



Memorandum

Date September 11, 2012

From Director, Program Planning and Workforce Management Branch

Subject Final FY 2013 Office of Regulatory Affairs (ORA) Field Workplan

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

We are pleased to release the Final FY 2013 ORA Field Workplan. Similar to previous years, the FY 2013 Workplan is based primarily on the Centers' compliance program forecasts. The FY 2013 Workplan reflects ORA's planning level of 2,325 operational Full-Time Equivalents (FTEs), in addition to 21 operational FTEs for the Tobacco program. This level reflects an increase in operational investigational FTEs, which is a direct result of ORA hiring and training efforts since FY 2007. These new hires will be fully operational in FY 2013, thereby allowing ORA to increase the operational investigational FTE allocations for all program areas: 1) Foods and Cosmetics, 2) Biologics, 3) Human Drugs, 4) Animal Drugs and Feeds, 5) Devices and Radiological Health, and 6) Tobacco.

Please note that the FY 2013 Workplan only includes resources for ORA investigators and analysts; it does not plan operations conducted by States under contract. Additionally, please note that the FY 2013 Workplan includes two major modifications:

MAJOR MODIFICATION (1):

As in FY 2012, the FY 2013 Foods Workplan was reformatted by CFSAN to align with the Food Safety and Modernization Act (FSMA) inspectional frequency goals. CFSAN has maintained the change in format for the FY 2013 Workplan, with 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 Program and Project Structure (PPS). New to the FY 2013 Foods and Cosmetics Workplan is the planning of collection and analyses operations, by compliance program, under the corresponding PPS. This change should assist the ORA Field Laboratories plan and budget for the year. To assist the Field in workplanning, CFSAN provided ORA with the high-risk and non-high-risk inventories, during a Webinar organized for 2013


FSMA Firms on 7/26/12. In addition, new to the FY 2013 Foods and Cosmetics Workplan is the issuance of the Sample Collection Operation Planning Effort (SCOPE), which is being released in conjunction with the FY 2013 Workplan. The Division of Planning, Evaluation, and Management (DPEM) has included an electronic copy of SCOPE on the Workplan CD, and a link to SCOPE will be located on CFSAN's intranet site at the following URL:
<http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm272937.htm>. CFSAN will update SCOPE throughout the year, and therefore this intranet site should be monitored periodically.

MAJOR MODIFICATION (2):

In response to comments from the Laboratories, sample analyses will be planned in operations, and will no longer be planned as hours, except for Methods Validation/Development and Applied Technology Center, which are traditionally planned as hours. As in FY 2012, DPEM received laboratory allocations from the Division of Field Science (DFS). Since the Servicing Laboratories table served as the basis for laboratory allocations, it has been included in this document as a reference. Questions regarding the laboratory sections of this Workplan should be directed to DFS.

ADDITIONAL WORKPLAN DOCUMENTS

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



FY 2013 Workplan Changes:

The "FY 2013 Workplan Changes" spreadsheets provide a comprehensive listing of FY 2013 program levels compared to the FY 2012 ORA Field Workplan. These documents can be used to identify specific resource shifts and programmatic cuts or increases.

Servicing Laboratories Table:

The Servicing Laboratories Table is included to serve as a reference. DFS based FY 2013 laboratory allocations on this Table.

Compliance Programs and Reporting Program Assignment Codes (PACs):

This document provides a listing of reporting PACs, by Compliance Program, which is included in the Foods and Cosmetics section of the Workplan. DPEM included this list as a reference for Field Investigators and Analysts, since the Foods Workplan is organized by PPS and only includes Planning PACs. The listing should match the PODS Report 7E PAC groupings. Since new PACs may be added or archived throughout the year please check DPEM's intranet site for an up-to-date PAC Master List organized by program Centers:


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

FY 2013 Workplan CD:

The FY 2013 Workplan is also published in a CD format. You may make and distribute as many copies of this CD as needed. For further printing 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

NEW to the FY 2013 Workplan CD is the inclusion of the SCOPE table. Please submit any questions about the SCOPE table to Monali Yajnik (CFSAN) at Monali.Yajnik@fda.hhs.gov

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


Carrie M. Mampilly

FOODS AND COSMETICS

FY 2013 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	FTE DIFFERENCE
03F810*	Foodborne Biological Hazards	452.6	460.5	7.9
03F811*	Domestic High-Risk Inspections	248.1	242.2	-5.9
03F812*	Domestic Non-High-Risk Inspections	25.9	44.0	18.1
03F830*	CFSAN Environmental Sampling Assignments	90.4	97.7	7.3
03R233*	Foreign Food Inspections	44.2	44.2	
03R839	Outbreak and Emergency Response	136.8	116.4	-20.4
03	Foodborne Biological Hazards	998.0	1005.0	7.0
04F810*	Pesticides and Chemical Contaminants	117.4	172.6	55.2
04839	Total Diet Study	28.6	28.6	
04	Pesticides and Chemical Contaminants	146.0	201.2	55.2
07001	Mycotoxins in Domestic and Imported Foods	18.9	18.9	
07	Molecular Biology and Natural Toxins	18.9	18.9	
09F810*	Food and Color Additives Petition Review	13.2	15.0	1.8
09	Food and Color Additives Petition Review	13.2	15.0	1.8
18F810*	Technical Assistance: Food & Cosmetics	3.2	3.2	
18002	Retail Food Protection- State Program	26.0	27.0	1.0
18003	(NCIMS) Milk Safety Program	20.0	20.1	0.1
18004	Molluscan Shellfish Evaluation Program	14.7	14.5	-0.2
18	Technical Assistance: Food & Cosmetics	63.9	64.8	0.9
21F810*	Food Composition, Standards, Labeling, & Econ	44.8	39.6	-5.2
21	Food Composition, Standards, Labeling, & Econ	44.8	39.6	-5.2
29001	Cosmetics: Domestic and Imports	7.3	8.6	1.3
29	Colors and Cosmetics Technology	7.3	8.6	1.3
	Total Mission Direct: Pre and Annual Planned FTEs	1292.1	1353.1	61.0

* 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.

BIOLOGICS

FY 2013 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	FTE DIFFERENCE
41002B,C,D	Inspection of Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps)	31.0	39.0	8.0
41808	Good Laboratory Practices	.	.	
41809	Institutional Review Board	.	.	
41810	Sponsors, Monitors, CROs	.	.	
41811	Clinical Investigators	5.0	5.0	
41848A-D,F,G	Inspection of Cell and Gene Therapy Products	†	0.7	0.7
41	Human Cellular, Tissue, & Gene Therapies	36.0	44.7	8.7
42001F,G,H	Blood Banks	54.5	55.5	1.0
42002A,F,G	Source Plasma Establishments	11.9	11.9	
42007 [§]	Imported CBER-Regulated Products	4.0	4.0	
42008A,F,G	Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER	2.5	2.5	
42809	Institutional Review Board	.	.	
42810	Sponsors, Monitors, CROs	.	.	
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	3.5	3.3	-0.2
42	Blood & Blood Products	81.3	82.1	0.8
45809	Institutional Review Board	.	.	
45810	Sponsors, Monitors, CROs	.	.	
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	5.5	-0.5
45	Vaccines & Allergenic Products	13.7	13.2	-0.5
	Total Mission Direct: Pre and Annual Planned FTEs	131.0	140.0	9.0

* BIMO: 41808, 41809, and 41810 are planned under 41811; 42809 & 42810 are planned under 42811; PACs 45808, 45809 & 45810 are planned under 45811.

† In FY 2012, resources for all 41848 PACs were planned in a separate column on the Plasma Derivatives of Human Origin workplanning sheet (0.2 FTE under PAC 41848F). For FY 2013 a separate workplanning sheet was created for this program under PPS 41.

§ 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 2013 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	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	
46	New Drug Evaluation	25.0	25.0	
48001,A	In Vivo Bioequivalence (Domestic)	6.0	6.5	0.5
48001,A,D,E	Foreign Inspections (In Vivo, GLP, CI)	5.0	7.2	2.2
48808	Good Laboratory Practices	3.0	3.1	0.1
48809,A	Institutional Review Boards	7.8	10.0	2.2
48810	Sponsors, Contract Research Orgs, Monitors	5.3	6.3	1.0
48811	Clinical Investigators (Domestic)	34.5	22.2	-12.3
48811F	Clinical Investigators (Domestic) Follow-Up and Complaints		14.8	14.8
48811,D	Clinical Investigators (Foreign)	16.2	17.3	1.1
48	Bioresearch Monitoring	77.8	87.4	9.6
52832,B,C	ANDA Pre-Approval Inspections/Investigations (Domestic)	4.0	5.0	1.0
52832,B,C,E	ANDA Pre-Approval Inspections/Investigations (Foreign)	9.0	12.0	3.0
52832P	Positron Emission Tomography (PET)	2.4	3.4	1.0
52	Generic Drug Evaluation	15.4	20.4	5.0
53001A	Enforcement of the Adverse Drug. Exp. Rpt. Regul (Domestic and Foreign)	9.0	8.7	-0.3
53001C	Risk Evaluation Mitigation System (REMS)	2.0	2.1	0.1
53	Postmarket Surv. & Epidemiology	11.0	10.8	-0.2
56002A,B,D	Drug Process Inspections-Domestic	54.0	48.0	-6.0
56002A-D	Foreign Drug Inspections	53.0	62.0	9.0
56002E	Drug Process Inspections - Gas Manufacturers	10.0	12.0	2.0
56002F,L	Drug Process Inspections API Manufs (Dom/For)	9.0	13.0	4.0
56002M	Drug Process Inspections - Biotech Manufacturers	5.0	6.0	1.0
56002P,Q	Positron Emission Tomography (PET)	3.0	2.0	-1.0
56008A,L	Drug Quality Sampling & Testing Program	18.5	18.0	-0.5
56008H	Drug Product Surveillance (Import)	37.9	49.0	11.1
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	2.0	2.0	
56R010	Drug Process Inspections - Global Parity Initiative		4.0	4.0
56R011	Drug Process Inspections - OEI Clean-Up		2.0	2.0
56R838	Forensic Evaluation and Sample Analysis	10.0	10.0	
56	Drug Quality Assurance	212.9	238.5	25.6
63001A	Internet, Health Fraud, & OTC Monographs	10.4	11.4	1.0
63002	New Drugs (Prescription) Not Covered by Approved NDAs	3.0	4.5	1.5
63	Unapproved & Misbranded Drugs	13.4	15.9	2.5
88---	Shelf Life Extension Projects	12.0	12.0	
88	Interagency Cooperative Activities	12.0	12.0	
	Total Mission Direct: Pre and Annual Planned FTEs	367.5	410.0	42.5

ANIMAL DRUGS AND FEEDS

FY 2013 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	FTE DIFFERENCE
68001,G	NADA Pre-Approval Inspections	4.9	4.5	-0.4
68808,G	(Pre-Market) GLP and Spon/Mon/Com	2.4	2.7	0.3
68810*	Sponsors Contract Research Orgs./Monitors	*	*	
68811,G	(Pre-Market) Clinical Investigators	2.6	2.9	0.3
68	Pre-Approval Eval. of Animal Drugs & Food Additives	9.9	10.1	0.2
71001,A,B†	Animal Drug Manufacturing Inspections	13.0	12.3	-0.7
71003A,B,C,E,G-K	Feed Contaminants	25.6	32.1	6.5
71004,A	Feed Manufacturing	5.4	5.2	-0.2
71006,M	Illegal Drug Residues in Meat and Poultry	40.5	39.5	-1.0
71009, 71R844§	Ruminant Feed Ban Rule (BSE) Program	30.8	31.0	0.2
71V030¶	FY 13 High Risk Feed Inspection Pilot Assignments (FSMA)		6.3	6.3
71R816	Methods Validation/Development Program	5.0	5.0	
71R838	Forensic Evaluation and Sample Analysis	1.0	1.0	
71V800, 71V022¶	Center Initiated Assignments	1.0	2.7	1.7
71	Monitoring of Marketed Animal Drugs, Feed, & Devices	122.3	135.1	12.8
	Total Mission Direct: Pre and Annual Planned FTEs	132.2	145.2	13.0

* 68810,G planned under 68808

† 71005 / A planned under 71001

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

¶ NEW PACs: 71V030 - FY 13 High Risk Feed Inspection Pilot Assignments (FSMA); 71V022 - FY 13 Poultry Hatchery Assignment

MEDICAL DEVICES AND RADIOLOGICAL HEALTH

FY 2013 WORKPLAN CHANGES

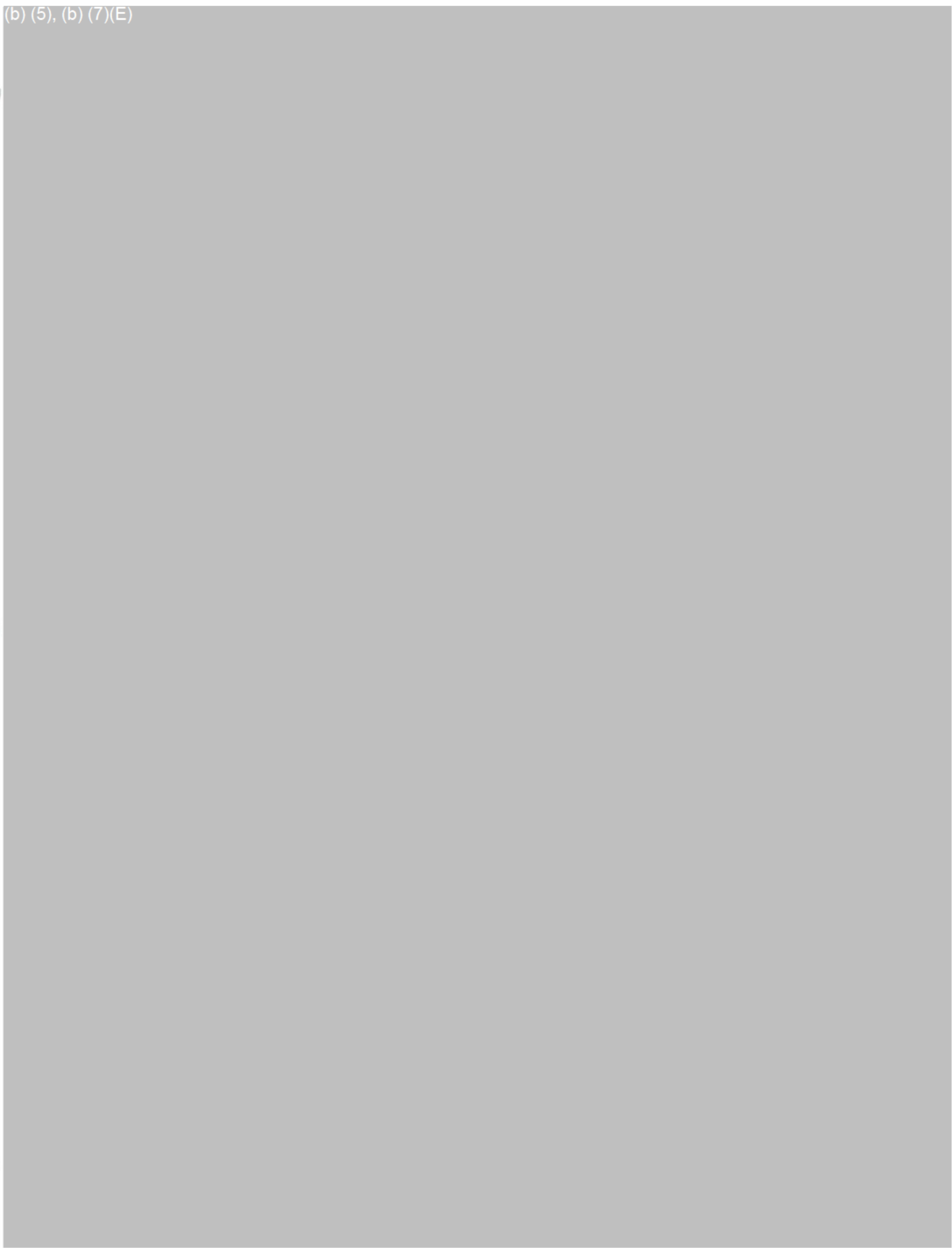
PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	FTE DIFFERENCE
81010	Med Dev Problem Reporting-MDR/DEN F/U	1.0	1.0	
81	Postmarket Assurance: Devices	1.0	1.0	
82008	Monitoring Device of Foreign Origin-Imports	43.0	44.0	1.0
82845A,B,C,G,H,S	Inspection of Medical Dev Mfgs: GMP Domestic	97.3	100.3	3.0
82845B	Inspection of Medical Dev Mfgs: GMP Foreign	23.9	25.2	1.3
82845H	Inspection of Medical Dev Mfgs: Hi-Risk Foreign	2.1	4.0	1.9
82845P	Inspection of Accredited Persons: MDUFMA	1.0	0.5	-0.5
82845J	Audits of Accredited Persons	0.3	0.2	-0.1
82Z002	Condom Assignment	3.6	3.6	
82Z003	Mfgs & Importers of Surgical/Exam Gloves	7.5	5.5	-2.0
82Z800	Center Initiated Assignments	4.3	5.3	1.0
82R816	Methods Validation/Development Program	2.0	2.0	
82R838	Forensic Evaluation and Sample Analysis	0.3	0.3	
82	Compliance: Devices	185.3	190.9	5.6
83001,A	Med Dev Premkt/Postmkt Insp Domestic	7.1	6.2	-0.9
83001,A	Med Dev Premkt/Postmkt Insp Foreign	2.6	2.5	-0.1
83808-11	Bioresearch Monitoring Domestic	24.0	23.2	-0.8
83810-11	Bioresearch Monitoring Foreign	2.5	2.0	-0.5
83	Project Evaluation: Devices	36.2	33.9	-2.3
84Z002	Test Method Development & Evaluation	3.7	3.7	
84R816	Methods Validation/Development Program	2.0	2.0	
84	Science: Devices	5.7	5.7	
85014	Mammography Facilities Insp Program Domestic	14.5	14.5	
85014	Mammography Facilities Insp Program Foreign	0.1	0.1	
85	Mammography Quality Standards Act (MQSA)	14.6	14.6	
86001	Inspection of Mfgs of Laser Products Domestic	4.3	4.3	
86001	Inspection of Mfgs of Laser Products Foreign	0.9	0.9	
86002	Field Implementation of Sunlamp Products	0.3	0.3	
86003	Field Compliance Testing of Diag X-Ray Equip Domestic	7.6	7.7	0.1
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	2.8	2.8	
86006	Compliance Testing of Elec Prod at WEAC Foreign	0.3	0.3	
86007	Imported Electronic Products	8.5	8.1	-0.4
86008	Med Dev & Rad Hlth Use Control & Policy Implementation	3.0	3.0	
86009	Emergency Planning & Response Activities	2.0	2.0	
86	Radiation Control & Health Safety Act (RCHSA)	31.2	30.9	-0.3
	Total Mission Direct: Pre and Annual Planned FTEs	274.0	277.0	3.0

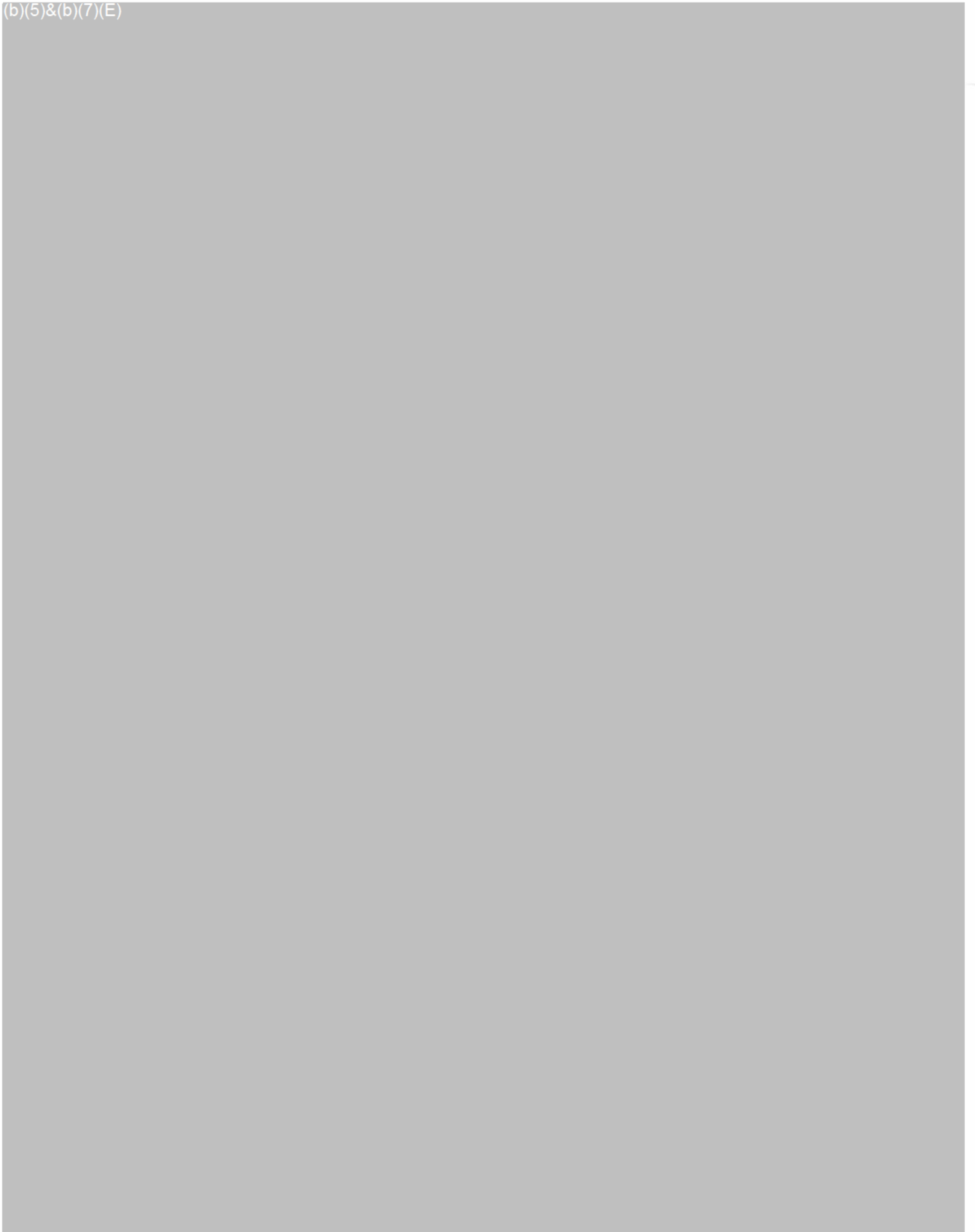
TOBACCO PRODUCTS

FY 2013 WORKPLAN CHANGES

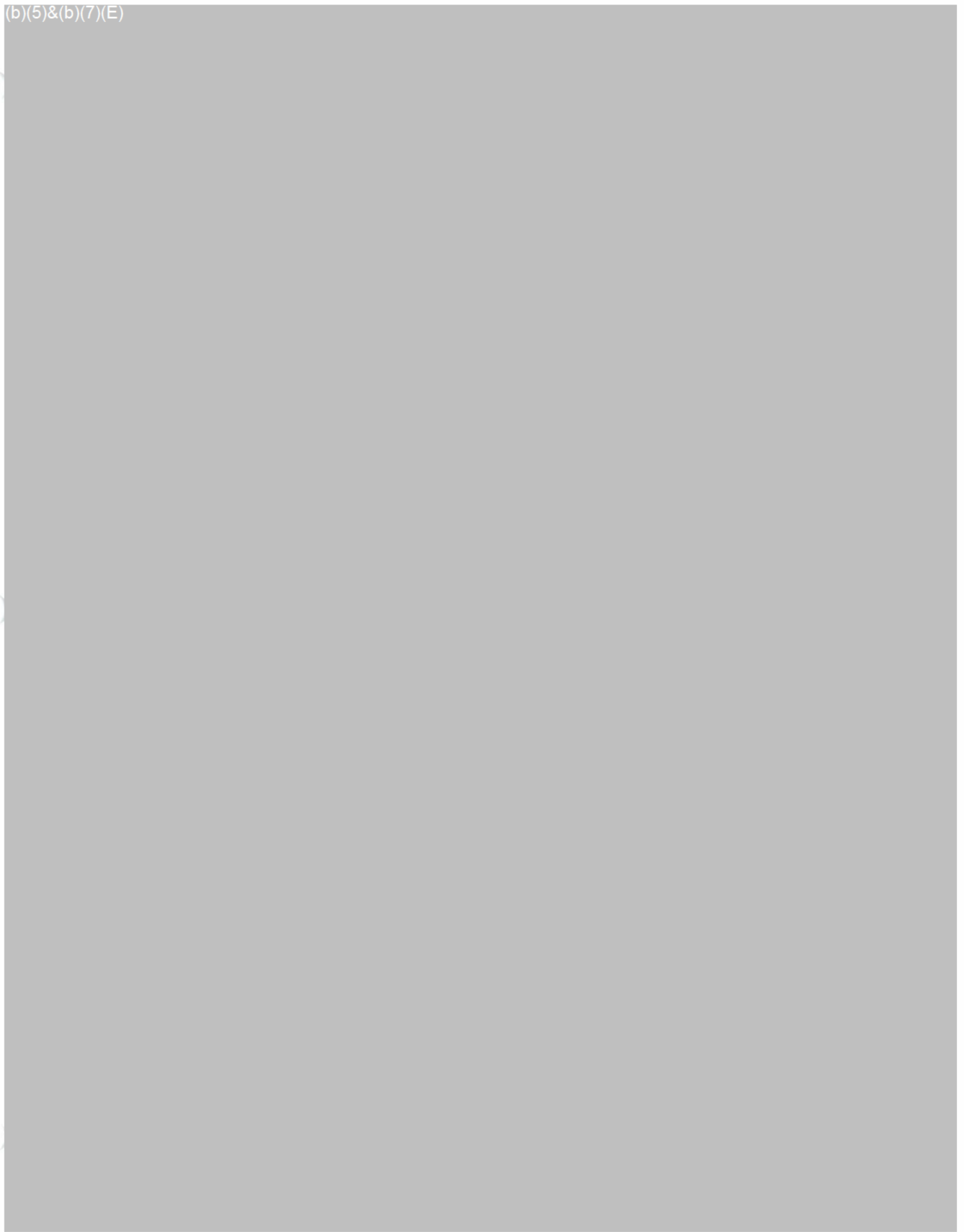
PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	FTE DIFFERENCE
96R800,96T800*	Regulated Tobacco Products: Domestic and Import	18.7	21.0	2.3
	Total Mission Direct: Pre and Annual Planned FTEs	18.7	21.0	2.3

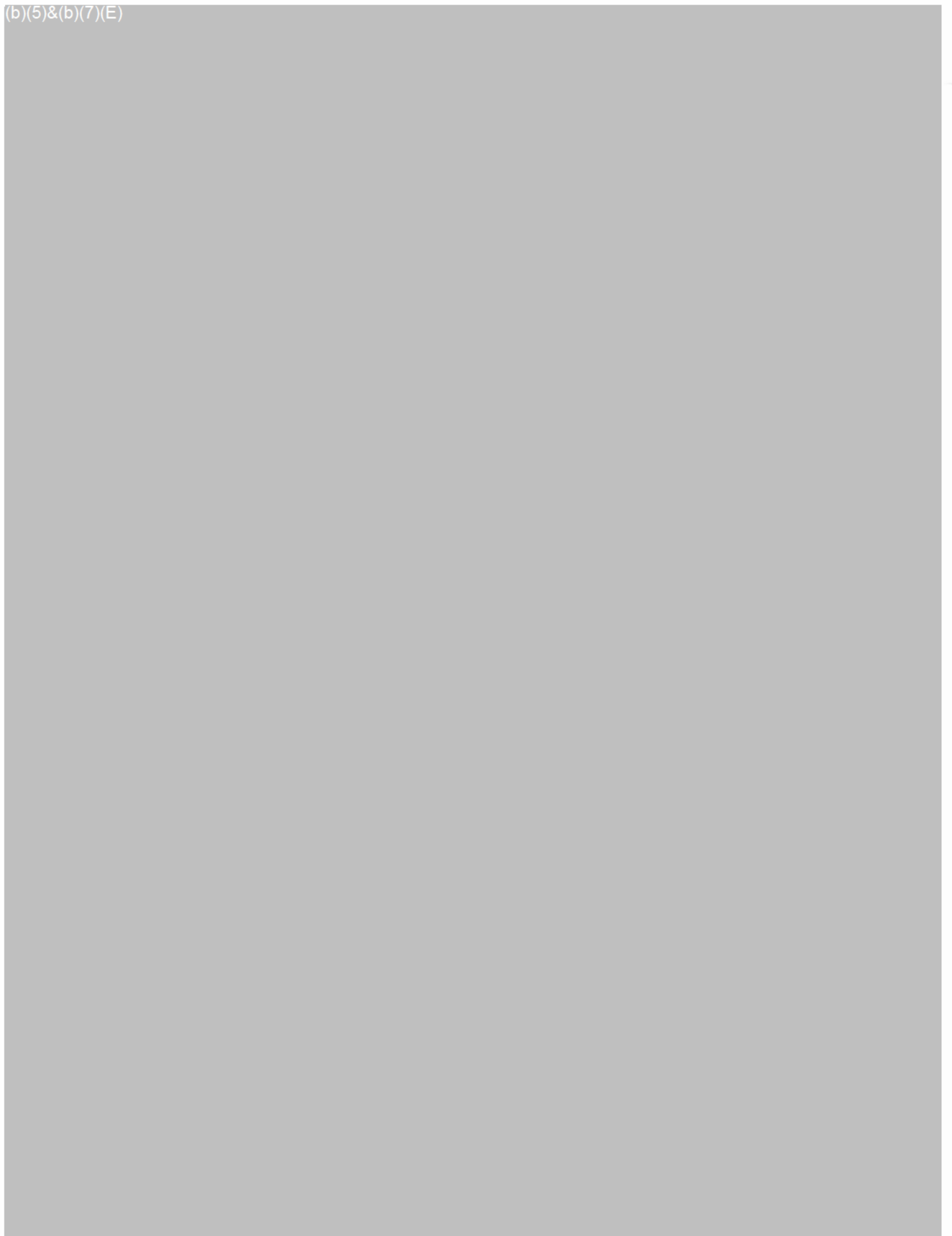
* Includes 96R824 and 96R833

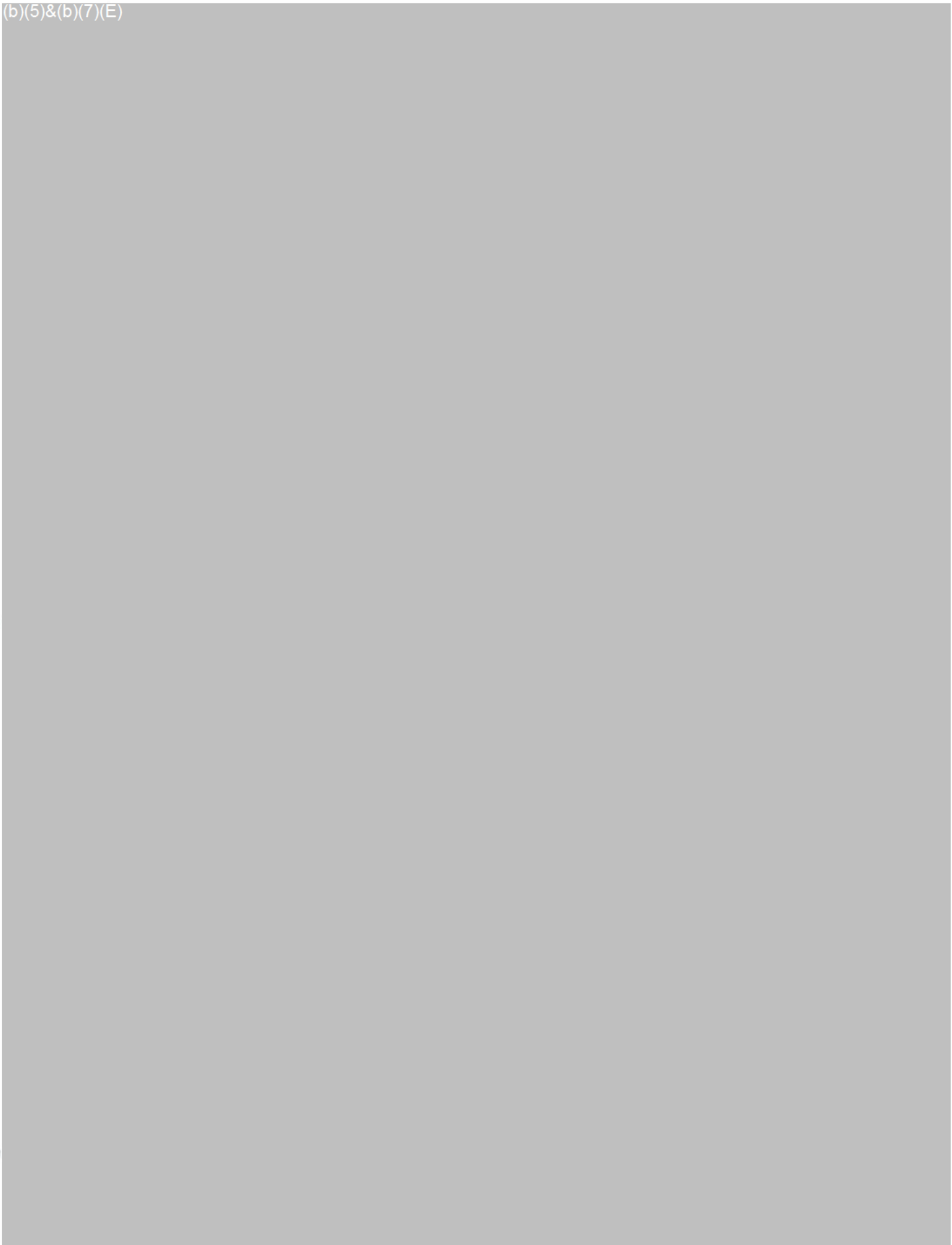


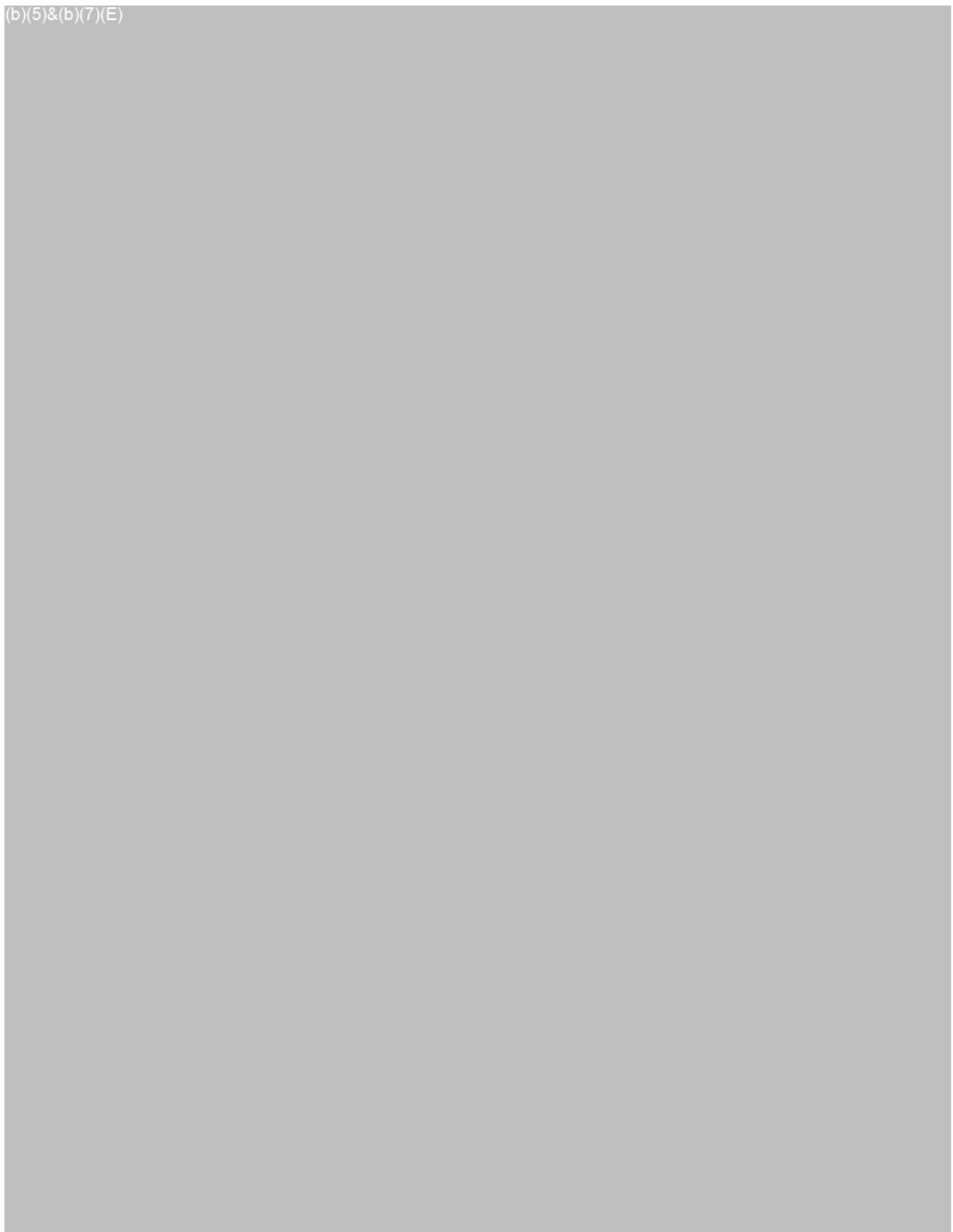


(b)(5)&(b)(7)(E)



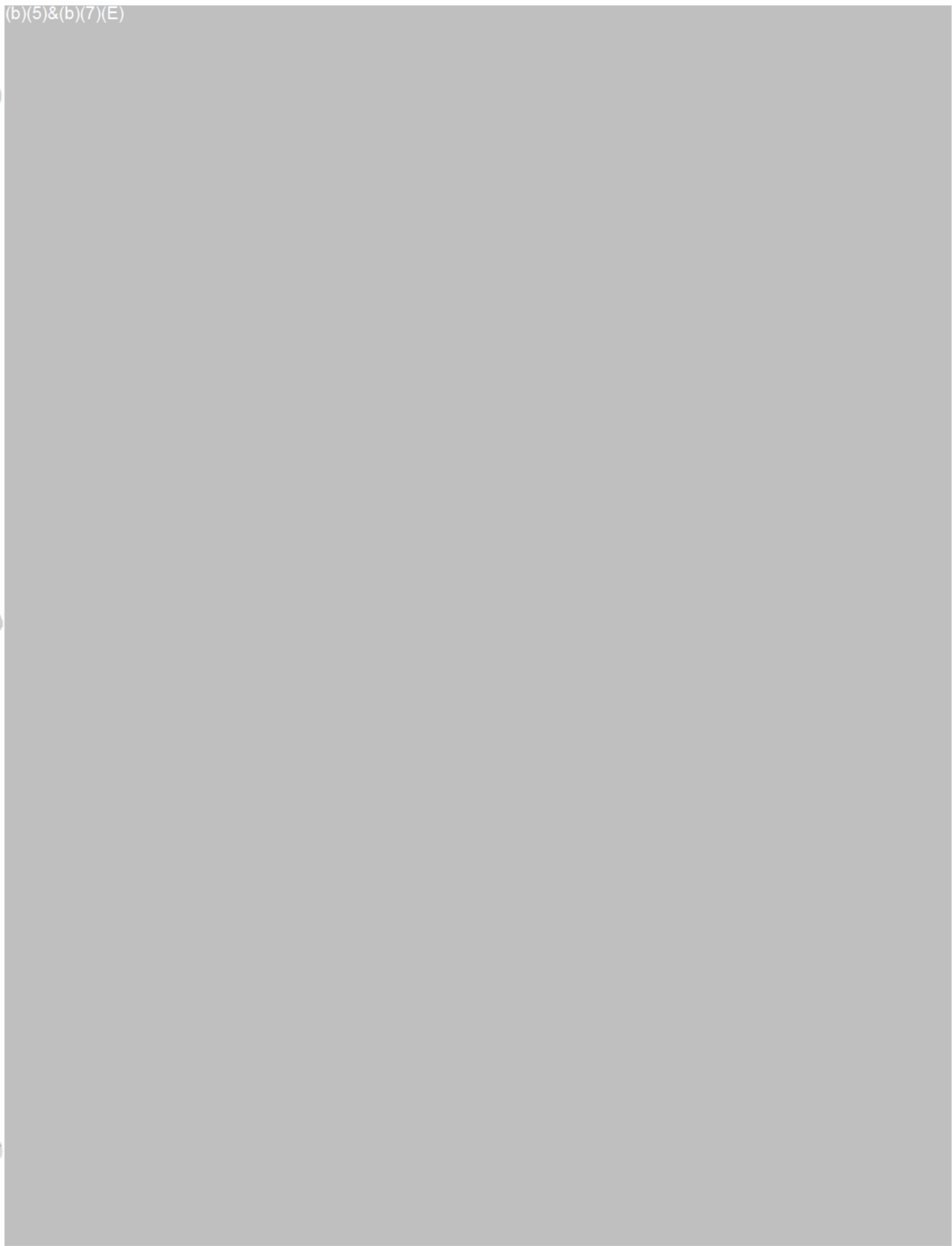


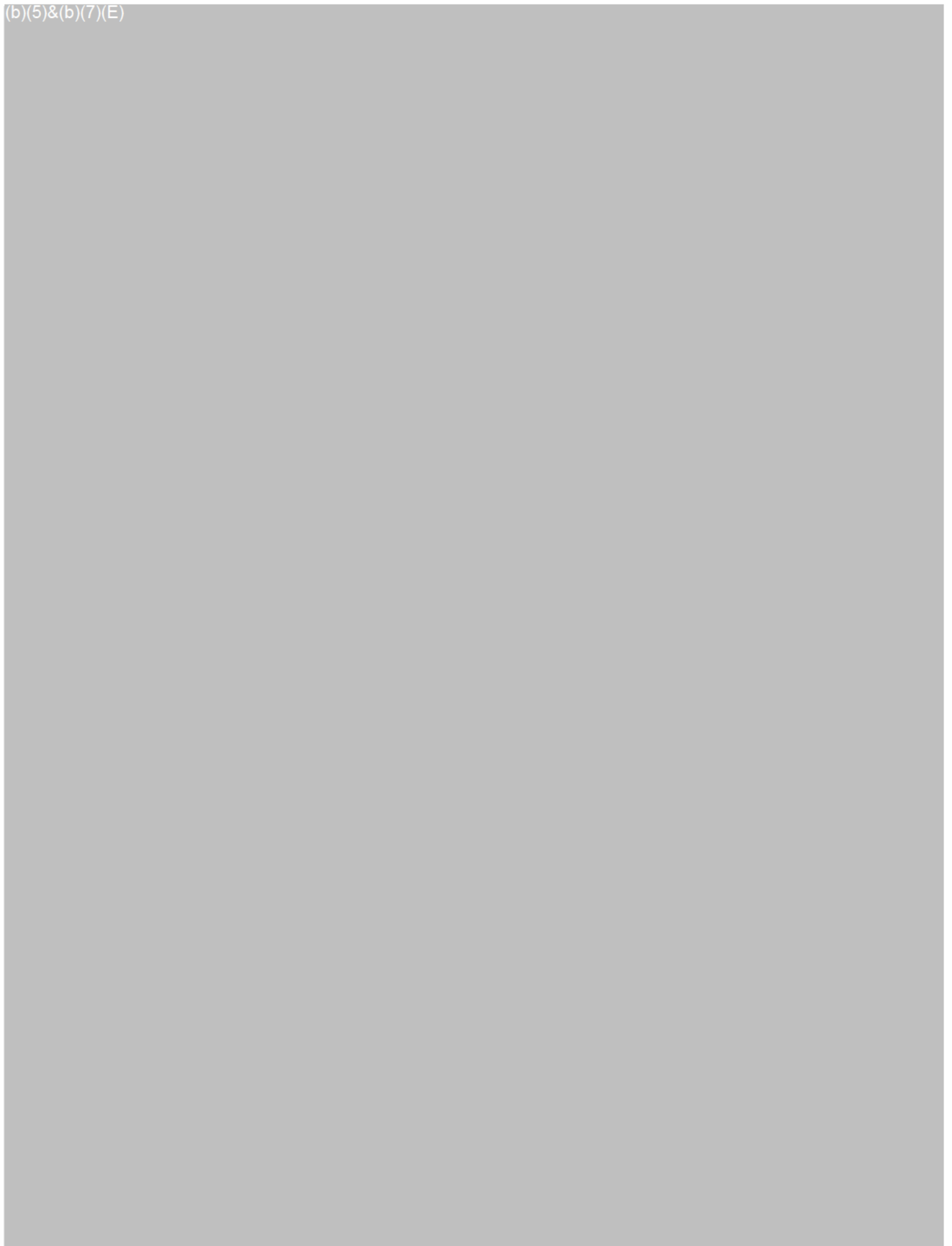








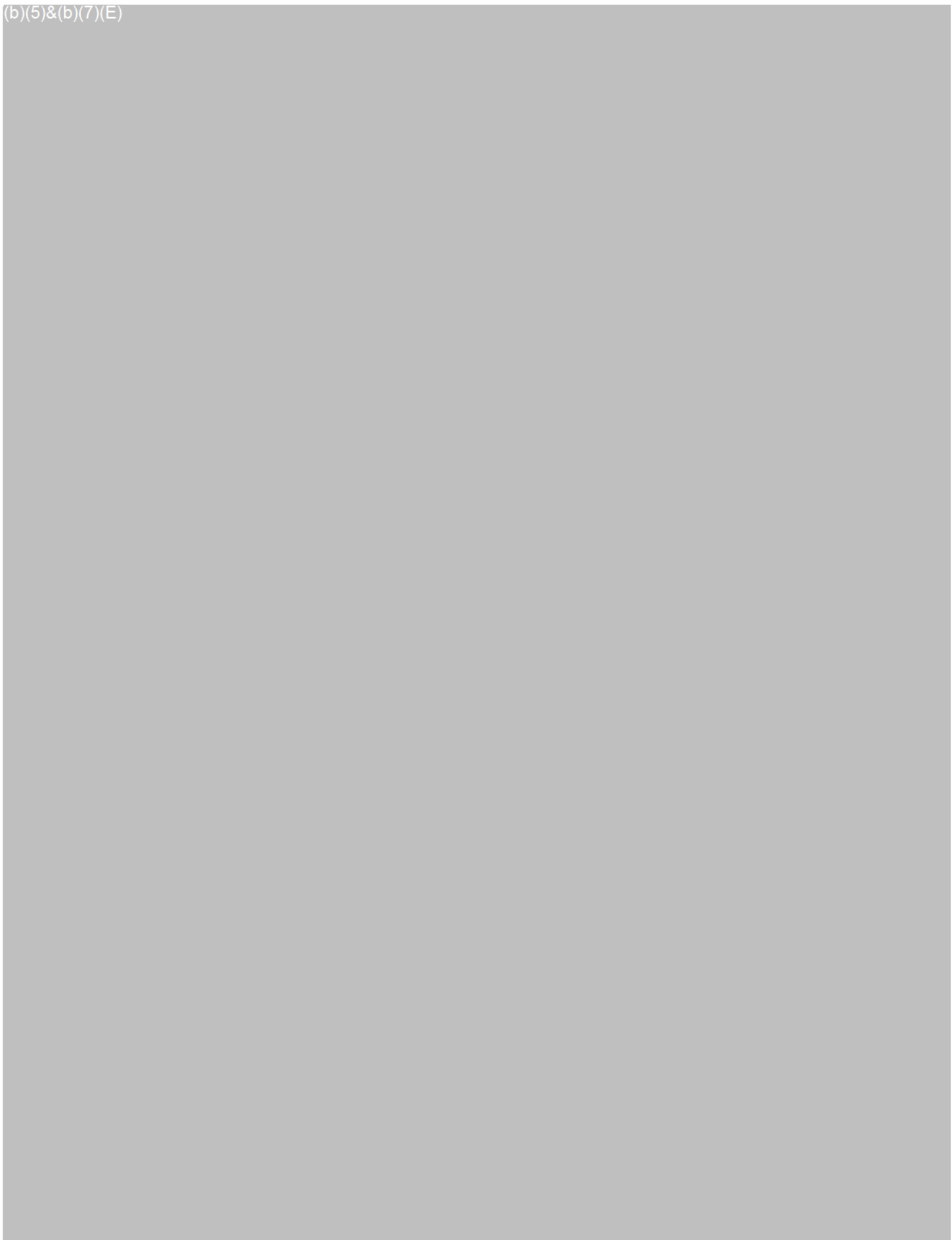




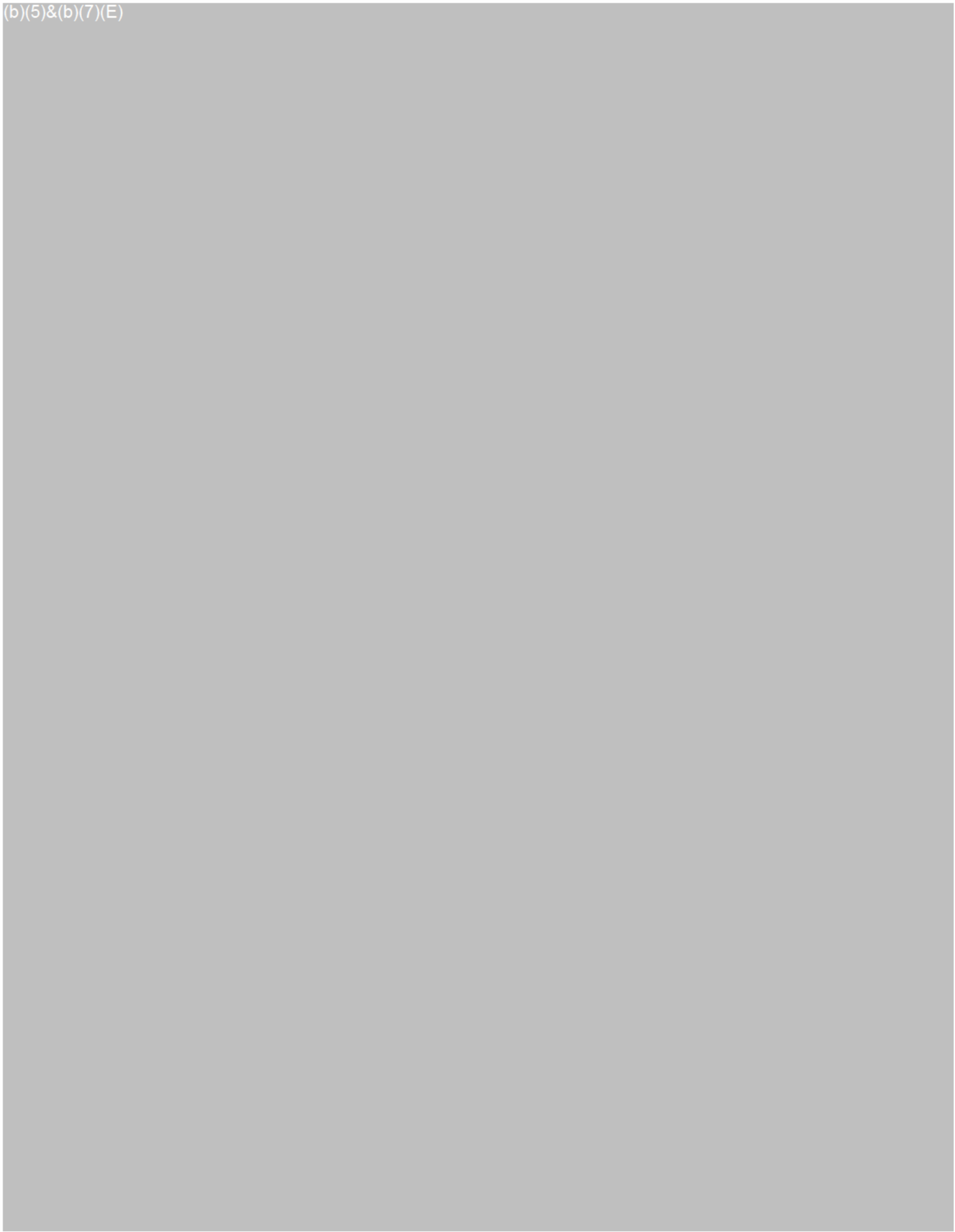
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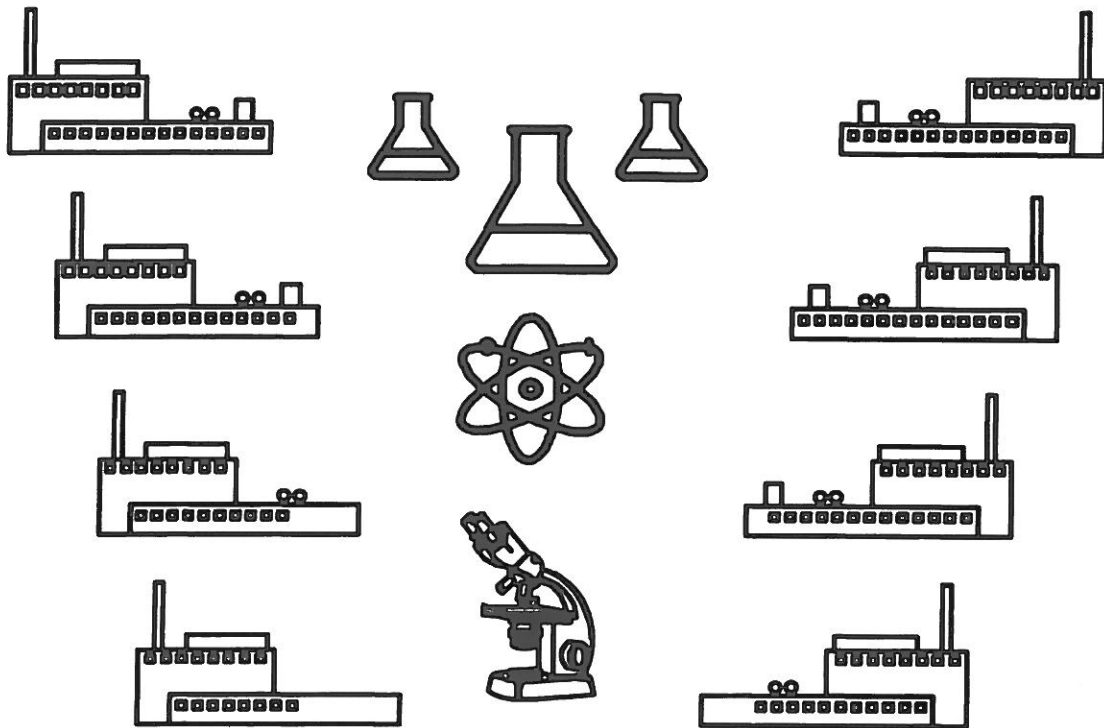
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FY 2013 SERVICING LABORATORIES



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

OCTOBER 2012

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2013**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	841.3	467.6	44.2	1353.1
3	FOODBORNE BIOLOGICAL HAZARDS	606.3	354.5	44.2	1005.0
4	PESTICIDES AND CHEMICAL CONTAMINANTS	125.9	75.3		201.2
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	12.2	6.7		18.9
9	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		15.0		15.0
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	64.8			64.8
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	27.2	12.4		39.6
29	COLOR AND COSMETICS TECHNOLOGY	4.9	3.7		8.6

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, 03482J, 04842A, 04842H, 07842, 07842H, 09842, 09842E, 09842F, 09842H, 21842

Imported Seafood Products

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

Juice HACCP Inspection Program

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

Import & Domestic Micro Assignments

Reporting PACS: 03F098, 03F100

CFSAN Environmental Sampling Assignments

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

Unspecified Foreign Inspections / Assessments

Reporting PACS: 03R233

Outbreak and Emergency Response

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

Food Defense

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

04 PESTICIDES & CHEMICAL CONTAMINANTS

Pesticides & Industrial Chemicals in Domestic & Imported Foods

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

Chemotherapeutics in Seafood

Reporting PACS: 04018

Toxic Elements in Foods (Domestic and Import)

Reporting PACS: 04019A, 04019U, 04019X

Toxic Elements in Foodware (Domestic and Import)

Reporting PACS: 04019B

Radionuclides in Foods (Domestic & Import)

Reporting PACS: 04019C

Total Diet Study

Reporting PACS: 04839

Field Assignments for Chemical Contaminants

Reporting PACS: 04F800, 04F106, 04F107

Forensic Evaluation and Sample Analysis

Reporting PACS: 04R838, 04R831

07 MOLECULAR BIOLOGY / NATURAL TOXINS: FOOD & COSMETICS

Mycotoxins in Domestic & Imported Foods

Reporting PACS: 07001

09 FOOD & COLOR ADDITIVES PETITION REVIEW & POLICY

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

18 TECHNICAL ASSISTANCE: FOOD & COSMETICS

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

21 FOOD COMPOSITION, STANDARDS, LABELING & ECONOMICS

Medical Foods (Domestic & Import)
Reporting PACS: 21002

Domestic Food Labeling and Economics Program
Reporting PACS: 21003

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

Infant Formula Program
Reporting PACS: 21006

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

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

29 COLORS AND COSMETICS TECHNOLOGY

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

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 checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 460.5 [110.6]			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW (Hours) (1)	2 IMPORT INTERNATIONAL MAIL FACILITY (Hours)	2 IMPORT MAIL COURIER REVIEW (Hours)	2 DOMESTIC INVEST- IGATION (Hours)	2 IMPORT INVEST- IGATION (Hours)	2 DOMESTIC EMERGING ISSUES CSO (Hours) (2)	3 DOMESTIC SAMPLE COLL PRODUCE 03F100	3 DOMESTIC SAMPLE COLL SEAFOOD 03842	3 DOMESTIC SAMPLE COLL FOOD SAFETY 03803
	TOTAL FIELD		90804	950	2850	5000	5000	10583	1200	280
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	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)								
HOURS PER OPERATION								3.0	5.0	6.0
TOTAL HOURS		90804	950	2850	5000	5000	10583	3600	1400	3798
CONVERSION FACTOR		1200	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		75.67	1.00	3.00	5.26	5.26	11.14	3.79	1.47	4.00
7. REMARKS										
<p>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.</p> <p>(1) - Import Entry Review Hours: Resources for these activities cover All Import Food Programs.</p> <p>NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.</p> <p>(2) - Emerging issues is a new category of resources placed in PPS 03, PPS 04, and PPS 21 to cover any issues or events that do not qualify as an emergency or outbreak, but are considered of importance due to potential impact or other policy imperative reason. These resources can be used for sample collections or other CSO operations and will be allocated through assignments unless otherwise instructed.</p>										

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 460.5 [13.4]				
R E G I O N	6	3	3	3	3	3	3	4	4	4
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL JUICE HACCP 03847	DOMESTIC SAMPLE COLL CHEESE 03037	DOMESTIC SAMPLE COLL AGED CHEESE ASSIGN 03037	DOMESTIC SAMPLE COLL ASSIGN SPECIES SUB IN FISH 03842	DOMESTIC SAMPLE COLL ASSIGN BOTTLED WATER 03803	DOMESTIC SAMPLE COLL LACF/AF 03803A	IMPORT SAMPLE COLL PRODUCE ASSIGN 03F100	IMPORT SAMPLE COLL LACF/AF 03003A	IMPORT SAMPLE COLL CHEESE 03037
TOTAL FIELD		75	290	204	100	57	210	1500	1400	630
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		5.0	4.0	4.0	5.0	6.0	6.0	3.0	1.8	2.0
TOTAL HOURS		375	1160	816	500	342	1260	4500	2520	1260
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		0.39	1.22	0.86	0.53	0.36	1.33	4.74	2.65	1.33
7. REMARKS										

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 460.5 [145.4]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	5	6	7	7	7	7	7
		IMPORT SAMPLE COLL IMPORT FOODS 03819	IMPORT SAMPLE COLL SEAFOOD 03844	FIELD EXAMS (1)	IMPORT FIELD EXAMS (2)	DOMESTIC SAMPLES TO BE ANALYZED LAC/IAF 03803A MICRO	DOMESTIC SAMPLES TO BE ANALYZED PRODUCE 03F100 MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEESE 03037 MICRO	DOMESTIC SAMPLES TO BE ANALYZED FOOD SAFETY 03803 MICRO	DOMESTIC SAMPLES TO BE ANALYZED SEAFOOD 03842 MICRO
TOTAL FIELD		7500	6400	1520	152139	210	1200	290	633	280
HEADQUARTERS		(b)(5)&(b)(7)(E)								
REGIONAL STAFF										
NEW ENGLAND										
NEW YORK										
REGIONAL LAB										
WEAC										
REGIONAL STAFF										
BALTIMORE										
CHICAGO										
CINCINNATI										
DETROIT										
MINNEAPOLIS										
NEW JERSEY										
PHILADELPHIA										
FORENSIC CHEM. CTR										
REGIONAL STAFF										
ATLANTA										
FLORIDA										
NEW ORLEANS										
SAN JUAN										
REGIONAL LAB										
REGIONAL STAFF										
DALLAS										
DENVER										
KANSAS CITY										
SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB										
REGIONAL STAFF										
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		2.2	2.6	1.0	0.5	14.0	13.0	18.0	10.0	14.0
TOTAL HOURS		16500	16640	1520	76070	2940	15800	5220	6330	3920
CONVERSION FACTOR		950	950	950	950	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		17.37	17.52	1.60	80.07	2.49	13.22	4.42	5.36	3.32
7. REMARKS										
<p>(1) - Field Exams are to include pH and canned seam evaluation.</p> <p>(2) - Import Field Exams are for Field Exams as required by the District to cover program priorities. Import Field Exams are to routinely include: Verification that the imported product is the same as declared (Reconciliation Exam); and assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc.); traditional safety concerns. These activities are to be reported as a single Import Field Exam under this Compliance Program and PAC. Only one exam should be reported per line entry. Only in the event of a Pre-Determined "for cause" CT Exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should the CT Exam be reported under the CT PAC (03R845, 04R845, etc.).</p> <p>NOTE: Laboratory allocations were planned by DFS.</p>										

1. PROGRAM/ASSIGNMENT TITLE Foodborne Biological Hazards	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 460.5 [77.0]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	7	7	7	8	8	8	8
		DOMESTIC EMERGING ISSUES ANALYST MICRO (Hours) (1)	DOMESTIC SAMPLES TO BE ANALYZED SPECIES SUB IN FISH ASSIGN MICRO 03842	DOMESTIC SAMPLES TO BE ANALYZED AGED CHEESE ASSIGN MICRO 03037	DOMESTIC SAMPLES TO BE ANALYZED BOTTLED WATER ASSIGN MICRO (03803)	DOMESTIC SAMPLES TO BE ANALYZED JUICE HACCP 03847 MICRO	IMPORT SAMPLES TO BE ANALYZED SEAFOOD CHEM 03844	IMPORT SAMPLES TO BE ANALYZED SEAFOOD MICRO 03844	IMPORT SAMPLES TO BE ANALYZED LACF/AF 03003A MICRO	IMPORT SAMPLES TO BE ANALYZED CHEESE 03037 MICRO
	TOTAL FIELD	21535	100	204	57	75	3000	3400	1400	630

	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		14.0	18.0	10.0	12.0	7.0	7.0	7.0	13.0
TOTAL HOURS	21535	1400	3672	570	900	21000	23800	9800	8190
CONVERSION FACTOR	1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs	18.25	1.19	3.11	0.48	0.76	17.80	20.17	8.31	6.94

7. REMARKS

NOTE: Laboratory allocations were planned by DFS.

(1) - Emerging issues is a new category of resources placed in PPS 03, PPS 04, and PPS 21 to cover any issues or events that do not qualify as an emergency or outbreak, but are considered of importance due to potential impact or other policy imperative reason. These resources can be used for laboratory analysis or other laboratory operations and will be allocated through assignments unless otherwise instructed.

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 460.5 [114.1]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8	8	9	9	9	9	9	9	9
		IMPORT SAMPLES TO BE ANALYZED IMPORT FOODS 03819 MICRO	IMPORT SAMPLES TO BE ANALYZED PRODUCE 03F088 MICRO	LEVEL II AUDITORS CERTI- FICATION (Hours) (1)	APPLIED TECH CENTER MICRO 03R816 (Hours)	METHODS VAL/DEV MICRO 03R816 (Hours)	PRIOR NOTICE REVIEW (Hours) (2)	OP CODE 92 PRIVATE LAB REVIEW IMPORT (Hours) (3)	BETTER PROCESSING SCHOOL TRAINING (Hours) (4)	CONTRACT MANAGE- MENT (Hours) 03R843 (5)
	TOTAL FIELD	7500	1500	1600	4720	3615	32400	4720	760	11400
	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	7.1	13.0							
	TOTAL HOURS	53250	19500	1600	4720	3615	32400	4720	760	11400
	CONVERSION FACTOR	1180	1180	950	1180	1205	1200	1180	950	950
	TOTAL OPERATIONAL FTEs	45.13	16.53	1.68	4.00	3.00	27.00	4.00	0.80	12.00

7. REMARKS

(1) - Level II Auditors Certification Time: These hours are to provide auditors the time to evaluate/train other investigators trying to maintain Level II Certification. District allocation was based on the current on board staffing provided by DHRD.

(2) - Resources in Headquarters are for review of prior notices at the Division of Food Defense Targeting (DFDT) formally known as the Prior Notice Center.

(3) - Private Laboratory Review Time is for NRL, SRL, ARL, PRS analysts to review private lab results submitted for imported foods. Review time MUST be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field. Without consistency in reporting, your time will not be found and credited.

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

(5) - Time planned for Contract management includes resources to conduct audits. Report Foods State Contract Inspection Audit time under operation 13 (Investigation Operations) PAC 03R843. NOTE: Non-operational FTE's, i.e. supervisors, should not report contract management time.

NOTE: Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Domestic High Risk Inspections	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 242.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	NON-FSMA	NON-FSMA	NON-FSMA	FSMA	1	1
		FDA FSMA HIGH RISK INSPECTIONS (1) (3)	FDA NON-FSMA HIGH RISK INSPECTIONS ONLY (2)	INTERSTATE TRAVEL WATERING PT INSPECTIONS GUIDANCE ONLY (2)	EGG FARM INSPECTIONS GUIDANCE ONLY (2)	MISCELLANEOUS PRODUCE INSPECTIONS GUIDANCE ONLY (2)	INFANT FORMULA MEDICAL FOODS FIRMS GUIDANCE ONLY (3)	PROJECTED FDA FOLLOW-UP OAI INSPEC- TIONS (4)	REINSPEC- TIONS OF FY 2011 FSMA FIRMS (5)
	TOTAL FIELD	3469	1100	500	300	300	37	228	1776

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																
	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										35.0	35.0					35.0	35.0
TOTAL HOURS										121415	38500					7980	62160
CONVERSION FACTOR										950	950					950	950
TOTAL OPERATIONAL FTEs										127.81	40.53					8.40	65.43

7. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Non-High Risk Inspections	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 44.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FDA NON-HIGH RISK FSMA INSPECTIONS (1)	1 PROJECTED FDA FOLLOW-UP OAI INSPECTIONS (2)	ITP NON-AIRLINE WATERING POINT INSPECTIONS GUIDANCE ONLY				
	TOTAL FIELD	1576	79	200				
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
WEAC								
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION	25.0	30.0					
	TOTAL HOURS	39400	2370					
	CONVERSION FACTOR	950	950					
	TOTAL OPERATIONAL FTEs	41.47	2.49					

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 CFISAN Environmental Sampling Assignments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 97.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	Environmental SAMPLE CSO HOURS EGG RULE INSPECTIONS	Environmental SAMPLE CSO HOURS INFANT AND DRY CEREALS	Environmental SAMPLE CSO HOURS SOFT CHEESE	Environmental SAMPLE CSO HOURS RTE COLD CUT SANDWICH	Environmental SAMPLE CSO HOURS DRIED (MILK/SOY) PROTEIN FOR SALMONELLA	Environmental SAMPLE CSO HOURS MILK POWDER FACILITY FOR CRONOBACTER	Environmental DOMESTIC LAB ANALYST (Hours) MICRO		
	TOTAL FIELD	(1)	(2)	(3)	(4)	(5)	(6)			
	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)								
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										
TOTAL HOURS		30000	15000	6600	11500	8000	7000	18314		
CONVERSION FACTOR		950	950	950	950	950	950	1180		
TOTAL OPERATIONAL FTEs		31.58	15.79	6.95	12.11	8.42	7.37	15.52		

7. REMARKS
 NOTE: PAC 03F830 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.
 CSO time to include inspections and sample collections. Report hours utilized under the appropriate operation code.
 (1) - Estimated (b) firms
 (2) - Estimated (5) firms
 (3) - Estimated (b) firms
 (4) - Estimated (b) firms (5) - Estimated (b) firms (6) - Estimated (b) firms
 Hours based on estimated 75 hours per inspection and 25 hours per sample collection. Additional time for inspections is included under the High Risk Inspections planned separately. **District spread of resources is for planning purposes only.** Above numbers are estimates only -- assignment parameters will dictate the final number of firms to be covered.
 Environmental sampling to follow-up on Outbreaks and Emergency Response activities is planned separately (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 - 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 44.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS INCLUDES CADRE (1)								
	TOTAL FIELD	1200								
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	35.0								
	TOTAL HOURS	42000								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	44.21								

7. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 116.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 CONSUMER SAFETY OFFICER (Hours) (1)	7 DOMESTIC LAB ANALYST (Hours) MICRO	7 DOMESTIC LAB ANALYST (Hours) CHEM					
	TOTAL FIELD	63469	45548	12980					
	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									
TOTAL HOURS		63469	45548	12980					
CONVERSION FACTOR		950	1180	1180					
TOTAL OPERATIONAL FTEs		66.81	38.60	11.00					

7. REMARKS

NOTE: 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 Resources 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). Also, report related inspections and analyses in response to pesticides and chemical contaminants against the appropriate Foodborne Emergency PAC (e.g. 04R078 Deep Water Horizon Water Spill Activities, or another PAC to be created in response to a future emergency).

(1) - Includes investigational hours for all domestic and import investigations, follow-up to RFR-RCR, and Food Defense Assignments. District allocations are based on 3 year accomplishment data.

NOTE: Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04				
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 172.6 [32.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 DOMESTIC INVESTIGATIONS (Hours)	2 IMPORT INVESTIGATIONS (Hours)	2 DOMESTIC EMERGING ISSUES CSO (Hours) (1)	3 DOMESTIC SAMPLE COLL PESTICIDE 04004A	3 DOMESTIC SAMPLE COLL CHEMO 04018	3 DOMESTIC SAMPLE COLL TOXIC ELE 04019A	3 DOMESTIC SAMPLE COLL FLD ASSIGN 04F800	3 DOMESTIC SAMPLE COLL EU AUDIT 04004
	TOTAL FIELD		5000	5000	10355	2250	100	335	50
	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					3.0	5.0	4.0	3.0	4.0
TOTAL HOURS		5000	5000	10355	6750	500	1340	150	1440
CONVERSION FACTOR		950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		5.26	5.26	10.90	7.11	0.53	1.41	0.16	1.52
7. REMARKS									
NOTE: PAC 04F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.									
NOTE: Hours per operation modules are for guidance only. Report actual time spent on operations.									
(1) - Emerging issues is a new category of resources placed in PPS 03, PPS 04, and PPS 21 to cover any issues or events that do not qualify as an emergency or outbreak, but are considered of importance due to potential impact or other policy imperative reason. These resources can be used for sample collections or other CSO operations and will be allocated through assignments unless otherwise instructed.									

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04														
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 172.6 [39.8]												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	4	4	4	5	6	7	7									
		IMPORT SAMPLE COLL PESTICIDE 04004A	IMPORT SAMPLE COLL CHEMO 04018	IMPORT SAMPLE COLL TOXIC ELE 04019A	IMPORT SAMPLE COLL RADIO- NUCLIDES 04019C	IMPORT SAMPLE COLL FLD ASSIGN 04F800	FIELD EXAMS/ TESTS	IMPORT FIELD EXAM (2)	DOMESTIC SAMPLES TO BE ANALYZED PESTICIDE 04004A	DOMESTIC SAMPLES TO BE ANALYZED DIOXIN 04004D									
TOTAL FIELD		3300	1000	625	250	400	25	6406	2250	536									
HEADQUARTERS (b)(5)&(b)(7)(E)																			
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)																	
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
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											1.6	2.5	1.8	2.5	3.0	0.7	0.5	6.5	28.0
TOTAL HOURS											5280	2500	1125	625	1200	18	3203	14625	15008
CONVERSION FACTOR											950	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs											5.56	2.63	1.18	0.66	1.26	0.02	3.37	12.39	12.72
7. REMARKS (2) - Import Field Exams are for Toxic Elements in Foodware (PAC 04019B) Laboratory allocations were planned by DFS.																			

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04					
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 172.6 [77.9]			
R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	7	7	7	7	7	8	8	8	8
	TOTAL FIELD	DOMESTIC SAMPLES TO BE ANALYZED CHEMO 04018	DOMESTIC SAMPLES TO BE ANALYZED TOX ELEM 04019A	DOMESTIC SAMPLES TO BE ANALYZED FLD ASSIGN 04F800	DOMESTIC SAMPLES TO BE ANALYZED EU AUDIT 04004	DOMESTIC EMERGING ISSUES ANALYST CHEM (Hours) (3)	IMPORT SAMPLES TO BE ANALYZED PESTICIDE 04004A	IMPORT SAMPLES TO BE ANALYZED CHEMO 04018	IMPORT SAMPLES TO BE ANALYZED TOX ELEM 04019A	IMPORT SAMPLES TO BE ANALYZED RADIONUC 04019C
	HEADQUARTERS	100	335	50	360	7195	3300	1000	625	250
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		24.0	12.0	11.0	46.5		7.8	24.0	12.0	15.0
TOTAL HOURS		2400	4020	550	16740	7195	25740	24000	7500	3750
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		2.03	3.41	0.47	14.19	6.10	21.81	20.34	6.36	3.18
7. REMARKS Laboratory allocations were planned by DFS.										
(3) - Emerging issues is a new category of resources placed in PPS 03, PPS 04, and PPS 21 to cover any issues or events that do not qualify as an emergency or outbreak, but are considered of importance due to potential impact or other policy imperative reason. These resources can be used for lab operations and will be allocated through assignments unless otherwise instructed.										

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Chemical Contaminants					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04				
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 172.6 [22.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED FLD ASSIGN 04F800	9 FORENSICS (Hours)	9 APPLIED TECH- NOLOGY CENTER CHEM (Hours)	9 METHODS VAL/DEV CHEM (Hours)				
	TOTAL FIELD	400	14460	5900	2410				
	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		11.0							
TOTAL HOURS		4400	14460	5900	2410				
CONVERSION FACTOR		1180	1205	1180	1205				
TOTAL OPERATIONAL FTEs		3.73	12.00	5.00	2.00				
7. REMARKS Laboratory allocations were planned by DFS.									

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04																																																																				
3. PROGRAM/ASSIGNMENT CODE(S) 04839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 28.6																																																																			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL (TOTAL) (DIET) (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	7 DOMESTIC SAMPLES TO BE ANALYZED RADIO- NUCLIDE (3)	7 DOMESTIC SAMPLES TO BE ANALYZED PERCHLOR- ATES (4)																																																																				
	TOTAL FIELD	60	1136	2	1136																																																																				
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)																																																																							
	REGIONAL STAFF																																																																								
	NEW ENGLAND																																																																								
	NEW YORK																																																																								
	REGIONAL LAB																																																																								
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CE	REGIONAL STAFF																																																																								
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SE	REGIONAL STAFF																																																																								
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	REGIONAL STAFF																																																																								
	LOS ANGELES																																																																								
	SAN FRANCISCO																																																																								
	SEATTLE																																																																								
	PACIFIC REGIONAL LABORATORY-SW																																																																								
	PACIFIC REGIONAL LABORATORY-NW																																																																								
HOURS PER OPERATION																																																																		26.0	20.1	2800.0	3.0				
TOTAL HOURS																																																																		1560	22834	5600	3408				
CONVERSION FACTOR																																																																		950	1180	1180	1180				
TOTAL OPERATIONAL FTEs																																																																		1.64	19.35	4.75	2.89				
7. REMARKS																																																																									
<p>(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.</p> <p>(2) - Represents the total number of food items analyzed for various attributes. VOC analyses will no longer be conducted on TDS foods.</p> <p>(3) - All TDS food items from two market baskets analyzed by WEAC for selected radionuclides.</p> <p>(4) - All TDS foods from each market basket are analyzed for perchlorates.</p> <p>Laboratory allocations were planned by DFS.</p>																																																																									

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001, 07R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input 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 SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM	9 METHOD VAL/DEV CHEM (Hours) 07R816	9 APPLIED TECHN- OLOGY CTR. MICRO (Hours) 07R816	9 APPLIED TECHN- OLOGY CTR. CHEM (Hours) 07R816									
	TOTAL FIELD	832	832	832	832	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																
	REGIONAL LAB																
SW	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
PA	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
	HOURS PER OPERATION	4.0	2.0	6.0	7.0												
	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.

1. PROGRAM/ASSIGNMENT TITLE Food & Color Additive Petition Review & Development				2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09					
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 15.0		
R E G I O N	8. DISTRICT/ SPECIALIZED LABORATORY	4. IMPORT SAMPLE FOOD ADDITIVES COLL	4. IMPORT SAMPLE COLOR ADDITIVES COLL	6. IMPORT FIELD EXAMS (1)	8. IMPORT SAMPLES TO BE ANALYZED FOOD ADD. CHEM	8. IMPORT SAMPLES TO BE ANALYZED COLOR ADD. CHEM			
	TOTAL FIELD		310	865	4804	310	865		
	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	1.4	0.5	13.0	10.0			
TOTAL HOURS		434	1211	2402	4030	8650			
CONVERSION FACTOR		950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs		0.46	1.27	2.53	3.42	7.33			
7. REMARKS NOTE: PAC 09F810 is for planning purpose only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS. Hours per operation modules are for guidance only. Report actual time spent on operations. (1) - All import field exams are to routinely include verification that the imported product is the same as that which was declared (reconciliation exams); and assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are reported as a single Import Field Exams for label review under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845,09R845, etc.) See IOM Section 5.4.1.4.1. for additional information on Food and Cosmetic Securities Activities. Laboratory allocations were planned by DFS.									

1. PROGRAM/ASSIGNMENT TITLE Technical Assistance - Food and Cosmetics				2. PPS PROJECT NAME/NUMBER Technical Assistance- Food and Cosmetics - 18					
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 3.2		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2. INVESTI- GATIONS (Hours)	3. DOMESTIC SAMPLE COLL FOR CAUSE CHEM	3. DOMESTIC SAMPLE COLL SURV. MICRO	7. DOMESTIC SAMPLES TO BE ANALYZED CHEM	7. DOMESTIC SAMPLES TO BE ANALYZED MICRO			
	TOTAL FIELD	850	20	180	20	180			
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION			4.0	4.0	12.0	8.0			
TOTAL HOURS		850	80	720	240	1440			
CONVERSION FACTOR		950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs		0.89	0.08	0.76	0.20	1.22			

7. REMARKS

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

Districts allocations were planned by CFSAN.

Laboratory allocations were planned by DFS.

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 27.0 [2.6]																																																																			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 CONFERENCE FOR FOOD PROTECTION ACTIVITIES (10)	9 FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (11)	9 IFSS WORK GROUPS (12)	9 TECHNICAL ASSISTANCE PRESIDENT INAUGURATION																																																																				
	TOTAL FIELD	1020	1120	100	850																																																																				
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																																																																									
TOTAL HOURS																																																																		1020	1120	100	850				
CONVERSION FACTOR																																																																		1200	1200	1200	1200				
TOTAL OPERATIONAL FTEs																																																																		0.85	0.93	0.08	0.71				
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 20.1 [16.9]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9	9	9	9	9	9	9	
		CHECK RATING PLANT (1)	CHECK RATING TRANSFER AND RECEIVING (1)	CHECK RATING BTU (1)	SINGLE SERVICE AUDITS (1)	STATE SAMPLING SURVEILL- ANCE OFF. CERTIFICA- TION (2)	STATE MILK SANITATION RATING OFF. INITIAL CERTIFICA- TION (2)	STATE PROGRAM EVALUATION (3)	STATE RATING OFFICER CERTIFICA- TION (4)	TECHNICAL ASSISTANCE (5)
	TOTAL FIELD	149	34	259	64	43	40	17	26	51

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

HOURS PER OPERATION	24.0	12.0	20.0	8.0	24.0	40.0	120.0	50.0	90.0
TOTAL HOURS	3576	408	5180	512	1032	1600	2040	1300	4590
CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs	2.98	0.34	4.32	0.43	0.86	1.33	1.70	1.08	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						
3. PROGRAM/ASSIGNMENT CODE(S) 18003		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 20.1 [3.2]				
R E G I O N	5. DISTRICT/ SPECIALIZED LABORATORY	9 RMS STANDARDI- ZATION	9 FOOD DEFENSE COORDI- NATION	9 TRAINING GIVEN	9 INTEGRATED FOOD SAFETY SYSTEM	9 NCIMS			
		(5)	(6)	(7)	(8)	(9)			
	TOTAL FIELD	11	20	32	5	20			
	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		40.0	20.0	40.0	20.0	80.0			
TOTAL HOURS		440	400	1280	100	1600			
CONVERSION FACTOR		1200	1200	1200	1200	1200			
TOTAL OPERATIONAL FTEs		0.37	0.33	1.07	0.08	1.33			

7. REMARKS

(5) - Activities include the Initial Standardization and 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 14.5 [12.3]
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R E G I O N	8. DISTRICT/ SPECIALIZED LABORATORY	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 INTIA- TIVES/LAB (7)	PLANT EVALUATION (8)	STANDARD IZATION & RE-STAN- DARD IZATION (9)
	TOTAL FIELD	193	20	2155	3734	3	2	7	142	14

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	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										

HOURS PER OPERATION	20.0	90.0			200.0	180.0	40.0	10.0	40.0
TOTAL HOURS	3860	1800	2155	3734	600	360	280	1420	560
CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs	3.22	1.50	1.80	3.11	0.50	0.30	0.23	1.18	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						
3. PROGRAM/ASSIGNMENT CODE(S) 18004			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 14.5 [2.2]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 NATIONAL TEAM WORKSHOP	9 TRAINING WORKSHOPS	9 REGIONAL SEMINARS	9 FOOD DEFENSE COORDINATION	9 ISSC COMMITTEE	9 IFSS WORKGROUP			
		(10)	(11)	(12)	(13)	(14)	(15)			
	TOTAL FIELD	9	11	11	10	14	5			
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
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	30.0	30.0	20.0	90.0	20.0			
	TOTAL HOURS	360	330	330	200	1260	100			
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200			
	TOTAL OPERATIONAL FTEs	0.30	0.28	0.28	0.17	1.05	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.										

1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics					2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 39.6 [5.4]			
R E G I O N	6.	3	3	3	3	3	4	4	4	4
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL MEDICAL FOODS 21002	DOMESTIC SAMPLE COLL ECONO. 21003	DOMESTIC SAMPLE COLL NLEA 21005	DOMESTIC SAMPLE COLL INFANT FORMULA 21006	DOMESTIC SAMPLE COLL DIETARY SUPPL 21008	IMPORT SAMPLE COLL MEDICAL FOODS 21002	IMPORT SAMPLE COLL NLEA 21005	IMPORT SAMPLE COLL INFANT FORMULA 21006	IMPORT SAMPLE COLL DIETARY SUPPL 21008
TOTAL FIELD		33	100	340	26	250	8	910	15	430
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		6.0	4.2	4.2	5.3	4.2	6.0	1.2	5.0	1.6
TOTAL HOURS		198	420	1428	138	1050	48	1092	75	688
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		0.21	0.44	1.50	0.15	1.11	0.05	1.15	0.08	0.72
7. REMARKS										
<p>NOTE: PAC 21F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see page I-III (after the Center Resource Summary Sheet) for a listing of compliance programs and corresponding reporting PACS.</p> <p>For Pac 21008 ~ Domestic Sample Collections and Field Exams (on page 21-32) may be conducted at packers/repackers, distributors, or warehouses if levels planned cannot be performed during the inspections.</p>										

1. PROGRAM/ASSIGNMENT TITLE Food Composition, Standards, Labeling and Economics					2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) See Remarks Section			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 39.6 [19.1]			
R E G I O N	6.	2	5	6	7	7	7	7	7	7
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC EMERGING ISSUES CSO (Hours) (1)	FIELD EXAMS/ TEST	IMPORT FIELD EXAMS (2)	DOMESTIC SAMPLES TO BE ANALYZED MED. FOODS CHEM 21002	DOMESTIC SAMPLES TO BE ANALYZED MED. FOODS MICRO 21002	DOMESTIC SAMPLES TO BE ANALYZED ECON CHEM 21003	DOMESTIC SAMPLES TO BE ANALYZED NLEA CHEM 21005	DOMESTIC SAMPLES TO BE ANALYZED INFANT FOR. CHEM 21006	DOMESTIC SAMPLES TO BE ANALYZED INFANT FOR- MICRO 21006
	TOTAL FIELD	630	2400	11209	21	12	100	340	18	8
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			0.4	0.5	101.1	30.0	19.0	19.1	100.0	120.0
TOTAL HOURS		630	960	5605	2123	360	1900	6494	1800	960
CONVERSION FACTOR		950	950	950	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.66	1.01	5.90	1.80	0.31	1.61	5.50	1.53	0.81

7. REMARKS

NOTE: Laboratory allocations were planned by DFS.

(1) - Emerging issues is a new category of resources placed in PPS 03, PPS 04, and PPS 21 to cover any issues or events that do not qualify as an emergency or outbreak, but are considered of importance due to potential impact or other policy imperative reason. These resources can be used for sample collections or other CSO operations and will be allocated through assignments unless otherwise instructed.

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

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

See IOM Section 5.4.1.4.1. for additional information on Food and Cosmetic Securities Activities.

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics - 29
--	---

3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.6
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1	3	4	3	7	7	8	8	6
		DOMESTIC INSPECT- IONS	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	DOMESTIC SAMPLE COLL PRESERVATIVE ASSIGNMENT	DOMESTIC SAMPLES TO BE ANALYZED (Micro)	DOMESTIC SAMPLES TO BE ANALYZED PRESERVATIVE ASSIGNMENT (Micro)	IMPORT SAMPLES TO BE ANALYZED (Micro)	IMPORT SAMPLES TO BE ANALYZED (Chem)	IMPORT FIELD EXAMS
	TOTAL FIELD	100	60	230	150	60	150	115	115	1600
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
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		17.0	4.4	1.5	3.0	13.0	13.0	13.0	13.0	0.5
TOTAL HOURS		1700	264	345	450	780	1950	1495	1495	800
CONVERSION FACTOR		950	950	950	950	1180	1180	1180	1180	950
TOTAL OPERATIONAL FTEs		1.79	0.28	0.36	0.47	0.66	1.65	1.27	1.27	0.84

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.

**RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2013**

	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs
	DOMESTIC	IMPORT	FOREIGN	
TOTAL ALL PROGRAMS	1523.9	604.6	217.8	2346.3
FOODS AND COSMETICS	841.3	467.6	44.2	1353.1
BIOLOGICS	129.6	4.0	6.4	140.0
HUMAN DRUGS	235.5	49.0	125.5	410.0
ANIMAL DRUGS AND FEEDS	121.8	17.7	5.7	145.2
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	179.8	61.2	36.0	277.0
TOBACCO	15.9	5.1		21.0

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2013**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	129.6	4.0	6.4	140.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	44.6		0.1	44.7
42	BLOOD AND BLOOD PRODUCTS	74.8	4.0	3.3	82.1
45	VACCINE AND ALLERGENIC PRODUCTS	10.2		3.0	13.2

1. PROGRAM/ASSIGNMENT TITLE Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41002B, C, D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 39.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC- TION S (1)	1 CBER PRI ORITY ESTABS (2)						
	TOTAL FIELD	815	135						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	NEW ENGLAND	(b)(5)&(b)(7)(E)							
	NEW YORK	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	WEAC	(b)(5)&(b)(7)(E)							
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	BALTIMORE	(b)(5)&(b)(7)(E)							
	CHICAGO	(b)(5)&(b)(7)(E)							
	CINCINNATI	(b)(5)&(b)(7)(E)							
	DETROIT	(b)(5)&(b)(7)(E)							
	MINNEAPOLIS	(b)(5)&(b)(7)(E)							
	NEW JERSEY	(b)(5)&(b)(7)(E)							
	PHILADELPHIA	(b)(5)&(b)(7)(E)							
SE	FORENSIC CHEM. CTR	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	ATLANTA	(b)(5)&(b)(7)(E)							
	FLORIDA	(b)(5)&(b)(7)(E)							
	NEW ORLEANS	(b)(5)&(b)(7)(E)							
SW	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)							
	DENVER	(b)(5)&(b)(7)(E)							
PA	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	45.5							
	TOTAL HOURS	37083							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	39.03							

9. REMARKS

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

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

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

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

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	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	43							
	HEADQUARTERS	(b)(5)&(b)							
	REGIONAL STAFF	(7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	110.5							
	TOTAL HOURS	4752							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	5.00							

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Cell and Gene Therapy Products (Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapeutics - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41848A,F,G and 41848B,C,D*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.7
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC (1)	1 INSPEC- TIONS FOREIGN (1)						
	TOTAL FIELD	4	1						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	NEW ENGLAND	(b)(5)&(b)(7)(E)							
	NEW YORK	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	WEAC	(b)(5)&(b)(7)(E)							
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	BALTIMORE	(b)(5)&(b)(7)(E)							
	CHICAGO	(b)(5)&(b)(7)(E)							
	CINCINNATI	(b)(5)&(b)(7)(E)							
	DETROIT	(b)(5)&(b)(7)(E)							
	MINNEAPOLIS	(b)(5)&(b)(7)(E)							
	NEW JERSEY	(b)(5)&(b)(7)(E)							
	PHILADELPHIA	(b)(5)&(b)(7)(E)							
SE	FORENSIC CHEM. CTR	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	ATLANTA	(b)(5)&(b)(7)(E)							
	FLORIDA	(b)(5)&(b)(7)(E)							
	NEW ORLEANS	(b)(5)&(b)(7)(E)							
SW	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)							
	DENVER	(b)(5)&(b)(7)(E)							
PA	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	149.5	67.0						
	TOTAL HOURS	598	67						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	0.63	0.07						

9. REMARKS

New Workplanning Sheet for FY2013, resources previously included on PAC 42848's Workplanning Sheet.

(1) - Resources for all 41848 PACs are planned under PAC 41848F. Use above resources for Domestic and Foreign Inspections as needed and report time under appropriate PAC and Operation Code. Report Foreign Inspections under Operation Code 11. All inspections will be performed by Team Biologics.

* PACs include:

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

Personnel Types required: Team Biologics Investigators

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G,H	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 55.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP CTIONS (1)	1 FOREIGN INSP CTIONS (2)	2 DOMESTIC INVEST IGATIONS (Hours) (3)	9 TECH ASST & COORDIN ATION (Hours) OP CODE 92 (4)				
	TOTAL FIELD	985	8	2400	2840				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		47.9	42.0						
TOTAL HOURS		47182	336	2400	2840				
CONVERSION FACTOR		950	950	950	950				
TOTAL OPERATIONAL FTEs		49.67	0.35	2.53	2.99				

9. REMARKS

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

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

(2) - Foreign Blood Bank Inspections spread by DFFI.

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

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

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE Inspections of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42002A,F,G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)							
	TOTAL FIELD	194							
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	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	58.3							
	TOTAL HOURS	11310							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	11.91							

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.

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	b.	2								
	DISTRICT/ SPECIALIZED LABORATORY	IMPORT INVESTI- GATION HOURS (1)								
TOTAL FIELD		3800								
NE	HEADQUARTERS		(b)(5)&(b) (7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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.

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42008A,F,G Domestic & Foreign (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC- TIONS	1 FOREIGN INSPEC- TIONS	2 DOMESTIC INVESTI- GATIONS (Hours) (2)											
	TOTAL FIELD	9	5	426											
	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									140.1	132.8	426				
TOTAL HOURS									1261	664	426				
CONVERSION FACTOR									950	950	950				
TOTAL OPERATIONAL FTEs									1.33	0.70	0.45				

9. REMARKS
 Program Title CHANGED from Licensed Viral Marker Test Kits to: Licensed In-Vitro Diagnostic (IVD) Devices.

(1) REVISED Titles, PACs: 42008A Pre-License Inspections - IVDs;
 42008F - Level 1 Inspection - Licensed IVDs;
 42008G - Level 2 Inspection - Licensed IVDs.
 PAC 42008 retired.
 No separate resources are planned for Pre-License Inspections, use above resources as needed.

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

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

Personnel Types Required: Team Biologics, Investigator

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)			2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42							
3. PROGRAM/ASSIGNMENT CODE(S) 42808-GLPs, 42809-IRBs, 42810-Spon/Mon/CROs, 42811 Clinical Investigators			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.4			
R E G I O N	5.	1								
	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS (1)								
TOTAL FIELD		43								
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									
	REGIONAL STAFF									
	LOS ANGELES									
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		97.3								
TOTAL HOURS		4184								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.40								

9. REMARKS

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

Personnel Types required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC T I O N S							
	TOTAL FIELD	12							
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	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	39.7							
	TOTAL HOURS	476							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	0.50							

9. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Plasma Derivatives of Human Origin	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42848A,F,G; 42848B,C,D Domestic & Foreign (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPEC- TIONS	1 FOREIGN LICENSED INSPEC- TIONS						
	TOTAL FIELD	8	10						
	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								
	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	130.0	210.0						
	TOTAL HOURS	1040	2100						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	1.09	2.21						

9. REMARKS

(1) - No separate resources are planned for Pre-License Inspections, use above resources as needed.
 All resources are planned under PAC 42848F. 42848A Pre-Licensed Inspection - Plasma Derivatives;
 42848F Level 1 CGMP Inspection - Plasma Derivative; 42848G Level 2 CGMP Inspection - Plasma Derivatives.
 NEW PACs in FY2011: 42848B Pre-Licensed Inspection - Recombinant Analogues;
 42848C Level 1 CGMP Inspection - Recombinant Analogues;
 42848D Level 2 CGMP Inspection - Recombinant Analogues.

Report ALL Accomplishments under Appropriate PAC and Operation Code.
 All Inspections will be performed by Team Biologics.

Team Biologics Compliance Program New in FY05 - Inspection of Biological Drug Products (CBER), previously covered by PAC 42006.

Personnel Types required: Team Biologics

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45808-GLPs, 45809-IRBs, 45810-Spon/Mon/CROs, 45811 Clinical Investigators	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.0
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)								
	TOTAL FIELD	68								
	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	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.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products (Post-Market & Pre-License)		2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45							
3. PROGRAM/ASSIGNMENT CODE(S) 45848A,F,G Domestic & Foreign (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.7		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	DOMESTIC INSP EC T I O N S						
	TOTAL FIELD	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								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		133.0							
TOTAL HOURS		665							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		0.70							

9. REMARKS

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

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
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3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic & Foreign (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.5
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1									
		DOMESTIC INSP EC- TION S	FOREIGN INSP EC- TION S									
	TOTAL FIELD	10	13									
	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		239.0	220.0									
TOTAL HOURS		2390	2860									
CONVERSION FACTOR		950	950									
TOTAL OPERATIONAL FTEs		2.52	3.01									

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.

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

Personnel Types Required: Team Biologics, Investigator

**CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2013**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	235.5	49.0	125.5	410.0
46	NEW DRUG EVALUATION	11.0		14.0	25.0
48	BIORESEARCH MONITORING HUMAN DRUGS	62.9		24.5	87.4
52	GENERIC DRUG EVALUATION	8.4		12.0	20.4
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	9.8		1.0	10.8
56	DRUG QUALITY ASSURANCE	115.5	49.0	74.0	238.5
63	UNAPPROVED AND MISBRANDED DRUGS	15.9			15.9
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Domestic (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46														
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46R845		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.5												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 CHEMIST ON INSPECTIONS (Hours) (1)	3 DOMESTIC SAMPLE COLL CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED PROFILE CHEM												
	TOTAL FIELD	141	703	17	35												
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
FORENSIC CHEM. CTR																	
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
REGIONAL LAB																	
SW	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
REGIONAL LAB																	
PA	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										55.8		7.1	11.8				
TOTAL HOURS										7868	703	121	413				
CONVERSION FACTOR										950	950	950	1180				
TOTAL OPERATIONAL FTEs										8.28	0.74	0.13	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							
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.	1	1							
	DISTRICT/ SPECIALIZED LABORATORY	INSPECTIONS	CHEMIST ON INSPECTIONS (Hours)							
		(2)	(3)							
	TOTAL FIELD	98	5470							
	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	70.2								
	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 DFFI.										

1. PROGRAM/ASSIGNMENT TITLE Pre-Licensed Biotech (BLA) Inspections/Investigations - Domestic and Foreign (PDUFA)				2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46						
3. PROGRAM/ASSIGNMENT CODE(S) 46832M			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)	1 INSPECTIONS Foreign							
	TOTAL FIELD	6	9							
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
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		152.9	110.2							
TOTAL HOURS		917	992							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.97	1.04							

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 type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)								
	TOTAL FIELD	24								
NE	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)								
	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	20.4								
	TOTAL HOURS	490								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	0.52								

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence - Pre-Approval (PDUFA)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs), 48001A (NDAs)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPECTIONS	1 48001A NDA INSPECTIONS						
	TOTAL FIELD	36	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		85.4	84.3						
TOTAL HOURS		3074	3119						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		3.24	3.28						
9. REMARKS									
<p>Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification.</p> <p>An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 45%, PDUFA 48001A (NDA) 55%.</p> <p>Please note: District inspection allocation may be subject to change as a result of CDER's final site selections.</p>									

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA; ANDA - PRE-APPROVAL)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48001D,E, 48811D NDA & ANDA (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPECTIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPECTIONS (PRE-APPVL)						
	TOTAL FIELD	33	32						
	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 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	108.0	102.8						
	TOTAL HOURS	3564	3290						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	3.75	3.46						

9. REMARKS

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

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

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

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

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 19.4				
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, CRO, MONITORS INSP CTIONS 48810 (3)				
	TOTAL FIELD	27	99	118	50				
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								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		105.7		80.5	120.5				
TOTAL HOURS		2854	99	9499	6025				
CONVERSION FACTOR		950	950	950	950				
TOTAL OPERATIONAL FTEs		3.00	0.10	10.00	6.34				

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 48-06).

(1) - Institutional Review Board

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

(3) - Sponsors, Contract Research Organizations, and Monitors

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

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48									
3. PROGRAM/ASSIGNMENT CODE(S) 48811, F* <small>NEW</small>			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 54.3								
R E G I O N	B.	DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP CTIONS	2 NAT'L EXPERT INVESTI- GATIONS (Hours)	1 DOMESTIC INSP CTIONS Follow-Up & Complaints 48811F	1 FOREIGN INSP CTIONS								
	TOTAL FIELD		177	102	118	175								
		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			118.8		119.1	94.0								
TOTAL HOURS			21028	102	14054	16450								
CONVERSION FACTOR			950	950	950	950								
TOTAL OPERATIONAL FTEs			22.13	0.11	14.79	17.32								
9. REMARKS <small>NEW</small> * - Report domestic follow-up and complaints as inspections under PAC 48811F.														
Please note: District inspection allocation may be subject to change as a result of CDER's final site selections.														

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Investigations - Domestic	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAS TO INSPECT	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED PROFILE CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED BIOTEST CHEM				
	TOTAL FIELD	66	35	13	22				
	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	53.1	6.7	50.0	28.5				
	TOTAL HOURS	3505	235	650	627				
	CONVERSION FACTOR	950	950	1180	1180				
	TOTAL OPERATIONAL FTEs	3.69	0.25	0.55	0.53				

9. REMARKS

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Investigations - Foreign					2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52														
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B ,52832C, 52832E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 12.0													
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	4	8	8												
		INSPECTIONS (1) (Foreign) (2)	CHEMIST INSPECTIONS (Hours) (Foreign) (3)	INVESTI- GATIONS (Hours)	IMPORT SAMPLE COLL (4)	IMPORT SAMPLES TO BE ANALYZED PROFILE CHEM (5)	IMPORT SAMPLES TO BE ANALYZED BIOTEST CHEM (5)												
	TOTAL FIELD	83	2200	147	151	75	76												
	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											79.7			3.0	16.8	15.5			
TOTAL HOURS											6615	2200	147	453	1260	1178			
CONVERSION FACTOR											950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs											6.96	2.32	0.15	0.48	1.07	1.00			
9. REMARKS																			
<p>(1) - Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;</p> <p>(2) - PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).</p> <p>Profile ISCs & ISAs -52832B; Biotest ISCs & ISAs under PAC 52832C.</p> <p>(3) - Includes microbiologists on inspections</p> <p>(4) - Samples are collected at foreign manufacturers.</p> <p>(5) - NRL analyzes all Profile/Biotest ISCs and methods development ISAs.</p> <p>Laboratory allocations were planned by DFS. Chem-On foreign inspsections planned by DFFI.</p>																			

1. PROGRAM/ASSIGNMENT TITLE Positron Emission Tomography (PET) Pre-Approval Inspections/Investigations			2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52							
3. PROGRAM/ASSIGNMENT CODE(S) 52832P			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.4			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	AND A P E T I N S P E C T I O N S (1)							
	TOTAL FIELD	150								
	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		21.5								
TOTAL HOURS		3225								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		3.39								
9. REMARKS (1) - Inspections are to determine compliance of establishments with GMPs prior to approval of pending ANDAs. ANDA bulk products are collected for profile analysis.										

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulation	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001A (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1						
		DOMESTIC INSP- CTIONS	FOREIGN INSP- CTIONS						
	TOTAL FIELD	93	15						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	NEW ENGLAND	(b)(5)&(b)(7)(E)							
	NEW YORK	(b)(5)&(b)(7)(E)							
	REGIONAL LAB	(b)(5)&(b)(7)(E)							
	WEAC	(b)(5)&(b)(7)(E)							
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	BALTIMORE	(b)(5)&(b)(7)(E)							
	CHICAGO	(b)(5)&(b)(7)(E)							
	CINCINNATI	(b)(5)&(b)(7)(E)							
	DETROIT	(b)(5)&(b)(7)(E)							
	MINNEAPOLIS	(b)(5)&(b)(7)(E)							
	NEW JERSEY	(b)(5)&(b)(7)(E)							
	PHILADELPHIA	(b)(5)&(b)(7)(E)							
SE	FORENSIC CHEM. CTR	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF	(b)(5)&(b)(7)(E)							
	ATLANTA	(b)(5)&(b)(7)(E)							
	FLORIDA	(b)(5)&(b)(7)(E)							
	NEW ORLEANS	(b)(5)&(b)(7)(E)							
SW	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)							
	DENVER	(b)(5)&(b)(7)(E)							
PA	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	78.6	63.5						
	TOTAL HOURS	7310	953						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	7.69	1.00						

9. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Risk Evaluation and Mitigation System (REMS)	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001C	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S (1)								
	TOTAL FIELD	27								
NE	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
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		72.6								
TOTAL HOURS		1960								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		2.06								

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, A-D, *56002H, I, J, K, 56832, 56R359	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 48.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 CERTIFI C A T I O N A U D I T S (INV Hours) (1)	1 CHEMIST ON INSP EC T I O N S (Hours)	1 MICRO ON INSP EC T I O N S (Hours)	3 DOMESTIC S A M P L E C O L L (2)	3 DOMESTIC S A M P L E C O L L (CHEM) (3)	3 DOMESTIC S A M P L E C O L L (MICRO) (3)	7 DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M	7 DOMESTIC S A M P L E S T O B E A N A L Y Z E D M I C R O
	TOTAL FIELD	436	1900	2499	1200	196	156	40	156	40

	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	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	76.2					7.9			36.8	18.0
TOTAL HOURS	33223	1900	2499	1200		1548			5741	720
CONVERSION FACTOR	950	950	950	950		950			1180	1180
TOTAL OPERATIONAL FTEs	34.97	2.00	2.63	1.26		1.63			4.87	0.61

9. REMARKS

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

(2) - DSCs not analyzed are documentary samples.

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



* The following PACS are for Abbreviated Inspections

- 56002H - ABBREVIATED DRUG PROCESS INSPECTIONS (DPI)
- 56002I - ABBREVIATED DPI / SMALL VOLUME PARENTERALS
- 56002J - ABBREVIATED DPI / DRUG REPACKERS AND RELABELLERS
- 56002K - ABBREVIATED DPI / RADIOACTIVE DRUGS

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, 56832, 56R359			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 62.0			
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP EC TIONS (1)	1 CHEMIST ON INSP ECTIONS FOREIGN (Hours) (2)							
TOTAL FIELD		659	7200							
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		78.5								
TOTAL HOURS		51732	7200							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		54.45	7.58							
9. REMARKS (1) - Report time under appropriate PACs (56002, 56002A, B, C, D, 56832, 56R359) under operation 11. (2) - Time planned in this column may be used by chemists or microbiologists. Foreign Inspections include the Foreign Cadre inspection time. Laboratory allocations were planned by DFFI.										

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Gas Manufacturers (Domestic)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S M E D I C A L G A S (1)										
	TOTAL FIELD	295										
	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	38.6										
	TOTAL HOURS	11387										
	CONVERSION FACTOR	950										
	TOTAL OPERATIONAL FTEs	11.99										

9. REMARKS

(1) - Total number of planned gas inspections in the Program for FY 2013.


1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Active Pharmaceutical Ingredients (APIs) - (Domestic and Foreign)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002F, 56002L*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC T I O N S	1 FOREIGN INSP EC T I O N S							
	TOTAL FIELD	45	138							
	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	63.4	68.5							
	TOTAL HOURS	2853	9453							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	3.00	9.95							

9. REMARKS

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

* The following PAC is for Abbreviated Inspections: 


56002L - ABBREVIATED ACTIVE PHARMACEUTICAL INGREDIENT PROCESS INSPECTIONS

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Biotech Manufacturers (Domestic)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002M	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS								
	TOTAL FIELD	59								
NE	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)								
	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		96.4								
TOTAL HOURS		5688								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		5.99								

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, 56002Q*			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.0				
R E G I O N	b.	1									
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S (1)									
	TOTAL FIELD	51									
N E	HEADQUARTERS	(b)(5)&(b) (7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
C E	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
S E	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
S W	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
P A	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	37.5									
	TOTAL HOURS	1913									
	CONVERSION FACTOR	950									
	TOTAL OPERATIONAL FTEs	2.01									
9. REMARKS (1) - Inspections are to evaluate the conditions under which drug products are manufactured, tested, packaged and held. Manufacturers are required to adhere to USP <823>; 21 CFR Part 212 (effective December 2011). * The following PAC is for Abbreviated Inspections:  56002Q - ABBREVIATED PET INSPECTIONS											

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Sampling and Testing Program					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56008A, L (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 18.0 [3.7]				
R E G I O N	6.	2	3	3	3	3	3	3	7	7
	DISTRICT/ SPECIALIZED LABORATORY	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	DOMESTIC IMPORT SAMPLE COLL 56008L (1)	DOMESTIC IMPORT SAMPLE COLL CHEM 56008L	DOMESTIC IMPORT SAMPLE COLL MICRO 56008L	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	219	36	20	16	380	300	80	20	10
	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			6.3			5.5			51.6	21.9
TOTAL HOURS		219	227			2090			1032	219
CONVERSION FACTOR		950	950			950			1180	1180
TOTAL OPERATIONAL FTEs		0.23	0.24			2.20			0.87	0.19
9. REMARKS										
<p>The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.</p> <p>(1) Reporting Guidance: Report domestic sample collections and sample analyses under 56008A. ALL domestic-import sample collections and sample analyses should be reported under NEW PAC 56008L.</p> <p>Laboratory allocations were planned by DFS.</p>										

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Sampling and Testing Program				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56									
3. PROGRAM/ASSIGNMENT CODE(S) 56008A, L (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 18.0 [14.3]							
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC IMPORT SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC IMPORT SAMPLES TO BE ANALYZED MICRO	9 METHODS VAL/DEV (Hours) CHEM (2)									
	TOTAL FIELD	300	80	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		36.3	16.5										
TOTAL HOURS		10890	1320	4661									
CONVERSION FACTOR		1180	1180	1180									
TOTAL OPERATIONAL FTEs		9.23	1.12	3.95									
9. REMARKS (1) Reporting Guidance: Report domestic sample collections and sample analyses under 56008A. ALL domestic-import sample collections and sample analyses should be reported under NEW PAC 56008L. (2) - Methods Validation/Development hours include resources for development activities coordinated through DFS. Laboratory allocations were planned by DFS.													

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56													
3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 49.0										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGA- TIONS HOURS (1)	6 IMPORT FIELD EXAM HOURS	2 INTERNATIONAL MAIL FACILITY REVIEWS INV HOURS	2 MAIL COURIER REVIEWS INV HOURS	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED API CHEM	8 IMPORT SAMPLES TO BE ANALYZED FIN-DOSE CHEM								
	TOTAL FIELD	14780	4523	7156	15901	1710	393	155	178								
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												1.0			2.7	20.1	13.5
TOTAL HOURS										14780	4523	7156	15901	1710	1061	3116	2403
CONVERSION FACTOR										1200	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs										12.32	4.76	7.53	16.74	1.80	1.12	2.64	2.04
9. REMARKS																	
<p>Reporting Guidance:</p> <ul style="list-style-type: none"> - 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. <p>(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.</p> <p>Use CT PAC 56R845 only when specific CT work is performed.</p> <p>Laboratory allocations were planned by DFS.</p>																	

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/NDA-Field Alert Reporting					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56												
3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 DQRS FARS INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLES COLL (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED (Hours) CHEM												
	TOTAL FIELD	46	1425	17	28												
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										37.6		7.4	42.8				
TOTAL HOURS										1730	1425	126	1198				
CONVERSION FACTOR										950	950	950	1180				
TOTAL OPERATIONAL FTEs										1.82	1.50	0.13	1.02				
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													
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 INSP EC- TION S	2 INVE STI- GATI ONS (Hours)	3 DOM ESTIC SAMP LES COLL (Hours)	7 DOM ESTIC SAMP LES TO BE ANAL YZED CHEM												
	TOTAL FIELD	21	294	27	34												
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	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										60.7		2.5	11.0				
TOTAL HOURS										1275	294	68	374				
CONVERSION FACTOR										950	950	950	1180				
TOTAL OPERATIONAL FTEs										1.34	0.31	0.07	0.32				
9. REMARKS																	
Laboratory allocations were planned by DFS.																	

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Domestic		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56												
3. PROGRAM/ASSIGNMENT CODE(S) 56843			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 2.0						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	INSPEC- TIONS											
	TOTAL FIELD		44											
NE	HEADQUARTERS	(b) (5)&(b) (7)(E)												
	REGIONAL STAFF													
	NEW ENGLAND													
	NEW YORK													
	REGIONAL LAB													
	WEAC													
CE	REGIONAL STAFF													
	BALTIMORE													
	CHICAGO													
	CINCINNATI													
	DETROIT													
	MINNEAPOLIS													
	NEW JERSEY													
	PHILADELPHIA													
FORENSIC CHEM. CTR														
SE	REGIONAL STAFF													
	ATLANTA													
	FLORIDA													
	NEW ORLEANS													
	SAN JUAN													
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			43.1											
TOTAL HOURS			1896											
CONVERSION FACTOR			950											
TOTAL OPERATIONAL FTEs			2.00											
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
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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								
	TOTAL FIELD	53								
	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	36.1								
	TOTAL HOURS	1913								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	2.01								

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56											
3. PROGRAM/ASSIGNMENT CODE(S) 56D015			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 2.0					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS											
	TOTAL FIELD	24											
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		80.6											
TOTAL HOURS		1934											
CONVERSION FACTOR		950											
TOTAL OPERATIONAL FTEs		2.04											

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

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - Global Parity Initiative		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Desk Audits INVESTIG- ATIONS (Hours)										
	TOTAL FIELD	3800										
	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												
TOTAL HOURS		3800										
CONVERSION FACTOR		950										
TOTAL OPERATIONAL FTEs		4.00										

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - OEI Clean Up		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56									
3. PROGRAM/ASSIGNMENT CODE(S) 56R011			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	Desk Audits INVESTI- GATIONS (Hours)								
	TOTAL FIELD	1900									
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											
TOTAL HOURS			1900								
CONVERSION FACTOR			950								
TOTAL OPERATIONAL FTEs			2.00								
9. REMARKS											
Investigation hours are to help address the foreign inventory accuracy, contact information, registration, and related maintenance.											

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

9. REMARKS

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

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs				2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63			
3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 11.4	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L (1)	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D C H E M	
	TOTAL FIELD		79	2252	269		199
	HEADQUARTERS		(b)(5)&(b)(7)(E)				
N E	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
C E	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
S E	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
S W	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
P A	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
SEATTLE							
PACIFIC REGIONAL LABORATORY-SW							
PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION			43.4		5.5		22.8
TOTAL HOURS			3429	2252	1480		4537
CONVERSION FACTOR			960	950	950		1180
TOTAL OPERATIONAL FTEs			3.61	2.37	1.56		3.85

9. REMARKS

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

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

Laboratory allocations were planned by 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					5. OPERATIONAL FTE POSITIONS 4.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)								
	TOTAL FIELD	82	200								
	HEADQUARTERS	(b)(5)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	49.6									
	TOTAL HOURS	4067	200								
	CONVERSION FACTOR	950	950								
	TOTAL OPERATIONAL FTEs	4.28	0.21								
9. REMARKS Report work under New Drugs (Rx) without Approved NDAs (formerly PAC 52002) to PAC 63002.											

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 SAMPLES TO BE ANALYZED CHEM										
	TOTAL FIELD	14160										
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											
	REGIONAL STAFF											
PA	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.												

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2013**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	121.8	17.7	5.7	145.2
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	6.3		3.8	10.1
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS, AND DEVICES	115.5	17.7	1.9	135.1

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections			2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68					
3. PROGRAM/ASSIGNMENT CODE(S) 68001, 68001G			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1				
		FOREIGN INSP CTIONS (1)	DOMESTIC INSP CTIONS (2)	CHEMIST ON INSP				
	TOTAL FIELD	40	5	850				
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)						
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF	(b)(5)&(b)(7)(E)						
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB	(b)(5)&(b)(7)(E)						
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT	(b)(5)&(b)(7)(E)						
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
PACIFIC REGIONAL LABORATORY-SW	(b)(5)&(b)(7)(E)							
PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		80.0	50.0					
TOTAL HOURS		3200	250	850				
CONVERSION FACTOR		950	950	950				
TOTAL OPERATIONAL FTEs		3.37	0.26	0.89				

7. REMARKS

(1) - Foreign inspections spread by DFFI. 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									
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 5.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP EC TIONS 68810	1 FOREIGN INSP EC TIONS 68811	1 DOMESTIC INSP EC TIONS 68808	1 DOMESTIC INSP EC TIONS 68811						
	TOTAL FIELD	2	3	30 (1)	44						
	HEADQUARTERS	(b)(5)&(b)(7)(E)									
	REGIONAL STAFF										
NE	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
CE	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
PA	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		90.0	60.0	80.0	58.0						
TOTAL HOURS		180	180	2400	2552						
CONVERSION FACTOR		950	950	950	950						
TOTAL OPERATIONAL FTEs		0.19	0.19	2.53	2.69						
7. REMARKS											
(1) - Domestic resources for 68808 and 68810 are planned under 68808. Report Inspections under the appropriate PAC. Foreign inspections are for sponsor/monitors (68810) and clinical investigators (68811). Inspections are to be conducted only when assignments are received from CVM. Resources for Generic Good Laboratory Practices (68808G) and Generic Sponsors, Contract Research Organizations & Monitors (68810G) are planned under 68808. Report Inspections under the appropriate PAC. Resources for Generic Clinical Investigators (68811G) are planned under 68811. Report Inspections under the appropriate PAC. Workload Source: FACTS database (BIMO firms in IND 67, 68, and 69 with Status of "Operational").											

1. PROGRAM/ASSIGNMENT TITLE Animal Drug Manufacturing Inspection/ Type A Medicated Articles				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71													
3. PROGRAM/ASSIGNMENT CODE(S) PACs 71001, A, B, 71005, A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.3										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	3	3	6	7								
		FOREIGN INSPEC- TIONS (1)	DOMESTIC INSPEC- TIONS (2)	CHEM ON INSPEC (Hours)	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL (3)	DOMESTIC SAMPLE COLL CHEM	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM								
TOTAL FIELD		33	205	600	250	50	20	100	20								
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
FORENSIC CHEM. CTR																	
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
REGIONAL LAB																	
SW	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
REGIONAL LAB																	
PA	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										49.0	40.0			7.0		0.8	35.0
TOTAL HOURS										1617	8200	600	250	350		80	700
CONVERSION FACTOR										950	950	950	950	950		950	1180
TOTAL OPERATIONAL FTEs										1.70	8.63	0.63	0.26	0.37		0.08	0.59

7. REMARKS

(1) - Foreign Inspections spread by Division of Foreign Field Investigations (DFFI).

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

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

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

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

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

Laboratory allocations were planned by 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 32.1 [8.1]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL Metals 71003B	3 DOMESTIC SAMPLE COLL Mycro 71003C	3 DOMESTIC SAMPLE COLL Micro 71003E (2) (a)	3 DOMESTIC SAMPLE COLL Micro 71003E (b)	3 DOMESTIC SAMPLE COLL Chem 71003A	3 DOMESTIC SAMPLE COLL Dioxin 71003G (c)	3 DOMESTIC SAMPLE COLL Antibiotics 71003K (3)
	TOTAL FIELD	(1)	(2)	60	395	600	100	290	150	20

	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	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	25.0	4.2								
TOTAL HOURS	925	6783								
CONVERSION FACTOR	950	950								
TOTAL OPERATIONAL FTEs	0.97	7.14								

7. REMARKS

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

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

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

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

EXPECT THREE CENTER ASSIGNMENTS:

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

b. A second micro assignment under 71003E will cover milk replacers collected at commercial feed stores/mills, analyzing for *Salmonella*.

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

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

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Domestic	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A,B,C,E,G-K	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 32.1 [17.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	7	7	7	7	7	9	9
		DOMESTIC SAMPLES TO BE ANALYZED Metals 71003B	DOMESTIC SAMPLES TO BE ANALYZED Myco 71003C	DOMESTIC SAMPLES TO BE ANALYZED Micro 71003E	DOMESTIC SAMPLES TO BE ANALYZED Micro 71003E	DOMESTIC SAMPLES TO BE ANALYZED Chem 71003A	DOMESTIC SAMPLES TO BE ANALYZED Dioxin 71003G (4)	DOMESTIC SAMPLES TO BE ANALYZED Antibiotics 71003K	METHODS VAL/DEV CONTAM ID CHEM (Hours) 71003A (5)	METHODS VAL/DEV MICRO (Hours) 71003E (6)
	TOTAL FIELD	60	395	300	100	290	150	20	2065	1180
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		18.0	11.0	13.0	13.0	6.6	30.0	23.0		
TOTAL HOURS		1080	4345	3900	1300	1914	4500	460	2065	1180
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.92	3.68	3.31	1.10	1.62	3.81	0.39	1.75	1.00

7. REMARKS

Laboratory allocations were planned by DFS.

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

(5) - Develop/adapt methods to search for chemical contaminants in feed/feed ingredients, including pet food/treats. Report time under operations for research/method validation as necessary for PAC 71003A.

(6) - Micro resources used for two projects:

- i. Adapting a method for *Listeria monocytogenes* in food for animal feed (0.3 FTE's).
- ii. Developing a method for detecting methicillin resistant Staph. Aureus (MRSA) in pet food/treats (0.7 FTE's).

Report time under operations for research/method validation as necessary for PAC 71003E.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants- Import					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71				
3. PROGRAM/ASSIGNMENT CODE(S) 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 32.1 [6.4]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	4	4	8	8	8	8
		IMPORT SAMPLE COLL (7)	IMPORT SAMPLE COLL Chem	IMPORT SAMPLE COLL Micro 71003E	IMPORT SAMPLE COLL Antibiotics	IMPORT FIELD EXAMS	IMPORT SAMPLES TO BE ANALYZED Chem	IMPORT SAMPLES TO BE ANALYZED Micro (7)	IMPORT SAMPLES TO BE ANALYZED Antibiotics
TOTAL FIELD		550	250	280	20	300	250	280	20
HEADQUARTERS		(b)(5)&(b)(7)(E)							
REGIONAL STAFF									
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		2.5				0.6	7.0	12.0	23.0
TOTAL HOURS		1375				180	1750	3360	460
CONVERSION FACTOR		950				950	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.45				0.19	1.48	2.85	0.39
7. REMARKS									
<p>The shaded area serves as a guideline for districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.</p> <p>(7) - Import Sample Collections and Analyses: 71003E, sample collections are for pig ears, pet treats, and pet foods as well as other animal feed ingredients.</p> <p>Laboratory allocations were planned by DFS.</p>									

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71			
3. PROGRAM/ASSIGNMENT CODE(S) PACs 71004, A		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.2	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP TIONS	2 DOMESTIC INSP TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL GUIDANCE (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM
	TOTAL FIELD	5	141	60	15	15
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)				
	REGIONAL STAFF					
	NEW ENGLAND					
	NEW YORK					
	REGIONAL LAB					
	WEAC					
CE	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
	PHILADELPHIA					
	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	28.0	7.8		25.0
TOTAL HOURS		250	3948	468		375
CONVERSION FACTOR		950	950	950		1180
TOTAL OPERATIONAL FTEs		0.26	4.16	0.49		0.32

7. REMARKS

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

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

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

Laboratory allocations were planned by DFS.

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71006, M			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 39.5			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	7	9	9			
		DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL MILK (2)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (3)	METHODS VAL/DEV CHEM (Hours) (4)	TECH SUPPORT (Hours) (5)			
	TOTAL FIELD	600	930	400	580	360	1900			
	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									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		39.0	7.0	2.5	9.4					
TOTAL HOURS		23400	6510	1000	5452	360	1900			
CONVERSION FACTOR		950	950	950	1180	1180	950			
TOTAL OPERATIONAL FTEs		24.63	6.85	1.05	4.62	0.31	2.00			

7. REMARKS

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

(1) - Documentary samples collected during inspections.
 (2) - 400 Milk samples will be collected by the FDA from October through November FY13, at state certified labs and analyzed by regional laboratories to complete the milk assignment begun in FY12. 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: CVM allocated the number of Inspections and Sample Collections based on their risk model for ranking residue violations in this program.

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71																
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 31.0 [27.9]												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	3	4	6	7	7									
		DOMESTIC INSP CTIONS (1)	DOMESTIC INVESTI- GATIONS (Hours) (2)	IMPORT ENTRY REVIEW (Hours) (3)	IMPORT INVESTI- GATIONS (Hours) (4)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (5)									
TOTAL FIELD		1205	1000	8440	1530	640	200	3200	425	215									
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											8.5				4.0	2.5	0.4	6.0	4.0
TOTAL HOURS											10243	1000	8440	1530	2560	500	1280	2550	860
CONVERSION FACTOR											950	950	1200	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs											10.78	1.05	7.03	1.61	2.69	0.53	1.35	2.16	0.73

7. REMARKS

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

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

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

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

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

Laboratory allocations were planned by DFS.

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

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71				
3. PROGRAM/ASSIGNMENT CODE(S) PACs 71009, 71R844, 71R843 (99R833, 71R833, 71R824)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 31.0 [3.1]	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8. IMPORT SAMPLES TO BE ANALYZED CHEM	9. TECHNICAL SUPPORT (Hours) (6)				
	TOTAL FIELD	200	2248				
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
	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		4.3					
TOTAL HOURS		860	2248				
CONVERSION FACTOR		1180	950				
TOTAL OPERATIONAL FTEs		0.73	2.37				

7. REMARKS

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

Laboratory allocations were planned by DFS.

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program

2. PPS PROJECT NAME/NUMBER

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

9. Remarks

Inspection Priorities.

The first inspectional priority under this program is to inspect those firms that have a violative history classified by the FDA "Official Action Indicated" or OAI. These inspections should be conducted with the intent that regulatory action will be pursued should the firm be unwilling or unable to take immediate actions to correct the violations. 21 CFR 589.2000 and 589.2001 address a wide variety of firms and animal product operations that involve the manufacture, distribution, transportation, and feeding of animals. 21 CFR 589.2000 prohibits the feeding of specific mammalian proteins to ruminant animals, 21 CFR 589.2001 prohibits the use of specific cattle-origin tissues in the feed of all animals, including pet food. As a result, the regulations have broad applications, including at operations that do not involve ruminant feeds or the feeding of ruminant animals. Inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with regulations be encountered. CVM has developed a mathematical system for prioritizing inspections, which ORA has used the last several years to help with the annual work-planning. The following list of firm/industry types generally describes our priorities, in descending order:

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

1. PROGRAM/ASSIGNMENT TITLE Methods Validation			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 METHODS VAL/DEV CHEM (Hours)	9 APPLIED TECHNOLOGY CENTER CHEM (Hours)							
	TOTAL FIELD	1205	4720							
	HEADQUARTERS	(b)(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										
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 Marketed Animal Drugs, Feeds, and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71R838			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 1.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	1205								
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									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		1205								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		1.00								
7. REMARKS Workload Source - Determined by Division of Field Science, ORO										

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71V800, 71V022		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.7				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP CTIONS 71V022 (1)	3 INVEST GATIONS (Hours)	7 DOMESTIC LAB ANALYST CHEM	7 DOMESTIC LAB ANALYST MICRO				
	TOTAL FIELD	90	950	295	590				
	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 STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	10.0							
	TOTAL HOURS	900	950	295	590				
	CONVERSION FACTOR	950	950	1180	1180				
	TOTAL OPERATIONAL FTEs	0.95	1.00	0.25	0.50				

7. REMARKS

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

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

(1) - The FY13 Poultry Hatchery Assignment instructs the Field to inspect designated poultry hatcheries (chicken and turkey) for possible misuse/extralabel use of antimicrobials. Report Inspections under PAC 71V022 Op 12.

Laboratory allocations were planned by DFS.

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2013**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	179.8	61.2	36.0	277.0
81	POSTMARKET ASSURANCE: DEVICES	1.0			1.0
82	COMPLIANCE: DEVICES	108.6	53.1	29.2	190.9
83	PRODUCT EVALUATION: DEVICES	29.4		4.5	33.9
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	20.6	8.1	2.2	30.9

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up					2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81				
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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S (1)	2 INVEST I G A T I O N S (Hours) (2)	3 DOMESTIC SAMPLE COLL CHEM CHEM	3 DOMESTIC SAMPLE COLL STER STER	3 DOMESTIC SAMPLE COLL ENG ENG	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (3)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (4)	7 DOMESTIC SAMPLES TO BE ANALYZED ENG (5)
	TOTAL FIELD		45	30	1	1	1	1	1
(b)(5)&(b)(7)(E)									
HEADQUARTERS									
REGIONAL STAFF									
NEW ENGLAND									
NEW YORK									
REGIONAL LAB									
WEAC									
REGIONAL STAFF									
BALTIMORE									
CHICAGO									
CINCINNATI									
DETROIT									
MINNEAPOLIS									
NEW JERSEY									
PHILADELPHIA									
FORENSIC CHEM. CTR									
REGIONAL STAFF									
ATLANTA									
FLORIDA									
NEW ORLEANS									
SAN JUAN									
REGIONAL LAB									
REGIONAL STAFF									
DALLAS									
DENVER									
KANSAS CITY									
SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB									
REGIONAL STAFF									
LOS ANGELES									
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		16.4		8.0	8.0	8.0	36.0	20.0	37.0
TOTAL HOURS		828	30	8	8	8	36	20	37
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.87	0.03	0.01	0.01	0.01	0.03	0.02	0.03
9. REMARKS									
(1)-Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.									
(2)-Investigational hours for MDR followup at medical facilities.									
(3)-Performance testing of chemical and serological test kits.									
(4)-Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.									
(5)-MDR samples to confirm reported defects.									

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 44.0 [43.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	4	6	8	8
		ENTRY REVIEW (Hours)	IMPORT INVESTI- GATION HOURS (1)	MAIL COURIER REVIEW	INTERNATIONAL MAIL FACILITY REVIEW	IMPORT SAMPLE COLL (Physical) MICRO (2)	IMPORT SAMPLE COLL (Physical) ENG	IMPORT FIELD EXAMS	IMPORT SAMPLES TO BE ANALYZED MICRO (3)	IMPORT SAMPLES TO BE ANALYZED ENG
	TOTAL FIELD	26062	4037	2200	300	60	120	20900	60	150
	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						2.2	2.2	0.4	30.4	30.4
TOTAL HOURS		26062	4037	2200	300	132	264	8360	1824	4560
CONVERSION FACTOR		1200	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		21.72	4.25	2.32	0.32	0.14	0.28	8.80	1.55	3.86
9. REMARKS										
(1)-Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams are planned in a separate column.										
(2)-Audit samples for problems other than failure to register or list (eg. special assignment, import alert).										
(3)-Sterile devices to be tested by USP XX method.										
Reporting Guidance:										
- Import Entry Reviews (Electronic and Manual--operation code 14, PAC 82R833);										
- Filer Evaluations (operation code 95, PAC 99R833); and										
- Follow-up to Refusals (PAC 82R824).										
Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.										

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

9. REMARKS

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 130.2 [126.1]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS LEVEL I DOMESTIC 82845A	1 INSPEC- TIONS LEVEL II DOMESTIC 82845B	1 INSPEC- TIONS LEVEL III COMPLIANCE DOMESTIC 82845C	1 INSPEC- TIONS FOREIGN 82845B	1 INSPEC- TIONS FOR CAUSE DOMESTIC 82845G	1 INSPEC- TIONS FOR CAUSE HIGH RISK DOMESTIC 82845H	1 INSPEC- TIONS FOR CAUSE HIGH RISK FOREIGN 82845H	1 INSPEC- TIONS ACCRED PERSONS DOMESTIC 82845P	2 INVESTI- GATIONS (Hours) 82845B
	TOTAL FIELD		782	530	115	368	113	43	38	9
HEADQUARTERS (b)(5)&(b)(7)(E)										
REGIONAL STAFF										
NEW ENGLAND										
NEW YORK										
REGIONAL LAB										
WEAC										
REGIONAL STAFF										
BALTIMORE										
CHICAGO										
CINCINNATI										
DETROIT										
MINNEAPOLIS										
NEW JERSEY										
PHILADELPHIA										
FORENSIC CHEM. CTR										
REGIONAL STAFF										
ATLANTA										
FLORIDA										
NEW ORLEANS										
SAN JUAN										
REGIONAL LAB										
REGIONAL STAFF										
DALLAS										
DENVER										
KANSAS CITY										
SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB										
REGIONAL STAFF										
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		39.6	63.1	115.0	65.0	72.3	99.9	100.0	53.0	
TOTAL HOURS		30967	33443	13225	23920	8170	4296	3800	477	1494
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		32.60	35.20	13.92	25.18	8.60	4.52	4.00	0.50	1.57
9. REMARKS The hours/operation module for Level I inspections has been planned at 39.6 hours/operation to include additional time for MDR review. Level II inspection hours/operation modules have also been adjusted to reflect actual work. Quality Systems Inspection Technique (QSIT) Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G,H) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "For Cause" inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Reprogram any unused resources into Level 1 and 2 inspections. Inspectional modules include time for 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. The Headquarters line includes 30 Foreign National Expert and 146 Foreign Cadre inspections. Accredited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program.										

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 130.2 [0.6]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTIGATIONS (Hours) A.P. AUDITS MDUFMA 82845J	3 DOMESTIC SAMPLE COLL 82845C	3 DOMESTIC SAMPLE COLL ENG 82845C	3 DOMESTIC SAMPLE COLL MICRO 82845C	3 DOMESTIC SAMPLE COLL CHEM 82845C	3 DOMESTIC SAMPLE COLL 82845H	3 DOMESTIC SAMPLE COLL 82845S	3 DOMESTIC SAMPLE COLL BIOBURDEN 82845S	3 DOMESTIC SAMPLE COLL STERILITY 82845S
	TOTAL FIELD	190	42	10	26	6	12	15	10	5
(b)(5)&(b)(7)(E)										
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									
	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			6.0				6.0	4.7		
TOTAL HOURS		190	252				72	71		
CONVERSION FACTOR		950	950				950	950		
TOTAL OPERATIONAL FTEs		0.20	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 130.2 [3.5]									
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845H	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82845S									
	TOTAL FIELD	10	26	6	12	10	5									
	HEADQUARTERS	(b)(5)&(b)(7)(E)														
NE	REGIONAL STAFF															
	NEW ENGLAND															
	NEW YORK															
	REGIONAL LAB															
	WEAC															
CE	REGIONAL STAFF															
	BALTIMORE															
	CHICAGO															
	CINCINNATI															
	DETROIT															
	MINNEAPOLIS															
	NEW JERSEY															
	PHILADELPHIA															
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		80.0	62.0	38.0	88.3	25.0	29.5									
TOTAL HOURS		800	1612	228	1060	250	148									
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180									
TOTAL OPERATIONAL FTEs		0.68	1.37	0.19	0.90	0.21	0.13									
9. REMARKS MICRO Sample Analyses: Antisera and Products Media Testing to support GMP observations at WEAC; Disinfectant/Cold Sterilant Testing at WEAC 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.																

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4	4	8	8	9			
		IMPORT SAMPLE COLL (Physical) CHEM	IMPORT SAMPLE COLL (Physical) ENG	IMPORT SAMPLES TO BE ANALYZED (Physical) CHEM	IMPORT SAMPLES TO BE ANALYZED (Physical) ENG	OTHER OPERATIONS (Hours) ENG			
	TOTAL FIELD	360	303	360	303	1180			
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	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	2.3	2.3	5.2	5.2				
	TOTAL HOURS	828	697	1872	1576	1180			
	CONVERSION FACTOR	950	950	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	0.87	0.73	1.59	1.34	1.00			
9. REMARKS Resources to cover Glove Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin. Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824). Other Operations (Hours) are for Private Lab Review Technical Assistance/Coordination at WEAC: Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field; without this consistency in reporting, your time will not be found and credited.									

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z005, 82Z800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.3				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS CENTER- INITIATED 82Z800	3 DOMESTIC SAMPLE COLL (1) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY (3) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82Z800	9 OTHER OPER- ATIONS (Hours) ENG (5) 82Z800		
	TOTAL FIELD	31	50	5	11	15	11	1600		
	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	43.2	8.0	15.0	50.0	50.0	100.0			
	TOTAL HOURS	1339	400	75	550	750	1100	1600		
	CONVERSION FACTOR	950	950	1180	1180	1180	1180	1180		
	TOTAL OPERATIONAL FTEs	1.41	0.42	0.06	0.47	0.64	0.93	1.36		
9. REMARKS Planned BSE Inspections (82Z005) were cancelled in FY 2008; PAC will remain active for reporting purposes and any Center-Initiated Assignments involving BSE should be reported in PAC 82Z005. (1)-Includes Documentary Samples and Analytical Samples. (2)-WEAC--Ad Hoc testing of test kits or reagents. (3)-WEAC--Sterility samples. (4)-WEAC--Ad Hoc testing of media. (5)-WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.										

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
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)						
	TOTAL FIELD	1205	1205						
NE	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								
PA	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		1205	1205						
CONVERSION FACTOR		1205	1205						
TOTAL OPERATIONAL FTEs		1.00	1.00						
9. REMARKS									

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	360								
NE	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		360								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		0.30								

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83001, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.7
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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				
	TOTAL FIELD	67	31	34	19				
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
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	70.9	49.0	33.8	45.0				
	TOTAL HOURS	4750	1519	1149	855				
	CONVERSION FACTOR	950	950	950	950				
	TOTAL OPERATIONAL FTEs	5.00	1.60	1.21	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							
3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.2		
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN						
	TOTAL FIELD	300	25						
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	73.5	75.5						
	TOTAL HOURS	22050	1888						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	23.21	1.99						
9. REMARKS Device Bioresearch Monitoring inspections should be prioritized according to the following scheme: -For Cause with 30-day due dates; -Directed data audit for expedited PMA; -Directed data audit for non-expedited PMA; -For Cause with 60-90 day due dates; -OAI Follow-up (6 months); -Early Intervention (Probability Sampling, Vulnerable Population, and IDE-based); -Routine Surveillance. Please contact Ruth Hinckley (301-796-5658) or Jim Saviola (301-796-5432) with any questions.									

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84Z002	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) METH DEV ENG								
	TOTAL FIELD	4390								
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									
	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	4390								
	CONVERSION FACTOR	1180								
	TOTAL OPERATIONAL FTEs	3.72								

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program				2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85						
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.6 [11.0]			
R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	9	9
		INSPEC- TIONS 85014 (1)	INSPEC- TIONS FOREIGN 85014 (2)	INSPEC- TIONS 85014 (3)	INSPEC- TIONS 85014 (4)	INSPEC- TIONS 85014F (5)	INSPEC- TIONS 85014F (6)	INVESTI- GATIONS (Hours) 85014A (7)	OTHER OPERA- TIONS (Hours) 85014C (8)	OTHER OPERA- TIONS (Hours) 85014C (9)
TOTAL FIELD		541	15	119	45	9	9	2211	3374	1200
(b)(5)&(b)(7)(E)										
HEADQUARTERS										
REGIONAL STAFF										
NEW ENGLAND										
NEW YORK										
REGIONAL LAB										
WEAC										
REGIONAL STAFF										
BALTIMORE										
CHICAGO										
CINCINNATI										
DETROIT										
MINNEAPOLIS										
NEW JERSEY										
PHILADELPHIA										
FORENSIC CHEM. CTR										
REGIONAL STAFF										
ATLANTA										
FLORIDA										
NEW ORLEANS										
SAN JUAN										
REGIONAL LAB										
REGIONAL STAFF										
DALLAS										
DENVER										
KANSAS CITY										
SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB										
REGIONAL STAFF										
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.0	8.0	8.0	8.0	11.0	11.0			
TOTAL HOURS		4328	120	952	360	99	99	2211	3374	1200
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1200
TOTAL OPERATIONAL FTEs		3.73	0.10	0.82	0.31	0.09	0.09	1.91	2.91	1.00
7. REMARKS										
RRHRs 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: RRHRs.										

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [3.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) 85014C (10)	9 OTHER OPERATIONS (Hours) 85014C (11)						
	TOTAL FIELD	4164	59						
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								
	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		4164	59						
CONVERSION FACTOR		1160	1160						
TOTAL OPERATIONAL FTEs		3.59	0.05						

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

PROJECT SUMMARY SHEET

FY 2013

1. PROGRAM CATEGORY Medical Devices and Radiological Health		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		20.6	8.1	2.2	30.9	
1	Inspection and Field Testing of Radiation-Emitting Electronic Products:		5.1		0.9	6.0	86-24-25
	Inspection of Manufacturers of Laser Products	86001	(4.3)		(0.9)	(5.2)	
	Field Implementation of the Sunlamp & Sunlamp Products Performance Standard as Amended	86002	(0.3)			(0.3)	
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	(0.5)			(0.5)	
2	Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-Ray Equipment	86003	7.7		1.0	8.7	86-26-32
3	Compliance Testing of Electronic Products at WEAC	86006, A, D, E	2.8		0.3	3.1	86-33
4	Imported Electronic Products	86007 *		8.1		8.1	86-34
5	Radiological Health Control Activities:		5.0			5.0	86-35-36
	Medical Device and Radiological Health Use	86008	(3.0)			(3.0)	
	Control and Policy Implementation						
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	
	* In addition to PAC 86007, includes reporting PACs 86R824, 86R833, and 99R833.						

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

ORA PLANNER/TELEPHONE
Kristen Kamas 301-796-4391

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.0 [4.7]				
R E G I O N	6.	1	1	1	1	2	2	3	5	5
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S 86001 (1)	INSP EC T I O N S F O R E I G N 86001 (2)	INSP EC T I O N S 86002 (3)	INSP EC T I O N S 86004 (4)	INVEST I G A T I O N S (H o u r s) 86001 (5)	INVEST I G A T I O N S (H o u r s) 86004	D O M E S T I C S A M P L E C O L L 86001	F I E L D E X A M S/ T E S T S 86001 (6)	F I E L D E X A M S/ T E S T S 86002 (7)
TOTAL FIELD		105	30	3	22	658	31	5	75	30
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		17.3	36.0	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
TOTAL OPERATIONAL FTEs		1.91	0.92	0.11	0.46	0.69	0.03	0.02	0.39	0.14
7. REMARKS										
<p>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).</p> <p>Sunlamps and sunlamp products (86002): (3) - Inspectional figures are only for biennial or for cause inspections of manufactures of sunlamp products (e.g. sunlamps, booths, or beds). Because sunlamp products are also medical devices, a joint QSIT and electronic product radiation control inspection should be conducted. Examination of sunlamp products at a user facility (e.g. tanning parlor, athletic club) are NOT counted as inspections because they are field tests. (7) - Each sunlamp product tested may be counted as a separate field test, even if located in a single facility. NOTE: RRHR's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).</p> <p>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.</p>										

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products			2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86									
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.0 [1.3]					
R E G I O N	6.	9	9									
	DISTRICT/ SPECIALIZED LABORATORY	OTHER OPERA- TIONS (Hours) 86001 (8)	OTHER OPERA- TIONS (Hours) 86002									
TOTAL FIELD		1197	75									
NE	HEADQUARTERS	(b)(5)&(b)(7)(E)										
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
CE	WEAC											
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	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		1197	75									
CONVERSION FACTOR		950	950									
TOTAL OPERATIONAL FTEs		1.26	0.08									
7. 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 8.7 [7.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2	2	5	5B	5
		INSP CTIONS DOMESTIC (1)	INSP CTIONS FOREIGN (2)	INSP CTIONS DIRECTED (3)	INSP CTIONS (4)	INVESTI GATIONS (Hours) (5)	INVESTI GATIONS (Hours) (6)	FIELD EXAMS/ TESTS (7)	AUDITS (7)	FIELD EXAMS/ TESTS ENG (7)
TOTAL FIELD		52	15	5	18	884	1051	345	30	50
HEADQUARTERS		(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	NEW ENGLAND	(b)(5)&(b)(7)(E)								
	NEW YORK	(b)(5)&(b)(7)(E)								
	REGIONAL LAB	(b)(5)&(b)(7)(E)								
	WEAC	(b)(5)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(5)&(b)(7)(E)								
	BALTIMORE	(b)(5)&(b)(7)(E)								
	CHICAGO	(b)(5)&(b)(7)(E)								
	CINCINNATI	(b)(5)&(b)(7)(E)								
	DETROIT	(b)(5)&(b)(7)(E)								
	MINNEAPOLIS	(b)(5)&(b)(7)(E)								
	NEW JERSEY	(b)(5)&(b)(7)(E)								
	PHILADELPHIA	(b)(5)&(b)(7)(E)								
SE	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)								
	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 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		50.0	65.0	50.0	16.0			3.0	4.0	3.0
TOTAL HOURS		2600	975	250	288	884	1051	1035	120	150
CONVERSION FACTOR		950	950	950	950	950	950	950	950	1180
TOTAL OPERATIONAL FTEs		2.74	1.03	0.26	0.30	0.93	1.11	1.09	0.13	0.13
7. REMARKS (1) - Domestic inspections to be conducted based on the OEI of diagnostic x-ray equipment manufacturers. Joint QSIT and electronic product radiation control inspections should be conducted if possible. (2) - Foreign inspections should be joint QSIT and electronic product radiation control inspections if possible. (3) - Directed Inspections based on the OEI of diagnostic x-ray equipment manufacturers. (4) - Inspections based on the OEI of diagnostic x-ray equipment assemblers. (5) - Investigation hours for review and planning of activities under columns 1 (Domestic), 2 (Foreign), and 3 (Directed) Inspections. (6) - Investigation hours for review of 2579 forms (reports of assembly) in preparation for performing field tests and field test follow up activities. (7) - Field tests and audits are obtained from Attachment A and provided by CDRH's OCER/DMQRP Diagnostic Devices Branch, HFZ-240. Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor.										

1. PROGRAM/ASSIGNMENT TITLE Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86							
3. PROGRAM/ASSIGNMENT CODE(S) 86003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 8.7 [1.0]					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) (8)									
	TOTAL FIELD	965									
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										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
PA	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION											
TOTAL HOURS		965									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTEs		1.02									
7. REMARKS (8) - Coordination/technical assistance hours for field test activities.											

**ATTACHMENT A - 2013 WORKPLAN
INSPECTIONS OF MANUFACTURERS (FOREIGN AND
DOMESTIC) AND FIELD COMPLIANCE TESTING
OF DIAGNOSTIC X-RAY EQUIPMENT**

NEW ENGLAND DISTRICT

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

NEW YORK DISTRICT

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

CE REGIONAL STAFF (STATES IN BALTIMORE DISTRICT)

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

CE REGIONAL STAFF (STATES IN CHICAGO DISTRICT)

State	Number	FDA	FDA	Audits
	Systems Installed			
IL	(b)(5)&(b)(7)(E)			

CE REGIONAL STAFF (STATES IN CINCINNATI DISTRICT)

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

CE REGIONAL STAFF (STATES IN DETROIT DISTRICT)

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

CE REGIONAL STAFF (STATES IN MINNEAPOLIS DISTRICT)

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

CE REGIONAL STAFF (STATES IN NEW JERSEY DISTRICT)

State	Number	FDA	FDA	Audits
	Systems Installed			
NJ	(b)(5)&(b)(7)(E)			

CE REGIONAL STAFF (STATES IN PHILADELPHIA DISTRICT)

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

ATLANTA DISTRICT

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

FLORIDA DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
FL	(b)(5)&(b)(7)(E)			

NEW ORLEANS DISTRICT

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

SAN JUAN DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
PR	(b)(5)&(b)(7)(E)			

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

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

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

State	Number	FDA	FDA	Audits
	Systems Installed			
CO	(b)(5)&(b)(7)(E)			
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				

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 8.1				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INV (Hours) (1)	4 IMPORT FIELD EXAMS	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED ENG				
	TOTAL FIELD	6515	1400	400	25	25				
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION			0.7	5.7	34.0				
	TOTAL HOURS	6515	1400	280	143	850				
	CONVERSION FACTOR	1200	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	5.43	1.47	0.29	0.15	0.72				
7. REMARKS (1) - Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams are planned in a separate column. Reporting Guidance: Import Entry Reviews (Electronic and Manual--operation code 14, PAC 86R833) Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 86R824). Laboratory allocations were planned by 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	6. DISTRICT/ SPECIALIZED LABORATORY	9 MISC (Hours) RRHR 86008 (1)	9 TECHNICAL ASSISTANCE (Hours) RRHR 86009							
	TOTAL FIELD	3600	2400							
	HEADQUARTERS	(b)(5)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
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	3600	2400							
	CONVERSION FACTOR	1200	1200							
	TOTAL OPERATIONAL FTEs	3.00	2.00							
7. REMARKS See Continuation Sheet for footnotes, guidance, etc.										

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

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

7. Remarks

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

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

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

Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended (PAC 86002);

Field Compliance Testing of Diagnostic X-Ray Equipment (PAC 86003);

Field Compliance Testing of Cabinet X-Ray Equipment (PAC 86004);

Medical Device and Radiological Health Use Control and Policy Implementation (PAC 86008);

Emergency Planning and Response Activities (PAC 86009);

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

FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):

Technical Assistance hours will be performed by RRHRs.

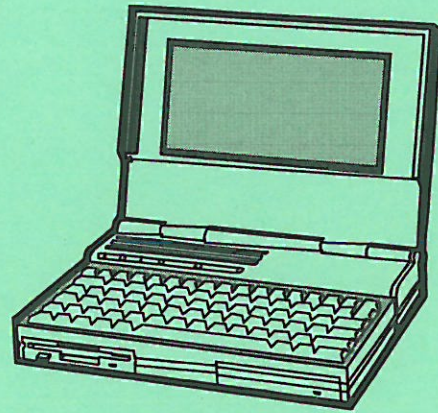
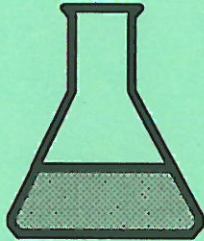
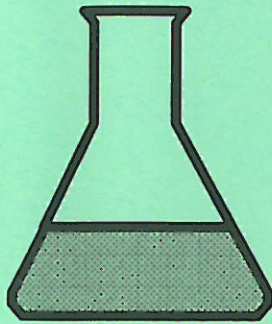
Program activities include: providing technical assistance to state and local agencies regarding emergency response planning; reviewing and evaluating emergency plans related to nuclear power plants.

**CENTER FOR TOBACCO
RESOURCE SUMMARY
FY 2013**

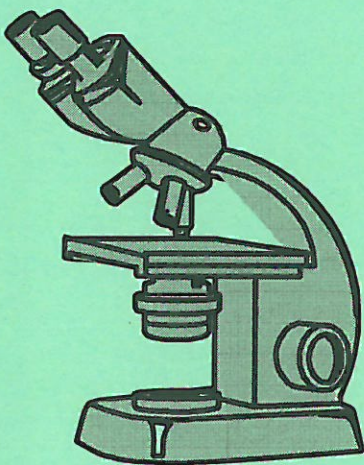
PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	15.9	5.1		21.0
96	REGULATED TOBACCO PRODUCTS: DOMESTIC AND IMPORT	15.9	5.1		21.0

1. PROGRAM/ASSIGNMENT TITLE Regulated Tobacco Products: Domestic and Import					2. PPS PROJECT NAME/NUMBER Tobacco - 96					
3. PROGRAM/ASSIGNMENT CODE(S) 96R800, 96T800, 96R824, 96R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 21.0 [13.8]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	2	2	3	4	7
		PRE- APPROVAL INSP- CTIONS DOMESTIC (1)	INSP- CTIONS DOMESTIC (2)	INSP- CTIONS ASSIGN- MENTS DOMESTIC (1)	INVESTI- GATIONS (Hours) (3)	IMPORT INVESTI- GATIONS (Hours) (4)	IMPORT ENTRY REVIEW (Hours)	DOMESTIC SAMPLE COLL (5)	IMPORT SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED CHEM
TOTAL FIELD		10	50	10	1425	2000	2500	120	60	60
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		87.0	87.0	87.0				6.0	6.0	9.9
TOTAL HOURS		870	4350	870	1425	2000	2500	720	360	594
CONVERSION FACTOR		950	950	950	950	950	1200	950	950	1180
TOTAL OPERATIONAL FTEs		0.92	4.58	0.92	1.50	2.11	2.08	0.76	0.38	0.50
7. REMARKS										
<p>(1) - The Domestic Pre- Approval and Inspection Assignment columns represent the Center's potential need for Inspections. There may not be any Pre-Approval Inspections conducted in FY 2013.</p> <p>(2) - Represents the locations of half the registered tobacco facilities. FDA is required to inspect each registered facility at least once in a two year period. Note 1: All Inspections are to be conducted by investigators trained in tobacco regulation and not all Districts have such investigators. Therefore, a tobacco-trained investigator may perform a tobacco inspection in other Districts. Note 2: Inspectional module includes time for label exams to be conducted on inspections. Please refer to the Assignment Memo when issued for more detailed guidance.</p> <p>(3) - Represents assignments that include complaint follow-up, smokeless free sample events, and other similar investigative assignments.</p> <p>(4) - Includes Import Label Exams.</p> <p>(5) - Represents samples that may be collected during an Inspection, Investigation, or Sample Assignments.</p>										


1. PROGRAM/ASSIGNMENT TITLE Regulated Tobacco Products: Domestic and Import				2. PPS PROJECT NAME/NUMBER Tobacco - 96						
3. PROGRAM/ASSIGNMENT CODE(S) 96R800, 96T800, 96R824, 96R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 21.0 [7.2]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7. DOMESTIC SAMPLES TO BE ANALYZED CHEM ASSIGN	8. IMPORT SAMPLES TO BE ANALYZED CHEM	9. METHODS VAL/DEV CHEM (Hours) (6)						
	TOTAL FIELD	60	60	7531						
	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	9.9	9.9							
	TOTAL HOURS	594	594	7531						
	CONVERSION FACTOR	1180	1180	1205						
	TOTAL OPERATIONAL FTEs	0.50	0.50	6.25						
7. REMARKS (6) - The hours allocated for FCC are to support 0.25 FTE for collaborative efforts with SRL and 2.0 FTEs for OCI-related work.										




OPERATIONS



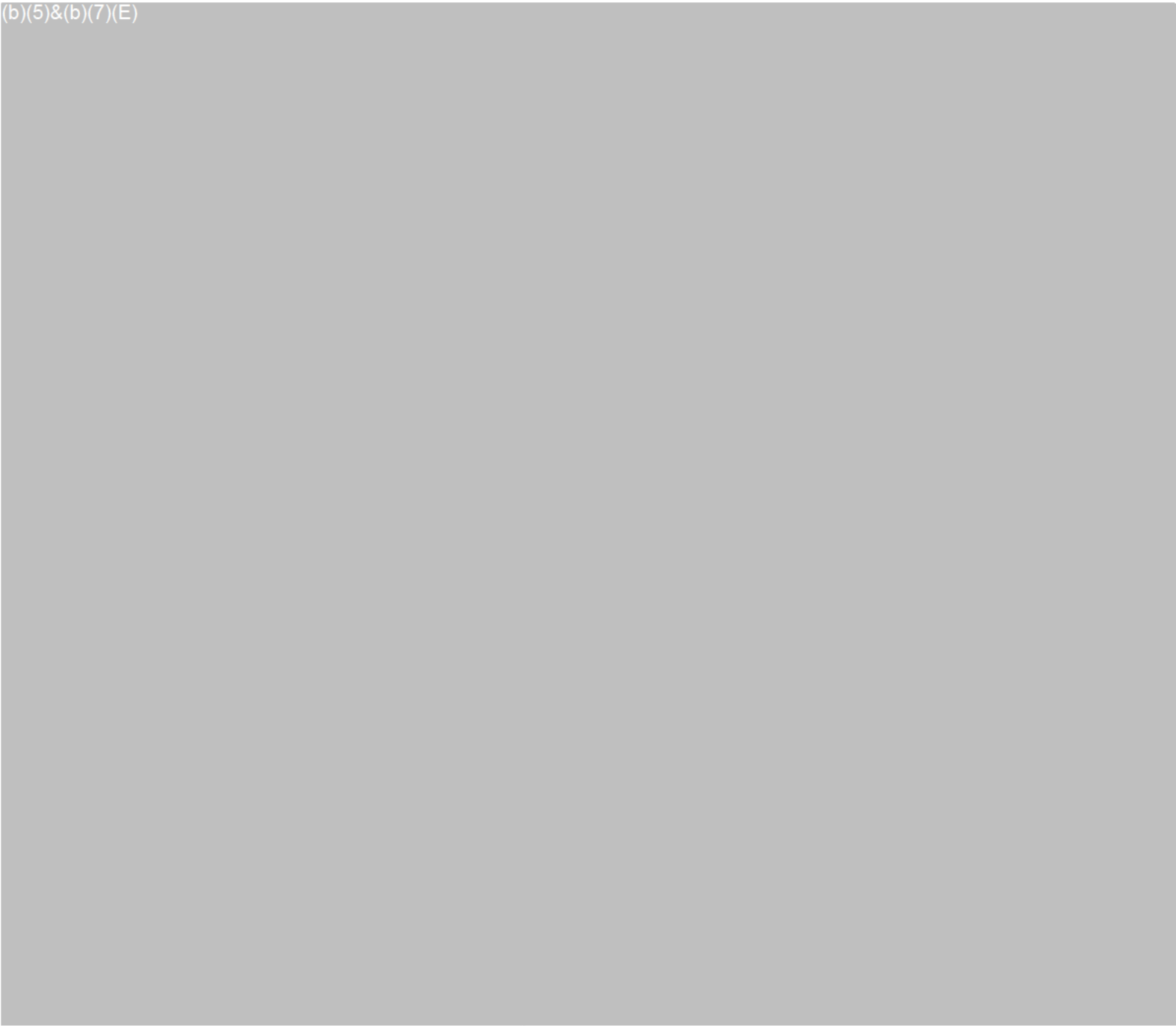
(b)(5)&(b)(7)(E)




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




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




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




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




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



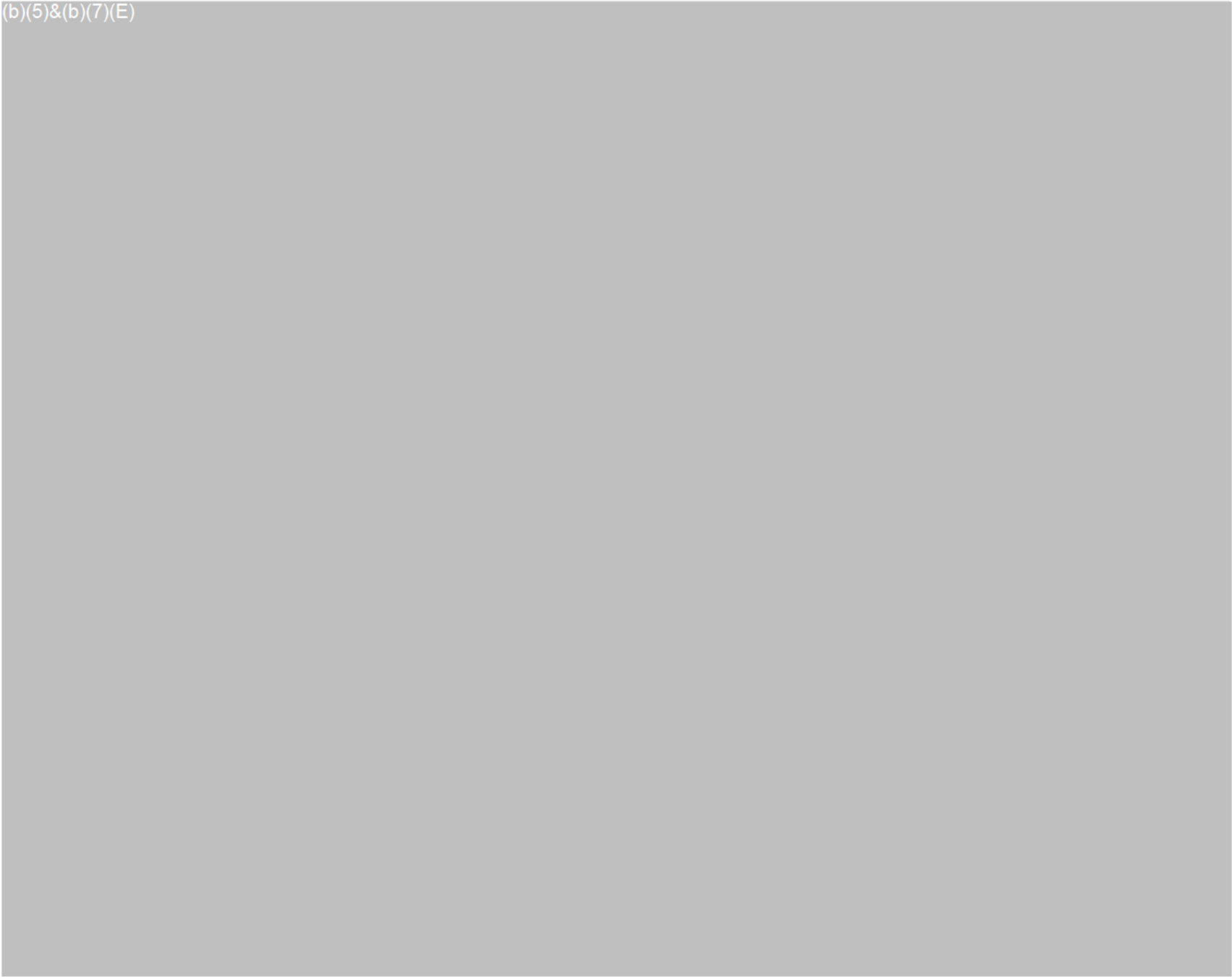
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(b)(5)&(b)(7)(E)



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



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



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WORKPLAN SUMMARY / COMBINED OPERATIONS
Workplan 0 - 2013

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Report Type: Complete

Region: NE 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
REGION TOTAL	1833	87.93	0	70.60	1172	7.75	7742	18.16	498	0.73
FOOD SAFETY/COS	801	32.90	0	46.25	718	5.09	7131	16.46	341	0.23
03	788	32.67	0	42.55	203	2.82	5240	12.90	129	0.14
04	0	0.00	0	3.29	310	1.40	907	1.96	10	0.01
07	0	0.00	0	0.00	79	0.33	194	0.41	0	0.00
09	0	0.00	0	0.00	0	0.00	325	0.48	0	0.00
18	0	0.00	0	0.16	20	0.09	0	0.00	0	0.00
21	0	0.00	0	0.26	77	0.35	377	0.57	202	0.09
29	13	0.23	0	0.00	29	0.11	88	0.14	0	0.00
BIOLOGICS	192	10.41	0	0.84	0	0.00	0	0.00	0	0.00
41	87	4.44	0	0.00	0	0.00	0	0.00	0	0.00
42	98	5.25	0	0.84	0	0.00	0	0.00	0	0.00
45	7	0.72	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	273	19.46	0	14.63	112	0.71	109	0.32	0	0.00
46	20	1.17	0	0.00	2	0.01	0	0.00	0	0.00
48	58	6.08	0	0.00	0	0.00	0	0.00	0	0.00
52	25	0.80	0	0.02	4	0.03	23	0.07	0	0.00
53	22	1.80	0	0.00	0	0.00	0	0.00	0	0.00
56	126	8.52	0	14.30	77	0.50	86	0.24	0	0.00
63	22	1.10	0	0.30	29	0.17	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	175	5.83	0	3.45	313	1.76	261	0.69	0	0.00
68	7	0.49	0	0.00	0	0.00	0	0.00	0	0.00
71	168	5.34	0	3.45	313	1.76	261	0.69	0	0.00
DEVICES & RAD H	390	19.16	0	4.30	19	0.12	224	0.59	157	0.50
81	15	0.29	0	0.00	3	0.03	0	0.00	0	0.00
82	233	13.36	0	2.32	15	0.10	222	0.58	0	0.00
83	55	4.02	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	0.77	0	0.00	0	0.00	0	0.00
86	36	1.13	0	1.21	1	0.00	2	0.01	157	0.50
TOBACCO PROD	2	0.18	0	1.14	10	0.06	17	0.11	0	0.00
96	2	0.18	0	1.14	10	0.06	17	0.11	0	0.00

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	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
REGION TOTAL	66004	35.09	1424	52.65	7593	62.15	212	27.26	276	18.02
FOOD SAFETY/COS	59859	31.51	785	33.08	6428	48.13	212	13.27	90	3.32
03	52272	27.51	287	21.54	4715	31.73	0	3.09	90	3.32
04	2341	1.23	311	10.19	877	9.58	0	0.50	0	0.00
07	0	0.00	108	0.55	319	1.89	0	0.08	0	0.00
09	1328	0.70	0	0.00	368	3.37	0	0.00	0	0.00
18	0	0.00	20	0.15	0	0.00	212	9.60	0	0.00
21	3163	1.67	0	0.00	35	0.30	0	0.00	0	0.00
29	755	0.40	59	0.65	114	1.26	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
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
HUMAN DRUGS	1520	1.60	243	9.14	155	2.25	0	0.96	130	10.82
46	0	0.00	1	1.01	0	0.00	0	0.00	13	1.01
48	0	0.00	0	0.00	0	0.00	0	0.00	26	2.69
52	0	0.00	32	1.34	93	1.24	0	0.00	12	1.01
53	0	0.00	0	0.00	0	0.00	0	0.00	2	0.13
56	1520	1.60	190	6.40	62	1.01	0	0.96	77	5.98
63	0	0.00	20	0.39	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
ANIMAL D & F	1179	0.53	142	1.32	187	1.47	0	1.18	12	0.82
68	0	0.00	0	0.08	0	0.00	0	0.00	6	0.51
71	1179	0.53	142	1.24	187	1.47	0	1.18	6	0.31
DEVICES & RAD H	3446	1.46	254	9.11	823	10.29	0	11.85	44	3.06
81	0	0.00	3	0.08	0	0.00	0	0.00	0	0.00
82	3415	1.44	99	4.98	798	9.57	0	4.36	33	2.37
83	0	0.00	0	0.00	0	0.00	0	0.00	8	0.49
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	0.67	0	0.00
86	31	0.02	152	4.05	25	0.72	0	1.10	3	0.21
TOBACCO PROD	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
96	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS
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Region: NE REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	380.33	402162.30
FOOD SAFETY/COS	230.23	247182.70
03	178.26	188842.80
04	28.15	31420.30
07	3.26	3685.00
09	4.55	5096.00
18	9.99	11925.00
21	3.23	3134.50
29	2.78	3079.10
BIOLOGICS	11.25	10685.70
41	4.44	4218.50
42	6.09	5782.60
45	0.72	684.60
HUMAN DRUGS	59.88	59692.60
46	3.20	3039.50
48	8.77	8331.30
52	4.51	4789.50
53	1.93	1832.20
56	39.52	39755.00
63	1.95	1945.10
88	0.00	0.00
ANIMAL D & F	17.04	17698.20
68	1.07	1019.00
71	15.97	16679.20
DEVICES & RAD H	60.45	65351.10
81	0.39	393.00
82	39.07	41854.60
83	4.51	4281.50
84	5.72	6750.00
85	1.81	2101.00
86	8.96	9971.00
TOBACCO PROD	1.49	1552.00
96	1.49	1552.00


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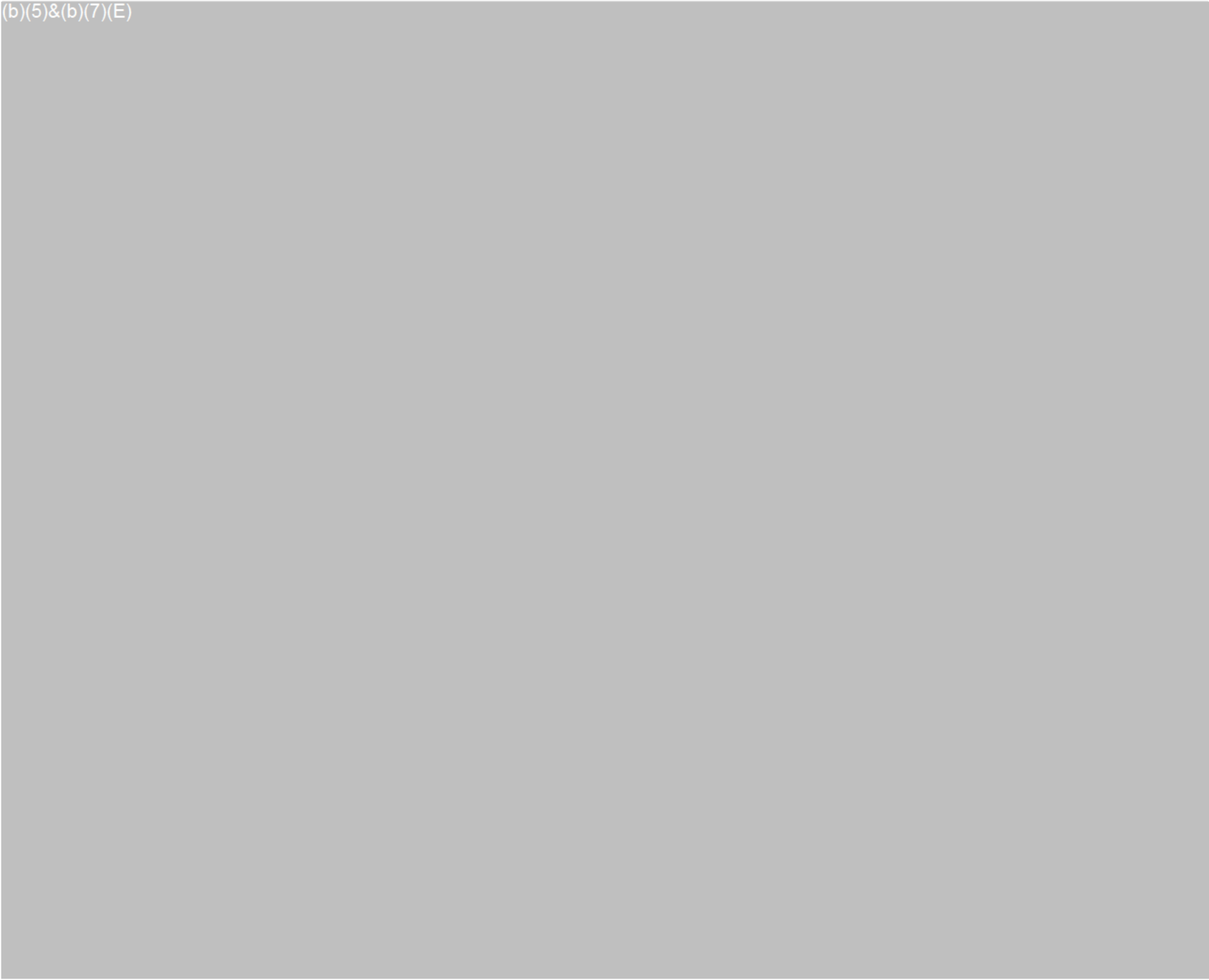
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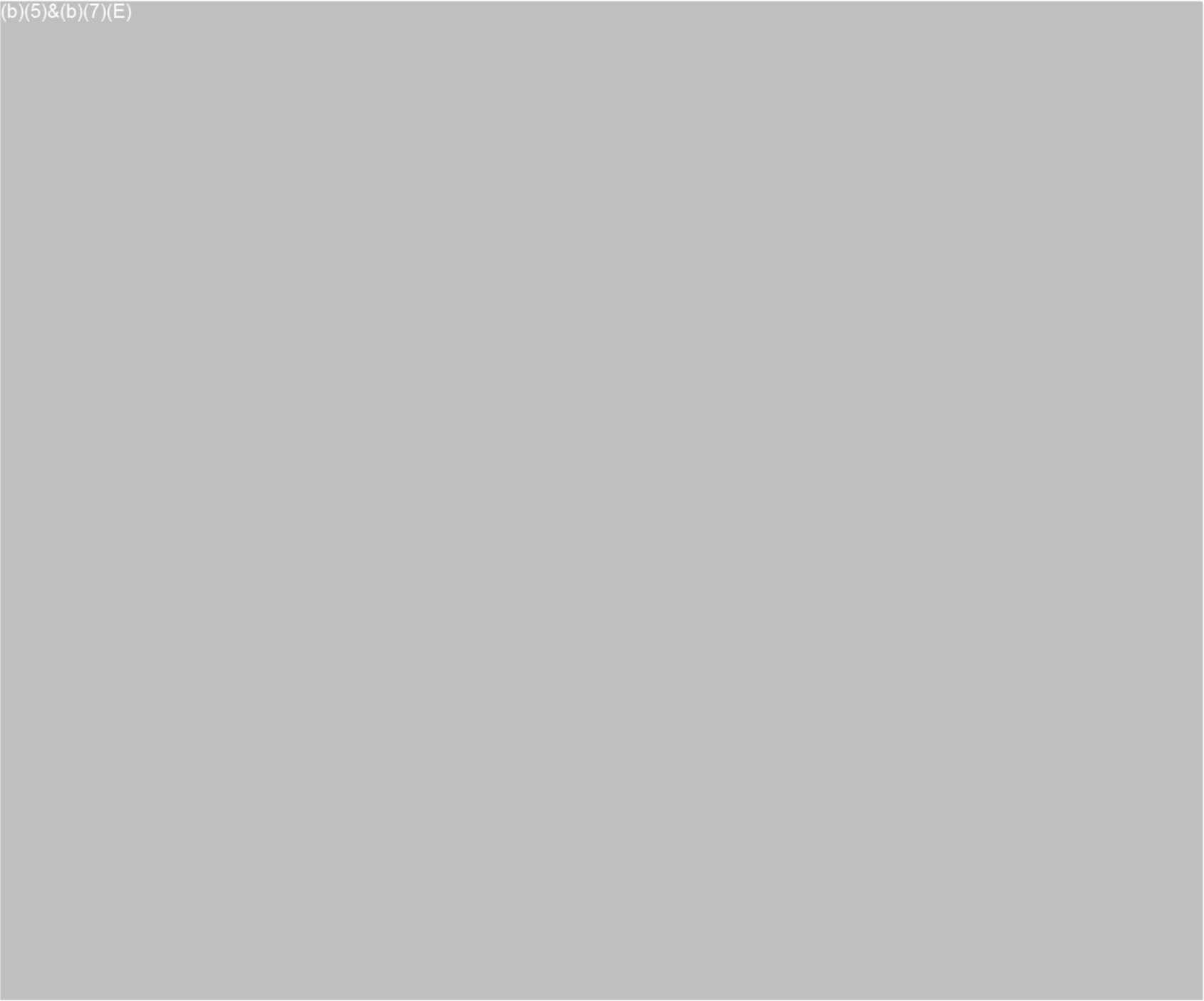
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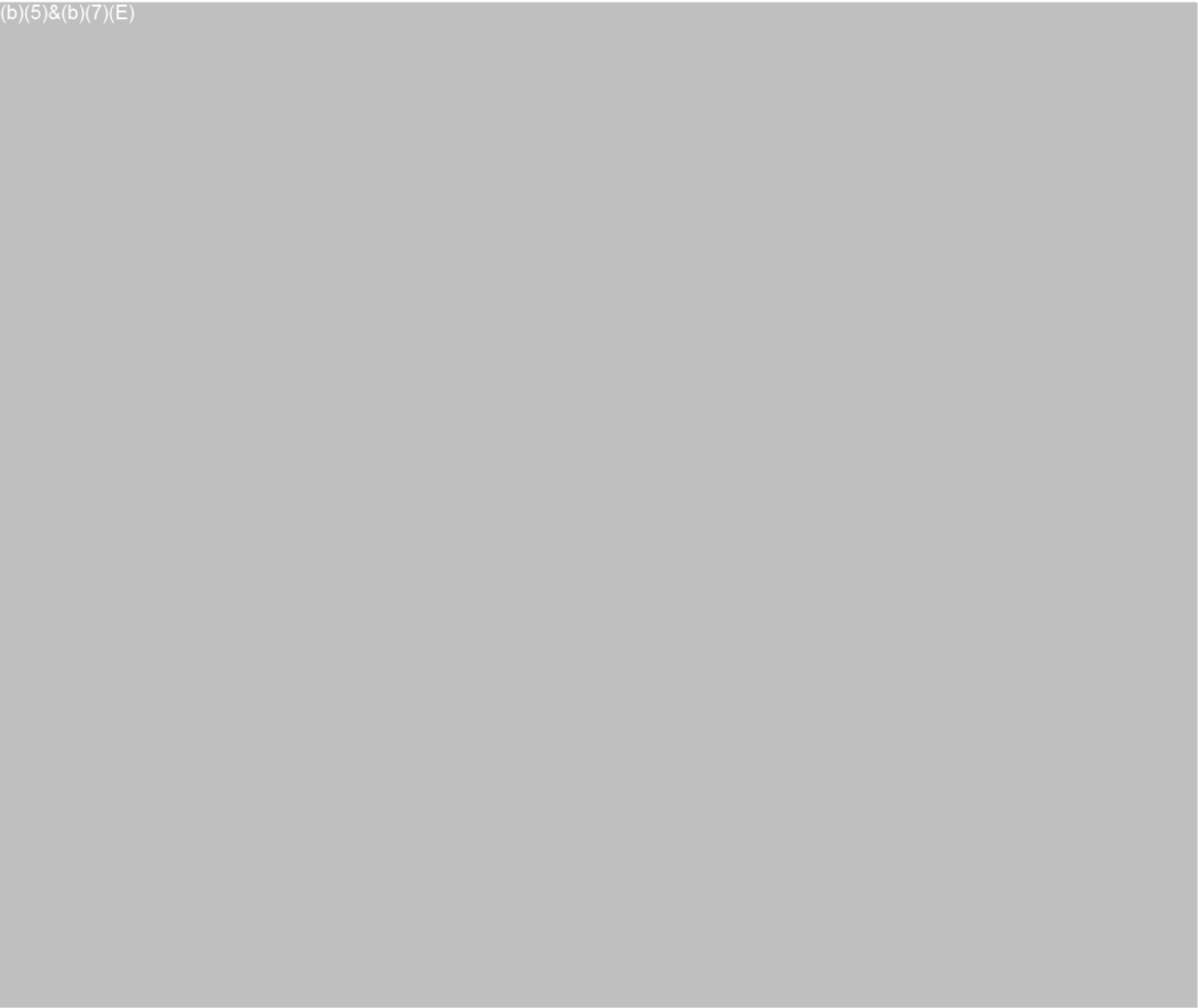
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Region: CE REGN	1		2		3		4		5	
	DOMESTIC INSPECTIONS		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
REGION TOTAL	5989	272.00	0	57.62	4201	29.23	4632	10.84	1437	1.37
FOOD SAFETY/COS	2505	113.16	0	37.15	2452	19.82	4126	9.39	1298	0.87
03	2473	112.59	0	30.72	987	13.58	2738	6.79	504	0.53
04	0	0.00	0	6.04	782	3.29	638	1.31	0	0.00
07	0	0.00	0	0.00	324	1.36	254	0.54	0	0.00
09	0	0.00	0	0.00	0	0.00	209	0.31	0	0.00
18	0	0.00	0	0.26	50	0.21	0	0.00	0	0.00
21	0	0.00	0	0.13	241	1.13	239	0.37	794	0.34
29	32	0.57	0	0.00	68	0.24	48	0.08	0	0.00
BIOLOGICS	635	34.58	0	1.08	0	0.00	0	0.00	0	0.00
41	231	11.89	0	0.00	0	0.00	0	0.00	0	0.00
42	385	20.74	0	1.08	0	0.00	0	0.00	0	0.00
45	19	1.96	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	762	53.08	0	7.21	274	1.78	128	0.38	0	0.00
46	75	4.31	0	0.00	10	0.07	0	0.00	0	0.00
48	162	17.76	0	0.00	0	0.00	0	0.00	0	0.00
52	99	3.21	0	0.05	16	0.11	54	0.17	0	0.00
53	54	4.40	0	0.00	0	0.00	0	0.00	0	0.00
56	335	21.52	0	6.96	232	1.50	74	0.21	0	0.00
63	37	1.89	0	0.20	16	0.09	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	1032	24.76	0	3.16	1381	6.97	226	0.60	0	0.00
68	26	1.90	0	0.00	0	0.00	0	0.00	0	0.00
71	1006	22.86	0	3.16	1381	6.97	226	0.60	0	0.00
DEVICES & RAD H	1029	44.03	0	7.23	56	0.43	135	0.37	139	0.51
81	5	0.10	0	0.02	0	0.00	0	0.00	0	0.00
82	497	29.60	0	2.74	55	0.42	128	0.33	0	0.00
83	136	10.09	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	327	2.27	0	1.58	0	0.00	0	0.00	0	0.00
86	64	1.97	0	2.89	1	0.00	7	0.04	139	0.51
TOBACCO PROD	26	2.38	0	1.79	38	0.24	17	0.11	0	0.00
96	26	2.38	0	1.79	38	0.24	17	0.11	0	0.00

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Region: CE 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
REGION TOTAL	24289	13.75	251	45.53	191	2.16	480	35.73	802	52.09
FOOD SAFETY/COS	19314	10.16	0	14.87	131	1.23	480	20.98	261	9.62
03	15423	8.12	0	2.87	0	0.00	0	3.63	261	9.62
04	837	0.44	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	876	0.46	0	0.00	118	1.09	0	0.00	0	0.00
18	0	0.00	0	0.00	0	0.00	480	17.35	0	0.00
21	1847	0.97	0	0.00	0	0.00	0	0.00	0	0.00
29	331	0.17	0	0.00	13	0.14	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	2.99	0	0.00
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	2.99	0	0.00
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	2278	2.40	251	29.36	60	0.92	0	3.80	388	31.94
46	0	0.00	31	1.77	0	0.00	0	0.00	31	2.34
48	0	0.00	0	0.00	0	0.00	0	0.00	78	7.99
52	0	0.00	3	0.58	35	0.50	0	0.00	27	2.27
53	0	0.00	0	0.00	0	0.00	0	0.00	5	0.34
56	2278	2.40	204	17.76	25	0.43	0	3.80	247	19.00
63	0	0.00	13	0.25	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
ANIMAL D & F	1301	0.58	0	1.00	0	0.00	0	1.78	27	2.02
68	0	0.00	0	0.00	0	0.00	0	0.00	19	1.60
71	1301	0.58	0	1.00	0	0.00	0	1.78	8	0.42
DEVICES & RAD H	1396	0.61	0	0.30	0	0.00	0	3.93	126	8.52
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	1330	0.56	0	0.30	0	0.00	0	0.00	93	6.81
83	0	0.00	0	0.00	0	0.00	0	0.00	22	1.27
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	1.58	5	0.03
86	66	0.05	0	0.00	0	0.00	0	2.35	6	0.41
TOBACCO PROD	0	0.00	0	0.00	0	0.00	0	2.25	0	0.00
96	0	0.00	0	0.00	0	0.00	0	2.25	0	0.00

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Region: CE REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	520.32	516561.90
FOOD SAFETY/COS	237.25	235849.00
03	188.44	181805.10
04	23.08	24983.10
07	1.90	1804.00
09	1.86	2015.60
18	17.82	21268.00
21	2.94	2793.50
29	1.21	1179.70
BIOLOGICS	38.65	36717.00
41	11.89	11290.50
42	24.81	23568.30
45	1.96	1858.20
HUMAN DRUGS	130.87	132123.50
46	8.49	8141.00
48	25.75	24464.10
52	6.88	6683.00
53	4.73	4495.90
56	73.58	75349.10
63	2.43	2370.40
88	9.00	10620.00
ANIMAL D & F	40.86	39631.70
68	3.51	3328.00
71	37.36	36303.70
DEVICES & RAD H	65.92	65076.70
81	0.12	113.00
82	40.76	39177.30
83	11.37	10798.30
84	0.00	0.00
85	5.46	6350.00
86	8.22	8638.10
TOBACCO PROD	6.77	7164.00
96	6.77	7164.00

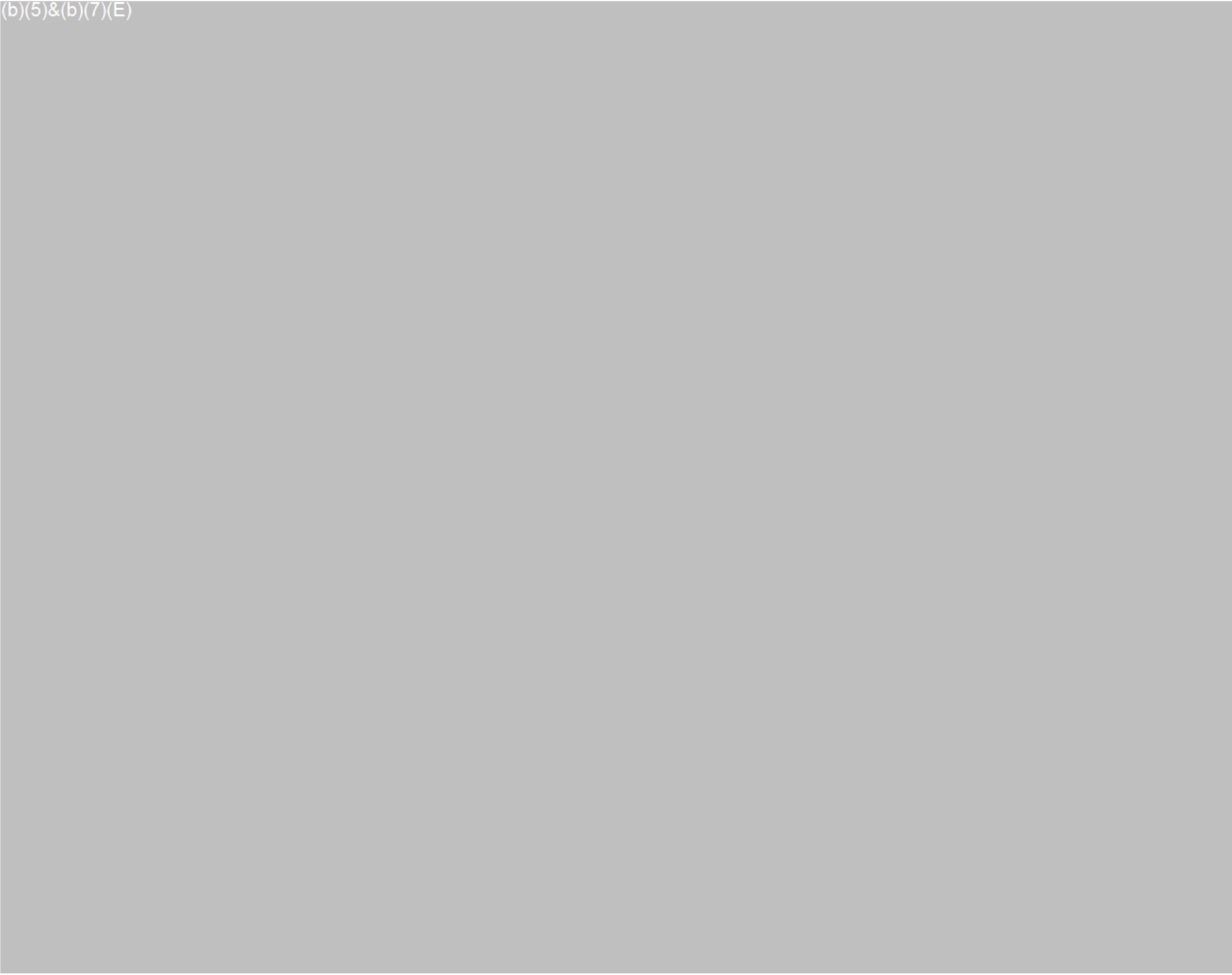
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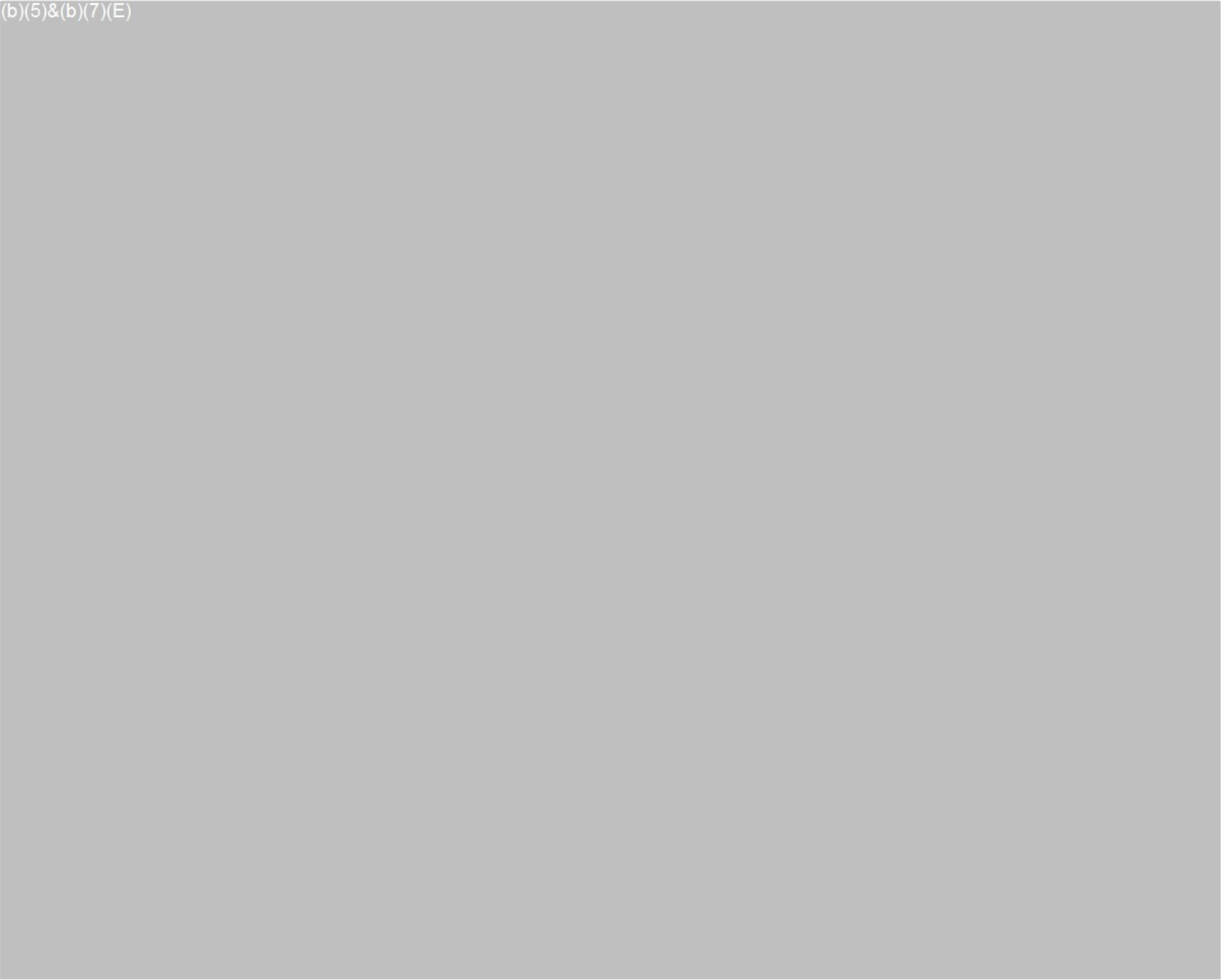
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Region: SE REGN

	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
REGION TOTAL	3077	148.50	0	42.92	2085	11.92	3366	8.25	586	0.54
FOOD SAFETY/COS	1379	54.56	0	27.29	1336	7.87	3000	7.15	539	0.36
03	1361	54.24	0	24.53	530	4.65	2003	5.13	208	0.22
04	0	0.00	0	2.54	514	1.98	714	1.57	0	0.00
07	0	0.00	0	0.00	98	0.41	63	0.13	0	0.00
09	0	0.00	0	0.00	0	0.00	87	0.13	0	0.00
18	0	0.00	0	0.16	44	0.19	0	0.00	0	0.00
21	0	0.00	0	0.06	112	0.50	109	0.15	331	0.14
29	18	0.32	0	0.00	38	0.14	24	0.04	0	0.00
BIOLOGICS	519	27.68	0	0.86	0	0.00	0	0.00	0	0.00
41	192	9.74	0	0.00	0	0.00	0	0.00	0	0.00
42	314	16.60	0	0.86	0	0.00	0	0.00	0	0.00
45	13	1.34	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	464	34.10	0	6.92	242	1.51	96	0.28	0	0.00
46	30	1.68	0	0.00	2	0.01	0	0.00	0	0.00
48	126	14.46	0	0.00	0	0.00	0	0.00	0	0.00
52	35	1.16	0	0.03	6	0.04	28	0.09	0	0.00
53	18	1.46	0	0.00	0	0.00	0	0.00	0	0.00
56	207	13.02	0	6.03	143	0.93	68	0.19	0	0.00
63	48	2.34	0	0.86	91	0.53	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	278	6.62	0	0.67	431	2.07	22	0.06	0	0.00
68	18	1.18	0	0.00	0	0.00	0	0.00	0	0.00
71	260	5.44	0	0.67	431	2.07	22	0.06	0	0.00
DEVICES & RAD H	399	22.05	0	5.48	14	0.08	235	0.68	47	0.18
81	3	0.06	0	0.01	0	0.00	0	0.00	0	0.00
82	260	16.11	0	3.26	13	0.08	232	0.66	0	0.00
83	67	4.95	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	44	0.32	0	0.99	0	0.00	0	0.00	0	0.00
86	25	0.61	0	1.23	1	0.00	3	0.02	47	0.18
TOBACCO PROD	38	3.48	0	1.70	62	0.39	13	0.08	0	0.00
96	38	3.48	0	1.70	62	0.39	13	0.08	0	0.00

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Region: SE 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
REGION TOTAL	26549	14.39	4332	75.01	3953	32.69	207	28.79	425	27.91
FOOD SAFETY/COS	23389	12.31	3577	55.98	3717	30.46	207	18.12	120	4.42
03	21523	11.33	824	27.78	2712	18.02	0	2.95	120	4.42
04	397	0.21	640	4.91	565	6.30	0	0.17	0	0.00
07	0	0.00	279	1.42	141	0.84	0	3.09	0	0.00
09	368	0.19	0	0.00	87	0.80	0	0.00	0	0.00
18	0	0.00	68	0.47	0	0.00	207	11.41	0	0.00
21	940	0.50	1694	20.61	183	4.20	0	0.51	0	0.00
29	161	0.08	72	0.79	29	0.32	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	3	0.13
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	0.13
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	1155	1.22	209	14.04	65	1.07	0	2.98	219	17.91
46	0	0.00	0	1.53	0	0.00	0	0.00	19	1.45
48	0	0.00	0	0.00	0	0.00	0	0.00	41	4.16
52	0	0.00	0	0.71	15	0.21	0	0.00	14	1.18
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.20
56	1155	1.22	139	7.45	50	0.85	0	2.98	142	10.93
63	0	0.00	70	1.35	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
ANIMAL D & F	192	0.09	426	3.99	111	0.65	0	1.36	17	1.14
68	0	0.00	0	0.15	0	0.00	0	0.00	8	0.67
71	192	0.09	426	3.84	111	0.65	0	1.36	9	0.47
DEVICES & RAD H	1813	0.77	0	0.00	0	0.00	0	2.33	66	4.31
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	1782	0.75	0	0.00	0	0.00	0	0.00	42	3.10
83	0	0.00	0	0.00	0	0.00	0	0.00	16	0.98
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	1.06	5	0.03
86	31	0.02	0	0.00	0	0.00	0	1.27	3	0.21
TOBACCO PROD	0	0.00	120	1.01	60	0.50	0	4.00	0	0.00
96	0	0.00	120	1.01	60	0.50	0	4.00	0	0.00

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Region: SE REGN

	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	390.91	404322.90
FOOD SAFETY/COS	218.52	233723.10
03	153.27	158648.60
04	17.68	19411.30
07	5.89	6822.00
09	1.12	1250.80
18	12.22	14567.00
21	26.66	31158.50
29	1.69	1864.90
BIOLOGICS	28.68	27242.20
41	9.74	9256.00
42	17.59	16714.80
45	1.34	1271.40
HUMAN DRUGS	80.02	78945.60
46	4.67	4435.10
48	18.62	17683.80
52	3.42	3294.10
53	1.66	1575.30
56	43.59	43286.20
63	5.07	5131.10
88	3.00	3540.00
ANIMAL D & F	16.65	16993.50
68	2.00	1906.00
71	14.64	15087.50
DEVICES & RAD H	35.88	35336.50
81	0.06	60.20
82	23.95	23156.80
83	5.93	5629.60
84	0.00	0.00
85	2.40	2788.00
86	3.54	3701.90
TOBACCO PROD	11.16	12082.00
96	11.16	12082.00

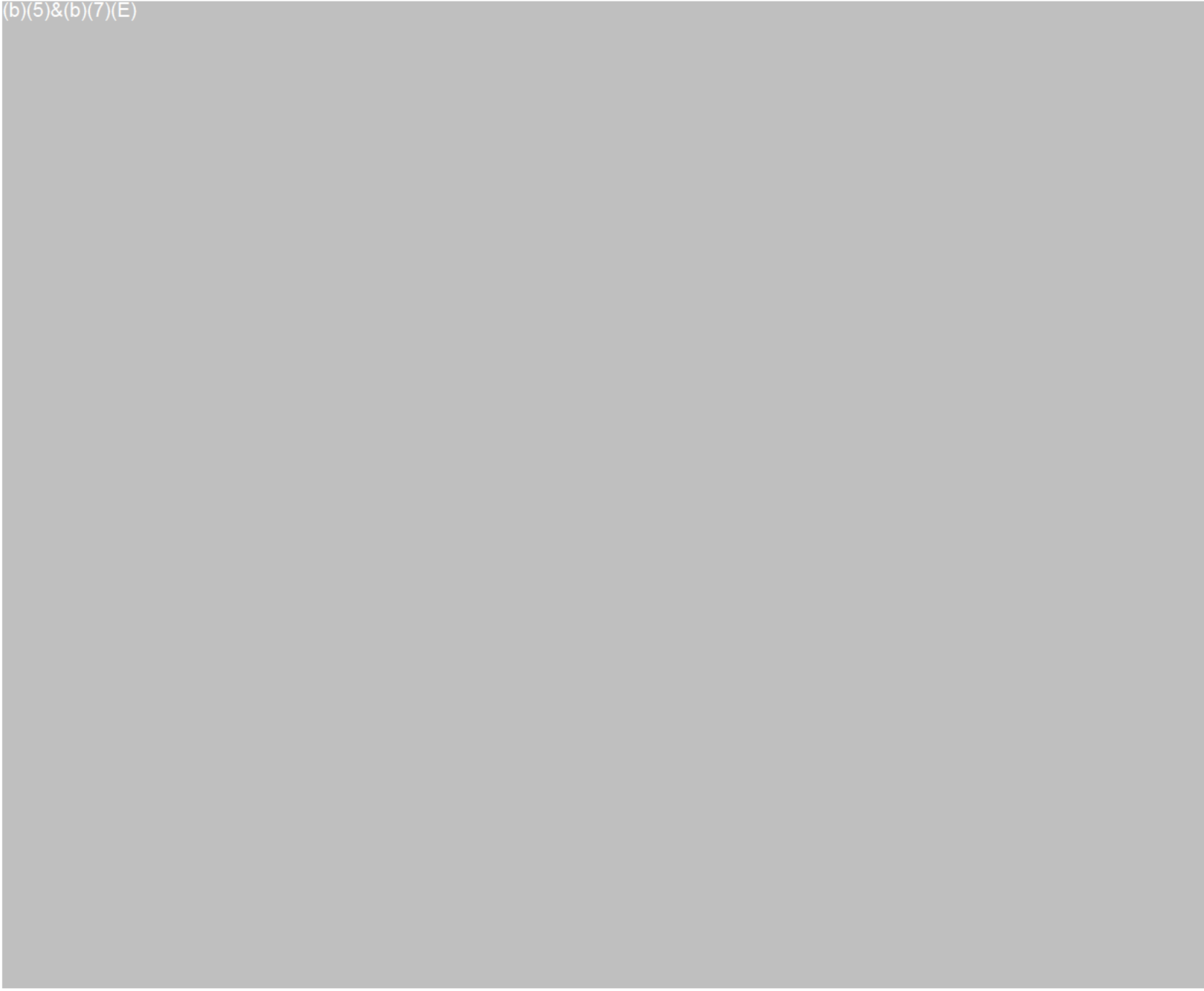
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Region: SW REGN

	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
REGION TOTAL	3110	128.59	0	62.84	2271	13.70	7156	15.54	747	0.72
FOOD SAFETY/COS	1170	49.71	0	34.39	1230	8.50	6795	14.58	671	0.45
03	1156	49.46	0	31.03	385	5.08	3542	8.91	257	0.27
04	0	0.00	0	3.27	510	2.00	2390	4.35	7	0.01
07	0	0.00	0	0.00	154	0.65	147	0.31	0	0.00
09	0	0.00	0	0.00	0	0.00	363	0.54	0	0.00
18	0	0.00	0	0.00	31	0.13	0	0.00	0	0.00
21	0	0.00	0	0.09	121	0.54	327	0.44	407	0.17
29	14	0.25	0	0.00	29	0.11	26	0.04	0	0.00
BIOLOGICS	428	23.47	0	0.62	0	0.00	0	0.00	0	0.00
41	170	8.55	0	0.00	0	0.00	0	0.00	0	0.00
42	241	13.16	0	0.62	0	0.00	0	0.00	0	0.00
45	17	1.75	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	321	23.46	0	4.63	120	0.77	79	0.23	0	0.00
46	20	1.17	0	0.00	3	0.02	0	0.00	0	0.00
48	99	10.88	0	0.00	0	0.00	0	0.00	0	0.00
52	17	0.52	0	0.02	3	0.02	21	0.07	0	0.00
53	9	0.73	0	0.00	0	0.00	0	0.00	0	0.00
56	163	9.51	0	4.50	104	0.67	58	0.17	0	0.00
63	13	0.66	0	0.11	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
ANIMAL D & F	668	14.15	0	1.07	905	4.33	42	0.11	0	0.00
68	19	1.31	0	0.00	0	0.00	0	0.00	0	0.00
71	649	12.84	0	1.07	905	4.33	42	0.11	0	0.00
DEVICES & RAD H	520	17.53	0	21.61	8	0.05	234	0.58	76	0.27
81	7	0.14	0	0.00	0	0.00	0	0.00	0	0.00
82	188	11.27	0	18.79	8	0.05	227	0.54	0	0.00
83	51	3.76	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	251	1.74	0	0.57	0	0.00	0	0.00	0	0.00
86	23	0.63	0	2.25	0	0.00	7	0.04	76	0.27
TOBACCO PROD	3	0.28	0	0.51	8	0.05	6	0.04	0	0.00
96	3	0.28	0	0.51	8	0.05	6	0.04	0	0.00

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	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
REGION TOTAL	56400	29.37	7219	104.55	7259	59.29	218	28.47	333	22.15
FOOD SAFETY/COS	41882	22.04	5363	79.95	6948	57.09	218	20.72	101	3.72
03	36493	19.21	1004	26.15	4172	29.16	0	3.99	101	3.72
04	634	0.33	3931	51.42	2142	22.72	0	5.76	0	0.00
07	0	0.00	355	1.81	193	1.15	0	0.25	0	0.00
09	1421	0.75	0	0.00	411	3.73	0	0.00	0	0.00
18	0	0.00	57	0.40	0	0.00	218	10.73	0	0.00
21	3289	1.73	0	0.00	0	0.00	0	0.00	0	0.00
29	45	0.02	16	0.18	30	0.33	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
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
HUMAN DRUGS	1862	1.96	63	5.82	9	0.13	0	0.13	175	14.45
46	0	0.00	3	1.64	0	0.00	0	0.00	17	1.35
48	0	0.00	0	0.00	0	0.00	0	0.00	37	3.76
52	0	0.00	0	0.39	8	0.11	0	0.00	10	0.84
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.20
56	1862	1.96	53	3.66	1	0.02	0	0.13	108	8.30
63	0	0.00	7	0.14	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
ANIMAL D & F	211	0.10	1781	18.18	302	2.08	0	5.90	13	0.86
68	0	0.00	0	0.57	0	0.00	0	0.00	7	0.55
71	211	0.10	1781	17.61	302	2.08	0	5.90	6	0.31
DEVICES & RAD H	12445	5.27	12	0.59	0	0.00	0	1.72	44	3.12
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	12341	5.20	12	0.59	0	0.00	0	0.00	30	2.27
83	0	0.00	0	0.00	0	0.00	0	0.00	11	0.64
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	0.50	0	0.00
86	104	0.08	0	0.00	0	0.00	0	1.23	3	0.21
TOBACCO PROD	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
96	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

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	OPR FTE'S	PERSNHR
REGION TOTAL	465.22	494780.80
FOOD SAFETY/COS	291.15	317199.60
03	176.98	185849.80
04	89.85	103753.30
07	4.16	4691.00
09	5.01	5613.70
18	11.26	13469.00
21	2.97	2825.70
29	0.93	997.10
BIOLOGICS	24.09	22884.10
41	8.55	8125.00
42	13.79	13096.50
45	1.75	1662.60
HUMAN DRUGS	51.58	50143.10
46	4.18	3973.00
48	14.64	13907.70
52	1.97	1900.40
53	0.93	885.90
56	28.90	28528.30
63	0.97	947.80
88	0.00	0.00
ANIMAL D & F	46.78	50066.50
68	2.43	2311.00
71	44.34	47755.50
DEVICES & RAD H	50.75	53605.50
81	0.14	128.80
82	38.71	40974.70
83	4.40	4178.00
84	0.00	0.00
85	2.81	3263.00
86	4.70	5061.00
TOBACCO PROD	0.88	882.00
96	0.88	882.00


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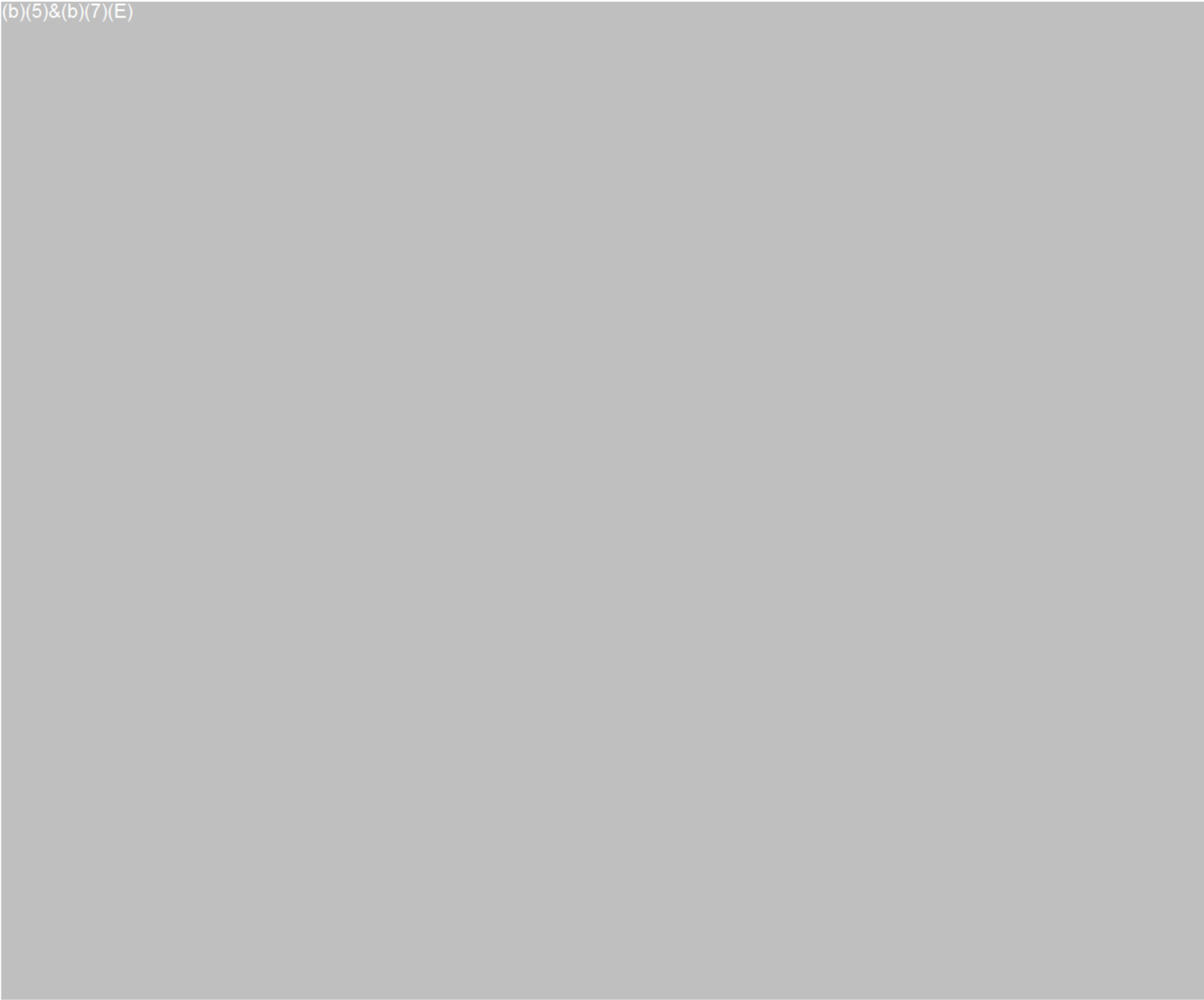
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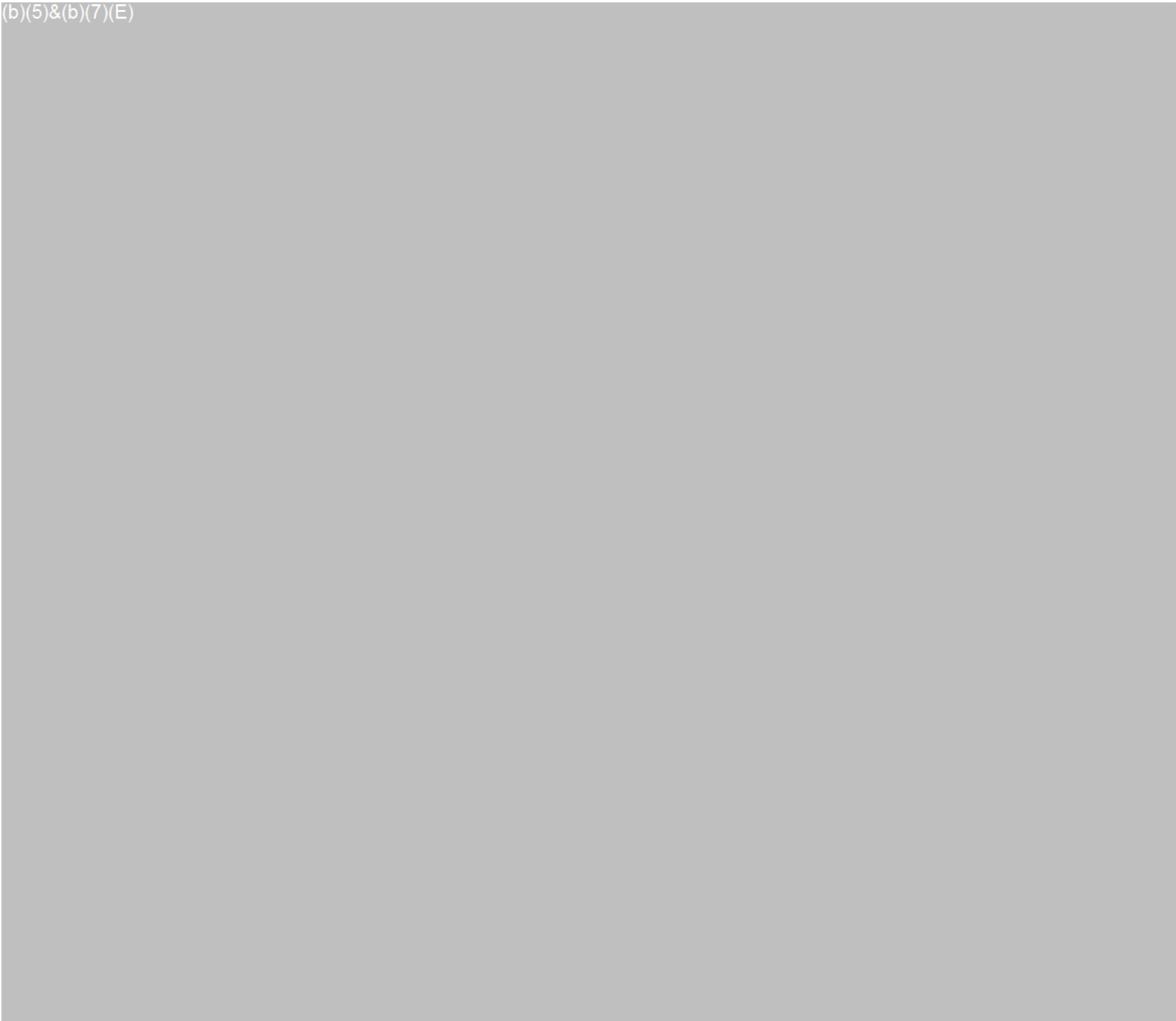
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	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
REGION TOTAL	4204	192.37	0	64.16	3385	19.20	6255	15.06	1207	1.15
FOOD SAFETY/COS	2337	94.24	0	46.03	2459	14.09	5553	13.17	1096	0.73
03	2314	93.83	0	39.31	944	8.38	3907	9.87	422	0.45
04	0	0.00	0	6.29	1039	3.68	926	2.12	8	0.01
07	0	0.00	0	0.00	177	0.75	174	0.37	0	0.00
09	0	0.00	0	0.00	0	0.00	191	0.28	0	0.00
18	0	0.00	0	0.32	55	0.23	0	0.00	0	0.00
21	0	0.00	0	0.12	198	0.89	311	0.47	666	0.28
29	23	0.41	0	0.00	46	0.16	44	0.07	0	0.00
BIOLOGICS	382	20.97	0	1.05	0	0.00	0	0.00	0	0.00
41	178	9.42	0	0.00	0	0.00	0	0.00	0	0.00
42	192	10.32	0	1.05	0	0.00	0	0.00	0	0.00
45	12	1.24	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	420	31.39	0	8.75	229	1.43	132	0.38	0	0.00
46	26	1.44	0	0.00	0	0.00	0	0.00	0	0.00
48	118	13.62	0	0.00	0	0.00	0	0.00	0	0.00
52	36	1.18	0	0.03	6	0.04	25	0.08	0	0.00
53	17	1.38	0	0.00	0	0.00	0	0.00	0	0.00
56	182	11.86	0	7.61	100	0.68	107	0.30	0	0.00
63	41	1.91	0	1.11	123	0.71	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	404	10.55	0	2.62	665	3.47	199	0.52	0	0.00
68	9	0.59	0	0.00	0	0.00	0	0.00	0	0.00
71	395	9.96	0	2.62	665	3.47	199	0.52	0	0.00
DEVICES & RAD H	660	35.14	0	5.17	30	0.20	364	0.94	111	0.41
81	15	0.29	0	0.00	0	0.00	0	0.00	0	0.00
82	446	26.44	0	2.18	28	0.19	358	0.90	0	0.00
83	92	6.60	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	50	0.35	0	0.90	0	0.00	0	0.00	0	0.00
86	57	1.46	0	2.09	2	0.01	6	0.04	111	0.41
TOBACCO PROD	1	0.09	0	0.55	2	0.01	7	0.05	0	0.00
96	1	0.09	0	0.55	2	0.01	7	0.05	0	0.00

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	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
REGION TOTAL	34972	18.36	2557	62.17	9010	61.84	211	30.58	366	23.11
FOOD SAFETY/COS	31714	16.69	2165	52.72	8236	56.08	211	26.06	129	4.75
03	26428	13.91	934	39.40	5831	35.95	0	10.95	129	4.75
04	2197	1.16	1023	11.76	1991	16.82	0	0.58	0	0.00
07	0	0.00	90	0.46	179	1.06	0	1.09	0	0.00
09	811	0.43	0	0.00	191	1.76	0	0.00	0	0.00
18	0	0.00	55	0.41	0	0.00	211	12.45	0	0.00
21	1970	1.04	0	0.00	0	0.00	0	1.00	0	0.00
29	308	0.16	63	0.69	44	0.49	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	3	0.13
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	0.13
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	341	0.36	171	7.42	195	2.37	0	0.08	175	14.45
46	0	0.00	0	0.90	0	0.00	0	0.00	17	1.35
48	0	0.00	0	0.00	0	0.00	0	0.00	32	3.30
52	0	0.00	0	0.38	0	0.00	0	0.00	14	1.18
53	0	0.00	0	0.00	0	0.00	0	0.00	2	0.13
56	341	0.36	82	4.42	195	2.37	0	0.08	110	8.49
63	0	0.00	89	1.72	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
ANIMAL D & F	717	0.33	221	2.04	150	1.25	0	2.20	14	0.89
68	0	0.00	0	0.10	0	0.00	0	0.00	5	0.42
71	717	0.33	221	1.94	150	1.25	0	2.20	9	0.47
DEVICES & RAD H	2200	0.98	0	0.00	429	2.14	0	2.24	45	2.89
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	2032	0.86	0	0.00	429	2.14	0	0.00	32	2.37
83	0	0.00	0	0.00	0	0.00	0	0.00	8	0.48
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	0.83	5	0.03
86	168	0.12	0	0.00	0	0.00	0	1.40	0	0.00
TOBACCO PROD	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
96	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

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	Total	
	OPR FTE'S	PERSNHRS
REGION TOTAL	487.99	501868.50
FOOD SAFETY/COS	324.57	341746.60
03	256.79	265919.20
04	42.42	47017.10
07	3.72	4139.00
09	2.47	2750.90
18	13.40	15934.00
21	3.79	3828.20
29	1.99	2158.20
BIOLOGICS	22.15	21036.20
41	9.42	8944.00
42	11.49	10918.60
45	1.24	1173.60
HUMAN DRUGS	66.63	64879.20
46	3.70	3510.30
48	16.92	16069.50
52	2.88	2736.60
53	1.51	1433.20
56	36.18	35559.50
63	5.45	5570.10
88	0.00	0.00
ANIMAL D & F	23.85	24194.60
68	1.10	1048.00
71	22.75	23146.60
DEVICES & RAD H	50.10	49283.90
81	0.30	280.00
82	35.08	34053.30
83	7.08	6727.60
84	0.00	0.00
85	2.12	2464.00
86	5.53	5759.00
TOBACCO PROD	0.70	728.00
96	0.70	728.00

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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
GRAND TOTAL	18401	842.24	0	331.02	13114	81.80	29151	67.85	4475	4.50
FOOD SAFETY/COS	8328	349.58	0	218.13	8195	55.36	26605	60.74	3945	2.63
03	8228	347.79	0	195.14	3049	34.50	17430	43.60	1520	1.60
04	0	0.00	0	21.43	3155	12.36	5575	11.30	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	0.66	749	3.40	1363	2.00	2400	1.01
29	100	1.79	0	0.00	210	0.75	230	0.36	0	0.00
BIOLOGICS	2196	123.78	0	6.98	0	0.00	0	0.00	0	0.00
41	862	44.67	0	0.00	0	0.00	0	0.00	0	0.00
42	1251	68.90	0	6.98	0	0.00	0	0.00	0	0.00
45	83	10.22	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	2252	162.65	0	44.39	977	6.20	544	1.59	0	0.00
46	171	9.76	0	0.00	17	0.12	0	0.00	0	0.00
48	563	63.00	0	0.00	0	0.00	0	0.00	0	0.00
52	216	7.09	0	0.15	35	0.25	151	0.48	0	0.00
53	120	9.76	0	0.00	0	0.00	0	0.00	0	0.00
56	1021	65.15	0	41.66	656	4.27	393	1.12	0	0.00
63	161	7.89	0	2.58	269	1.56	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	2557	61.91	0	10.96	3695	18.60	750	1.97	0	0.00
68	79	5.48	0	0.00	0	0.00	0	0.00	0	0.00
71	2478	56.44	0	10.96	3695	18.60	750	1.97	0	0.00
DEVICES & RAD H	2998	137.90	0	44.89	127	0.88	1192	3.16	530	1.87
81	45	0.87	0	0.03	3	0.03	0	0.00	0	0.00
82	1624	96.79	0	30.37	119	0.84	1167	3.01	0	0.00
83	401	29.42	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	723	5.04	0	4.82	0	0.00	0	0.00	0	0.00
86	205	5.79	0	9.67	5	0.02	25	0.15	530	1.87
TOBACCO PROD	70	6.41	0	5.69	120	0.76	60	0.38	0	0.00
96	70	6.41	0	5.69	120	0.76	60	0.38	0	0.00

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TOTAL FIELD	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
GRAND TOTAL	208214	110.96	15783	339.91	28006	218.12	1328	151.71	3126	198.32
FOOD SAFETY/COS	176158	92.71	11890	236.60	25460	192.99	1328	100.03	1200	44.21
03	152139	80.07	3049	117.74	17430	114.86	0	25.48	1200	44.21
04	6406	3.37	5905	90.29	5575	55.42	0	7.00	0	0.00
07	0	0.00	832	4.23	832	4.94	0	4.51	0	0.00
09	4804	2.53	0	0.00	1175	10.75	0	0.00	0	0.00
18	0	0.00	200	1.42	0	0.00	1328	61.53	0	0.00
21	11209	5.90	1694	20.61	218	4.49	0	1.51	0	0.00
29	1600	0.84	210	2.31	230	2.53	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	2.99	37	6.35
41	0	0.00	0	0.00	0	0.00	0	0.00	1	0.07
42	0	0.00	0	0.00	0	0.00	0	2.99	23	3.26
45	0	0.00	0	0.00	0	0.00	0	0.00	13	3.01
HUMAN DRUGS	7156	7.53	937	65.78	484	6.74	0	7.95	1295	107.25
46	0	0.00	35	6.85	0	0.00	0	0.00	107	8.33
48	0	0.00	0	0.00	0	0.00	0	0.00	240	24.53
52	0	0.00	35	3.40	151	2.07	0	0.00	83	6.97
53	0	0.00	0	0.00	0	0.00	0	0.00	15	1.01
56	7156	7.53	668	39.69	333	4.68	0	7.95	850	66.42
63	0	0.00	199	3.85	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
ANIMAL D & F	3600	1.62	2570	26.53	750	5.45	0	12.42	83	5.71
68	0	0.00	0	0.90	0	0.00	0	0.00	45	3.75
71	3600	1.62	2570	25.63	750	5.45	0	12.42	38	1.97
DEVICES & RAD H	21300	9.09	266	10.00	1252	12.44	0	22.07	511	34.79
81	0	0.00	3	0.08	0	0.00	0	0.00	0	0.00
82	20900	8.80	111	5.87	1227	11.72	0	4.36	406	29.18
83	0	0.00	0	0.00	0	0.00	0	0.00	75	4.49
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	4.64	15	0.10
86	400	0.30	152	4.05	25	0.72	0	7.36	15	1.03
TOBACCO PROD	0	0.00	120	1.01	60	0.50	0	6.25	0	0.00
96	0	0.00	120	1.01	60	0.50	0	6.25	0	0.00

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Time: 7:06:22 AM

WORKPLAN SUMMARY / COMBINED OPERATIONS
Workplan 0 - 2013
Report Type: Complete

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TOTAL FIELD

	Total	
	OPR FTE'S	PERSNHRS
GRAND TOTAL	2346.43	2423014.50
FOOD SAFETY/COS	1352.98	1431161.00
03	1005.01	1036525.50
04	201.18	226585.10
07	18.93	21141.00
09	15.01	16727.00
18	64.69	77163.00
21	39.58	43740.40
29	8.59	9279.00
BIOLOGICS	140.09	133083.30
41	44.74	42499.00
42	82.12	78018.90
45	13.23	12565.40
HUMAN DRUGS	410.09	405834.00
46	25.06	23888.90
48	87.54	83157.40
52	20.39	20094.20
53	10.76	10222.50
56	238.47	238346.50
63	15.87	15964.50
88	12.00	14160.00
ANIMAL D & F	145.18	148584.50
68	10.12	9612.00
71	135.06	138972.50
DEVICES & RAD H	277.09	281943.70
81	1.01	975.00
82	190.93	191910.70
83	33.91	32211.00
84	5.72	6750.00
85	14.59	16966.00
86	30.94	33131.00
TOBACCO PROD	21.00	22408.00
96	21.00	22408.00