80	1.56	0.00	0.17	0.50	22.27	22493.70
<b>DEVICES &amp; RAD H</b>	48.39	2.33	0.00	0.00	0.00	0.00	50.72	50068.40
81	0.25	0.00	0.00	0.00	0.00	0.00	0.25	242.00
82	31.77	2.33	0.00	0.00	0.00	0.00	34.10	33231.50
83	7.85	0.00	0.00	0.00	0.00	0.00	7.85	7454.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.36	0.00	0.00	0.00	0.00	0.00	2.36	2745.00
86	6.16	0.00	0.00	0.00	0.00	0.00	6.16	6395.40
<b>TOBACCO PROD</b>	1.37	0.00	0.00	0.00	0.00	0.00	1.37	1459.00
96	1.37	0.00	0.00	0.00	0.00	0.00	1.37	1459.00

TOTAL FIELD

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNIHRS
<b>GRAND TOTAL</b>	<b>1607.65</b>	<b>326.71</b>	<b>228.24</b>	<b>20.36</b>	<b>13.00</b>	<b>20.01</b>	<b>2215.95</b>	<b>2291373.80</b>
<b>FOOD SAFETY/COS</b>	<b>838.13</b>	<b>221.03</b>	<b>213.07</b>	<b>0.00</b>	<b>6.00</b>	<b>14.01</b>	<b>1292.23</b>	<b>1366692.30</b>
03	717.34	65.86	207.85	0.00	3.00	4.00	998.04	1031775.50
04	29.60	109.46	0.00	0.00	2.00	5.00	146.05	165886.50
07	5.25	9.17	0.00	0.00	0.50	4.01	18.93	21141.00
09	4.26	8.96	0.00	0.00	0.00	0.00	13.22	14622.00
18	62.43	0.20	1.22	0.00	0.00	0.00	63.85	76162.00
21	15.98	25.82	1.53	0.00	0.50	1.00	44.83	49236.30
29	3.27	1.56	2.48	0.00	0.00	0.00	7.31	7869.00
<b>BIOLOGICS</b>	<b>131.09</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>131.09</b>	<b>124529.10</b>
41	36.02	0.00	0.00	0.00	0.00	0.00	36.02	34219.40
42	81.34	0.00	0.00	0.00	0.00	0.00	81.34	77276.80
45	13.72	0.00	0.00	0.00	0.00	0.00	13.72	13032.90
<b>HUMAN DRUGS</b>	<b>292.22</b>	<b>72.32</b>	<b>3.18</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>367.71</b>	<b>364599.00</b>
46	18.16	6.85	0.00	0.00	0.00	0.00	25.01	23838.30
48	77.82	0.00	0.00	0.00	0.00	0.00	77.82	73932.40
52	9.95	5.49	0.00	0.00	0.00	0.00	15.44	15392.60
53	11.05	0.00	0.00	0.00	0.00	0.00	11.05	10498.50
56	165.71	44.14	3.18	0.00	0.00	0.00	213.03	213203.60
63	9.52	3.84	0.00	0.00	0.00	0.00	13.36	13573.60
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
<b>ANIMAL D &amp; F</b>	<b>91.61</b>	<b>27.27</b>	<b>8.34</b>	<b>0.00</b>	<b>1.00</b>	<b>4.00</b>	<b>132.22</b>	<b>136301.50</b>
68	9.04	0.90	0.00	0.00	0.00	0.00	9.93	9438.00
71	82.57	26.37	8.34	0.00	1.00	4.00	122.28	126863.50
<b>DEVICES &amp; RAD H</b>	<b>241.43</b>	<b>4.59</b>	<b>3.65</b>	<b>20.36</b>	<b>2.00</b>	<b>2.00</b>	<b>274.03</b>	<b>279108.90</b>
81	0.94	0.03	0.02	0.03	0.00	0.00	1.02	983.90
82	163.37	4.56	3.64	11.71	2.00	0.00	185.28	186545.70
83	36.17	0.00	0.00	0.00	0.00	0.00	36.17	34365.30
84	0.00	0.00	0.00	3.72	0.00	2.00	5.72	6750.00
85	14.60	0.00	0.00	0.00	0.00	0.00	14.60	16973.00
86	26.35	0.00	0.00	4.90	0.00	0.00	31.24	33491.00
<b>TOBACCO PROD</b>	<b>13.17</b>	<b>1.50</b>	<b>0.00</b>	<b>0.00</b>	<b>4.00</b>	<b>0.00</b>	<b>18.67</b>	<b>20143.00</b>
96	13.17	1.50	0.00	0.00	4.00	0.00	18.67	20143.00

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**POSITION CLASS**  
**COMBINED ANALYTICAL & DISTRICT RESOURCES**

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REGION: NE REGN

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRs
<b>REGION TOTAL</b>	<b>218.67</b>	<b>62.03</b>	<b>59.05</b>	<b>20.35</b>	<b>2.00</b>	<b>362.10</b>	<b>384797.40</b>
<b>FOOD SAFETY/COS</b>	<b>120.69</b>	<b>44.57</b>	<b>52.49</b>	<b>0.00</b>	<b>0.00</b>	<b>217.75</b>	<b>234695.80</b>
03	96.21	18.57	51.48	0.00	0.00	166.26	177062.60
04	7.55	16.72	0.00	0.00	0.00	24.27	26913.50
07	0.82	2.67	0.00	0.00	0.00	3.49	3924.00
09	1.26	2.91	0.00	0.00	0.00	4.17	4630.30
18	10.24	0.02	0.12	0.00	0.00	10.38	12393.00
21	3.72	3.00	0.00	0.00	0.00	6.72	7075.70
29	0.89	0.68	0.89	0.00	0.00	2.46	2696.70
<b>BIOLOGICS</b>	<b>10.42</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>10.42</b>	<b>9908.60</b>
41	3.32	0.00	0.00	0.00	0.00	3.32	3157.90
42	6.31	0.00	0.00	0.00	0.00	6.31	5999.90
45	0.79	0.00	0.00	0.00	0.00	0.79	750.80
<b>HUMAN DRUGS</b>	<b>40.73</b>	<b>12.60</b>	<b>0.97</b>	<b>0.00</b>	<b>0.00</b>	<b>54.30</b>	<b>54587.50</b>
46	2.77	1.00	0.00	0.00	0.00	3.77	3580.60
48	8.53	0.00	0.00	0.00	0.00	8.53	8101.40
52	1.34	3.55	0.00	0.00	0.00	4.89	5384.60
53	1.78	0.00	0.00	0.00	0.00	1.78	1688.70
56	25.06	7.25	0.97	0.00	0.00	33.28	33697.60
63	1.25	0.80	0.00	0.00	0.00	2.05	2134.60
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>ANIMAL D &amp; F</b>	<b>11.94</b>	<b>1.96</b>	<b>1.46</b>	<b>0.00</b>	<b>0.00</b>	<b>15.36</b>	<b>16109.70</b>
68	0.94	0.08	0.00	0.00	0.00	1.02	963.00
71	11.00	1.88	1.46	0.00	0.00	14.34	15146.70
<b>DEVICES &amp; RAD H</b>	<b>30.97</b>	<b>2.90</b>	<b>4.13</b>	<b>20.35</b>	<b>2.00</b>	<b>60.35</b>	<b>65351.80</b>
81	0.31	0.03	0.02	0.03	0.00	0.39	383.90
82	20.36	2.87	4.11	11.71	0.00	39.05	41910.40
83	4.85	0.00	0.00	0.00	0.00	4.85	4605.60
84	0.00	0.00	0.00	3.72	2.00	5.72	6750.00
85	1.93	0.00	0.00	0.00	0.00	1.93	2242.00
86	3.52	0.00	0.00	4.89	0.00	8.41	9459.90
<b>TOBACCO PROD</b>	<b>3.92</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>3.92</b>	<b>4144.00</b>
96	3.92	0.00	0.00	0.00	0.00	3.92	4144.00



















REGION: CE REGN

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRs
<b>REGION TOTAL</b>	<b>457.17</b>	<b>47.92</b>	<b>2.90</b>	<b>0.00</b>	<b>0.00</b>	<b>507.99</b>	<b>504507.70</b>
<b>FOOD SAFETY/COS</b>	<b>230.98</b>	<b>13.34</b>	<b>2.90</b>	<b>0.00</b>	<b>0.00</b>	<b>247.22</b>	<b>245356.00</b>
03	201.60	0.24	2.90	0.00	0.00	204.74	197657.60
04	5.95	12.00	0.00	0.00	0.00	17.95	20117.50
07	1.75	0.00	0.00	0.00	0.00	1.75	1662.00
09	0.72	0.92	0.00	0.00	0.00	1.64	1770.00
18	16.65	0.00	0.00	0.00	0.00	16.65	19848.00
21	3.41	0.00	0.00	0.00	0.00	3.41	3235.30
29	0.90	0.18	0.00	0.00	0.00	1.08	1065.60
<b>BIOLOGICS</b>	<b>38.18</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>38.18</b>	<b>36254.10</b>
41	11.09	0.00	0.00	0.00	0.00	11.09	10535.80
42	24.70	0.00	0.00	0.00	0.00	24.70	23450.50
45	2.39	0.00	0.00	0.00	0.00	2.39	2267.80
<b>HUMAN DRUGS</b>	<b>88.30</b>	<b>32.28</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>120.58</b>	<b>122270.30</b>
46	6.56	1.82	0.00	0.00	0.00	8.38	8039.90
48	22.09	0.00	0.00	0.00	0.00	22.09	20980.90
52	3.72	0.45	0.00	0.00	0.00	4.17	3949.40
53	4.23	0.00	0.00	0.00	0.00	4.23	4015.20
56	50.26	19.56	0.00	0.00	0.00	69.82	71579.70
63	1.44	1.45	0.00	0.00	0.00	2.89	3085.20
88	0.00	9.00	0.00	0.00	0.00	9.00	10620.00
<b>ANIMAL D &amp; F</b>	<b>33.59</b>	<b>1.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>34.59</b>	<b>33541.90</b>
68	3.33	0.00	0.00	0.00	0.00	3.33	3162.00
71	30.26	1.00	0.00	0.00	0.00	31.26	30379.90
<b>DEVICES &amp; RAD H</b>	<b>63.00</b>	<b>0.30</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>63.30</b>	<b>62700.40</b>
81	0.12	0.00	0.00	0.00	0.00	0.12	115.00
82	37.67	0.30	0.00	0.00	0.00	37.97	36562.40
83	11.95	0.00	0.00	0.00	0.00	11.95	11353.90
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	5.63	0.00	0.00	0.00	0.00	5.63	6555.00
86	7.63	0.00	0.00	0.00	0.00	7.63	8114.10
<b>TOBACCO PROD</b>	<b>3.12</b>	<b>1.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>4.12</b>	<b>4385.00</b>
96	3.12	1.00	0.00	0.00	0.00	4.12	4385.00













Date: 13-SEP-2011  
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Workplan Summary / Position Class (Combined Anal & District Resources)  
 Workplan 0 - 2012 (2012 WORKPLAN)  
 Output Reflects: OPR FTE'S (Complete)

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REGION: SE REGN

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRs
<b>REGION TOTAL</b>	<b>243.88</b>	<b>66.26</b>	<b>42.84</b>	<b>0.00</b>	<b>3.00</b>	<b>355.98</b>	<b>368555.40</b>
<b>FOOD SAFETY/COS</b>	<b>111.14</b>	<b>40.45</b>	<b>39.56</b>	<b>0.00</b>	<b>3.00</b>	<b>194.15</b>	<b>207434.40</b>
03	92.88	6.90	36.98	0.00	0.00	136.76	140990.00
04	3.43	11.40	0.00	0.00	0.00	14.83	16708.50
07	0.55	2.26	0.00	0.00	3.00	5.81	6725.00
09	0.24	0.42	0.00	0.00	0.00	0.66	713.20
18	12.12	0.03	0.47	0.00	0.00	12.62	15036.00
21	1.45	19.32	1.53	0.00	0.00	22.30	25984.30
29	0.47	0.12	0.58	0.00	0.00	1.17	1277.40
<b>BIOLOGICS</b>	<b>24.83</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>24.83</b>	<b>23591.60</b>
41	6.84	0.00	0.00	0.00	0.00	6.84	6495.40
42	16.70	0.00	0.00	0.00	0.00	16.70	15872.60
45	1.29	0.00	0.00	0.00	0.00	1.29	1223.60
<b>HUMAN DRUGS</b>	<b>59.56</b>	<b>15.30</b>	<b>0.86</b>	<b>0.00</b>	<b>0.00</b>	<b>75.72</b>	<b>74834.40</b>
46	3.38	1.52	0.00	0.00	0.00	4.90	4661.60
48	15.76	0.00	0.00	0.00	0.00	15.76	14972.80
52	1.53	0.70	0.00	0.00	0.00	2.23	2122.10
53	2.12	0.00	0.00	0.00	0.00	2.12	2008.20
56	33.73	8.80	0.86	0.00	0.00	43.39	43141.00
63	3.04	1.28	0.00	0.00	0.00	4.32	4388.70
88	0.00	3.00	0.00	0.00	0.00	3.00	3540.00
<b>ANIMAL D &amp; F</b>	<b>9.39</b>	<b>6.01</b>	<b>2.42</b>	<b>0.00</b>	<b>0.00</b>	<b>17.82</b>	<b>18800.60</b>
68	2.01	0.15	0.00	0.00	0.00	2.16	2048.00
71	7.38	5.86	2.42	0.00	0.00	15.66	16752.60
<b>DEVICES &amp; RAD H</b>	<b>35.30</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>35.30</b>	<b>34854.40</b>
81	0.11	0.00	0.00	0.00	0.00	0.11	103.00
82	22.37	0.00	0.00	0.00	0.00	22.37	21673.20
83	5.94	0.00	0.00	0.00	0.00	5.94	5644.80
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.64	0.00	0.00	0.00	0.00	2.64	3074.00
86	4.24	0.00	0.00	0.00	0.00	4.24	4359.40
<b>TOBACCO PROD</b>	<b>3.66</b>	<b>4.50</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>8.16</b>	<b>9040.00</b>
96	3.66	4.50	0.00	0.00	0.00	8.16	9040.00













REGION: SW REGN

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRs
<b>REGION TOTAL</b>	<b>289.46</b>	<b>103.15</b>	<b>55.15</b>	<b>0.00</b>	<b>8.50</b>	<b>456.26</b>	<b>482288.60</b>
<b>FOOD SAFETY/COS</b>	<b>160.88</b>	<b>80.54</b>	<b>51.23</b>	<b>0.00</b>	<b>5.00</b>	<b>297.65</b>	<b>320670.40</b>
03	140.56	20.09	50.43	0.00	0.00	211.08	220604.40
04	3.70	54.27	0.00	0.00	5.00	62.97	73462.40
07	0.91	2.41	0.00	0.00	0.00	3.32	3723.00
09	1.36	0.37	0.00	0.00	0.00	1.73	1723.00
18	10.49	0.10	0.28	0.00	0.00	10.87	12987.00
21	3.54	3.00	0.00	0.00	0.00	6.54	6902.00
29	0.32	0.30	0.52	0.00	0.00	1.14	1268.60
<b>BIOLOGICS</b>	<b>22.40</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>22.40</b>	<b>21274.10</b>
41	7.07	0.00	0.00	0.00	0.00	7.07	6717.00
42	13.56	0.00	0.00	0.00	0.00	13.56	12869.50
45	1.77	0.00	0.00	0.00	0.00	1.77	1687.60
<b>HUMAN DRUGS</b>	<b>39.41</b>	<b>5.32</b>	<b>0.49</b>	<b>0.00</b>	<b>0.00</b>	<b>45.22</b>	<b>43528.10</b>
46	2.11	1.61	0.00	0.00	0.00	3.72	3539.40
48	14.27	0.00	0.00	0.00	0.00	14.27	13553.60
52	1.11	0.40	0.00	0.00	0.00	1.51	1431.10
53	1.16	0.00	0.00	0.00	0.00	1.16	1102.20
56	20.17	3.31	0.49	0.00	0.00	23.97	23335.90
63	0.59	0.00	0.00	0.00	0.00	0.59	565.90
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>ANIMAL D &amp; F</b>	<b>17.49</b>	<b>17.23</b>	<b>2.90</b>	<b>0.00</b>	<b>3.50</b>	<b>41.12</b>	<b>44331.60</b>
68	1.79	0.57	0.00	0.00	0.00	2.36	2241.00
71	15.70	16.66	2.90	0.00	3.50	38.76	42090.60
<b>DEVICES &amp; RAD H</b>	<b>48.20</b>	<b>0.06</b>	<b>0.53</b>	<b>0.00</b>	<b>0.00</b>	<b>48.79</b>	<b>51369.40</b>
81	0.14	0.00	0.00	0.00	0.00	0.14	140.00
82	36.20	0.06	0.53	0.00	0.00	36.79	38924.20
83	5.04	0.00	0.00	0.00	0.00	5.04	4786.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.03	0.00	0.00	0.00	0.00	2.03	2357.00
86	4.79	0.00	0.00	0.00	0.00	4.79	5162.20
<b>TOBACCO PROD</b>	<b>1.08</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>1.08</b>	<b>1115.00</b>
96	1.08	0.00	0.00	0.00	0.00	1.08	1115.00













Date: 13-SEP-2011  
 Time: 10:20:21 AM

Workplan Summary / Position Class (Combined Anal & District Resources)  
 Workplan 0 - 2012 (2012 WORKPLAN)  
 Output Reflects: OPR FTE'S (Complete)

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REGION: PA REGN

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRS
<b>REGION TOTAL</b>	<b>299.68</b>	<b>56.34</b>	<b>72.28</b>	<b>0.00</b>	<b>6.51</b>	<b>434.81</b>	<b>450525.20</b>
<b>FOOD SAFETY/COS</b>	<b>166.76</b>	<b>45.12</b>	<b>69.87</b>	<b>0.00</b>	<b>6.01</b>	<b>287.76</b>	<b>306383.70</b>
03	138.38	20.05	69.04	0.00	4.00	231.47	243340.90
04	8.97	17.07	0.00	0.00	0.00	26.04	28684.60
07	1.24	2.32	0.00	0.00	1.01	4.57	5107.00
09	0.69	4.35	0.00	0.00	0.00	5.04	5785.50
18	12.96	0.05	0.35	0.00	0.00	13.36	15898.00
21	3.83	1.00	0.00	0.00	1.00	5.83	6007.00
29	0.69	0.28	0.48	0.00	0.00	1.45	1560.70
<b>BIOLOGICS</b>	<b>20.51</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>20.51</b>	<b>19484.30</b>
41	7.70	0.00	0.00	0.00	0.00	7.70	7313.30
42	11.52	0.00	0.00	0.00	0.00	11.52	10947.40
45	1.29	0.00	0.00	0.00	0.00	1.29	1223.60
<b>HUMAN DRUGS</b>	<b>43.41</b>	<b>6.83</b>	<b>0.86</b>	<b>0.00</b>	<b>0.00</b>	<b>51.10</b>	<b>49612.10</b>
46	2.65	0.90	0.00	0.00	0.00	3.55	3370.00
48	14.52	0.00	0.00	0.00	0.00	14.52	13794.50
52	1.64	0.38	0.00	0.00	0.00	2.02	1922.20
53	1.78	0.00	0.00	0.00	0.00	1.78	1684.20
56	19.64	5.23	0.86	0.00	0.00	25.73	25442.00
63	3.18	0.32	0.00	0.00	0.00	3.50	3399.20
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>ANIMAL D &amp; F</b>	<b>19.23</b>	<b>2.06</b>	<b>1.55</b>	<b>0.00</b>	<b>0.50</b>	<b>23.34</b>	<b>23517.70</b>
68	0.98	0.09	0.00	0.00	0.00	1.07	1024.00
71	18.25	1.97	1.55	0.00	0.50	22.27	22493.70
<b>DEVICES &amp; RAD H</b>	<b>48.40</b>	<b>2.33</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>50.73</b>	<b>50068.40</b>
81	0.26	0.00	0.00	0.00	0.00	0.26	242.00
82	31.76	2.33	0.00	0.00	0.00	34.09	33231.50
83	7.85	0.00	0.00	0.00	0.00	7.85	7454.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.37	0.00	0.00	0.00	0.00	2.37	2745.00
86	6.16	0.00	0.00	0.00	0.00	6.16	6395.40
<b>TOBACCO PROD</b>	<b>1.37</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>1.37</b>	<b>1459.00</b>
96	1.37	0.00	0.00	0.00	0.00	1.37	1459.00

Date: 13-SEP-2011  
 Time: 10:20:22 AM

Workplan Summary / Position Class (Combined Anal & District Resources)  
 Workplan 0 - 2012 (2012 WORKPLAN)  
 Output Reflects: OPR FTE'S (Complete)

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TOTAL FIELD

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHR
<b>GRAND TOTAL</b>	<b>1607.75</b>	<b>335.70</b>	<b>232.22</b>	<b>20.35</b>	<b>20.01</b>	<b>2216.03</b>	<b>2291373.80</b>
<b>FOOD SAFETY/COS</b>	<b>838.24</b>	<b>224.02</b>	<b>216.05</b>	<b>0.00</b>	<b>14.01</b>	<b>1292.32</b>	<b>1366692.30</b>
03	717.39	65.85	210.83	0.00	4.00	998.07	1031775.50
04	29.60	111.46	0.00	0.00	5.00	146.06	165886.50
07	5.27	9.66	0.00	0.00	4.01	18.94	21141.00
09	4.27	8.97	0.00	0.00	0.00	13.24	14622.00
18	62.46	0.20	1.22	0.00	0.00	63.88	76162.00
21	15.98	26.32	1.53	0.00	1.00	44.83	49236.30
29	3.27	1.56	2.47	0.00	0.00	7.30	7869.00
<b>BIOLOGICS</b>	<b>131.10</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>131.10</b>	<b>124529.10</b>
41	36.02	0.00	0.00	0.00	0.00	36.02	34219.40
42	81.36	0.00	0.00	0.00	0.00	81.36	77276.80
45	13.72	0.00	0.00	0.00	0.00	13.72	13032.90
<b>HUMAN DRUGS</b>	<b>292.21</b>	<b>72.33</b>	<b>3.18</b>	<b>0.00</b>	<b>0.00</b>	<b>367.72</b>	<b>364599.00</b>
46	18.15	6.85	0.00	0.00	0.00	25.00	23838.30
48	77.83	0.00	0.00	0.00	0.00	77.83	73932.40
52	9.95	5.48	0.00	0.00	0.00	15.43	15392.60
53	11.07	0.00	0.00	0.00	0.00	11.07	10498.50
56	165.71	44.15	3.18	0.00	0.00	213.04	213203.60
63	9.50	3.85	0.00	0.00	0.00	13.35	13573.60
88	0.00	12.00	0.00	0.00	0.00	12.00	14160.00
<b>ANIMAL D &amp; F</b>	<b>91.64</b>	<b>28.26</b>	<b>8.33</b>	<b>0.00</b>	<b>4.00</b>	<b>132.23</b>	<b>136301.50</b>
68	9.05	0.89	0.00	0.00	0.00	9.94	9438.00
71	82.59	27.37	8.33	0.00	4.00	122.29	126863.50
<b>DEVICES &amp; RAD H</b>	<b>241.41</b>	<b>5.59</b>	<b>4.66</b>	<b>20.35</b>	<b>2.00</b>	<b>274.01</b>	<b>279108.90</b>
81	0.94	0.03	0.02	0.03	0.00	1.02	983.90
82	163.35	5.56	4.64	11.71	0.00	185.26	186545.70
83	36.18	0.00	0.00	0.00	0.00	36.18	34365.30
84	0.00	0.00	0.00	3.72	2.00	5.72	6750.00
85	14.60	0.00	0.00	0.00	0.00	14.60	16973.00
86	26.34	0.00	0.00	4.89	0.00	31.23	33491.00
<b>TOBACCO PROD</b>	<b>13.15</b>	<b>5.50</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>18.65</b>	<b>20143.00</b>
96	13.15	5.50	0.00	0.00	0.00	18.65	20143.00

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**Center for Food Safety & Applied Nutrition**  
**PROGRAM DESCRIPTIONS**  
**FY2012**

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Domestic Acidified & Low-Acid Canned Foods PAC 03803A	<b>2. PPS PROJECT NAME/NUMBER</b> Foodborne Biological Hazards - 03
<b>3. PROGRAM TYPE</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To determine if the firms comply with 21 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act. To perform annual inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods.  A continued priority will remain with out-of-compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Please refer to the compliance program for guidance.	
<b>5. PROGRAM JUSTIFICATION</b> Low-Acid Canned Foods: Inspections conducted in prior year's programs have demonstrated that the degree of compliance with low-acid canned food regulations relate directly to the degree of freedom from hazard to consumers found in the food produced. High risk industry segments, identified under previous programs, as well as re-inspection of the remaining portions of the industry are needed to establish and maintain compliance with the low-acid canned food regulations.  Acidified Foods: The program is needed to ensure that the acidified food industry's degree of freedom from public health hazard continues and to monitor industry's compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas which need emphasis in future programs.	
<b>6. FIELD OBLIGATIONS</b> Special situation firms are to be inspected according to the guidance in the Compliance Program (see program). State contract inspections are to be used to increase firm coverage under this program.  State inspections may be conducted in addition to the number of inspections assigned per District. Resources include coverage of food security issues (see IOM) at domestic processors. See full program for more detail.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> See Compliance Program.	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 16, 20-22, 24, 25, 27, 35, 37, 38, 40, 41
<b>e. EXAM TYPE</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety PACs 03803,B,C,D,E		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. Resources to conduct foreign inspections of food establishments are also planned here.  Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate District will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program.  Resources from this program may be directed to monitor chicken eggs for <i>Salmonella enteritidis</i> and for Follow-Up Assignments. Also, resources needed for inspections of domestic firms for FDA E.U. certification will be taken from this program. Food security issues are to be covered during all inspections (See IOM).			
5. PROGRAM JUSTIFICATION Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibility of assuring that foreign and domestic manufacturers produce these products under current Good Manufacturing Practices.			
6. FIELD OBLIGATIONS To conduct domestic and foreign inspections, focusing on high-risk firms with additional program resources to provide coverage consistent with priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk and non-high-risk firms. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Food Products (except Industry Code 12, 16)		d. INDUSTRY/PRODUCT CODE(S) 02-11, 13-15, 17-41, 45, 46, 50, 54	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Filth, Decomposition and Microbiological Contamination (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - General PACs 03819,A,B,C		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or are not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.			
6. FIELD OBLIGATIONS To conduct activities directed by CFSAN, identified through compliance programs, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth, disease vector, or decomposition.  Districts should emphasize priority products from CFSAN's Import Risk-Based Priorities List posted on the intranet. Districts should deemphasize coverage of products that are not consistent with priorities noted in the list. See full Program for more details.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Food Products ( except Industry Code 12, 16, 40, 41)		d. INDUSTRY/PRODUCT CODE(S) 02-09, 13-15, 17-39, 45-54	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Microbiological Contamination, Filth, and Decomposition (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Produce Assignments PACs 03F098, 03F100		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE		<input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected types of produce of domestic and foreign origin for pathogenic microorganisms as needed and directed by CFSAN assignments.			
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens have reached an unacceptably high level in the U.S. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. Produce continues to be one of the major contributors to outbreaks.			
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the FY12 Produce Assignments issued by CFSAN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER	
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh fruits and vegetables as specified in the assignment.		d. INDUSTRY/PRODUCT CODE(S) 20-22, 24, 25	
e. EXAM TYPE			
CHEMICAL		<input checked="" type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
		<input type="checkbox"/> ENGINEERING	
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

1. PROGRAM/ASSIGNMENT TITLE Unspecified Foreign Inspections/Assessments PAC 03R233		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted to take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety  Inspections are planned and conducted under the appropriate domestic compliance program. An additional block of resources are set aside as reserve for as yet unidentified foreign inspections.			
5. PROGRAM JUSTIFICATION As part of the Agency's strategy of focusing on risk based firms FDA plans to work with foreign governments and Federal partners to ensure that foods produced in foreign facilities meet the U.S. safety requirements.			
6. FIELD OBLIGATIONS ORA/DFFI shall plan inspections of foreign firms recommended by CFSAN in so far as contacting the firms and foreign governments and working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN for review and classification. See full program for more detail.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All foods, with emphasis on: Ready-To-Eat foods, fresh produce, and foods implicated in food-borne infection.		d. INDUSTRY/PRODUCT CODE(S) 02-50, 54	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Check appropriate domestic compliance program for details.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Resources for samples collected as part of infant formula or medical food foreign inspections are planned under those programs.			

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

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

1. PROGRAM/ASSIGNMENT TITLE Contract Management PAC 03R843		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To conduct an effective state contract inspection program, augmenting regulatory inspections conducted by Agency investigators. To perform audits of inspections by states that are under contract to FDA to conduct food inspections.			
5. PROGRAM JUSTIFICATION Over 10,000 food inspections are anticipated to be contracted out in FY12 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.			
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the District. Inspections should be planned by the Field. Report under Operation Code 13 (Domestic Investigations). Audits are not considered inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Food Products		d. INDUSTRY/PRODUCT CODE(S) 02-41, 45, 46, 50	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Contract Management</i> )			
f. CHECK THE FOLLOWING ATTRIBUTES Following DFRS guidance.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

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

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood PAC 04018	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM TYPE  COMPLIANCE PROGRAM       PROGRAM CIRCULAR       ASSIGNMENT

4. OBJECTIVES  
To sample and analyze selected imported and domestic aquaculture seafood products. To determine the presence of unapproved chemical compounds such as drugs or antifungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.

5. PROGRAM JUSTIFICATION  
Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.

6. FIELD OBLIGATIONS  
Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 12 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or as additional validated methods are ready to implement. As a budget relief, two agent analyses should be run per sample for all products except crab, provided the second agent is one of interest for that product. Individual subsample analyses will only be required for crab and shrimp samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining samples will be a composite of 12 sub-samples. Refer to the FY 12 Collection Schedule for additional instruction.

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

b. INSPECTION TYPE  
 COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
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e. EXAM TYPE  
 CHEMICAL       MICROBIOLOGICAL       PHYSICAL       ENGINEERING  
 MICROANALYTICAL       OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES  
Unapproved drugs per the Compliance Program and the Collection Schedule.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic) PAC 04019A,B,C		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine the incidence and levels of lead, arsenic, cadmium, mercury and other toxic elements of significance and radionuclides in domestic and imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in foodware and to take regulatory action against any food or foodware found to contain levels of toxic elements or radionuclides of regulatory significance.			
5. PROGRAM JUSTIFICATION The continuing monitoring of domestic and imported foods (including seafoods) for toxic elements and radionuclides as necessary to determine the occurrence of toxic elements and radionuclides in the U.S. food supply that may pose a health hazard and to take regulatory action to remove those products from human food channels. Also, this monitoring will provide additional data on background levels of toxic elements and radionuclides in foods that will assist in identifying unusual levels that may be of health significance for follow up regulatory action.			
6. FIELD OBLIGATIONS Foods that may be significant sources of lead in children are candy, chocolate/cocoa, and seafood. These products are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" Program and assignments (to be issued). CFSAN will issue collection schedules and direct other FY 12 food work. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides. The Program should be maintained to keep expertise and proficiency in this area. Surveillance activities will be reported under, and credited to the Program PAC.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) 02-41, 52A	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Lead, cadmium, mercury and other toxic elements as directed. Domestic - tritium, 90 Sr & gamma ray emitters; IMPORTS; 134 Cs, 137 Cs, 90 Sr			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Radiochemical analysis capability. (Available only at WEAC). Graphite furnace atomic absorption with Zeeman background correction.			

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

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants PAC 04F800		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected food products of domestic and foreign origin for chemical contaminants as directed by CFSAN field assignments. Assignments are anticipated for perchlorate in foods, contaminants in honey, and general pesticides and toxic elements in dietary supplements. Selected TDS samples will be analyzed for perchlorate in foods.			
5. PROGRAM JUSTIFICATION Monitoring of foods for suspected chemical contaminants is necessary to ensure a safe food supply. Perchlorates and furan have recently been identified as suspect contaminants and monitoring is required to provide the Agency with incidence and level data to properly evaluate their presence in the food supply. Contaminants like fluoroquinilone and nitrofurans have been detected in imported honey. Sample collection and analysis of imported honey will continue as directed by the "Import Bulletin." There are concerns regarding pesticides and toxic elements in dietary supplements yet there are minimal monitoring data available to the Agency for these products.			
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the assignment(s) issued by CFSAN. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to the Program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Selected human foods and dietary supplements		d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignments	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Chemical contaminants as directed by CFSAN field assignments.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by the assignments.			

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Outbreak and Emergency Operations PAC 04R839	<b>2. PPS PROJECT NAME/NUMBER</b> Pesticides and Chemical Contaminants - 04
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3. PROGRAM TYPE     COMPLIANCE PROGRAM     PROGRAM CIRCULAR     ASSIGNMENT

**4. OBJECTIVES**  
 Conduct follow-up investigations, inspections, sample collections and analyses related to outbreaks and illness attributed to pesticide or chemical contamination of food products.

Follow-up to Reportable Food Registry reports are also planned under this category.

**5. PROGRAM JUSTIFICATION**  
 Each year the field expends increasing amounts of resources to follow-up on reports of outbreaks and illnesses linked to contaminated food products. Resources are set aside in the workplan specifically to conduct the emergency operations associated with these investigations.

**6. FIELD OBLIGATIONS**  
 Based on directives issued by CFSAN and ORA, districts will be requested to conduct investigations and collect documents and samples needed to determine whether a link exists between a reported illness or outbreak and a specific product and/or firm.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

BY DISTRICT OFFICE     BY CENTER     BY BOTH

b. INSPECTION TYPE     COMPREHENSIVE     ABBREVIATED     DIRECTED

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

MICROANALYTICAL     OTHERS (SPECIFY)

**f. CHECK THE FOLLOWING ATTRIBUTES**  
 To be specified in assignments

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods PAC 07001		2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze domestic and import samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin. To remove from interstate commerce, or detain upon entry, those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established. Data from current monitoring will be used to establish enforcement levels.			
5. PROGRAM JUSTIFICATION Mycotoxins are metabolic products of specific molds commonly found on foods, some (the aflatoxins) of which are hepatocarcinogens in a number of animal species, and until proven otherwise must be assumed to be carcinogenic. The FDA, in conjunction with other agencies and the food industries, has devised and will continue to improve on practical programs for ensuring minimum exposure of the population to mycotoxins without jeopardizing the food supply.  Descriptions of the following specific Mycotoxins included in this program are located in the Mycotoxins In Domestic and Imported Foods compliance program (C.P. 7307.001). 1. Aflatoxins 2. Patulin 3. Deoxynivalenol (DON) 4. Fumonisins (Fumonisin FB <sub>1</sub> , FB <sub>2</sub> and FB <sub>3</sub> ) 5. Ochratoxin A			
6. FIELD OBLIGATIONS The Field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic and imported products as directed by the Compliance Program.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited, to the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) See Attachment "A" C.P. 7307.001 for list of Products.		d. INDUSTRY/PRODUCT CODE(S) See Attachment "A" C.P. 7307.001 for list of Product Codes.	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Aflatoxins, Fumonisins (Fumonisin FB <sub>1</sub> , FB <sub>2</sub> and FB <sub>3</sub> ), Deoxynivalenol (DON), Ochratoxin A, and Patulin.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program (C.P.) 7307.001			

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

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

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

6. FIELD OBLIGATIONS  
Conduct activities under this program as directed by the Division of Field Science.

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

b. INSPECTION TYPE     COMPREHENSIVE     ABBREVIATED     DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities PAC 18029		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To inspect and investigate passenger conveyances to certify and approve sanitary systems on conveyances and approve their watering points, their support facilities and their food sources based on Public Health Service Act, the Food, Drug and Cosmetic (the Act), regulations, program guidance, Food Code, and in cooperation with the regulated industry and cooperating third party organizations. Also to identify risk factors related to environmental conditions or management practices that may lead to foodborne illnesses, waterborne illnesses, and the transmission of communicable diseases. The program includes administrative compliance and regulatory actions as appropriate to ensure conformance with the public health principles embodied in the Acts and their regulations. The goals of the program are to cooperate with the regulated industries, trade associations, and others to promote voluntary compliance and to coordinate activities with FAA, CDC, DOT, EPA, Department of Homeland Security (USCG, TSA) and other domestic and foreign government health officials to ensure the protection of the traveling public, and crew member of conveyances under construction and in operation and at related watering points, caterers, commissaries and servicing area on conveyances.			
5. PROGRAM JUSTIFICATION This program directs Agency efforts in fulfilling Public Health Service Act responsibilities delegated to the Commissioner of Food and Drugs [21 CFR 5.10(a)(2) and (4)]. Sections 311, 361, and 368 of the Act address federal-state cooperation, the controls of communicable disease, and penalties of noncompliance. The Agency also bases the Interstate Travel Program, in part, on provisions of the Federal Food, Drug and Cosmetic Act and related regulations. The United States must comply with the updated International Health Regulations (IHR 2005) as of July 17, 2007 that protect the health of people around the world. As one of the competent authorities, FDA as an agency is responsible for monitoring baggage, cargos, containers, conveyances and goods so that they are maintained free from sources of infection or contamination including vectors and reservoirs. There are specific requirements for ships and aircraft and delivery of food and water to affected conveyances.			
6. FIELD OBLIGATIONS The field is to perform the operations assigned in the Workplan, conduct comprehensive inspections of food operations and support facilities, initiate administrative or regulatory actions as needed to ensure compliance, support the maintenance of official classification list of FDA approved support facilities, establish and maintain technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication between CFSAN and ORA Headquarters regarding significant program issues and activities.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human food, water, and waste; conveyance environmental conditions		d. INDUSTRY/PRODUCT CODE(S) Inspections/Investigations: Industry 51, All food codes including water 29W (Y30).	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Food and water surveillance and contamination, mostly micro. with chem. analysis for heavy metals in water on a for cause basis e.g. lead, cadmium, cooper in portable water systems at new support facilities and conveyances after construction or major renovation.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Catering point inspections will be conducted by persons standardized in the use of FDA's Food Code and procedures established for the Interstate Travel Program.			

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import PAC 21002		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods.  To collect and analyze domestic and imported medical foods to assure that they are properly formulated and labeled and free from microbial contaminants.			
5. PROGRAM JUSTIFICATION Medical foods are formulated to be consumed or administered enterally under the supervision of a physician and are intended for specific dietary management of specific disease or condition with distinctive nutritional requirements, based on recognized scientific principles established by medical evaluation. The products are often used for life support and are subject to compositional errors and microbiological contamination. In addition to four infant deaths in 1986, there have been a number of medical food recalls associated with compositional deviations and under processing.  Foreign inspections of medical foods firms are also planned in this program. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03819. Resources are planned in this program for collection and analysis of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food security issues are to be covered during all inspections.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Medical Foods		d. INDUSTRY/PRODUCT CODE(S) 41G[ ][ ] Use appropriate product identification number	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Label Reviews</i> )			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> and Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Economic Fraud PAC 21003		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE		<input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected food products as directed by CFSAN field assignments.			
5. PROGRAM JUSTIFICATION Monitoring of foods for suspected economic deception and food standard deviations is necessary to ensure a safe food supply.			
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the assignment(s) issued by CFSAN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input checked="" type="checkbox"/> BY CENTER	
		<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Selected human foods		d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignment(s)	
e. EXAM TYPE			
<input checked="" type="checkbox"/> CHEMICAL		<input type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
<input type="checkbox"/> MICROANALYTICAL		<input checked="" type="checkbox"/> OTHERS ( <i>Label Review</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES As directed by CFSAN field assignment(s)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by CFSAN field assignment(s)			

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

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import PAC 21006		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure compliance with the Infant Formula Act and regulations promulgated there under by inspection of domestic and foreign manufacturers of infant formula and collection and analysis of infant formula samples.			
5. PROGRAM JUSTIFICATION Serious infant health problems arising from inadequate nutrient content of infant formula prompted Congress to pass the Infant Formula Act of 1980. This inspection and analysis program assures adherence to the provisions of the Act. Violations and recalls over the past several years (and the continuing keen interest by Congress, as evidenced in part by the 1986 amendments to the Act) indicate the need for continued compliance monitoring. The large number of applications for approval of the formulas exempt from the Act requires expansion of oversight activities into this area.  Additional resources have been budgeted to allow annual inspection and sample collection from infant formula firms. Inspections of foreign infant formula are planned in this program. Investigation time to determine admissibility of import lots of infant formula from foreign manufacturers are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples. Atlanta Center for Nutrient Analysis (ACNA) will perform nutrient analyses and label reviews. Southeast Regional Laboratory, Microbiology Branch will perform microbiological analyses. CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed. Food security issues (see IOM) are to be covered during all inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Infant Formula		d. INDUSTRY/PRODUCT CODE(S) 40C	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Label Reviews)			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrients as required by the Act. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

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

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

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

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

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

6. FIELD OBLIGATIONS  
Conduct activities under this program as directed by the Division of Field Science.

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

b. INSPECTION TYPE         COMPREHENSIVE         ABBREVIATED         DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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# Center for Biologics Evaluation & Research

## PROGRAM DESCRIPTIONS

FY2012

PAC CODE	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PAGE NO.
41002B,C,D	Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)	BI-1
41808, 41809, 41810, 41811	GLPs (Nonclin. Lab), IRBs, Spon/Mon/CROs, Clinical Investigators (PDUFA)	BI-2
42001F,G	Inspection of Licensed and Unlicensed Blood Banks	BI-3
42002A,F,G	Inspection of Source Plasma Establishments	BI-4
42007, 42R833, 42R824, 99R833, 41R824, 45R824	Imported CBER- Regulated Products	BI-5
42008,A	Inspections of Licensed Viral Marker Test Kits	BI-6
42809, 42810, 42811	IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	BI-7
42845A,B,C	Inspection of Medical Device Manufacturers (Biologics)	BI-8
42848A,F,G, 42848B,C,D, 41848C,D, 41848F,G	Inspections of Plasma Derivatives of Human Origin	BI-9
45809, 45810, 45811	IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	BI-10
45848A,F,G	Inspection of Licensed Allergenic Products	BI-11
45848B,C,D,H	Inspection of Licensed Vaccine Products	BI-12

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

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

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

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

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

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

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspections of Plasma Derivatives of Human Origin PACs 42848A,F,G; 42848B,C,D *	<b>2. PPS PROJECT NAME/NUMBER</b> Blood and Blood Products - 42
<b>3. PROGRAM TYPE</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which Plasma Derivatives are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.  Other PACs included: 41848C,D; 41848F,G	
<b>5. PROGRAM JUSTIFICATION</b> Plasma Derivatives are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.	
<b>6. FIELD OBLIGATIONS</b> ORA will <b>perform inspections</b> that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a <b>Biennial Basis</b> . Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Fractionation Products	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 57
<b>e. EXAM TYPE</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

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

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

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

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**Center for Drug Evaluation & Research**  
**PROGRAM DESCRIPTIONS**  
**FY2012**

<b>PAC CODE</b>	<b>FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS</b>	<b>PAGE NO.</b>
46832B,C	NDA Pre-Approval Inspections/Investigations - Domestic (PDUFA)	HD-1
46832B,C,D	NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)	HD-2
46832M	BLA Pre-Approval Inspections/Investigations- Domestic and Foreign	HD-3
46832P	PET NDA Pre-Approval Inspections/Investigations	HD-4
48001,A	In Vivo Bioequivalence (PDUFA) - Domestic	HD-5
48001,A,D,E	In Vivo Bioequivalence (PDUFA) - Foreign Inspections	HD-6
48808	Good Laboratory Practice (Nonclinical Laboratory)	HD-7
48809,A	Institutional Review Boards (IRB); Radioactive Drug Research Committee (RDRC)	HD-8
48810	Sponsors, Contact Research Organizations, & Monitors	HD-9
48811,A,B	Clinical Investigators	HD-10
52832,B,C	ANDA - Pre-Approval Inspections/Investigations - Domestic	HD-11
52832,B,C,E	ANDA - Pre-Approval Inspections/Investigations - Foreign	HD-12
52832P	PET ANDA Pre-Approval Inspections/Investigations	HD-13
53001A,B	Enforcement of the Adverse Drug Experience Reporting Regulations	HD-14
53001C	Risk Evaluation and Mitigation System (REMS)	HD-15
56002A-D,F	Drug Process Inspections	HD-16
56002A-D,F	Foreign Drug Inspections	HD-17
56002M	Drug Process Inspections: Lincensed Biological Therapeutic Drug Products	HD-18
56002P	Drug Process Inspections- PET Domestic	HD-19
56008A,L	Drug Product Surveillance	HD-20
56021A,B	Drug Quality Reporting System - DQRS NDA-Field Alert Reporting	HD-21
56022	Enforcement of the Prescription Drug Marketing Act (PDMA)	HD-22
56843	Post Approval Inspections/Investigations (Domestic and Foreign)	HD-23
56D015	Pharmacy Compounding Assignments	HD-24
56R838	Forensic Evaluation and Sample Analysis	HD-25
63001A,63D012	Internet, Health Fraud, and OTC Monographs	HD-26
63002	New Drug (Prescription) Without Approved NDAs	HD-27
88---	Shelf Life Extension Projects	HD-28

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-Clinical Laboratory) PAC 48808	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM TYPE     COMPLIANCE PROGRAM         PROGRAM CIRCULAR         ASSIGNMENT

4. OBJECTIVES  
To assure compliance with current Good Laboratory Practice Regulations (21 CFR 58) by nonclinical laboratories and to assure validity of data through associated data audits.

5. PROGRAM JUSTIFICATION  
Animal Studies are vital prerequisites to human clinical trials of drugs and other FDA regulated products. Past experience has shown serious deficiencies in the conduct of nonclinical laboratories in recordkeeping, adherence to study protocol, and in some cases fraudulent practices.

6. FIELD OBLIGATIONS  
Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER.  
District may make classification and recommend compliance actions.

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

b. INSPECTION TYPE         COMPREHENSIVE         ABBREVIATED         DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
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e. EXAM TYPE     CHEMICAL         MICROBIOLOGICAL         PHYSICAL         ENGINEERING  
 MICROANALYTICAL         OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE PET ANDA Pre-Approval Inspections/Investigations PAC 52832P	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM TYPE     COMPLIANCE PROGRAM     PROGRAM CIRCULAR     ASSIGNMENT

4. OBJECTIVES  
To verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending ANDAs.  
ANDA bulk products are collected for profile analysis.

5. PROGRAM JUSTIFICATION  
Compliance of manufacturing establishments must be assessed before ANDA approvals.

6. FIELD OBLIGATIONS  
Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.

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

b. INSPECTION TYPE     COMPREHENSIVE     ABBREVIATED     DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
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e. EXAM TYPE     CHEMICAL     MICROBIOLOGICAL     PHYSICAL     ENGINEERING  
 MICROANALYTICAL     OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  
Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.

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

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

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

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

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

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

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

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

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

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Forensic Evaluation and Sample Analysis PAC 56R838	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
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<b>3. PROGRAM TYPE</b> <input checked="" type="checkbox"/> <b>N/A</b> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input checked="" type="checkbox"/> ASSIGNMENT
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**4. OBJECTIVES**  
 Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations.  
 This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.

**5. PROGRAM JUSTIFICATION**  
 Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.

**6. FIELD OBLIGATIONS**  
 Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic activities PAC 56R838 or OCI PAC 56R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report time spent on these activities as PODS Operation Code 03, PAC 56R838 Petition Validation, Methods Development, or Forensic Evaluation. Please consult DFS and/or DPEM for additional reporting guidance.

**7a. SELECTION OF ESTABLISHMENTS TO BE COVERED**

<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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**b. INSPECTION TYPE**

<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b>
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**e. EXAM TYPE**

<input checked="" type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (SPECIFY)		

**f. CHECK THE FOLLOWING ATTRIBUTES**

**g. SPECIAL EQUIPMENT, METHODS, AND HANDLING**

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Internet, Health Fraud, and OTC Monographs PAC 63001A, 63D012	<b>2. PPS PROJECT NAME/NUMBER</b> Unapproved and Misbranded Drugs - 63
<b>3. PROGRAM TYPE</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To identify and evaluate OTC drug products and to assure their compliance with specific OTC drug monographs or other regulations; 2) to detect, investigate and take action against fraudulent drug products that present the public with a direct and indirect health hazard and economic fraud; and, 3) to monitor, investigate and take regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal off-shore pharmacy operations associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases.	
<b>5. PROGRAM JUSTIFICATION</b> 1) In the Federal Register of 1/5/72, the Commissioner announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory panels. As a result, final monographs are published (21 CFR Part 330 through Part 358) which establish conditions under which OTC drugs can be generally recognized as safe and effective and not misbranded; 2) to combat the deceptive and misleading sale of fraudulent drug products; and, 3) FDA must monitor the promotion and sale of drug products on the Internet to identify activities which violate the law and pose a risk to the public health.	
<b>6. FIELD OBLIGATIONS</b> The Field conducts inspections and investigations, develops evidence, collects and analyzes samples, evaluates product labeling, performs surveillance activities, and recommends compliance actions concerning OTC drugs, fraudulent drugs and drugs sold on the Internet as set forth in applicable compliance programs and CDER guidance and requests for follow-up.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Human Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> Industry Codes: 50, 54, and 60-66
<b>e. EXAM TYPE</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> New Drug (Prescription) Without Approved NDAs PAC 63002	<b>2. PPS PROJECT NAME/NUMBER</b> Unapproved and Misbranded Drugs - 63
<b>3. PROGRAM TYPE</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To establish uniform procedures for removal from the market of all prescription drug products described by FDA to be new drugs not covered by approved New Drug Applications consistent with the enforcement policy articulated in Compliance Policy Guide (CPG) 440.100 "Marketed Unapproved Drugs."	
<b>5. PROGRAM JUSTIFICATION</b> The Drug Amendments of 1962 to the FD&C Act require that all marketed drug products be safe and effective. For historical reasons, some drugs are available in the United States that lack the required FDA-approval. In June 2006, the FDA announced a new drug safety initiative to remove unapproved drugs from the market, including a final guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide (CPG)," outlining its enforcement policies aimed at efficiently and rationally bringing all such drugs into the approval process. The FDA uses a risk-based enforcement program in order to concentrate its resources on those products that pose the highest threat to public health and without imposing undue burdens on consumers, or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:  1) Drugs with potential safety risks, 2) Drugs that lack evidence of effectiveness, 3) Health fraud drugs, 4) Drugs that present direct challenges to the new drug approval and OTC drug monograph systems, 5) Unapproved new drugs that are also violative of the Act in other ways, and 6) Drugs that are reformulated to evade an FDA enforcement action.	
<b>6. FIELD OBLIGATIONS</b> -Assign District Coordinator, whose name shall be supplied to CDER/OC/DNDLC. -Maintain records of all activities under this program, including a list of drug products voluntarily removed from the market in compliance with the warning letters, products removed by recall, etc. -Initiate regulatory actions, where appropriate, to assure compliance with program.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Human Prescription Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> Industry Codes: 54, 56 and 60-66
<b>e. EXAM TYPE</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

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

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**Center for Veterinary Medicine**  
**PROGRAM DESCRIPTIONS**  
**FY2012**

<b>PAC CODE</b>	<b>FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS</b>	<b>PAGE NO.</b>
68001,G	NADA Pre-Approval Inspections	AD-1
68808,G	Good Laboratory Practice (Non-clinical Laboratory)	AD-2
68810,G	Sponsors, Contact Research Organizations, and Monitors	AD-3
68811,G	Clinical Investigators	AD-4
71001,A,B	Animal Drug Manufacturing Inspections/Type A Medicated Articles	AD-5
71003A-K	Feed Contaminants	AD-6
71004,A	Feed Manufacturing	AD-7
71006	Illegal Drug Residues in Meat and Poultry	AD-8
71009	BSE/Ruminant Feed Ban Inspections	AD-9
71R816	Methods Validation/Development Program	AD-10
71R838	Forensic Evaluation and Sample Analysis	AD-11
71V800	Center Initiated Assignments, Pandemic Preparedness	AD-12

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

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

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

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

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

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

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

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

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

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

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

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

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**Center for Devices & Radiological Health**  
**PROGRAM DESCRIPTIONS**  
**FY2012**

<b>PAC CODE</b>	<b>FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS</b>	<b>PAGE NO.</b>
81010	Medical Device Problem Reporting - MDR Follow-up	DE-1
82008	Monitoring Devices of Foreign Origin - Import	DE-2
82845	Inspection of Medical Device Manufacturers	DE-3
82Z002	Condom Assignment	DE-4
82Z003	Manufacturers and Importers of Surgical/Examination Gloves	DE-5
82Z800	Center Initiated Assignments	DE-6
82R816	Methods Validation/Development Program	DE-7
82R838	Forensic Evaluation and Sample Analysis	DE-8
83001	Medical Device Premarket Approval and Postmarket Inspections	DE-9
83808, 83809, 83810, 83811	Bioresearch Monitoring	DE-10
84Z002	Test Method Development and Evaluation	DE-11
84R816	Methods Validation/Development Program	DE-12
85014	Mammography Facilities Inspection Program	DE-13
86001, 86002, 86004	Inspection and Field Testing of Radiation-Emitting Electronic Products	DE-14
86003	Inspection of Manufacturers (Foreign and Domestic) & Field Compliance Testing of Diagnostic X-Ray Equipment	DE-15
86006	Compliance Testing of Electronic Products at WEAC	DE-16
86007	Imported Electronic Products	DE-17
86008, 86009	Radiological Health Control Activities	DE-18

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers PAC 82845	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES  
To evaluate the manufacturing processes used for general and radiation-emitting medical devices and in vitro diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations.

5. PROGRAM JUSTIFICATION  
The Center's inspectional strategy requires that all manufacturers of Class II and III devices be inspected under the GMP Compliance Program on a biennial basis. FDA selects certain establishments for intensive GMP coverage. Establishments with a history of good GMP systems are subject to less-intensive inspections. All establishments are subject to complaint file reviews to assess compliance with the MDR regulation.

6. FIELD OBLIGATIONS  
Under the Quality Systems/GMP strategy, the field should conduct biennial inspections of high-risk device manufacturers and Class III device manufacturers that are not considered to be high risk. The remaining manufacturers (Class III, II, and I devices) should be inspected as each district's resources allow, and scheduled according to the priority outline described in Part II of the compliance program. For more detailed instructions on QSIT/GMP inspections as they relate to device manufacturers, refer to the Workplanning Sheet's Remarks section.

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

b. INSPECTION TYPE  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S) All Class II and III Devices and all Class I Devices which have been finally classified for one year.	d. INDUSTRY/PRODUCT CODE(S) 73-91
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e. EXAM TYPE  CHEMICAL  MICROBIOLOGICAL  PHYSICAL  ENGINEERING  
 MICROANALYTICAL  OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  
Engineering Samples: Subs/Sample will vary depending on cost, size, etc. Contact Center for guidance if the device presents such problems.

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

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

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

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

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

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Insp. of Manuf. (For and Dom) and Field Compliance Testing of Diag. X-Ray Equipment PAC 86003		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of inspections and tests conducted under this program are: 1. To ensure that the regulated products and manufacturer quality control programs conform to EPRC regulations; 2. To identify diagnostic x-ray products which fail to comply with the applicable performance standard requirements; 3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and 4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA.			
5. PROGRAM JUSTIFICATION Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Diagnostic x-ray manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary x-radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Because diagnostic x-ray equipment is also subject to performance standards, the manufacturer must also comply with Title 21 CFR 1010 and the equipment must comply with the specific standards found in 21 CFR 1020.30 - 1020.33. Manufacturers are required to self-certify their products comply with the applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. EPRC inspections and field tests verify that electronic products comply with performance standards, and that the manufacturer's quality control testing program ensures product compliance and radiation safety.			
6. FIELD OBLIGATIONS Field personnel will initiate and schedule inspections of diagnostic x-ray manufacturers and field tests of diagnostic x-ray equipment as instructed in Compliance Programs 7386.003 and 7386.003a. CDRH is generally responsible for the final review of inspections and field tests made under this program and for the issuance of letters resulting from inspections and field tests performed by field radiological health staff. Exceptions where the district has direct reference authority are noted in Compliance Program 7386.003 and 7386.003a. Joint EPRC/medical device (QSIT) inspections may be conducted under both Compliance Programs 7386.003a and 7382.845.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Diagnostic X-Ray Equipment		d. INDUSTRY/PRODUCT CODE(S) 94DS---	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Field tests will be performed by consumer safety officers who have received specialized training which includes approximately two weeks of on-the-job training with a qualified auditor.			

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

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

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

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**Center for Tobacco  
PROGRAM DESCRIPTIONS  
FY2012**

PAC CODE	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PAGE NO.
96R800	Regulated Tobacco Products - Domestic and Import	TP-1

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1. PROGRAM/ASSIGNMENT TITLE Regulated Tobacco Products - Domestic and Import PACs 96R800, 96T800, 96R824, 96R833		2. PPS PROJECT NAME/NUMBER Tobacco - 96	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To inspect domestic manufacturers of regulated and imported tobacco to determine compliance with the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act and its implementing regulations. To take administrative and/or enforcement action when violations are observed.			
5. PROGRAM JUSTIFICATION The Family Smoking Prevention and Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act and requires the agency to conduct inspections at least once in the two-year period beginning with the date of registration of such establishment and at least every successive two-year period thereafter.			
6. FIELD OBLIGATIONS CTP plans on issuing a multi-district inspection assignment at the beginning of the fiscal year. The scope of the inspections will cover all statutory and regulatory provisions in effect. CTP anticipates approximately half the universe of registered tobacco manufacturers to be inspected during the fiscal year. Further, CTP anticipates the collection of domestic samples for laboratory analysis to support enforcement actions as well as samples for other laboratory analysis (samples collected to develop laboratory methodology or ingredient identifications, etc.). CTP plans to develop import alerts and assignments for imported tobacco products.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco		d. INDUSTRY/PRODUCT CODE(S) All tobacco codes	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Label, Labeling, Advertising Reviews)			
f. CHECK THE FOLLOWING ATTRIBUTES Characterizing flavor Labeling/promotion information as requested in each assignment			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Gas Chromatography coupled with Mass Spectrometer and Gerstel autoanalyzer			

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