



Memorandum

Date

September 11, 2012

From

Director, Program Planning and Workforce Management Branch

Subject

To

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

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



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

		WORKPLAN	WORKPLAN	FTE
		FTEs	FTEs	DIFFERENCE
Language Language		FY 2012	FY 2013	
PAC	PROGRAM/ASSIGNMENT			
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	
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

	T :		WORKPLAN	
		FTEs FY 2012	FTEs FY 2013	DIFFERENCE
PAC	PROGRAM/ASSIGNMENT	F1 2012	F1 2013	
	Inspection of Human Cells, Tissues, and Cellular and Tissue			
41002B,C,D	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	1	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	1	1	
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

		WORKPLAN FTEs FY 2012	WORKPLAN FTEs FY 2013	FTE DIFFERENCE
PAC	PROGRAM/ASSIGNMENT			
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			1000
		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	10
52832,B,C,E	ANDA Pre-Approval Inspections/Investigations (Foreign)	9.0	12.0	1.0 3.0
52832P	Positron Emission Tomography (PET)	2.4	3.4	1.0
52	Generic Drug Evaluation	15.4	20.4	5.0
<u> </u>	Control 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
50000A D D	D. D. J.			
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		
56843	Post-Approval Inspections/Investigations (Foreign)		2.0	
		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
3001A	Internet, Health Fraud, & OTC Monographs	10.4	11.4	1.0
63002	Naw Drugs (Proporintion) Not Covered by Assessed NDA		4.5	4.5
	New Drugs (Prescription) Not Covered by Approved NDAs Unapproved & Misbranded Drugs	3.0	4.5	1.5
,,,	onepprotou a mismanaca prags	13.4	15.9	2.5
38	Shelf Life Extension Projects	12.0	12.0	
38	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

		WORKPLAN	WORKPLAN	FTE
		FTEs	FTEs	DIFFERENCE
PAC	PROGRAM/ASSIGNMENT	FY 2012	FY 2013	
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

		WORKPLAN FTEs	WORKPLAN FTEs	FTE DIFFERENCE
		FY 2012	FY 2013	DITTERCE
PAC	PROGRAM/ASSIGNMENT			
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 Mfgrs: GMP Domestic	97.3	100.3	3.0
82845B	Inspection of Medical Dev Mfgrs: GMP Foreign	23.9	25.2	1.3
82845H	Inspection of Medical Dev Mfgrs: 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		-0.1
82Z003	Mfgrs & Importers of Surgical/Exam Gloves		3.6	20
82Z800	Center Initiated Assignments	7.5	5.5	-2.0
82R816	Methods Validation/Development Program	4.3	5.3	1.0
82R838	Forensic Evaluation and Sample Analysis	2.0	2.0	
82		0.3	0.3	
62	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	
		311	0.1	
85	Mammography Quality Standards Act (MQSA)	14.6	14.6	
86001	Inspection of Mfgrs of Laser Products Domestic	4.3	4.3	
86001	Inspection of Mfgrs of Laser Products Foreign	0.9	0.9	
86002	Field Implementation of Sunlamp Products	0.3	0.3	
	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	V.,
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 86007	Compliance Testing of Elec Prod at WEAC Foreign Imported Electronic Products	0.3	0.3	0.4
	Med Dev & Rad Hith Use Control & Policy Implementation	8.5 3.0	8.1 3.0	-0.4
	Emergency Planning & Response Activities	2.0	2.0	
36	Radiation Control & Health Safety Act (RCHSA)	31.2	30.9	-0.3
9	Total Mission Direct: Pre and Annual Planned FTEs	274.0	277.0	3.0

TOBACCO PRODUCTS

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

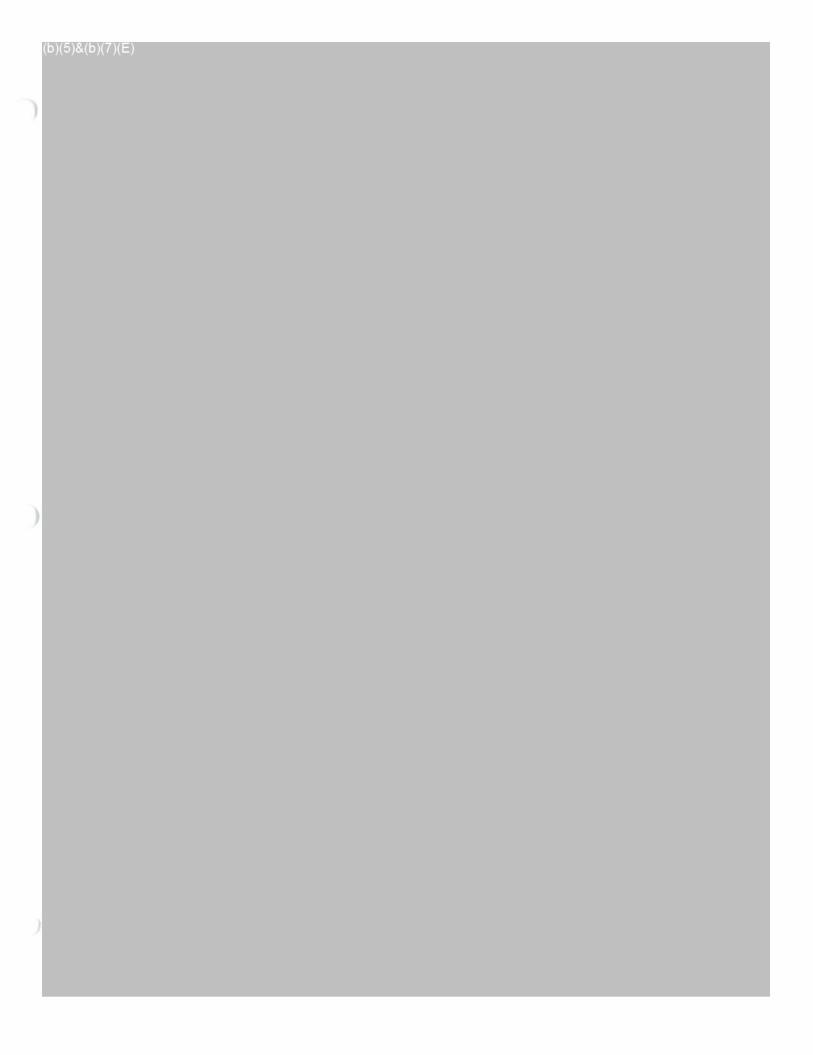
^{*} Includes 96R824 and 96R833

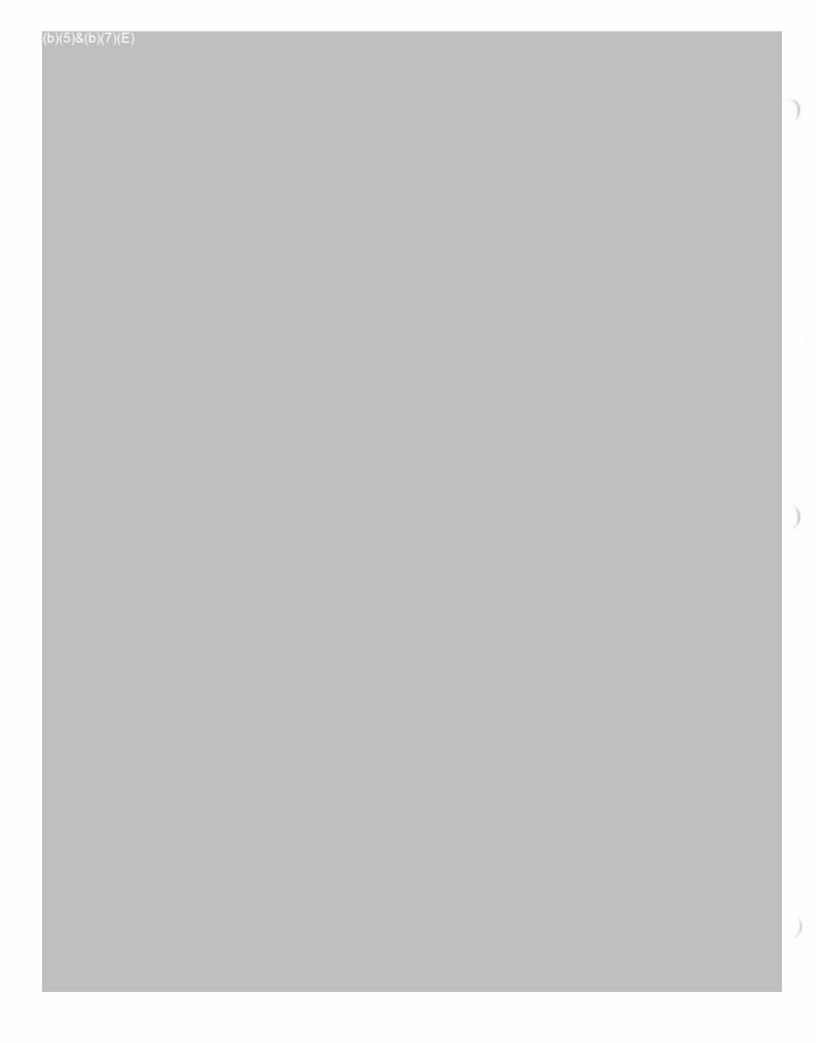
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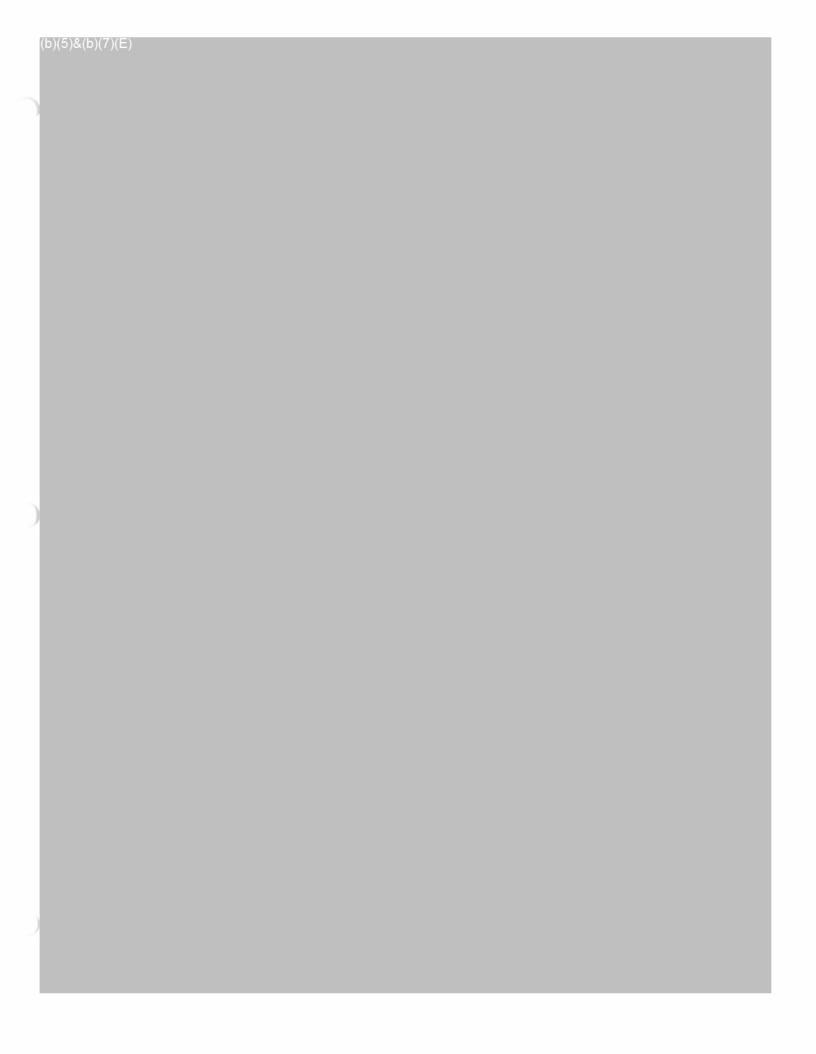
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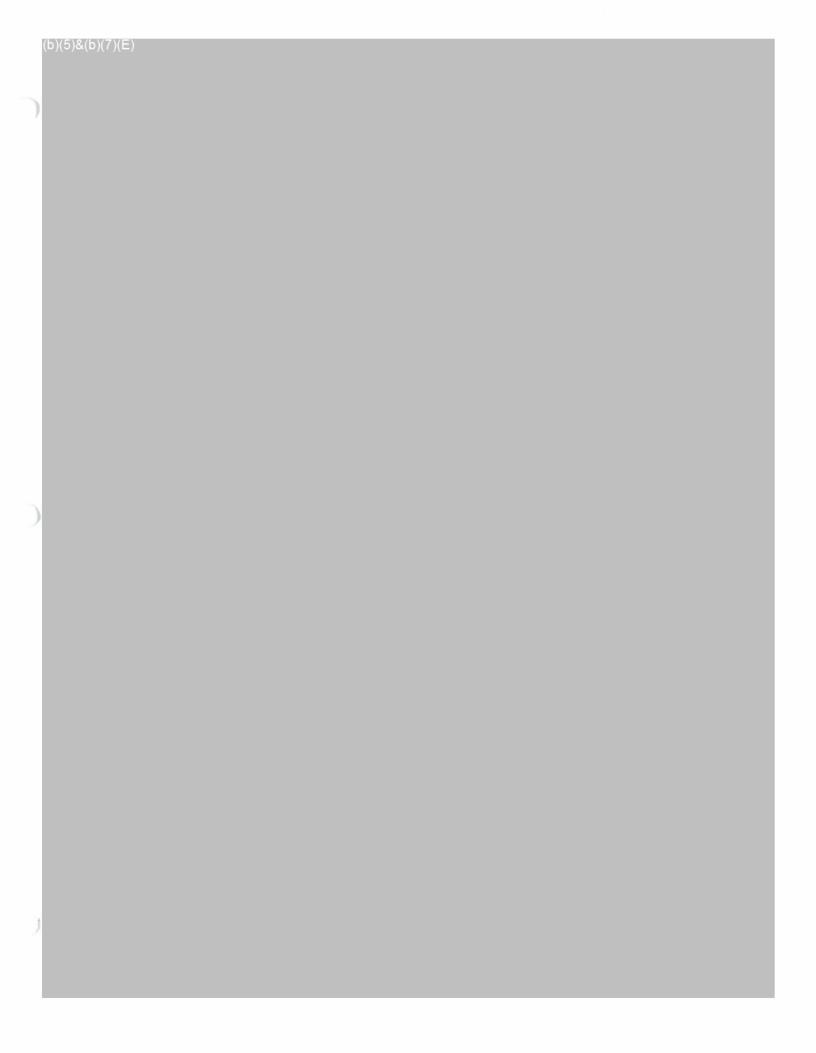
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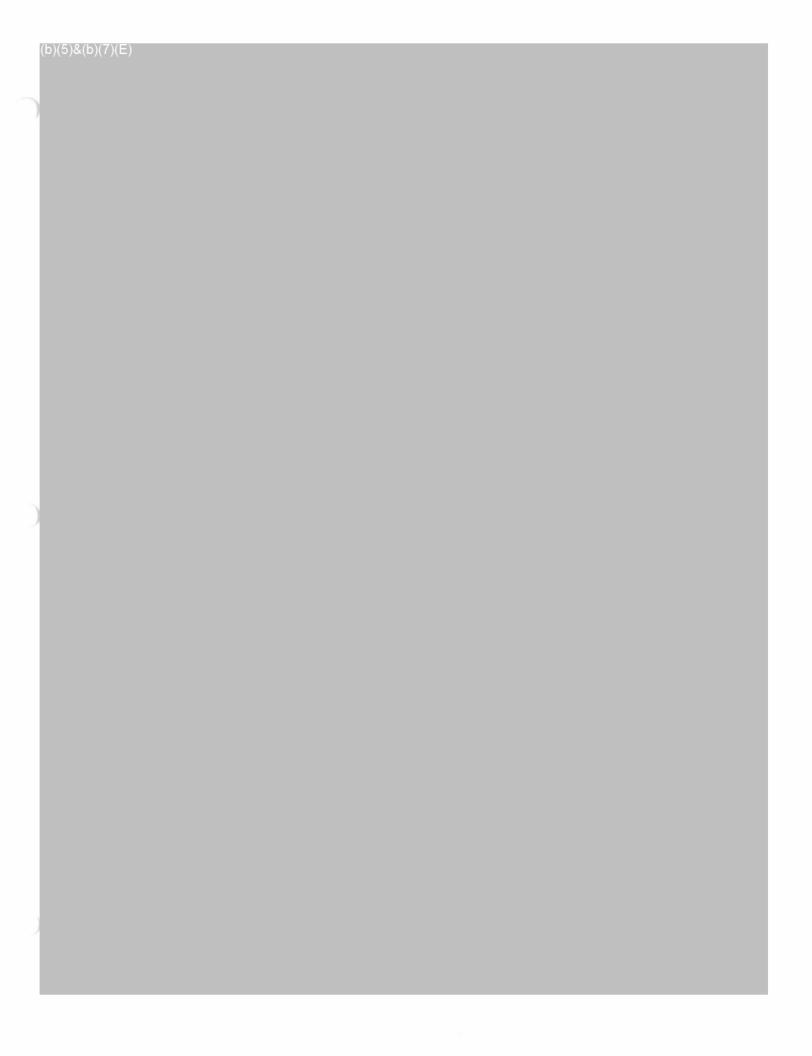




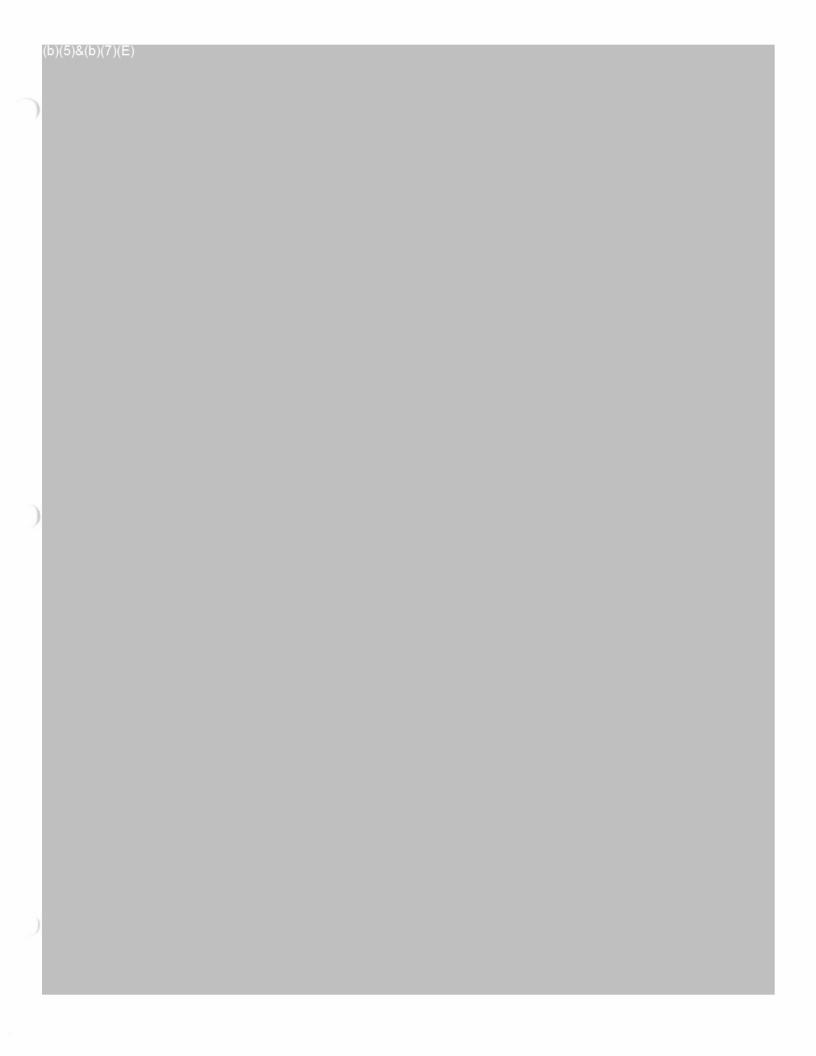
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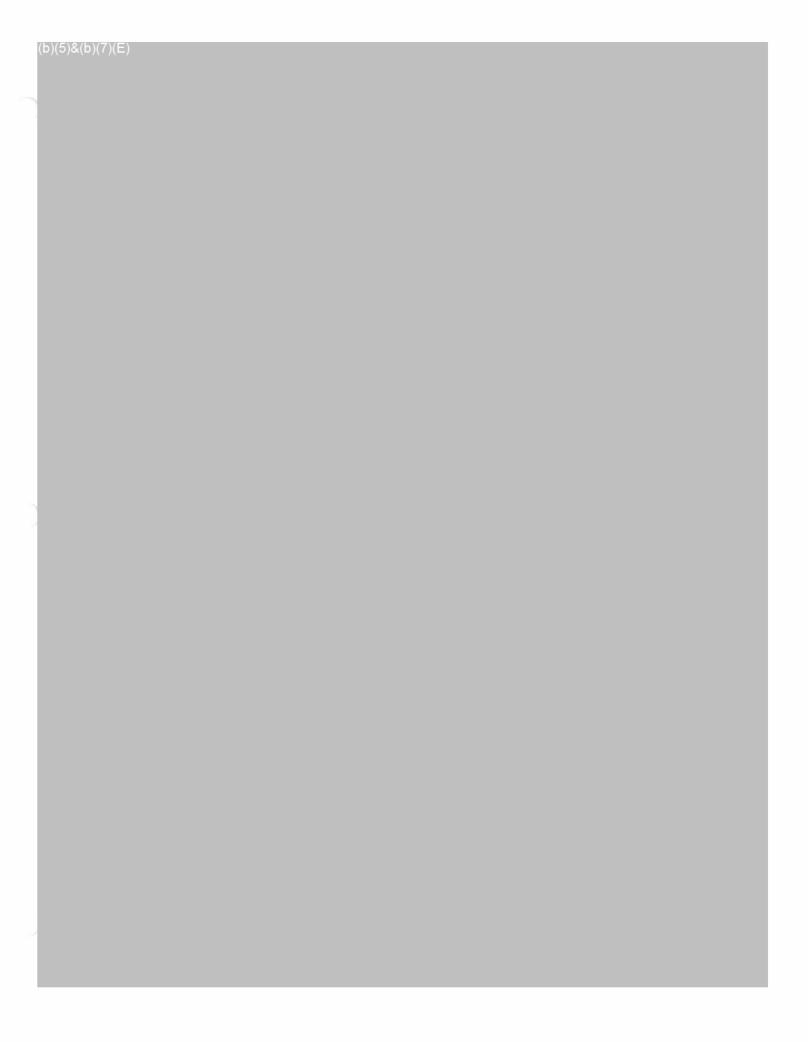
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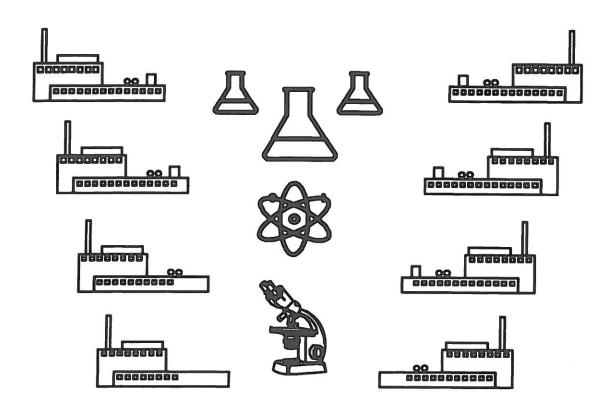
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FY 2013 SERVICING LABORATORIES



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

OCTOBER 2012

FOR GUIDANCE ONLY - CONTACT THE DIVISION OF FIELD SCIENCE FOR QUESTIONS

CHEMISTS / ENTOMOLOGISTS/BIOLOGISTS

REGIONS>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	>>>>>	NORT	HEAST			III.	CENTRA		111010	<i>y</i> G1 G 1	Sibic	SOUT	HEAST				0.171.045					
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FOOD & COSMETICS						0114	DLI	IVIIIV	MAAA	FILI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
03 FOODBORNE BIOLOG HAZARDS																		TX&NM	CA&AZ			
IMPORT A/L ACID CAN FD	03003.A	NRL	NRL	601																		
IMP CHEESE PRODUCTS (Filth)	03003,A 03037B	SRL	NRL	SRL	ARL	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL		DEN	KAN	ARL	PRS	PRS	SAN	PRN
DOM ACID/L ACID CAN FD	03803A	NRL	NRL	SRL	ARL	SRL	ARL	ARL		SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRN	PRS	SAN	PRN
DOMESTIC FOOD SAFETY (Filth)	03803A	NRL	NRL	SRL	ARL	SRL	DEN	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	KAN			PRS	SAN	PRN
DOMESTIC FOOD SAFETY	03803C	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	KAN	DEN	KAN		••	PRS	PRS	PRN
IMPORTED FDS-GENERAL (Filth)	03819A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	KAN	DEN	KAN	**		PRS	SAN	PRN
IMPORTED FDS-GENERAL	03819B	NRL	NRL	SRL	ARL	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL				ARL	PRS	PRS	PRS	PRN
DOM FISH & FISHERY PROD (Filth)		NRL	NRL	SRL	ARL	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL			-	ARL	PRS	PRS	SAN	PRN
DOM FISH & FISHERY PROD	03842C	NRL	NRL	SRL	ARL ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL			PRS	PRS	PRN
ORGANOLEPTIC ANALYSIS +	03842C	NRL	NRL	SKL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL		**	PRS	SAN	PRN
IMPORT SEAFOOD PROD	03844B	NRL	NRL	SRL					••			**								-		PRN
IMPORT SEAFOOD PROD	03844C	NRL	NRL	SRL	ARL	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL		ARL	ARL	ARL	PRS	PRS	PRS	PRN
ORGANOLEPTIC ANALYSIS ++	03844C	NRL	NRL	JAL	ARL.	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL		ARL	ARL	ARL	PRS	PRS	SAN	PRN
JUICE HACCP	03847H	NRL	NRL	SRL	CD!																	PRN
FOOD DEFENSE (Imp/Dom)	03R845	NRL	NRL	WEA	SRL WEA	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL			PRS	SAN	PRN
04 PESTICIDES & CHEM CONTAM.	0011045	MILL	MAL	WEA	VVEA	KAN	FCC	FCC	FCC	NRL	SRL	SRL	SRL	DEN	ARL	DEN	KAN	ARL	PRS	PRS	SAN	PRN
PEST & CHEM DOM FDS & SEAFD	04004A	NRL	NRL	SRL	ARL	SRL	401	451														
DIOXIN ANALYSIS	04004D	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	ARL -ARL-	ARL	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN			PRS	PRS	PRN
IMP FOODS - PESTICIDES	04004A	NRL	NRL	SRL	ARL	SRL		-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-			-ARL-	-ARL-	-ARL-
IMP FDS - PESTICIDES SEAFOOD	04004A	NRL	NRL	SRL	ARL	SRL	ARL	ARL		SRL	SRL	SRL	SRL	SRL		ARL	ARL	ARL	PRS	PRS	PRS	PRN
TOXIC ELM IN FDS D/I	04019A	NRL	NRL	SRL	KAN	SRL	KAN	ARL		SRL	SRL	SRL	SRL	SRL		KAN	KAN	ARL	PRS	PRS	PRS	PRN
TOXIC ELM TBL&CK WARE-D/I	04019B	NRL	NRL	SRL	KAN	SRL	KAN	KAN	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	SAN	SAN	SAN
RADIONUCLIDES IN FDS-D/I	04019C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	PRS	SAN	SAN
TOTAL DIET STUDY	04839	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	KAN	-KAN-	-WEA-	-KAN-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
07 MOL BIO & NATURAL TOXINS	0.1000	.0.01	1001	-10/14-	-10-114-	-TO-LIT-	IVAIN	-NAN-	-NAN-	-NAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-		-	-KAN-	-KAN-	-KAN-
MYCOTOXINS DOM FDS (AFLA)	07001	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	CDI	- CDI	001						
MYCOTOXINS DOM FDS (FUM)	07001	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-SKL-	100000000000000000000000000000000000000	-SRL-	-SRL-	-SRL-	-SRL-		-	-SRL-	-SRL-	-SRL-
	07001	NRL	NRL	NRL	KAN	NRL	KAN	KAN	NRL	NRL	KAN	KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-			-KAN-	-KAN-	-KAN-
	07001	NRL	NRL	NRL	SRL	NRL	SRL	SRL	NRL	NRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN		••	PRN	PRN	PRN
MYCOTOXINS IMP FDS (AFLA)	07001	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL		SRL	SRL	KAN	KAN	KAN			PRN	PRN	PRN
MYCOTOXINS IMP FDS (FUM)	07001	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	SRL -KAN-	SRL -KAN-	SRL	KAN	KAN	KAN	KAN	KAN	PRN	PRN	PRN
	07001	NRL	NRL	NRL	SRL	NRL	SRL	SRL	NRL	NRL	SRL	KAN	SRL	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-
	07001	NRL	NRL	NRL	SRL	NRL	SRL	SRL	NRL	NRL			200000000000	SRL	KAN	KAN	KAN	KAN	KAN	PRN	PRN	PRN
MYCO IMP FDS (SPEC SURV)	07001	-SRL-	SRL-	-SRL-	-SRL-	-SRL-	SRL	-SRL-	-SRL-		SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	PRN	PRN	PRN
09 FOOD & COLOR ADDITIVES	3,001		UIL	-OILL-	-OILL	-OILL-	JIL	-SKL-	-SKL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
IMPORT FOODS (FD ADDS)	09006A	NRL	NRL	NRL	DEN	NRL	DET	DEN		NRL	SRL	SRL	SRL	001	DEM	BEN						
	09006B	NRL	NRL	NRL	DEN	NRL	DET	DEN		NRL	SRL	SRL	SJN	SRL	DEN	DEN	DEN	DEN	DEN	SAN	SAN	SAN
DOM FD SAFETY (COLOR)	09803.E	NRL	NRL	NRL	DEN	NRL	DET	DEN		NRL	SRL	SRL	SJN	NLS	DEN DEN	DEN	DEN	DEN	DEN	SAN	SAN	SAN
	09803.F	NRL	NRL	NRL	DEN	NRL	DET	DEN		NRL	SRL	SRL	SRL	SJN	DEN	DEN DEN	DEN			SAN	SAN	SAN
18 TECH ASSIST: FOOD & COSMETI					02.11	1111	<u> </u>	DEN		MINE	SKL	SKL	SKL	SUN	DEN	DEN	DEN			SAN	SAN	SAN
INTERSTATE TRAVEL SANIT	18029A-F	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			DDN	554	221
21 FOOD COMP STDS LABEL & ECO	ON				71112	UITE	7116	_ AILL	JILL	SILL	SILL	SILL	JIL	SKL	DEN	DEN	DEN			PRN	PRN	PRN
	21002	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-			CDI	CDI	CDI
THE CONTROL OF THE CO	21005	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-				-SRL-	-SRL-	-SRL-
	21005	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-3KL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SKL-	-SRL-	-SRL- -SRL-	 -SRL-	-SRL-	-SRL- -SRL-	-SRL-	-SRL-
NLEA ENFORCEMENT D/I (Allergen)		NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	SRL	SRL	SRL.								-SRL-	-SRL-
	21006	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	SRL -SRL-	SRL	SRL	SRL	- CDI		SRL	SRL	SRL
	21008	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
	21839	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-SKL-	-KAN-	-SKL-	-SRL-	-SRL-	-SKL-	-SRL-	-SRL-	-SRL- -KAN-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
29 COSMETICS							11/11/19	-,174113	-ivair.	-10-014-	-IOMIN-	-1/VIA+	-IVAIV-	-IVMIN-	-IVAIV-	-NAN-	-KAN-			-KAN-	-KAN-	-KAN-
DOM/IMP COSMETICS	29001	NRL	NRL	NRL	DEN	NRL	DET	DEN	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	DEN	DEN	SAN	SAN	SAN
								DEIT	HILL	HILL	UNL	JIL	JIL	JIL	DEN	DEN	DEN	DEM	DEM	JAN	JAN	MAG

NATIONAL & SPECIAL SERVICING LABS INDICATED WITH DASHES (e.g. -WEA-)

⁺ National Expert: Collecting Districts Check with DFS (HFC-140) Except for Breaded Shrimp - See Compliance Program for list of laboratories

⁺⁺ National Expert: Collecting Districts Check with DFS (HFC-140)

FOR GUIDANCE ONLY - CONTACT THE DIVISION OF FIELD SCIENCE FOR QUESTIONS

CHEMISTS / ENTOMOLOGISTS/BIOLOGISTS

BECIONOSSISSISSISSISSISSISSISSISSISSISSISSISSI	[NODTI	FACT			-	CENTER		200	1010		SOUTH				80	UTHWE	eT.			PACIFIC	
REGIONS>>>>>>>>>>	->>>>	NORTH	1EAST				ENTRAL	-				30011					OTHVAE			The second	E 0.42.200.000.000	A CONTRACT
COLLECTING DISTRICT>>>>	>>>>>	NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
HUMAN DRUGS									2000									TX&NM	CA&AZ			
46 NEW DRUG EVALUATION																						
NDA CHEM INSP	46832	NRL	NRL	PHI	DET	FCC	DET	DET	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN			PRS	PRN	PRN
PRE APPROVAL PROFILE	46832B,C	NRL	NRL	FCC	FCC	FCC	FCC	FCC	FCC	FCC	NRL	NRL	NRL	NRL	FCC	FCC	FCC	••		FCC	FCC	FCC
PRE APPR FOREIGN CHEM INSP	46832	NRL	NRL	PHI	PHI	FCC	PHI	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN			PRS	SAN	PRN
PRE APPR FOREIGN PROFILE	46832B,C	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL			NRL	NRL	NRL
52 GENERIC DRUG EVALUATION																						
ANDA CHEM INSP	52832	NRL	NRL	PHI	PHI	FCC	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN			PRS	SAN	PRN
GEN PRE APPROV PROFILE	52832B,C	NRL	NRL	FCC	FCC	FCC	FCC	FCC	FCC	FCC	NRL	NRL	NRL	NRL	FCC	FCC	FCC			FCC	FCC	FCC
PRE APPR FOREIGN CHEM INSP	52832	NRL	NRL	PHI	PHI	PHI	PHI	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN			PRS	PRN	PRN
PRE APPR FOREIGN PROFILE	52832B,C	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	***		NRL	NRL	NRL
56 DRUG QUALITY ASSURANCE																						
DPI CHEM ON INSP	56002 A-F	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN			PRS	PRN	PRN
DRUG PROCESS INSP (DSA)	56002 A-F	NRI.	NRL	PHI	PHI	PHI	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	DEN		-	PRN	PRN	PRN
FOREIGN CHEM INSP	56002 A-F	PHI	NRL	PHI	PHI	FCC	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN			PRS	SAN	PRN
DRG QUAL SAMP/TEST (API)	56008A	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-
DRG QUAL SAMP/TEST (DPS)	56008A	NRL	NRL	PHI	PHI	PHI	DET	PHI	PHI	PHI	SRL	SJN	SRL	SJN	DEN	DEN	KAN			PRS	PRN	PRN
DPS API	56008H	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SJN	SJN	SJN				DEN	DEN	PRS	PRN	PRN
DPS FINISHED DOSAGE	56008H	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	***			-PRN-	-PRN-	-PRN-	-PRN-	-PRN-
DQRS/NDA FLD ALERT REPT	56021A,B	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SRL	SJN	SJN	DEN	DEN	DEN	**		PRN	PRN	PRN
RX DRG MKTG ACT (PDMA)	560022,A	NRL	NRL	PHI	PHI	PHI	PHI	PHI	PHI	PHI	SJN	SJN	SJN	SJN	DEN	DEN	DEN			PRN	PRN	PRN
63 INTERNET, FRAUD, OTC MONO	63001A	PHI	NRL	PHI	PHI	PHI	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	**		PRN	PRN	PRN

NATIONAL & SPECIAL SERVICING LABS INDICATED WITH DASHES (e.g. -WEA-)

The Analyzing Laboratories for Samples Collected Under 56008A/H, Drug Product Surveillance will be assigned by DFS (HFC-140) based on expertise of drug lab for each specific drug sampled.

SWID - TX & NM Column: Samples collected in TX or NM will be analyzed by the Labs listed.

SWID - CA & AZ Column: Samples collected in CA or AZ will be analyzed by the Labs listed.

FOR GUIDANCE ONLY - CONTACT THE DIVISION OF FIELD SCIENCE FOR QUESTIONS

CHEMISTS / ENTOMOLOGISTS/BIOLOGISTS

CHEMISTS / ENTOWOLOGISTS/BIOLOGISTS		
REGIONS>>>>>>> NORTHEAST CENTRAL SOUTHEAST SOUTHWEST	PACIFIC	
COLLECTING DISTRICT>>>>>>> NWE NYK BLT CHI CIN DET MIN NWJ PHI ATL FLA NOL SJN DAL DEN KAN SWID SWID I	LOS SAN SE	EA
ANIMAL DRUGS & FEEDS TX&NM CA&AZ		
68 PRE APPR MON ANIMAL DGS FEEDS		
NADA PRE APPROVAL INSP 68001 NRL NRL KAN KAN KAN KAN KAN KAN KAN KAN SRL SRL SRL KAN KAN KAN F	PRN PRN PR	DN
NADA PDE APPROVALINCE COMMC NEL NEL NAME NAME NAME NAME NAME NAME NAME NAME	PRN PRN PRI	33000
METHOD VALIDATION 68001 NRL NRL KAN KAN KAN KAN KAN KAN KAN SRI SRI SRI SRI SRI DEN DEN KAN E	PRN PRN PR	
GLP NON-CLINICAL 68808 NRL NRL KAN ARL KAN ARL SRI	PRN PRN PR	
GLP NON-CLINICAL 68808G NRL NRL KAN ARL KAN ARL SRI SRI KAN SRI	PRN PRN PR	10000
71 POST APPR MON ANIMAL DGS FEEDS	FRN PRN PR	(N
ANIMAL DRUG MANUF INSP 71001 NRL NRL SRL KAN SRL KAN SRL SRL SRL SRL SRL SRL KAN KAN KAN F	PRN PRN PR	ON
DOM/IMP FEED CONTAMIN 71003A NRL NRL SRL KAN SRL ARL KAN NRI NRI SRI SRI SRI SRI SRI SRI SRI SRI SRI S	PRS PRS PR	
FEED CONT METALS 71003B NRL NRL SRL KAN SRL KAN NRI NRI SRI SRI SRI SRI SRI SRI SRI SRI SRI S	SAN SAN SA	0000
FEED CONT MYCO (FUM) D/I 71003C -KAN	KANKANKA	2000
FEED CONT MYCOTOXINS D/I 71003C NRL NRL SRL ARL ARL ARL NRI NRI SRI SRI SRI SRI SRI SRI SRI SRI SRI S	PRN PRN PRI	3433
FEED CONT DIOXIN ANALY D/I 71003G -ARLA	ARLARLAR	
FEED CONT ANTIBIOTICS D/I 71003K NRL NRL SRL ARL SRL ARL ARL NRI NRI SRI SRI SRI SRI SRI SRI SRI SRI SRI S	PRN PRN PRI	
FEED MANUFACTURING 71004 -DEN-	DENDENDEI	33300
TYPE "A" MED ARTICLES 71005 -DEND	DENDENDEI	
ILL RESIDUES MEAT & PLTDY 74006 DEN DEN DEN DEN DEN DEN DEN	DENDENDEI	034.05
ILL RESIDUES IN MILK 71006M API API DEN DEN DEN DEN DEN DEN DEN DEN DEN		
METHOD VALIDATION 71006 DEN	DEN DEN DEI DENDENDEI	
RSE PROGRAM DOMESTIC 74000 NRI NRI CRI ARI CRI ARI		5000
BSE PROGRAM IMPORT 719844 DRIN ARI CRI ARI CRI ARI CRI ARI CRI ARI CRI ARI CRI CRI CRI CRI CRI CRI CRI CRI CRI C		
MEDICAL DEV & RAD HLTH	PRS PRS PRI	(IN
81 POSTMKT ASSURANCE: DEVICES		\dashv
PM/DEN F/U CH & SER TEST 81010 -WEA-	WEAWEAWE	EA
PM/DEN F/U RADIONUCLIDES 81010 -WEA-	NEAWEAWE	
82 COMPLIANCE: DEVICES	AEWAAEWAAE	-A-
MON DEV FOREIGN ORIGIN 82008 -WEA-	WEAWEAWE	= 1
MEDS DEACANTS POOLES META META META META	NEAWEAWE	
MEDS IN VITO	WEAWEAWE	
MEDS - SPONICIDAL SOCIAL MES	DEN DEN DEN	20035
MERS TUREPOUL OCIDAL 92945C WEA WEA WEA WEA WEA WEA WEA WEA	DEN DEN DEN	- 1
CONDOM ASSIC DOM JUND POZOGO MICA WICA WICA WICA WICA WICA WICA WICA W	PRS PRS PRS	
SUBCICAL EVANCIONES PRO	PRS PRS PRS	
CTD INIT ASCN. TEST MTD AC BOTTON MEA WEA WEA WEA WEA FRO PRO PRO PRO PRO	VEAWEAWE	
CTD INIT ACON DADIOMANIN COTOOS WEAT WEAT WEAT WEAT WEAT WEAT WEAT WEAT	VEAWEAWEA	628332-1

NATIONAL & SPECIAL SERVICING LABS INDICATED WITH DASHES (e.g. -WEA-)

SWID - TX & NM Column: Samples collected in TX or NM will be analyzed by the Labs listed. SWID - CA & AZ Column: Samples collected in CA or AZ will be analyzed by the Labs listed.

FOR GUIDANCE ONLY - CONTACT THE DIVISION OF FIELD SCIENCE FOR QUESTIONS

MICROBIOLOGISTS

	т			CENTRAL														PACIFIC				
REGIONS>>>>>>>>>	>>>>>	NORT	HEAST			(CENTRAL					SOUTH					UTHWE					
COLLECTING DISTRICT>>>>	>>>>>	NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
FOOD & COSMETICS																		TX&NM	CA&AZ			
03 FOODBORNE BIOLOG HAZA	RDS													99		10/10/2		sees asse	x (2x)			
IMPORT ACID/L ACID	03003,A	NRL	NRL	SRL	ARL	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
DOM ACID/L ACID CAN FD	03803A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRS	SAN	PRN
SPORE HEAT DETERMTN	03803A	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-			-SRL-	-SRL-	-SRL-
DOMESTIC FOOD SAFETY	03803D	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRS	SAN	PRN
IMP FOODS GENERAL*	03819C	NRL	NRL	SRL	DEN	SRL	DEN	DEN	***	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRN	PRS	SAN	PRN
DOM CHEESE PRODUCTS	03037D	SRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRS	SAN	PRN
IMP CHEESE PRODUCTS	03037D	SRL	NRL	SRL	ARL	SRL	ARL	ARL		SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	NRL	NRL	PRS	SAN	PRN
DOM FISH & FISHERY PROD	03842D	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	-		PRS	SAN	PRN
IMPORT SEAFOOD PROD	03844D	NRL	NRL	SRL	ARL	SRL	ARL	ARL		NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
IMPORT MICRO ASSIGN	03F098	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	DEN	PRS	SAN	PRN
DOMESTIC MICRO ASSIGN	03F100	NRL	NRL	ARL	ARL	ARL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRS	SAN	PRN
+ENVIRONMENTAL SAMPLING	03F800	WEA	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRS	SAN	PRN
FOOD DEFENSE (Imp/Dom)	03R845	NRL	NRL	NRL	NRL	NRL	SRL	SRL	SRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
OUTBREAK & EMERGENCY	03R839	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN		-	PRS	SAN	PRN
JUICE HACCP	03847H	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRS	SAN	PRN
18 TECH ASSIST: FOOD & COSM	IETICS																					
MILK SAFETY PROGRAM	18003	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	-	-	SAN	SAN	SAN
INTERSTATE TRAVEL SANIT	18029A-F	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			PRN	PRN	PRN
21 FOOD COMP STDS LABEL & E																						
MEDICAL FOODS DOM/IMP	21002	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-			-SRL-	-SRL-	-SRL-
INFANT FORMULA DOM/IMP	21006	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-			-SRL-	-SRL-	-SRL-
SELECT NUTR IN FOOD SURVEY	Υ									3												
MARKET BASKET	21839	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-			-SRL-	-SRL-	-SRL-
29 DOM/IMP COSMETICS/COLOR	29001	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	DEN	DEN	PRS	SAN	SAN
HUMAN DRUGS																						72
56 DRUG QUALITY ASSURANCE																						
DRUG PROC INSP, DSA/CHEM IN	56002	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	**		SAN	SAN	SAN
DRG QUAL SAMP/TEST	56008A	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			SAN	SAN	SAN
DQRS/NDA FLD ALERT REPT	56021A,B	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN		-	SAN	SAN	SAN
63 FRAUDULENT DRUGS	63001	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN			SAN	SAN	SAN

NATIONAL & SPECIAL SERVICING LABS INDICATED WITH DASHES (e.g. -WEA-)

^{*}Import Foods: SWID CA & AZ samples collected for micro analysis only go to PRL-NW. No split samples. Samples requiring any chem analysis go to PRL-SW. SWID - TX & NM Column: Samples collected in TX or NM will be analyzed by the Labs listed.

SWID - CA & AZ Column: Samples collected in CA or AZ will be analyzed by the Labs listed.

⁺ Detroit High Throughput Laboratory will serve as a Servicing Laboratory for Salmonella testing for all Districts.

SERVICING LABORATORIES FOR GUIDANCE ONLY - CONTACT THE DIVISION OF FIELD SCIENCE FOR QUESTIONS

MICROBIOLOGISTS

REGIONS >>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	NORT	HEAST				CENTRA		NOLO	GIOI		SOUTI	JEACT				UTHWE		66.2	г	DA OUTIO	
COLLECTING DISTRICT >>>>>>	NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL			CIN	DAL						PACIFIC	
ANIMAL DRUGS & FEED			- DE.		Oliv	DET	INTILA	IAAAD	Eni	AIL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
71 POST APPR MON ANIMAL DRUGS FDS	-															- 1756	TX8NM	CA&AZ			
DRUG PROCESS INSPECTION 71001	NRL	NRL	SRL	DEN	ODI	DEN														Minut	110000000000000000000000000000000000000
FEED CONTAMINANTS D/I 71003E	NRL	NRL		DEN	SRL	DEN	DEN	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN		•	SAN	SAN	SAN
MEDICATED FEEDS 71004	-DEN-	-DEN-	SRL	DEN	SRL	ARL	DEN	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	ARL	SAN	SAN	SAN
TYPE "A" MED ARTICLES 71005	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-			-DEN-	-DEN-	-DEN-
ILL RES IN MEAT/POULTRY 71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN	-DEN-	-DEN-		**	-DEN-	-DEN-	-DEN-
METHOD VALIDATION 71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN- -DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	**	-	-DEN-	-DEN-	-DEN-
AND COMPANY OF THE PARTY OF THE	-DLIV-	-DEI4-	-DEN-	-DEM-	-DEM-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-			-DEN-	-DEN-	-DEN-
MEDICAL DEV & RAD HLTH																					
81 POSTMKT ASSURANCE:DEVICES											-17. 17.55										
PR MDR/DEN F/U-STERILITY 81010	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
82 COMPLIANCE: DEVICES										*****			-1127	-11LA-	-11274-	-TVL/	-AACW-	-WEA-	-WEM-	-AACW-	-VVEA-
MON DEV FOREIGN - STERILE 82008	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WFA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MED DEV MFG STERILITY 82845S	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MED DEV MFG BIOBURDEN 82845S	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MED MFG BIOINDICATOR 82845S	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS - DISINFECT 82845C	WEA	WEA	WEA	WEA	WEA	WEA	WEA	WEA	WEA	WEA	WEA	WEA	WEA	DEN	DEN	DEN	-11274	-112	DEN	DEN	DEN
MFRS - ANTI-SERA 82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS - IN VITRO DIAGNOS 82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
CTR INIT ASSIGN - STERILITY 82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
CTR INIT ASGN - MEDIA TEST 82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
84 SCIENCE: DEVICES												,,_,		.,	****	-112A-	-IILM-	-11 LM-	-IICA-	-TTEM	-VIEA-
METHODS VALIDATION 84Z002	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-

NATIONAL & SPECIAL SERVICING LABS INDICATED WITH DASHES (e.g. -WEA-)

SWID - TX & NM Column: Samples collected in TX or NM will be analyzed by the Labs listed. SWID - CA & AZ Column: Samples collected in CA or AZ will be analyzed by the Labs listed.

FOR GUIDANCE ONLY - CONTACT THE DIVISION OF FIELD SCIENCE FOR QUESTIONS

ENGINEERS/PHYSICISTS

			1000000				11101	TILLE	WILLIA.	LOICE		- 200000 - 50	100 100 100	8 (0.000) 200	VACUUS CONTRACTOR	3 3 300 3		00-00-00000-00			200	20 10 10 1
REGIONS >>>>>>>>>	>>>>	NORTI	HEAST				CENTRA	L				SOUTI	HEAST			sc	UTHWE	ST			PACIFIC	;
COLLECTING DISTRICT>>	>>>>	NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
MEDICAL DEV & RAD H	ILTH																	TX&NM	CA&AZ			
81 POSTMKT ASSURANCE: DE	VICES																					1
PROB REPORT MDR/DN F/U	81010	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
82 COMPLIANCE: DEV				*******																		
MON DEV FOREIGN ORIG	82008	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS	82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
SURGICAL EXAM GLOVES	82Z003	-WEA-	-WEA-		-WEA-																	
CTR INITIATED ASGNMTS	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
84 SCIENCE: DEVICES																						
METHODS VALIDATION	84Z002	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
86 RCHSA AUTHORITY																						
COMP TEST ELECT PROD	86006A-E	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
IMPORTED ELECT PROD	86007	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-

NATIONAL & SPECIAL SERVICING LABS INDICATED WITH DASHES (e.g. -WEA-)

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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION RESOURCE SUMMARY FY 2013

		ОРЕ	RATIONAL F	TES	TOTAL OPERATIONAL
PPS NO.	PROJECT TITLE	DOMESTIC	IMPORT	FOREIGN	FTEs
	TOTAL	841.3	467.6	44.2	1353.1
3	FOODBORNE BIOLOGICAL HAZARDS	606.3	354.5	44.2	
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

PROJECT SUMMARY SHEET

		F1 2013		111			
Food a	GRAM CATEGORY and Cosmetics	2. PPS PROJECT NA Foodborne Biolog	gical Hazards				
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. C	PERATIONAL IMPORT	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL	0002	606.3	354.5	44.2	1005.0	
1	Foodborne Biological Hazards	03F810 *			77.2		
2	Domestic High Risk Inspections	03F810 * 03F811 *	106.0	354.5	-	460.5	03-2-6
3	Domestic Non-High Risk Inspections	03F812 *	242.2 44.0	******		242.2	03-7
4	CFSAN Environmental Sampling Assignments	03F830 *	97.7			44.0	03-8
5	Foreign Foods Inspections	03R233 *	91.1		44.0	97.7	03-9
6	Outbreak and Emergency Response	03R839 *	116.4		44.2	44.2	03-10
0	Outoreak and Emergency Response	03/8639	116.4		0000	116.4	03-11
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						
	appropriate program of assignment 1 AC.				27- 28-9/27		
					7		
							-
		3					
						3144	
	PROJECT MANAGER/TELEPHONE /ajnik 240-402-1616			DRA PLANNEI			
	ajnik 240-402-1010			Stephen Burt 3	su1-/96-4398	BAGE NO.	02.4

FORM FDA 2622 (10/09)

PAGE NO. 03-1

	OR LUCIO CONTRACT TOTAL	-	FY 2013 ORA	WORKPLAN						October 1, 2012
	OGRAM/ASSIGNMENT TITLE					ECT NAME/NUM				
Food	borne Biological Hazards				Foodborne	Biological H	azards - 03			
3. PR0	OGRAM/ASSIGNMENT CODE(S)		4. WORK AL	LOCATION P	LANNED BY			5. OPERATIO	NAL FTE POSIT	TIONS
	See Remarks Section			Х	ORA	X CENTE	R		460.5	[110.6]
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW (Hours)	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	633
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF	(-/(-/-(-/								
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI	1								
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA	1								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
100.00	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS	-								
	SAN JUAN	1								
	REGIONAL LAB	1								
	REGIONAL STAFF DALLAS	1								
sw	DENVER									
377	KANSAS CITY	i								
	SOUTHWEST IMPORT DISTRICT	1								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO	f								
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									

TOTAL HOURS

HOURS PER OPERATION

CONVERSION FACTOR

TOTAL OPERATIONAL FTES

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.

950

950

2850

950

5000

950

5.26

5000

950

10583

11 14

950

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

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

90804

75.67

(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.

3.0

1400

950

1.47

3798

950

4.00

3600

950

3.79

	GRAMASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER							
Foodl	oorne Biological Hazards			Foodborne	Biological Ha	azards - 03			- 1	
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATIO	NAL FTE POSI	TIONS
	See Remarks Section.			Х	ORA	CENTE	- 1	460.5 [13.4]		
	See itemating desirant				1				,	
R	6 DISTRICT/	3 DOMESTIC	3 DOMESTIC	3 DOMESTIC	3 DOMESTIC	3 DOMESTIC	3 DOMESTIC	4 IMPORT	4 IMPORT	4 IMPORT
E G	SPECIALIZED LABORATORY	SAMPLE COLL	SAMPLE	SAMPLE	SAMPLE COLL ASSIGN	SAMPLE COLL ASSIGN	SAMPLE	SAMPLE	SAMPLE COLL	SAMPLE COLL
1	S ISSIVITOR .	JUICE	CHEESE	AGED CHEESE	SPECIES	BOTTLED	LACF/AF	PRODUCE	LACFIAF	CHEESE
0 0		HACCP 03847	03037	ASSIGN 03037	SUB IN FISH 03842	WATER 03803	03803A	ASSIGN 03F100	03003A	03037
	TOTAL FIELD	75	290	204	100	57	210	1500	1400	630
	HEADQUARTERS	(b)(5)&(b)(7)(E)							
	REGIONAL STAFF									
1.00	NEW ENGLAND									
NE	NEW YORK REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA FLORIDA									
J.	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
sw	DENVER DENVER									
3**	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES SAN FRANCISCO									
EO	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION	5.0 375	4.0 1160				6.0 1260			2.0 1260
_	HOURS ERSION FACTOR	950	950				950			950
TOTAL	OPERATIONAL FTES	0.39	1.22				1 33			1.33
7, REN	MARKS									
						- / 2				
FORM	FDA 2621a (10/09)	ORA	WORKP	LANNIN	G SHEET	Γ (Continu	ied)		PAGE NO.	03-3

FY 2013 ORA WORKPLAN

October 1, 2012

Foodborne Biological Hazards Gamma Foodborne Biological Hazards Gamma		DGRAWASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER								
See Remarks Section	rood	nome Biological Hazards				Foodborne E	Biological Haz	cards - 03				
Second Start Second Se	3. PRO	GRAWASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATIONAL FTE POSITIONS			
DISTRICT: SAMPLE		See Remarks Section			X	ORA	CENTER	₹	ADDRESS OF THE PROPERTY.			
R	<u> </u>	ic.	, , , , , , , , , , , , , , , , , , , ,							į		
READOLATERS DIG State DIG	E G O	DISTRICT/ SPECIALIZED	SAMPLE COLL IMPORT FOODS	IMPORT SAMPLE COLL SEAFOOD	FIELD EXAMS	IMPORT FIELD EXAMS	SAMPLES TO BE ANALYZED LACF/AF 03803A	SAMPLES TO BE ANALYZED PRODUCE 03F100	DOMESTIC SAMPLES TO BE ANALYZED CHEESE 03037	SAMPLES TO BE ANALYZED FOOD SAFETY 03803	SAMPLES TO BE ANALYZED SEAFOOD 03842	
HEADQUARTERS DIGS (D) (T) (E)		TOTAL FIELD		6400								
New Page And D					1020	102.00	210	1200	230	633	280	
NEW YORK REGIONAL IAB WAZC REGIONAL STAFF REGIONAL LAB REGIONAL LABORATORY SW PACTE REGIONAL TELE REGIONAL PACTE REGION		REGIONAL STAFF		/)(L)								
BEGIONAL STAFF BALTIMORE CHICAGO CINCINNATI CE DETROIT MINNEAPOUS NEW JERSEY PHLADELPHIA FORENSIC CHEM OTR REGIONAL STAFF ATLANTA FORENSIC CHEM OTR REGIONAL STAFF ATLANTA FORENSIC CHEM OTR REGIONAL STAFF ATLANTA FORENSIC CHEM OTR REGIONAL LAB REGION												
WEAC REGIONAL STAFF BALTIMONE CHICAGO	NE	and the state of t										
REGIONAL STAFF BALTIMORE CHICAGO CINCINANTI CE ETROT IMMEAPOUS INEW JERSEY PHLADELPHIA FORENSIC CHEM CITR REGIONAL STAFE ATLANTA SE FLORIDA NEW OR EANS SAN JUAN REGIONAL LAB REGIONAL STAFF DALLAS SW DEMMER KINSAS CITY SOUTHWEST IMMORT DISTRICT REGIONAL LABORATORY-SW PACIFIC REGI			1									
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(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.).	7. REM	ARKS								is .		
(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.).	(1) - F	field Exams are to include pH and ca	anned seam e	valuation								
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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.).	and a	ssessment of security concerns related	ted to labeling	& source of	country (inc	luding contai	ner integrity,	signs of inter	ntional adult	teration.		
suspicions are raised while conducting routine work requiring follow-up, should the CT Exam be reported under the CT PAC (03R845, 04R845, etc.).	etc.);	traditional safety concerns. These a	ctivities are to	be reporte	d as a sing	le Import Fie	ld Exam unde	er this Comp	liance Progr	ram and		
(03R845, 04R845, etc.).	PAC.	Only one exam should be reported p	per line entry.	Only in the	event of a	Pre-Determi	ned "for caus	e" CT Exam	, or in the e	vent CT		
	suspic	cions are raised while conducting rou	ıtine work req	uiring follow	v-up, should	d the CT Exa	m be reporte	d under the (CT PAC			
NOTE: Laboratory allocations were planned by DFS.	(03R8	45, 04R845, etc.).										
TOTE. Laboratory anocations were planned by DFS.	NOTE	. Laboratory allocations were plane	ed by DES									
	NOIE	Laboratory anocations were plann	ed by DFS.									

FY 2013 ORA WORKPLAN

October 1, 2012

FY	2013	ORA	WORL	KPI	AN
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Charles and the	GRAMASSIGNMENT TITLE oorne Biological Hazards		112013 010	A WORKILAN	2. PPS PROJECT Foodborne B					Sciouci 1, 2012
3. PRO	GRAMASSIGNMENT CODE(S) See Remarks Section		4. WC	ORK ALLOCATIO	ON PLANNED BY		ITER	5. OPERATION	NAL FTE POSI 160.5 [77.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC EMERGING ISSUES ANALYST MICRO (Hours) (1)	7 DOMESTIC SAMPLES TO BE ANALYZED SPECIES SUB IN FISH ASSIGN MICRO 03842	7 DOMESTIC SAMPLES TO BE ANALYZED AGED CHEESE ASSIGN MICRO 03037	7 DOMESTIC SAMPLES TO BE ANALYZED BOTTLED WATER ASSIGN MICRO (03803)	7 DOMESTIC SAMPLES TO BE ANALYZED JUICE HACCP 03847 MICRO	8 IMPORT SAMPLES TO BE ANALYZED SEAFOOD CHEM 03844	8 IMPORT SAMPLES TO BE ANALYZED SEAFOOD MICRO 03844	8 IMPORT SAMPLES TO BE ANALYZED LACF/AF 03003A MICRO	8 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)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK REGIONAL LAB	-								
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
1	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	-								
PA	LOS ANGELES SAN FRANCISCO									
FA	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION		14.0							
	HOURS	21535								
	ERSION FACTOR OPERATIONAL FTEs	1180 18.25		1180 3.11						
_	IARKS	10.20	1.10	0.77	0.10	0.10	77.00			
(1) - I that o	E: Laboratory allocations were planned Emerging issues is a new category of ratio not qualify as an emergency or outby imperative reason. These resources ocated through assignments unless of	resources pla reak, but are can be used	considered of for laborator	of importance	e due to poter	ntial impact of	or other	ents		

			FY 2013 U	KA WOKKPLAN					Oc	ctober 1, 2012
1, PRC	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NU	IMBER			
Food?	borne Biological Hazards				Foodborne	Biological I	Hazards - ()3		
2 000	OCRALMACIONHENT CODE(C)									
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. V	VORK ALLOCATE				5. OPERATION		
	See Remarks Section			X	ORA	CE	NTER	4	60.5 [114.	1]
_	16.	8	8	T 9	9	9	9	9	9	9
R E G O N	DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLES TO BE ANALYZED IMPORT FOODS 03819 MICRO	IMPORT SAMPLES TO BE ANALYZED PRODUCE 03F098 MICRO	LEVEL II AUDITORS	APPLIED TECH CENTER MICRO 03R816 (Hours)	METHODS VAL/DEV MICRO 03R816 (Hours)	PRIOR NOTICE REVIEW (Hours)	OP CODE 92 PRIVATE LAB REVIEW IMPORT (Hours) (3)	BETTER PROCESSING SCHOOL TRAINING (Hours) (4)	CONTRACT MANAGE- MENT (Hours) 03R843 (5)
	TOTAL FIELD	7500	150	0 1600		3615	32400			
-	HEADQUARTERS	(b)(5)&(b)		1000	4,20	30131	32400	4720	760	1140
	REGIONAL STAFF									
ı	NEW ENGLAND	_								
NE	NEW YORK	-								
	REGIONAL LAB	-								
	WEAC	_								
	REGIONAL STAFF									
ı	BALTIMORE									
l	CHICAGO									
	CINCINNATI									
CE	DETROIT	-								
"-	MINNEAPOLIS									
ı	NEW JERSEY									
ı	PHILADELPHIA									
	FORENSIC CHEM. CTR	-								
	REGIONAL STAFF									
ı	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	S PER OPERATION	7.1	13.	0					100	I
TOTAL	HOURS	53250	1950	0 1600	4720	3615	32400	4720	760	1140
CONVE	ERSION FACTOR	1180	118	950	1180	1205	1200	1180		
COLLE	RSION FACTOR	45.13	110	930	1100	1200	1200	1100	950	95

- (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 Divison 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.

03-6

			FY 2013 ORA	WURKPLAN					Oc	tober 1, 20
1. PRO	GRAM/ASSIGNMENT TITLE	***************************************			2. PPS PROJE	CT NAME/NUM	BER			
	stic High Risk Inspections				Foodborne	Biological Ha	zards - 03			
Donne	and High Klak mapeedone					oronogreum ma				
	· · · · · · · · · · · · · · · · · · ·									
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATION	DNAL FTE PO	SITIONS
	See Remarks Section			×	ORA	CENTER	1		242.2	
							Secretary Advanced			
R	6. DISTRICT/	FDA	1 FDA	NON-FSMA INTERSTATE	NON-F5MA EGG	NON- FSMA MISCELLANEOUS	FSMA INFANT	1 PROJECTED	1 REINSPEC-	
E	SPECIALIZED	FSMA	NON-FSMA	TRAVEL	FARM	PRODUCE	FORMULA	FDA	TIONS	
G	LABORATORY	HIGH	HIGH RISK	WATERING PT	INSPECTIONS GUIDANCE	INSPECTIONS GUIDANCE	MEDICAL FOODS FIRMS	FOLLOW-UP OAI	OF FY 2011 FSMA	
0		RISK INSPECTIONS	ONLY	GUIDANCE	ONLY	ONLY	GUIDANCE	INSPEC-	FIRMS	
N		(1) (3)	(2)	ONLY (2)	(2)	(2)	ONLY (3)	TIONS (4)	(5)	
	TOTAL FIELD	3469	1100	500	300	300	37	228	1776	
	HEADQUARTERS	(b)(5)&(b)	(7)(E)					A BANCOLLUS AND		
	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									
100000	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
CIM	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									
HOUR	S PER OPERATION	35.0	35.0					35.0	35.0	
	HOURS	121415	38500					7980	62160	
-	ERSION FACTOR	950	950					950	950	
	OPERATIONAL FTEs	127.81	40.53					8.40	65.43	
_	MARKS									

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.

FORM FDA 2621a (10/09) ORA WORKPLANNING SHEET (Continued)

-			FY 2013 C	RA WORKPLAN		TA 14		October 1,	2012
1. PR	OGRAM/ASSIGNMENT TITLE				2. PPS PRO	DJECT NAME/NUMBER			
Dom	estic Non-High Risk Inspections				Foodborn	ne Biological Hazards	- 03		
1						8			
\vdash									
3. PR	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION PL	ANNED BY		5. OPERATIO	DNAL FTE POSITION	S
1	See Remarks Section			X	ORA	CENTER		44.0	
R	6. DISTRICT/	1 1	1 PROJECTED	ITP					
E	SPECIALIZED	FDA	FDA	NON-AIRLINE			1 1		
G	LABORATORY	NON-HIGH	FOLLOW-UP	WATERING			1 1		
0		RISK FSMA INSPECTIONS	OAI INSPECTIONS	POINT			1 1		
N		(1)	(2)	GUIDANCE ONLY					
1	TOTAL FIELD	1576	79	200					
THE REAL PROPERTY.	HEADQUARTERS	(b)(5)&(b)	(7)(E)	The second secon	-				-
	REGIONAL STAFF	(= /(= /= (=							
	NEW ENGLAND								-
NE	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
1	CHICAGO								000
1	CINCINNATI								
CE	DETROIT								
	MINNEAPOLIS				0.00				
1	NEW JERSEY								
1	PHILADELPHIA								1200
	FORENSIC CHEM. CTR								
	REGIONAL STAFF	-				3000			
0.000	ATLANTA	4							
SE	FLORIDA	-							
	NEW ORLEANS	4							
	SAN JUAN	-							
<u> </u>	REGIONAL LAB	-							
	REGIONAL STAFF	4							
CIA	DALLAS	-					\rightarrow		
SW	DENVER	4							-
l	KANSAS CITY SOUTHWEST IMPORT DISTRICT	-							
	REGIONAL LAB	1							
l	REGIONAL STAFF								-
	LOS ANGELES	1							
PA	SAN FRANCISCO	1					_		
1,05,50	SEATTLE	1							
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW	1							
HOUR	S PER OPERATION	25.0	30.0						
	HOURS	39400	2370						
	ERSION FACTOR	950	950	Action of the Party of the Part					
	OPERATIONAL FTEs	41.47	2.49						
7. REN	MARKS								
NOT	E: PAC 03F812 is for planning purpo	ses only.	Accomplishe	ed work must h	oe reporte	d against the appropr	riate program o	r	
assig	nment PAC. Please see page I-III (after the Ce	enter Resou	rce Summary	Sheet) for	a listing of compliant	ce programs	•	
and o	corresponding reporting PACS.					a noung or compliant	oo programo		
	g g								
(b)(5))&(b)(7)(E)								
NOTE	: Hours per operation modules are	for guidan	ce only. Re	port actual tim	ne spent o	n operations			
	. Treate per operation modules are	o ioi gaiaan	00 0/my. 110	port doldar illi	io openi o	п орстанопо.			
									0
		00	A MODIC	DI ANNUNI	CHEE	T (Continued)			-
F 1 12 RA	FDA 2621a (10/09)	UNK	- UVI IKK		- >	LUCATIBILACI		PAGE NO D3-	

FY 2013 ORA WORKPLAN

1. PROGRAM/ASSIGNMENT TITLE				2. PPS PROJECT NAME/NUMBER						
CESA	CFSAN Environmental Sampling Assignments				Foodborne	ards - 03				
		10029			D: 410.50 D:					
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK		PLANNED BY			5. OPERATION		HONS
	See Remarks Section			X	ORA	X CENTER			97.7	
		I Factorian and the	Environmental	E-desamental	Environmental	Factors	C Fredrice and all	Environmental		
R	6. DISTRICT/	Environmental SAMPLE	SAMPLE	Environmental SAMPLE	SAMPLE	Environmental SAMPLE	Environmental SAMPLE	DOMESTIC	- 1	
E G	SPECIALIZED LABORATORY	CSO HOURS EGG RULE	CSO HOURS INFANT	CSO HOURS SOFT	CSO HOURS RTE COLD CUT	CSO HOURS DRIED (MILK/SOY)	CSO HOURS MILK POWDER	LAB ANALYST	- 1	
1	LABORATORY	INSPECTIONS	AND DRY	CHEESE	SANDWICH	PROTEIN FOR	FACILITY FOR	(Hours)	1	
0			CEREALS			SALMONELLA	CRONOBACTER	MICRO	- 1	
N		(1)	(2)	(3)	(4)	(5)	(6)			
	TOTAL FIELD	30000	15000	6600	11500	8000	7000	18314		
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB	1								
	WEAC	ļ								
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	ł							-	
	CINCINNATI									
CE	DETROIT	1							-	
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
_	FORENSIC CHEM, CTR									
	REGIONAL STAFF	-								1000
	ATLANTA									
SE	FLORIDA	1								
	NEW ORLEANS	1								
	SAN JUAN	-								
\vdash	REGIONAL LAB	1								
	REGIONAL STAFF	1								
sw	DALLAS DENVER	1								
SW	KANSAS CITY	1								
	SOUTHWEST IMPORT DISTRICT									- 1 - 0
	REGIONAL LAB	1								
\vdash	REGIONAL STAFF	1								
	LOS ANGELES									
PA	SAN FRANCISCO									
EA	SEATTLE	1								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW	1								
HOUR	S PER OPERATION	1		1	1	I	I			
	L HOURS	30000	15000	6600	11500	8000	7000	18314		ALLON STREET
	ERSION FACTOR	950	950					1180		
	OPERATIONAL FTES	31.58	15.79						- w c - 1	
	AARKS									

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
- firms (2) - Estimated
- (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.

		F	Y 2013 ORA V	VORKPLAN				0	ctober 1, 2012	
1. PRO	OGRAM/ASSIGNMENT TITLE				2. PPS PRC	JECT NAME/NUM	BER			
Forei	gn Foods Inspections				Foodborn	e Biological Ha	zards - 03			
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK A	LLOCATION	PLANNED E	BY	5.0	PERATIONAL FTE P	OSITIONS	
	See Remarks Section			Х		CENTER		44.2		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS INCLUDES CADRE								
	TOTAL FIELD	1200				1			-	
-	HEADQUARTERS	(b)(5)&(b)				+				
	REGIONAL STAFF	(7)(E)			-	1			-	
	NEW ENGLAND	(/)(L)				1 1				
NE	NEW YORK			- DE OMESSA						
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF	-								
1	BALTIMORE	-								
	CHICAGO	-				+				
CE	DETROIT DETROIT	-								
L CE	MINNEAPOLIS	1				+			-	
	NEW JERSEY	1				+				
	PHILADELPHIA	1		10.0		1				
	FORENSIC CHEM. CTR]								
	REGIONAL STAFF									
	ATLANTA								-	
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB	-								
	REGIONAL STAFF DALLAS	-				-				
sw	DENVER	-				+				
""	KANSAS CITY	-	-			 			-	
	SOUTHWEST IMPORT DISTRICT	1				1			-	
	REGIONAL LAB					1				
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW	-								
HOUR	PACIFIC REGIONAL LABORATORY-NW	25.01				+				
	S PER OPERATION HOURS	35.0 42000				1				
	ERSION FACTOR	950				 		_	-	
	OPERATIONAL FTEs	44.21				1		-		
7. REM		-								
assign and c	E: PAC 03R233 is for planning purponment PAC. Please see page I-III (a corresponding reporting PACS. Foreign Inspections planned in HQ and the second in th	after the Cent	er Resource	e Summan	y Sheet) fo	or a listing of co	e appropriate pompliance pro	program or grams		
FORM	FDA 2621a (10/09)	ORA	MUBKBI	ANNIN	C SUEE	T (Continu	ad)	PAGE NO	03-10	

-			F1 2013 OKA						00	1, 2012
1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJ	JECT NAME/NUM	MBER			
Outbr	eak and Emergency Response				Foodborne	Biological Ha	azards - 03			
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED B	Y		5. OPERAT	IONAL FTE PO	SITIONS
	See Remarks Section			X	ORA	X CENTE	D		116.4	
	See Remarks Section			^_	OIG	LA CERTE	IN.		110.4	
_	6.	3 CONSUMER	7 DOMESTIC	7 DOMESTIC						
R	DISTRICT/ SPECIALIZED	SAFETY	LAB	LAB		1 1		1 1		
G	LABORATORY	OFFICER	ANALYST	ANALYST		1 1		1 1		
0		(Hours)	(Hours)	(Hours)		1 1				
N		(1)	MICRO	CHEM						
	TOTAL FIELD	63469	45548	12980						
	HEADQUARTERS	(b)(5)&(b)(7)	')(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK						-			
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									and the second
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
1	ATLANTA					1		1		
SE	FLORIDA									
ı	NEW ORLEANS									
ı	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
l	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT							-		
	REGIONAL LAB							-		
	REGIONAL STAFF							-		
	LOS ANGELES							1		
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW			,						
	S PER OPERATION									
TOTAL	HOURS	63469	45548	12980						
	ERSION FACTOR	950	1180	1180				1		
TOTAL	OPERATIONAL FTEs	66.81	38.60	11.00						
	AARKS	VII.)					2 (35)			

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.

PROJECT SUMMARY SHEET

PROGRAM CATEGORY 2. PRS PROJECT NAMENUMBER Posticides and Chemical Contaminants - 04			FY 2013						
3. NO 4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS C. OPERATIONAL, FTE OPERATIONAL T. TOTAL COUNTY						R-6000			
ASSIGNMENT CODE TOTAL	Food a	and Cosmetics	Pesticides and	Chemical Co	nical Contaminants - 04				
ASSIGNMENT CODE C	3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM	6. O	PERATIONAL	FTE	7. TOTAL	8. PAGE	
Pesticides and Chemical Contaminants				DOMESTIC	IMPORT	EODEICN			
Pesticides and Chemical Contaminants 04F810 * 97.3 75.3 172.6 04-13-18 2 Total Diet Study 04839 28.6 28.6 04-17 * These PACS are for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.		TOTAL	0002						
2 Total Diet Study 04839 28.6 28.6 04-17 * These PACS are for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.	1	Pesticides and Chemical Contaminants	04F810 *	97.3				04-13-16	
* These PACS are for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.					, , , ,				
Accomplished work must be reported against the appropriate program or assignment PAC.		,	0.1037	20.0			28.0		
Accomplished work must be reported against the appropriate program or assignment PAC.									
Accomplished work must be reported against the appropriate program or assignment PAC.		* Those PACS are for planning numerous only							
appropriate program or assignment PAC.				1					
EMTER PROJECT MANAGER/TELEPHONE ORA PLANNER/TELEPHONE								_	
		appropriate program or assignment PAC.							
		1 - 72 - 40 m Early & A.							
	-1								
	-		-						
			_						
								22.00	
						0.0			
								51.	
	_								
	_		 						
	ENTER	PROJECT MANAGER/TELEPHONE		<u></u>	DRA PI ANNE	R/TEI EDUON	IF.		
	Monali `	/ajnik 240-402-1616		, i	Kristen Kama	s 301-796-43	91		

DBC	OGRAM/ASSIGNMENT TITLE		FY 2013 ORA	-	-	EOT MANEAU	Mara		Oc	ctober 1, 2012
				ł		ECT NAME/NUI				
Pestic	cides and Chemical Contaminants				Pesticides a	and Chemical	l Contamina	ints - 04		
B. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	OSITIONS
	See Remarks Section			X	ORA	X CENTE	∃R		172.6	[32.2]
REG-OX	6. DISTRICT/ SPECIALIZED LABORATORY	2 DOMESTIC INVESTI- GATIONS (Hours)	2 IMPORT INVESTI- GATIONS (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	360
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF		(-/(-/							
	NEW ENGLAND	7								
NE	NEW YORK	1								
	REGIONAL LAB									
	WEAC	1								
	REGIONAL STAFF	1								
	BALTIMORE	1								
	CHICAGO	1								
	CINCINNATI	1								
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	1								
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW	1								
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION	\vdash			3.0		5.0	4.0	3.0	4.0
OTAL	HOURS	5000	5000	10355	6750		500	1340	150	1440

 CONVERSION FACTOR
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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.

950

es and Chemical Contaminants RAM/ASSIGNMENT CODE(S) See Remarks Section DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD EADQUARTERS EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB //EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT INNEAPOLIS EW JERSEY	4 IMPORT SAMPLE COLL PESTICIDE 04004A 3300 (b)(5)&(b)	4 IMPORT SAMPLE COLL CHEMO 04018		PESTICITION A PLANNED BY ORA 4 IMPORT SAMPLE COLL RADIO- NUCLIDES 04019C 250	X CENTER 4 IMPORT SAMPLE COLL FLD ASSIGN 04F800			ONAL FTE PO 172.6 7 DOMESTIC SAMPLES TO BE ANALYZED PESTICIDE 04004A 2250	OSITIONS [39,8] 7 DOMESTIC SAMPLES TO BE ANALYZED DIOXIN 04004D
See Remarks Section DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD EADQUARTERS EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB //EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT IINNEAPOLIS	IMPORT SAMPLE COLL PESTICIDE 04004A	4 IMPORT SAMPLE COLL CHEMO 04018	4 IMPORT SAMPLE COLL TOXIC ELE 04019A	4 IMPORT SAMPLE COLL RADIO- NUCLIDES 04019C	4 IMPORT SAMPLE COLL FLD ASSIGN 04F800	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAM (2)	7 DOMESTIC SAMPLES TO BE ANALYZED PESTICIDE 04004A	7 DOMESTIC SAMPLES TO BE ANALYZED DIOXIN 04004D
See Remarks Section DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD EADQUARTERS EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB //EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT IINNEAPOLIS	IMPORT SAMPLE COLL PESTICIDE 04004A	4 IMPORT SAMPLE COLL CHEMO 04018	4 IMPORT SAMPLE COLL TOXIC ELE 04019A	4 IMPORT SAMPLE COLL RADIO- NUCLIDES 04019C	4 IMPORT SAMPLE COLL FLD ASSIGN 04F800	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAM (2)	7 DOMESTIC SAMPLES TO BE ANALYZED PESTICIDE 04004A	7 DOMESTIC SAMPLES TO BE ANALYZED DIOXIN 04004D
DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD EADQUARTERS EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB //EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT IINNEAPOLIS	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)	SAMPLES TO BE ANALYZED PESTICIDE 04004A	SAMPLES TO BE ANALYZED DIOXIN 04004D
EADQUARTERS EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB /EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT			625	250	400	25	6406	2250	536
EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB //EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT	(b)(5)&(b)	(7)(E)							
EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB //EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT									
EW YORK EGIONAL LAB /EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT									
EGIONAL LAB /EAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT									
JEAC EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT									
EGIONAL STAFF ALTIMORE HICAGO INCINNATI ETROIT IINNEAPOLIS									
ALTIMORE HICAGO INCINNATI ETROIT IINNEAPOLIS									
HICAGO INCINNATI ETROIT IINNEAPOLIS									
INCINNATI ETROIT IINNEAPOLIS									
ETROIT IINNEAPOLIS									
IINNEAPOLIS									
THE RESERVE OF THE PROPERTY OF									
TLANTA									
LORIDA									
EW ORLEANS									
AN JUAN									
EGIONAL LAB									
EGIONAL STAFF									
ALLAS									
ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW									
PER OPERATION	1.6				3.0				
OURS	5280	2500			1200				1500
SION FACTOR									
	5.56	2.63	1.18	0.66	1.26	0.02	3.37	12.39	12,7
port Field Exams are for Toxic Ele		Foodware (I	PAC 04019	В)					
THE PARTY OF THE P	LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL STAFF OS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW DER OPERATION OURS SION FACTOR PERATIONAL FTES ENCOT FIEID Exams are for Toxic Electronic Control of the	DRENSIC CHEM. CTR EGIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL LAB EGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL STAFF DS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW PER OPERATION 1.6 DURS 5280 SION FACTOR 950 PERATIONAL FTES 5.56	DRENSIC CHEM. CTR EGIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL LAB EGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL STAFF DS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW PER OPERATION DURS 5280 2500 PERATIONAL FTES 5.56 2.63 RKS DOOT FIELD EXAMS ARE FOR TOXIC ELEMENTS IN FOODWATE (I	DRENSIC CHEM. CTR EGIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL LAB EGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL STAFF DS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW PER OPERATION DURS 5280 5500 1125 SION FACTOR 950 950 950 PERATIONAL FTES 5.56 2.63 1.18 EKS DORT FIEID EXAMS ARE FOR TOXIC Elements in Foodware (PAC 04019)	DRENSIC CHEM. CTR EGIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL LAB EGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL CAB EGIONAL LAB EGIONAL LAB EGIONAL CAB EGIONAL LAB EGIONAL CAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL TIMPORT DISTRICT EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW EFR OPERATION EFR OPERATION EFR OPERATION EFR OPERATION EFR OPERATIONAL FIES ESON FACTOR EFRATIONAL FIES ESON FACTOR EFRATIONAL FIES ESON FIEID EXAMS ARE FOR TOXIC Elements in Foodware (PAC 04019B)	ORENSIC CHEM, CTR ### CIGIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB ### CIGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT ### CIGIONAL LAB ### CIGIONAL LAB ### CIGIONAL LAB ### CIGIONAL STAFF DOS ANGELES AN FRANCISCO ### EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW ### CIFIC REGIONAL LABORATORY-NW ### OPERATION 1.6 2.5 1.8 2.5 3.0 DURS 5280 2500 1125 625 1200 ### Signo Factor ### Sign	DRENSIC CHEM. CTR GIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL STAFF DS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW PER OPERATION 1.6 2.5 1.8 2.5 3.0 0.7 OURS 5280 2500 1125 625 1200 18 SION FACTOR 950 950 950 950 950 950 PERATIONAL FTES 5.56 2.63 1.18 0.66 1.26 0.02 RKS OURT Field Exams are for Toxic Elements in Foodware (PAC 04019B)	DRENSIC CHEM. CTR GIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB GIONAL STAFF ALLAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL STAFF DS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW PER OPERATION 1.6 2.5 1.8 2.5 3.0 0.7 0.5 DURS 5280 2500 1125 625 1200 18 3203 SION FACTOR 950 950 950 950 950 950 PERATIONAL FTES 5.56 2.63 1.18 0.66 1.26 0.02 3.37 RKS DOOR Field Exams are for Toxic Elements in Foodware (PAC 04019B)	DRENSIC CHEM. CTR GIONAL STAFF TLANTA LORIDA EW ORLEANS AN JUAN EGIONAL LAB EGIONAL STAFF ALIAS ENVER ANSAS CITY OUTHWEST IMPORT DISTRICT EGIONAL LAB EGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW FER OPERATION 1.6 2.5 1.8 2.5 3.0 0.7 0.5 6.5 OURS 5280 2500 1125 625 1200 18 3203 14625 SION FACTOR 960 950 950 950 950 950 950 950 950 1180 PERATIONAL FITES 5.56 2.63 1.18 0.66 1.26 0.02 3.37 12.39 RISS BOORT Field Exams are for Toxic Elements in Foodware (PAC 04019B)

		I	FY 2013 ORA	WORKPLAN					Oc	tober 1, 2012
1. PRO	OGRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUI	MBER			
Pestio	eides and Chemical Contaminants				Pesticides a	nd Chemical	Contamina	ants - 04		
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATI	ONAL FTE PO	SITIONS
	See Remarks Section			Х	ORA	X CENTE	:R		172.6	[77.9]
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED CHEMO 04018	7 DOMESTIC SAMPLES TO BE ANALYZED TOX ELEM 04019A	7 DOMESTIC SAMPLES TO BE ANALYZED FLD ASSIGN 04F800	7 DOMESTIC SAMPLES TO BE ANALYZED EU AUDIT 04004	7 DOMESTIC EMERGING ISSUES ANALYST CHEM (Hours) (3)	8 IMPORT SAMPLES TO BE ANALYZED PESTICIDE 04004A	8 IMPORT SAMPLES TO BE ANALYZED CHEMO 04018	8 IMPORT SAMPLES TO BE ANALYZED TOX ELEM 04019A	8 IMPORT SAMPLES TO BE ANALYZED RADIONUC 04019C
	TOTAL FIELD	100	335	50	360	7195	3300	1000	625	250
	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	S 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
	RSION 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. REM								10.00		
	atory allocations were planned by i		- ulassad (s.	DDC 02 DI	20.041	DD0 84 /-				
(0) - E	merging issues is a new category	or resources	o biaced iu	rro 03, Pl	3 04, and i	- r 3 2 1 10 C	over any is	sues or ev	ents that	
do no	t qualify as an emergency or outbre	eak, but are	considered	or importa	nce due to	potential imp	pact or other	er policy in	nperative	
reaso	n. These resources can be used fo	r lab operat	ions and wi	II be alloca	led through	assignment	s unless of	herwise in	structed.	
										l
										- 1
										1

					DI (1111ED D)(5. OPERATIONAL FTE POSITIONS			
16	GRAM/ASSIGNMENT CODE(S)		4. WORK		PLANNED BY			5. OPERAT			
16	See Remarks Section			Х	ORA	X CENTE	R		172.6	[22.7]	
REG-ON	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						
H	HEADQUARTERS	(b)(5)&(b)	(7)(E)								
F	REGIONAL STAFF										
	NEW ENGLAND										
NE I	NEW YORK										
	REGIONAL LAB										
	WEAC										
F	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO							-	-	-	
	CINCINNATI							-		-	
	DETROIT							-			
_	MINNEAPOLIS							-			
-	NEW JERSEY									 	
-	PHILADELPHIA									-	
	FORENSIC CHEM. CTR REGIONAL STAFF								 	 	
_	ATLANTA										
	FLORIDA										
_	NEW ORLEANS									1	
	SAN JUAN									_	
_	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
-	DENVER										
_	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
F	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW									├	
	PACIFIC REGIONAL LABORATORY-NW		r							-	
	PER OPERATION	11.0									
DTAL	HOURS	4400	14460					ļ		1-	
ONVE	RSION FACTOR	1180	1205 12.00	1180				 	+	-	
OTAL	OPERATIONAL FTEs	3.73	12.00	5.00	2.001						

			FY 2013 ORA	WORKPLAN					0	ctober 1, 2012
1. PR	OGRAM/ASSIGNMENT TITLE				2. PPS PROJ	ECT NAME/NU	MBER			
Total	Diet Study				Pesticides a	and Chemica	Contamir	ants - 04		
	•					and chemica	· comuni	idina O1		
-					L					
3. PR	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	(5. OPERAT	IONAL FTE P	OSITIONS
1	04839			100	ORA	X CENT	ER	1	28.6	
R	6. DISTRICT/	3 DOMESTIC	7 DOMESTIC	7	7			T		
E	SPECIALIZED	SAMPLE	SAMPLES	DOMESTIC SAMPLES	DOMESTIC SAMPLES	1		1	I	
G	LABORATORY	COLL	TO BE	TO BE	TO BE	1		1	1	1
ı		(TOTAL) (DIET)	ANALYZED CHEM	ANALYZED RADIO-	PERCHLOR-			1	Į.	1
Ň		(1)	(2)	NUCLIDE (3)	ATES (4)				1	1
1	TOTAL FIELD	60	1136	2						
\vdash	HEADQUARTERS	(b)(5)&(b)			1100	-		_	\vdash	
	REGIONAL STAFF	(2)(2)2(2)						 		
1	NEW ENGLAND	-								
NE	NEW YORK	-								
	REGIONAL LAB							 		
	WEAC								 	-
	REGIONAL STAFF									
1	BALTIMORE							1.000		
	CHICAGO									
1	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS							1		l
1	NEW JERSEY									1
	PHILADELPHIA									
	FORENSIC CHEM, CTR									
	REGIONAL STAFF									
1	ATLANTA									
SE	FLORIDA									
l	NEW ORLEANS									
ı	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
1	DALLAS									
sw	DENVER									
1	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
<u> </u>	REGIONAL LAB									
1	REGIONAL STAFF									
DA.	LOS ANGELES							-		
PA	SAN FRANCISCO									
	SEATTLE PACIFIC REGIONAL LABORATORY-SW							-		
	PACIFIC REGIONAL LABORATORY-NW						- b_			
HOUR	S PER OPERATION	26.0	20.4	2800.0	2.0					
	HOURS	1560	20.1 22834	5600	3.0			-		
	ERSION FACTOR	950	1180	1180	3408 1180			-	 	
	OPERATIONAL FTES	1.64	19.35	4.75	2.89		200 200			
7. REM		1.54	10.00	7.75	2.03					
	Each DSC represents a District's w	eekly collec	tion of spec	sified food i	tome Each	market back	est collecti	on lo on	6.	
Wook	period and involves 3 separate dis	tricts Four	market has	kote oro pl	enis. Laci	ollu	ver collecti	on is sprea	ad over a in	ve
	Represents the total number of food						22 12 22			
foods		i items anai	iyzed idi va	nous aund	utes. VOC a	ınaiyses wiii	no longer	be conduc	cted on IDS	5
100000000000000000000000000000000000000		haalista aa	and the state of	A/E A O 5						
(3) - 1	All TDS food items from two market All TDS foods from each market bas	baskets an	alyzed by v	VEAC for s	elected radi	ionuclides.				
(4) - /	MIT IDS 1000S Ifom each market bas	sket are and	alyzed for p	erchiorates	i.					
l observe		DE0								
Labor	atory allocations were planned by I	DFS.								

FY 2013 ORA WORKPLAN

PROJECT SUMMARY SHEET FY 2013 1. PROGRAM CATEGORY 2. PPS PROJECT NAME/NUMBER Food and Cosmetics Molecular Biology & Natural Toxins - 07 7. TOTAL OPERATIONAL 4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS 5. PROGRAM 6. OPERATIONAL FTE 8. PAGE **ASSIGNMENT** CODE DOMESTIC IMPORT FOREIGN FTEs TOTAL 12.2 6.7 Mycotoxins in Domestic and Import Foods 07001,07R816 12.2 6.7 18.9 07-19

Monali Yajnik 240-402-1616 Lorraine B. Boykin 301-796-4393

FORM FDA 2622 (10/09) PAGE NO.

ORA PLANNER/TELEPHONE

07-18

CENTER PROJECT MANAGER/TELEPHONE

			FY 2013 ORA	WORKPLAN					0	ctober 1, 2012
	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NU	MBER			
Mycc	otoxins in Domestic and Import Food	ds			Molecular I	Biology & Na	atural Toxii	ns - 07		
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5 OPERAT	IONAL FTE P	OPITIONS
	07001, 07R816			X	ORA		-6	J. OFERAI		DSITIONS
	0,001,0,1010				UKA	CENTE	=K		18.9	
	6.	3	4	7	8	9	9	9		
R E	DISTRICT/ SPECIALIZED	DOMESTIC SAMPLE	IMPORT SAMPLE	DOMESTIC SAMPLES	IMPORT SAMPLES	METHOD VAL/DEV	APPLIED TECHN-	APPLIED TECHN-		
G	LABORATORY	COLL	COLL	TO BE	TO BE	CHEM	OLOGY	OLOGY		
0		1 1		ANALYZED CHEM	ANALYZED CHEM	(Hours)	CTR. MICRO (Hours)	CTR. CHEM (Hours)		
N						07R816	07R816	07R816		
	TOTAL FIELD	832	832	832	832	603	600	4130		
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND	1								
NE	NEW YORK REGIONAL LAB	1								
	WEAC	1								
	REGIONAL STAFF	1								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT	1								
	MINNEAPOLIS	1								
	NEW JERSEY	ł								
	PHILADELPHIA FORENSIC CHEM. CTR	1								
	REGIONAL STAFF									
	ATLANTA	İ								
SE	FLORIDA	I								
	NEW ORLEANS									
	SAN JUAN	Į.								
ļ	REGIONAL LAB									
	REGIONAL STAFF DALLAS	-								
sw	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT	Ì								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO SEATTLE	-								
	PACIFIC REGIONAL LABORATORY-SW	-								
	PACIFIC REGIONAL LABORATORY-NW	t								
HOURS	S PER OPERATION	4.0	2.0	6.0	7.0	1				
	HOURS	3328	1664	4992	5824	603	600	4130		
	ERSION FACTOR	950	950	1180	1180	1205	1180	1180		
	OPERATIONAL FTEs	3.50	1.75	4.23	4.94	0.50	0.51	3.50		
7. REM	ARKS									
NOTE	: Laboratory allocations were plan									
NOTE	Laboratory anocations were plan	ned by DFS								
EODII	FDA 2621a (10/09)	ODA	WORKE	I ANIMIA	COULE	T (Contin				
ORM	LPB 404 IN L10/091	URA	OUL JICK P	- ASIMININ	A SOFE	· · · · Ontin			PAGE NO	07-10

PROJECT SUMMARY SHEET

		FY 2013					
	GRAM CATEGORY and Cosmetics	2. PPS PROJECT Food & Color	NAME/NUMBE Additive Pet	ER tition Review	v & Policy	Development -	09
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. C	DPERATIONAL IMPORT	FTE	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL		DOMESTIC	15.0		15.0	
1	Food and Color Additive Petition Review & Policy	09F810*		15.0		15.0	09-21
	Development						
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the						No Victorial Control
	appropriate program or assignment PAC.						
			 				
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	50000		-				
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			-				

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	R PROJECT MANAGER/TELEPHONE			ORA PLANNE	R/TELEPHON	NE NE	
TANK KOMINSON	Yajnik 240-402-1616			Lorraine B. B	oykin 301-7	96-4393	00.00

1 PR	OGRAM/ASSIGNMENT TITLE		I I ZUIJ OKA	WORKS DAIN	2 PDS DDO II	ECT NAME/NUI	ADED		0	clober 1, 2012
Food	& Color Additive Petition Review &	& Developm	ent		Food & Col	or Additive	Petition Re	eview & Po	olicy	
					Developme	nt - 09				
3 PRO	OGRAM/ASSIGNMENT CODE(S)		4 WORK	ALLOCATION	PLANNED BY			6 OBERAT	TONAL ETE D	201710110
			4. WORK					S. OPERA	TIONAL FTE PO	DSITIONS
	See Remarks Section			X	ORA	CENTE	R	1	15.0	
<u> </u>	[6.	4 1		6						
R	DISTRICT/	IMPORT	4 IMPORT	6	8 IMPORT	8 IMPORT				
E G	SPECIALIZED LABORATORY	SAMPLE FOOD	SAMPLE	IMPORT	SAMPLES	SAMPLES		1		1
ĭ	LABORATORT	ADDITIVES	COLOR ADDITIVES	FIELD	TO BE ANALYZED	TO BE ANALYZED				l
0		COLL	COLL		FOOD ADD.	COLOR ADD.				
N	The second secon			(1)	CHEM	CHEM		-		
<u> </u>	TOTAL FIELD	310	865	4804	310	865				
<u> </u>	HEADQUARTERS	(b)(5)&(b))(7)(巨)							
	REGIONAL STAFF									
	NEW ENGLAND							ļ		
NE	NEW YORK									
	REGIONAL LAB									
-	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO						_		1	
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS								ļ	
	NEW JERSEY						_	-		
	PHILADELPHIA							-		
\vdash	FORENSIC CHEM. CTR REGIONAL STAFF							-		
	ATLANTA							-	<u> </u>	
SE	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB							-		
	REGIONAL STAFF									
	DALLAS								 	
sw	DENVER							1		
13.00	KANSAS CITY							1		
	SOUTHWEST IMPORT DISTRICT									
1	REGIONAL LAB							1		
	REGIONAL STAFF						-			
	LOS ANGELES									
PA	SAN FRANCISCO							1		
1	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	1.4	1.4	0.5	13.0	10.0				
TOTAL	HOURS	434	1211	2402	4030	8650				
	ERSION FACTOR	950	950	950	1180	1180				
TOTAL	OPERATIONAL FTES	0.46	1 27	2.53	3.42	7 33				

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.

PROJECT SUMMARY SHEET

		FY 2013		_			
	GRAM CATEGORY and Cosmetics	2. PPS PROJECT Technical Assi			etics -18		
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. C	PERATIONAL	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL		64.8	07,7	TORLIGIT	64.8	
1	Technical Assistance - Food and Cosmetics	18F810*	3.2			3.2	18-23
2	Retail Food Protection - State Program	18002	27.0			27.0	18-24-25
3	(NCIMS) Milk Safety Program	18003	20.1			20.1	18-26-27
4	Molluscan Shellfish Evaluation	18004	14.5			14.5	18-28-29
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						
		1					
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		_					
-							-
		_					
-							
				-			
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- 1							
	The second secon						
	The state of the s						
	PROJECT MANAGER/TELEPHONE	-			R/TELEPHON		
Monali `	Yajnik 240-402-1616				oykin 301-79		

			FY 2013 ORA	WORKPLAN					0	october 1, 2012
1. PRC	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUM	MBER			
Techi	nical Assistance - Food and Cosmetic	cs			Technical A	Assistance- Fo	ood and Co	osmetics -	18	
3. PR(OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	I PLANNED BY			5. OPERAT	ΓΙΟΝΑL FTE P	OSITIONS
The second	See Remarks Section		All Mark or result on the	X	ORA	CENTE	R		3.2	
					1 0.0.		-13		J.L	
R E G O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL FOR CAUSE CHEM	3 DOMESTIC SAMPLE COLL SURV. MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO				
IN .	TOTAL FIELD	850	20	180	20	180			 	
		(b)(5)&(b)		10.5		15-5		_	\vdash	
	REGIONAL STAFF		(1)(-)							
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC						70 0.0			
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	DETROIT								├──	
CE	MINNEAPOLIS								-	
	NEW JERSEY							 		
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN						-			
<u> </u>	REGIONAL LAB REGIONAL STAFF							-	 	
	DALLAS								-	
sw	DENVER									
2000	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE								<u> </u>	
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW							<u> </u>		-
HOUR	S PER OPERATION		4.0	4.0	12.0	8.0			 	
	HOURS	850	80	720						
	ERSION FACTOR	950	950	950						+
TOTAL	OPERATIONAL FTEs	0.89	0.08	0.76	0.20	1.22				
			10000							
assig corre	MARKS E: PAC 18F810 is for planning purp nment PAC. Please see page I-III of sponding reporting PACS.	(after the C	Accomplish Senter Reso	ed work mu urce Summ	ust be report nary Sheet) t	ted against t for a listing o	the approp of compliar	riate prog nce progra	ram or ams and	
	cts allocations were planned by CF ratory allocations were planned by I									

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJ	ECT NAME/NUI	MBER			
Retai	Food Protection - State Program				Technical A	Assistance: F	ood and Co	smetics - 1	18	
3 PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	OSITIONS
	18002				ORA	X CENTE	ER		27.0	[24.4]
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 NATIONAL RETAIL FOOD PROG. STAND- ARDS BASE- LINE SUPP. (1)	9 STANDARD- IZATION (ITP,CDC,IHS) STATE & LOCAL) (2)	9 RE-STANDARD IZATION (ITP,STATE &LOCAL) (3)	9 FDA FOOD BORNE ILLNESS RISK FACTOR STUDY (4)	9 TEAM LEADER SC/ NATIONAL (5)	9 NATIONAL TEAM WORK GROUP (6)	9 REGIONAL SEMINARS	9 TRAINING WORKSHOPS PRE-STAND- ARDIZATION TRAINING (8)	9 TECHNICAL ASSISTANCE
"	TOTAL FIELD	7500	44		2200		3640	1680		
\vdash	HEADQUARTERS	(b)(5)&(b)			2200		0040	1000		5500
\vdash	REGIONAL STAFF		\\'\\ _ \							
	NEW ENGLAND									
NE	NEW YORK									
INC.	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
1	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
"-	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
1	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
l	DALLAS									
SW	DENVER									
200000	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION		48.0							
TOTAL	HOURS	7500	2112	2304	2200	1200	3640	1680	2800	5900
	ERSION FACTOR	1200	1200							
ITOTAL	ODEDATIONAL ETE-	6.06	1 70	100	105	100	202	4.40	2 22	4.04

Report Counter Terrorism work performed only under 18R845.

- (1) Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards.
- (2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting inspections.
- (3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections.
- (4) Allocation of time to collect data, data entry, quality assurance, and data analysis.
- (5) Time allocated for team leaders for retail food program planning, development, and coordination.
- (6) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards and initiatives of National Importance.
- (7) Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the annual Regional Retail Food Seminars.
- (8) Includes training pre-standardization workshops, HACCP workshops, and other identified training topics as well as the presentation and training sessions given to stakeholder groups.
- (9) Includes technical assistance and consultation to enrolled state and local jurisdictions performing self assessments and developing, strategic plans for enhancing the effectiveness of their retail food programs.

The residence is not as the last			F1 2013 OKA	WORKPLAN					(october 1, 2012
1. PR	OGRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NU	MBER			
Retai	I Food Protection - State Program				Technical A	Assistance: F	ood and C	osmetics -	18	
3. PR	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE F	OSITIONS
	18002				ORA	X CENT	ER	0. 0. 2.0.	27.0	[2.6]
	6. DISTRICT/	9 CONFEDENCE	9 FOOD DEFENSE	9 IFSS	9					1
R E	SPECIALIZED	FOR FOOD	OTHER	WORK	TECHNICAL ASSISTANCE			1		
G	LABORATORY	PROTECTION	& CFSAN	GROUPS	PRESIDENT]	1	1	1
ò		ACTIVITIES	DIRECTED PROJECTS	1	INAUGURATION		1			i .
N		(10)	(11)	(12)						
	TOTAL FIELD	1020	1120	100	850					
	HEADQUARTERS	(b)(5)&(b))(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
_	WEAC REGIONAL STAFF							-		
	BALTIMORE							-	<u> </u>	+
	CHICAGO									+
	CINCINNATI								 	
CE	DETROIT							<u> </u>		1
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA							ļ		
SE	FLORIDA									
	NEW ORLEANS									-
	SAN JUAN REGIONAL LAB									-
	REGIONAL STAFF							1		
	DALLAS							 		
sw	DENVER									1
	KANSAS CITY									1
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO SEATTLE							-		
	PACIFIC REGIONAL LABORATORY-SW						 	 		-
	PACIFIC REGIONAL LABORATORY-NW							 		1
HOUR	S PER OPERATION		- 1					_		+
	HOURS	1020	1120	100	850					
CONV	ERSION FACTOR	1200	1200	1200	1200					1
TOTAL	OPERATIONAL FTEs	0.85	0.93	0.08	0.71					
(10) - (11) - relate	MARKS Includes all committee work and portion allocated for the presentation of the CFSAN priority assignments in Provides time for supporting FDA's	n and distri n response	bution of FD to National	A materials Food Safet	related to f y needs.	ood defens	e. Includes	o. s Specialis	t activities	

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NU	MBER			1,2012	
NCD	MS) Milk Safety Program				Technical A	ssistance: F	and Co	emetics - 1	8	- 1	
поп	vis) with safety i rogram				recinited 1	issistance. 1	ood and co	Silictics - 1	· ·	1	
			, wone	ALL COATION	DI ANNIED DV	· · · · · · · · · · · · · · · · · · ·		E 005047			
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATI	5. OPERATIONAL FTE POSITIONS		
	18003				ORA	X CENTE	R		20.1	[16.9]	
	6.	9	9	9	9	9	9	9	9		
R	DISTRICT/		CHECK	CHECK	SINGLE	STATE	STATE MILK	STATE	STATE	TECHNICAL	
E G	SPECIALIZED LABORATORY	CHECK RATING	RATING TRANSFER	RATING BTU	SERVICE AUDITS	SAMPLING SURVEILL-	SANITATION RATING OFF.	PROGRAM EVALUATION	RATING	ASSISTANCE	
ĭ	ENDOINT OTT	PLANT	AND	5.0		ANCE OFF.	INITIAL		CERTIFICA-		
20		(1)	RECEIVING (1)	(1)	(1)	CERTIFICA- TION (2)	CERTIFICA- TION (2)	(3)	TION (4)	1	
	TOTAL FIELD	149	34	259	64	43	40		26	51	
	HEADQUARTERS	(b)(5)&(b)	(7)(E)								
	REGIONAL STAFF										
	NEW ENGLAND										
NE	NEW YORK										
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS										
1	NEW JERSEY										
l	PHILADELPHIA										
	FORENSIC CHEM. CTR										
ı	REGIONAL STAFF										
	ATLANTA										
SE	FLORIDA										
l	NEW ORLEANS										
l	SAN JUAN										
<u> </u>	REGIONAL LAB										
i	REGIONAL STAFF										
0144	DALLAS										
SW	DENVER										
	KANSAS CITY SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
\vdash	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
100	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOUR	S PER OPERATION	24.0	12.0	20.0	8.0	24.0	40.0	120.0	50.0	90.0	
_	HOURS	3576	408	5180	512	1032	1600		1300		
-	ERSION FACTOR	1200	1200	1200	1200	1200	1200		1200		
	OPERATIONAL FTEs	2.98	0.34	4.32	0.43						

- (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).

Milk Safety Program RAM/ASSIGNMENT CODE(S) 18003	9 1	4. WORK	ALLOCATION	Technical A PLANNED BY		ood and C	osmetics -		POSITIONS
18003	9	4. WORK	ALLOCATION				5. OPERAT	TIONAL ETE	POSITIONS
18003		D2590 146 HA 980 T 25.0 T 34 O HO HA							
	9			ORA	X CENTE	R		20.1	[3.2]
SPECIALIZED LABORATORY	RMS STANDARD(- 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				
	(b)(5)&(b)	(7)(E)							
							 		
							-		
	-					44,4	-	-	
								 	-
							+	-	
ALTIMORE							1		
HICAGO									1
NCINNATI									
TROIT									
NNEAPOLIS									
EW JERSEY									
HILADELPHIA									
							-		
							-		
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							+	-	-
							+		
							+	 	
						100000000000000000000000000000000000000	1		1
ALLAS								1	1
NVER								1	
NSAS CITY									
OUTHWEST IMPORT DISTRICT									
GIONAL LAB						-			
							-		-
							-	450 TE	-
							 		+
	40.0	20.0	40 n	20.0	80.08		+		+
									+
ION FACTOR	1200	1200	1200						
			1.07	0.08					
	EADQUARTERS EGIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB EAC EGIONAL STAFF ALTIMORE HICAGO NCINNATI ETROIT NNEAPOLIS EW JERSEY HILADELPHIA DRENSIC CHEM. CTR GIONAL STAFF LANTA ORIDA EW ORLEANS EN JUAN EGIONAL LAB GIONAL LAB GIONAL STAFF ALLAS ENVER ENSAS CITY DUTHWEST IMPORT DISTRICT EGIONAL LAB GIONAL LAB GIONAL LAB GIONAL STAFF S ANGELES N FRANCISCO EATTLE CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-NW ER OPERATION EURS	TOTAL FIELD ADQUARTERS GIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB EAC GIONAL STAFF ALTIMORE HICAGO NCINNATI ETROIT NNEAPOLIS EW JERSEY HILADELPHIA ORENSIC CHEM. CTR GIONAL STAFF LANTA ORIDA EW ORLEANS IN JUAN EGIONAL LAB GIONAL STAFF ALLAS ENVER ENVER ENSAS CITY DUTHWEST IMPORT DISTRICT EGIONAL LAB GIONAL STAFF ES ANGELES IN FRANCISCO EATTLE CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-NW ER OPERATION URS 40.0	TOTAL FIELD 11 20 ADQUARTERS GIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB EAC GIONAL STAFF ALTIMORE HICAGO NCINNATI ETROIT NNEAPOLIS EW JERSEY HILADELPHIA ORENSIC CHEM, CTR GIONAL STAFF LANTA ORIDA EW ORLEANS IN JUAN EGIONAL LAB GIONAL LAB GIONAL STAFF ALLAS ENVER INSAS CITY DUTHWEST IMPORT DISTRICT EGIONAL LAB GIONAL STAFF ES ANGELES IN FRANCISCO EATTLE CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-NW ER OPERATION 40.0 20.0 HURS 440 400	TOTAL FIELD 11 20 32 ADQUARTERS GIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB EAC GIONAL STAFF HICAGO NCINNATI ETROIT NNEAPOLIS EW JERSEY HILABELPHIA ORENSIC CHEM. CTR GIONAL STAFF LANTA ORIDA EW ORLEANS IN JUAN EGIONAL LAB GIONAL STAFF NLLAS ENVER INSAS CITY DUTHWEST IMPORT DISTRICT EGIONAL LAB GIONAL STAFF S ANGELES N FRANCISCO ATITLE CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-NW ER OPERATION 40.0 20.0 40.0 IURS 440 400 1280	TOTAL FIELD 11 20 32 5 ADQUARTERS (GIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB EAC GIONAL STAFF ALTIMORE HICAGO NCINNATI ETROIT NNEAPOLIS EW JERSEY HILADELPHIA PRENSIC CHEM. CTR GIONAL STAFF LANTA ORIDA EW ORLEANS IN JUAN EGIONAL LAB GIONAL STAFF LANTA ORIDA EW ORLEANS IN JUAN EGIONAL LAB GIONAL STAFF NEVER NSAS CITY DUTHWEST IMPORT DISTRICT GIONAL STAFF S ANGELES N FRANCISCO ATTLE CIFIC REGIONAL LABORATORY-NW ER OPERATION 40.0 20.0 40.0 20.0 URS 440 400 1280 100	TOTAL FIELD 11 20 32 5 20 ADQUARTERS GIONAL STAFF EW ENGLAND EW YORK EGIONAL LAB EAC GIONAL STAFF LITIMORE HICAGO NCINNATI ETTROIT NNEAPOLIS EW JERSEY HILADELPHIA PRENSIC CHEM. CTR GIONAL STAFF LANTA ORIDA EW ORLEANS IN JUAN EGIONAL LAB GIONAL STAFF LLAS ENVER INJUAN EGIONAL STAFF LLAS ENVER INSAS CITY DUTHWEST IMPORT DISTRICT EGIONAL STAFF S ANGELES IN FRANCISCO ATTLE CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-NW ER OPERATION EN OPERATION FOR DEPTATION HURS 440 400 1260 100 1600	TOTAL FIELD 11 20 32 5 20 ADQUARTERS (GIONAL STAFF EW ENGLAND EW YORK GIONAL LAB EAC GIONAL STAFF ALTIMORE HICAGO NICININATI ETROIT NINEAPOLIS EW JERSEY HILADELPHIA ORIBA OR	TOTAL FIELD 11 20 32 5 20 ADQUARTERS (IDINAL STAFF WENGLAND WYORK GIONAL LAB EAC GIONAL STAFF LITIMORE HICAGO NICINNATI ETROIT NINEAPOLIS WYERSEY HILADELPHIA DIRENSIC CHEM. CTR GIONAL STAFF LANTA CORIDA WORLEANS IN JUAN EGIONAL LAB GIONAL STAFF LANTA CORIDA WORLEANS IN JUAN EGIONAL STAFF SINDER WILADELPHIA DIRENSIC CHEM. CTR GIONAL STAFF LANTA CORIDA WORLEANS IN JUAN EGIONAL STAFF GIONAL STAFF SINDER SIN	TOTAL FIELD 11 20 32 5 20 ADQUARTERS (b)(5)&(b)(7)(E) GIONAL STAFF WE ENGLAND WY YORK GIONAL SAB EAC GIONAL STAFF LITIMORE HICAGO NCINNATI ETROIT NNEAPOLIS WY JERSEY HILADELPHIA DRENSIC CHEM. CTR GIONAL STAFF LANTA CRIDA WHORLEANS IN JUAN GIONAL STAFF LANTA CRIDA WHORLEANS IN JUAN GIONAL STAFF LLASS INVER INSAS CITY JUTHWEST IMPORT DISTRICT GIONAL LAB GIONAL LAB GIONAL LAB GIONAL LAB GIONAL LAB GIONAL LAB GIONAL STAFF LASS INVER INSAS CITY JUTHWEST IMPORT DISTRICT GIONAL STAFF GIONAL LAB GIONAL LABORATORY-NW CIFIC REGIONAL LABORATORY-SW CIFIC REGIONAL LABORATORY-NW GIO REGIONAL LABORATORY-NW

1. PROG	RAM/ASSIGNMENT TITLE				2. PPS PROJECT NAME/NUMBER						
Mollus	can Shellfish Evaluation				Technical A	Assistance: Fo	ood and Co	smetics - 1	8		
3. PROG	GRAM/ASSIGNMENT CODE(S)	-	4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	OSITIONS	
	18004				ORA	ORA X CENTER			14.5 [12.3]		
R E G I	DISTRICT/ SPECIALIZED LABORATORY	9 GROWING AREA EVALUATION	9 CONTROL OF HARVEST	9 VIBRIO SPECIES MANAGEMENT (Hours)	9 TECHNICAL ASSISTANCE (Hours)	9 FOREIGN EVALUATION	9 NATIONAL TEAM REPS	9 CENTER INTIA- TIVES/LAB	9 PLANT EVALUATION	9 STANDARD IZATION & RE-STAN- DARD IZATION	
N -		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
\vdash	TOTAL FIELD	193	20	2155	3734	3	2	7	142	14	
_	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										
1 7	SAN JUAN										
	REGIONAL LAB										
F	REGIONAL STAFF										
	DALLAS										
SW I	DENVER										
<u> </u>	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
-	REGIONAL LAB										
-	REGIONAL STAFF										
	LOS ANGELES										
1000000	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW	00.01	00.0		1	0000	4000	1 400	1 40.0	40.0	
	PER OPERATION	20.0 3860	90.0		3734	200.0	180.0 360				
TOTAL	RSION FACTOR	1200	1200	2155 1200			1200				
THE RESERVE AND LABOR.	OPERATIONAL FTEs	3.22	1.50			4	0.30	-			

- (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					2. PPS PROJ	ECT NAME/NU	MBER			0.0001 1, 2012
Molli	iscan Shellfish Evaluation				Technical (Assistance: F	and and Ca	ematics 1	10	
I VIOIN	Sean Silenian Evaluation				I confical A	ASSISTANCE, F	ood and Co	smetics - i	10	
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATIONAL FTE POSITIONS		
	18004				ORA	X CENTE	R	14.5 [2.2]		
				-					17. 105	[]
R	6. DISTRICT/	9 NATIONAL	9 TRAINING	9 REGIONAL	9 FOOD	9 ISSC	9 IFSS			
E	SPECIALIZED	TEAM	WORKSHOPS	SEMINARS	DEFENSE	COMMITTEE	WORKGROUP		l	l
G	LABORATORY	WORKSHOP			COORDINATION					
o		1		l .	l				l	
N	4400	(10)	(11)	(12)	(13)	(14)	(15)			
	TOTAL FIELD	9	11	11	10	14	5			
	HEADQUARTERS	(b)(5)&(b	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK							3		
	REGIONAL LAB									
	WEAC	Į.								
	REGIONAL STAFF	l.								
	BALTIMORE	Į.								
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
1	NEW JERSEY	ŀ								
	PHILADELPHIA	-						_		
-	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA FLORIDA	+						_		
SE	NEW ORLEANS									
	SAN JUAN	}								-
	REGIONAL LAB							-		
\vdash	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
200-2001	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB							2.40		
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW	-								
	PACIFIC REGIONAL LABORATORY-NW									
-	S PER OPERATION	40.0	30.0	30.0	20.0	90.0	20.0			
	HOURS	360	330	330	200	1260	100			
	ERSION FACTOR	1200	1200	1200	1200	1200	1200			
TOTAL	OPERATIONAL FTEs	0.30	0.28	0.28	0.17	1.05	0.08		I	

- (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.

PROJECT SUMMARY SHEET

		FY 2013					
Food	GRAM CATEGORY and Cosmetics	2. PPS PROJECT Food Composi	tion, Standar	ds, Labeling	222		
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. O	PERATIONAL	FTE FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL	0002	27.2	12.4	CHEIGH	39.6	
1	Food Composition, Standards, Labeling and Economics	21F810*	27.2	12.4		39.6	21-31-33
-	. coa composition, standards, saccing and secondines	211010	21.2	12.4		39.0	41-31-33
	*These PACS are for planning purposes only.		_			ļ	
	Accomplished work must be reported against the						·
	appropriate program or assignment PAC.						
					-		
					-		
-							
		_	-				

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-	T						
\dashv		-					
\dashv							
	0				57 (815) (870)		
							-
					-		
ENTER	PROJECT MANAGER/TELEPHONE		(DRA PLANNE	R/TELEPHON		
Ionali '	Yajnik 240-402-1616			Lorraine B. Be			
ORM F	FDA 2622 (10/09)		7A(4)	W 47 C		PAGE NO.	21-30

			FY 2013 ORA	WORKPLAN					Oc	tober 1, 2012
1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUI	MBER			
Food	Composition, Standards, Labeling an	d Economic	S		Food Comp	osition, Stan	dards, Labe	ling and E	conomics -	21
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	1		5. OPERATI	ONAL FTE PO	OSITIONS
	See Remarks Section				1 004	CONTR	ъ			60001 5
	See Remarks Section			X	ORA	X CENTE	:R		39.6	[5.4]
R E G I O	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL MEDICAL FOODS	3 DOMESTIC SAMPLE COLL ECONO. 21003	3 DOMESTIC SAMPLE COLL NLEA 21005	3 DOMESTIC SAMPLE COLL INFANT FORMULA	3 DOMESTIC SAMPLE COLL DIETARY SUPPL	4 IMPORT SAMPLE COLL MEDICAL FOODS	4 IMPORT SAMPLE COLL NLEA 21005	4 IMPORT SAMPLE COLL INFANT FORMULA	4 IMPORT SAMPLE COLL DIETARY SUPPL
N		21002			21006	21008	21002		21006	21008
	TOTAL FIELD	33	100	340	26	250	8	910	15	430
	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									
	DACIEIO DECIONAL LABORATORY, SMI									

TOTAL HOURS

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.

4.2

420

950

0.44

4.2

1428

950

1.50

5,3

138

950

0.15

4.2

1050

950

1,11

6.0

48

950

0.05

1.2

1092

950

1.15

5.0

75

950

0.08

1.6

688

950

0.72

6.0

198

950

0.21

For Pac 21008 ~

HOURS PER OPERATION

TOTAL OPERATIONAL FTES

CONVERSION FACTOR

PACIFIC REGIONAL LABORATORY-NW

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

1. PRC	OGRAM/ASSIGNMENT TITLE				2. PPS PROJEC	T NAME/NUMI	BER			
	Composition, Standards, Labeling a	and Economic	·c		Food Compos			ing and Eco	nomics - 21	4
roou	Composition, Standards, Labering a	IIII ECONOMIC	,	1	T CAM COMPAN	mun, ouna	IIII, Later	ng mid Lean	Italinos - Z.	
3 PR(OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	N PLANNED BY			5. OPERATIO	ONAL FTE POSIT	TIONS
J. 1 110	And the state of t					X CENTE	FD.			[19.1]
	See Remarks Section			X	ORA	X CENTE	ir.		39.0	[19.1]
_	6.	2 DOMESTIC	5	6	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC
R	DISTRICT/ SPECIALIZED	EMERGING	FIELD	IMPORT	SAMPLES	SAMPLES	SAMPLES	SAMPLES	SAMPLES	SAMPLES
G	LABORATORY	ISSUES	EXAMS/	FIELD	TOBE	TO BE	TO BE	TO BE	TO BE	TO BE
0	1	CSO (Hours)	TEST	EXAMS	ANALYZED MED. FOODS	ANALYZED MED. FOODS	ANALYZED ECON	ANALYZED NLEA	ANALYZED INFANT FOR.	ANALYZED INFANT FOR-
N		(Hours) (1)		(2)	CHEM 21002	MICRO 21002	CHEM 21003	CHEM 21005	CHEM 21006	MICRO 21006
	TOTAL FIELD	630	2400	11209	21	12	100	340	18	8
77000	HEADQUARTERS	(b)(5)&(b)(7)	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									
HOUF	RS PER OPERATION		0.4	0.5	101.1	1 30.0	19.0	19.1	1 100.0	0 120
	L HOURS	630,	960	5605	2123	3 360	1900	6494	1800	0 96
	ERSION FACTOR	950	950	950	1180	1180	1180	1180	1180	0 118
TOTA	OPERATIONAL FTES	0.66	1.01	5.90	1.80	0.31	1 1.61	1 5.50	1.53	3 0.8

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.

- 200			F1 2013 ORA	WORKI LAIN					00	ctober 1, 2012
	OGRAM/ASSIGNMENT TITLE			¥	2. PPS PROJE	ECT NAME/NU	MBER			
Food	Composition, Standards, Labeling an	d Economics	\$		Food Comp	osition, Stan	dards, Label	ing and Econo	mics - 21	
3. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	-		5. OPERATIONAL FTE POSITIONS		
	See Remarks Section				_			J. OF EIGHTON		(51,55)
				X	ORA	X CENTE	:R		39.6	[15.1]
R E G - O Z	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED DIET SUPPL CHEM 21008	7 DOMESTIC SAMPLES TO BE ANALYZED TDS CHEM 21839	8 IMPORT SAMPLES TO BE ANALYZED MED. FOODS CHEM 21002	8 IMPORT SAMPLES TO BE ANALYZED NLEA CHEM 21005	8 IMPORT SAMPLES TO BE ANALYZED INFANT FOR- CHEM 21006	8 IMPORT SAMPLES TO BE ANALYZED DIET SUPPL CHEM 21008	7 DOMESTIC EMERGING ISSUES TO BE ANAL. CHEM (Hours) (3)	9 METHODS VAL/DEV CHEM (Hours)	9 APPLIED TECHN- OLOGY CENTER (Hours)
1 '	TOTAL FIELD	155	1040	8				1	615	1180
	HEADQUARTERS	(b)(5)&(b)								1150
	REGIONAL STAFF		(1-)(-)							
, 1	NEW ENGLAND	1								
NE	NEW YORK									
,	REGIONAL LAB	1								
1	WEAC	1								
	REGIONAL STAFF									
, ,	BALTIMORE									
, ,	CHICAGO									
, ,	CINCINNATI									
CE	DETROIT									
OL I	MINNEAPOLIS	1								
, ,	NEW JERSEY									
1	PHILADELPHIA	1								
I = I	FORENSIC CHEM. CTR	1								
	REGIONAL STAFF									
, ,	ATLANTA	1								
SE	FLORIDA	1								
SE I		1								
, !	NEW ORLEANS	1								
, ,	SAN JUAN	1								
	REGIONAL STAFF									
, 1	REGIONAL STAFF	1								
sw	DALLAS DENVER	+								
SVV	-2	t								
I = I	KANSAS CITY									
, 1	SOUTHWEST IMPORT DISTRICT									
	REGIONAL STAFE									
, 1	REGIONAL STAFF									
200	LOS ANGELES	1								
PA	SAN FRANCISCO	+								
, 1	SEATTLE	+								
	PACIFIC REGIONAL LABORATORY-SW	ł –								
	PACIFIC REGIONAL LABORATORY-NW	ar of								
	S PER OPERATION	25.0	3.8				25.0		L	
	HOURS	3875	3952	800	1250	1500	1750		615	1180
	ERSION FACTOR	1180	1180	The second secon	1180		1180		1205	1180
TOTAL	OPERATIONAL FTES	3.28	3.35	0.68	1.06	1.27	1.48	2,42	0.51	1.00

(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 sample analyses or other lab operations and will be allocated through assignments unless otherwise instructed.

PROJECT SUMMARY SHEET

		FY 2013					
	GRAM CATEGORY	2. PPS PROJECT I					
Food	and Cosmetics	Colors and Cost	metics Tech	nology - 29			
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT	6. O	PERATIONAL	FTE	7. TOTAL OPERATIONAL	8. PAGE
		CODE	DOMESTIC	IMPORT	FOREIGN	FTEs	
	TOTAL		4.9	3.7		8.6	
1	Cosmetics: Domestic and Imports	29001; 29R833;	4.9	3.7		8.6	29-35
		29R824;					
		99R833					
0				****			
		1					
<u> </u>						-	
		-					
		_				-	
							,
							100.00
			7,000,000,000				
							300 300
-		-		-			
-							
							1
					ports differ to	1,000	
					1		
CENTER	R PROJECT MANAGER/TELEPHONE			DRA PLANNE	R/TELEPHON	NE .	
Monali`	Yajnik 240-402-1616		I	Danita Dyer 3	01-796-9694	<u> </u>	

		F	FY 2013 ORA V	WORKPLAN					0	ctober 1, 2012
1. PRC	OGRAM/ASSIGNMENT TITLE				2. PPS PROJ	IECT NAME/NU	JMBER			
Cosm	netics: Domestic and Imports				Colors and	Cosmetics -	29			
3. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	N PLANNED BY	1		5 OPERAT	TIONAL FTE PO	OSITIONS
	29001, 29R833, 29R824, 99R8	333		Х		CENT	ER		8.6	Joines
R E G - O N	6 DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPECT- IONS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	3 DOMESTIC SAMPLE COLL PRESERVATIVE ASSIGNMENT		7 DOMESTIC SAMPLES TO BE ANALYZED PRESERVATIVE ASSIGNMENT (Micro)	TO BE	8 IMPORT SAMPLES TO BE ANALYZED (Chem)	6 IMPORT FIELD EXAMS
'	TOTAL FIELD	100	60	230	150	60	150	115	115	1600
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
i '	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
1 '	BALTIMORE									
i '	CHICAGO									
CE	CINCINNATI									
	DETROIT									
π-	MINNEAPOLIS									
1	NEW JERSEY									
1	PHILADELPHIA									
'	FORENSIC CHEM, CTR									
	REGIONAL STAFF									
'	ATLANTA									
SE	FLORIDA									
0_	NEW ORLEANS									
i '	SAN JUAN									
l '	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									
HOUR	S PER OPERATION	17.0	4.4	1.5	3.0	13.0	13.0	13.0	13.0	0.5
	HOURS	1700	264	345	450					
	ERSION FACTOR	950	950	950		-		1		
	ODERATIONAL ETER	1.70	0.00	0.00	0.47		1100	1100	1100	950

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

	ОРЕ	RATIONAL F	TES	TOTAL OPERATIONAL
	DOMESTIC	IMPORT	FOREIGN	FTEs
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

		OPERATIONAL FTES					
PPS NO.	PROJECT TITLE	DOMESTIC	IMPORT	FOREIGN	FTEs		
	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		

		FY 2013					
1. PRO Biolog	GRAM CATEGORY	2. PPS PROJECT				1	
	ics	Human Cellula	r, rissue and	Gene The	rapeutics - 4	1	
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PROGRAM ASSIGNMENT	6. C	PERATIONAL	- FTE	7. TOTAL	8. PAGE
		CODE	DOMESTIC	IMPORT	FOREIGN	OPERATIONAL FTEs	
28,72	TOTAL		44.6		0.1	44.7	
1	Inspection of Human Cells, Tissues and Cellular & Tissue-	41002B,C,D					41-2
	Based Products (HCT/Ps)		39.0			39.0	
2	Bioresearch Monitoring Programs *		5.0			5.0	
	Good Laboratory Practices (Nonclinical Labs)	41808	*				
	Institutional Review Boards	41809	*				
	Sponsors, Monitors, and Contract Research Organizations	41810	*				
	Clinical Investigators *	41811	(5.0)				41-3
3	Inspection of Cell and Gene Therapy Products	41848A,F,G &			1000 20000000		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
		41848B,C,D	0.6		0.1	0.7	41-4
						1000	
	* All resources are planned under PAC 41811.						
							· · · · ·
					2002-01/1990 NV 1903-0		
							VI (2008)
		100000					
						77-10-	
					*		
						_	
	PROJECT MANAGER/TELEPHONE			ORA PLANNE	R/TELEPHON	IE .	
	nimoto 301-827-6220				erber 301-796		

	GRAM/ASSIGNMENT TITLE an Cells, Tissues, & Cellular & Tiss		oducts (HCT			ECT NAME/NUI Ilular, Tissue		Γherapies ·		1, 2012
3. PRO	GRAM/ASSIGNMENT CODE(S) 41002B, C, D		4. WORK AL	LOCATION	PLANNED BY ORA	CENT	ER	5. OPERAT	IONAL FTE PO 39.0	SITIONS
R E G - ON	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS (1)	CBER PRIORITY ESTABS (2)							
	TOTAL FIELD	815	135							
	HEADQUARTERS	(b)(5)&(b)((7)(E)			<u> </u>				
	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		-		20000 100000					
11	SEATTLE		_		<u> </u>					
0	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW		-							
MOUR	S PER OPERATION	45.5				 		_		
	HOURS	-	***************************************			——				
	ERSION FACTOR	37083 950			20 - B - 37	-				
TOTAL	OPERATIONAL FTES	39.03	****			-				
9 REN		00.00								

- (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.

Personnel Types Required: Investigator

GRAM/ASSIGNMENT TITLE						mt 8 sc		clober 1, 2012
	inical Investi	gators	Human	Cellular, l'issue	and Gene	Therapeuti	cs - 41	
		1						
			CATION PLANNEI			5. OPERAT		SITIONS
808-GLPs, 41809-IRBs, 41810-Spc	on/Mon/CRC	s	X ORA	CENTE	R		5.0	
The state of the s	1 1					-		
DISTRICT/		1	- 1	1 1				
			- 1					
	(1)	I	- 1					
TOTAL FIELD	43							
REGIONAL STAFF								
NEW ENGLAND	(
NEW YORK								
REGIONAL LAB	_				_			
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						1		
NEW JERSEY								
PHILADELPHIA								
FORENSIC CHEM. CTR								
REGIONAL STAFF								
ATLANTA	_							
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KANSAS CITY								
SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB	_							
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PACIFIC REGIONAL LABORATORY-NW	-						 	1
	110.5							·
	4752							r la super s
ERSION FACTOR	950							
L OPERATIONAL FTES	5.00							
Resources for PACs 41808, 41809 above resources for Foreign Inspec actions are to be conducted only wh	tions as nee en assignm	ded. Report Fo	reign Inspect	ions under Opera				
S I I	S, IRBs, Sponsor/Monitor/CROs, Cli JFA Domestic & Foreign) DGRAM/ASSIGNMENT CODE(S) 1808-GLPs, 41809-IRBs, 41810-Spotential Investigators E. DISTRICT/SPECIALIZED LABORATORY TOTAL FIELD 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 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 RS PER OPERATION L HOURS /ERSION FACTOR L OPERATIONAL FTES MARKS Resources for PACs 41808, 41809 above resources for Foreign Inspeceetions are to be conducted only whe	s, IRBs, Sponsor/Monitor/CROs, Clinical Investignation JFA Domestic & Foreign) DGRAM/ASSIGNMENT CODE(S) 1808-GLPs, 41809-IRBs, 41810-Spon/Mon/CRO 41811 Clinical Investigators E. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD 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 RES PER OPERATION 110.5 L HOURS 4752 VERSION FACTOR L OPERATIONAL FTES 5.00 MARKS RESOURCES FOR PACS 41808, 41809, 41810, and above resources for Foreign Inspections as nee	S, IRBs, Sponsor/Monitor/CROs, Clinical Investigators JFA Domestic & Foreign) DGRAM/ASSIGNMENT CODE(S) 1808-GLPs, 41809-IRBs, 41810-Spon/Mon/CROs 41811 Clinical Investigators DISTRICT/ SPECIALIZED	S, IRBs, Sponsor/Monitor/CROs, Clinical Investigators JFA Domestic & Foreign) DGRAMASSIGNMENT CODE(S) 8.08-GLPs, 41809-IRBs, 41810-Spon/Mon/CROs 41811 Clinical Investigators S. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD TOTAL FIELD TOTAL FIELD HEADQUARTERS (b)(5)&(b) REGIONAL STAFF REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL LAB REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATILE PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW SPER OPERATION L HOURS 4762 L DEPRATIONAL FTES MARKS RESOURCES for PACS 41808, 41809, 41810, and 41811 are planned under PA above resources for Foreign Inspections as needed. Report Foreign Inspect	S, IRBs, Sponsor/Monitor/CROs, Clinical Investigators Human Cellular, Tissue JEA Domestic & Foreign) JORAMASSIGNMENT CODE(S) 1808-GLPs, 41809-IRBs, 41810-Spon/Mon/CROs 41811 Clinical Investigators S. DISTRICT/ SPECIALZED LABORATORY TOTAL FIELD TOTAL FIELD TOTAL FIELD 43 HEADQUARTERS (b) (5) & (b) REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL LAB WEAC CRICIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM CTR REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL STAFF JOALLAS DENNER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF JOALLAS DENNER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LABORATORY-NW SPER OPERATION 110.5 L HOURS 4752 JOAN JO	AT DOMINETIC & Foreign) SIR AD SOMESTIC & FOREIGN A WORK ALLOCATION PLANNED BY A WORK ALLOCATION PL	S. IRBs, Sponsor/Monitor/CROs, Clinical Investigators IFA Domestic & Foreign) JEA Domestic & Foreign JEA Domestic & JE	S, IRBs, Sponsor/Monitor/CROs, Clinical Investigators IFA Domestic & Foreign) JEA TRANSE JEA TRANS

Personnel Types required: Investigator

			FY 2013 ORA	WORKPLAN	The second second				Oc	tober 1, 2012
1. PRC	OGRAM/ASSIGNMENT TITLE				2. PPS PROJ	ECT NAME/NUI	MBER	2000		
Inspe	ction of Cell and Gene Therapy Pro	ducts			Human Cel	lular, Tissue	and Gene	Therapeuti	ics - 41	1
(Don	nestic & Foreign)									
	OGRAM/ASSIGNMENT CODE(S)		4 WORK	ALLOCATION	PLANNED BY			C ODEDAT	ONN FTE DO	
			I WORK					5. OPERAT	IONAL FTE PO	SITIONS
4	1848A,F,G and 41848B,C,D*			X	ORA	CENTI	ER	N.	0.7	1
-	[6.	1	1							
R E G - O Z	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS DOMESTIC (1)	INSPEC- TIONS FOREIGN (1)							
	TOTAL FIELD	4	1							
	HEADQUARTERS	(b)(5)&(b)	(7)(E)		1					
	REGIONAL STAFF							1		
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC							1		
	REGIONAL STAFF				†					
	BALTIMORE							<u> </u>		
	CHICAGO									
	CINCINNATI				100	-		-		
CE	DETROIT									-
	MINNEAPOLIS							 		
	NEW JERSEY									
	PHILADELPHIA					-		 		
	FORENSIC CHEM. CTR							-		
	REGIONAL STAFF					-	100	-		
	ATLANTA								_	
SE	FLORIDA				-			-		
	NEW ORLEANS									
	SAN JUAN						-	-		
	REGIONAL LAB									
	REGIONAL STAFF							_		
	DALLAS								-	
sw	DENVER									
	KANSAS CITY							-		
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB							2000		
	REGIONAL STAFF							1		
	LOS ANGELES									
PA	SAN FRANCISCO							1		
1.00.00	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW							—		
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	149.5	67.0				-			
	HOURS	598	67							
	ERSION FACTOR	950	950							
	OPERATIONAL FTEs	0.63	0.07							t
9. REM						Ca		n.		-

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

41-4

A	NO.	4 EDA COMPLIANCE PROCESSAS AND ACCIONATIVE	E DECCEPT:				,	
Inspection of Licensed & Unlicensed Blood Banks	. NO.	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PROGRAM ASSIGNMENT	6. O	PERATIONAL	FTE	7. TOTAL OPERATIONAL	8. PAGI
Inspection of Licensed & Unlicensed Blood Banks		TOTAL	CODE		The state of the s	The second secon	FTEs	
National Experts 2.5 0.1 2.6	1		12004F G 17		4.0			
Inspection of Donor Centers	1		42001F,G,H					42-6
Inspection of Reference Laboratories	\dashv			2.5		0.1	2.6	
Inspection of Blood/Plasma Brokers	\dashv							
Inspection of Blood Product Contractors	\dashv							
Technical Assistance and Coordination * 3.0 3.0 3.0	\dashv					· · · · · · · · · · · · · · · · · · ·		
2 Inspection of Source Plasma Establishments	\dashv							
1				3.0			3.0	
42 Inspection of Licensed In-Vitro Diagnostic (IVD) Devices 42008A,F,G 1.3 0.7 2.0				11.9			11.9	42-7
4 Inspection of Licensed In-Vitro Diagnostic (IVD) Devices 42008A,F,G 1.3 0,7 2.0 Regulated by CBER (Team Biologics) 5 0.5 0.5 0.5 5 Biorescarch Monitoring Programs ** 4.4 4.4 4.4 Good Laboratory Practices (Nonclinical Labs) 42808 * - - Institutional Review Boards 42809 * -	3	Imported CBER - Regulated Products	42007,42R833,		4.0		4.0	42-8
Regulated by CBER (Team Biologics) 0.5 Field Investigations 0.5 Biorescarch Monitoring Programs ** 4.4 Good Laboratory Practices (Nonclinical Labs) 42808 Institutional Review Boards 42809 Sponsors, Monitors, and Contract Research Organizations 42810 Clinical Investigators ** 42811 National Experts 42808, 42811 Inspection of Medical Device Manufacturers 42845A,B,C Inspection of Plasma Derivatives of Human Origin 42845A,F,G (Team Biologies) 1.1 * For BLT-DO to Assist & Coordinate ARC Information. ** ** All Domestic & Foreign Resources are planned under Domestic	_		42R824,99R833					
Field Investigations 5 Bioresearch Monitoring Programs ** Good Laboratory Practices (Nonclinical Labs) Institutional Review Boards Sponsors, Monitors, and Contract Research Organizations Clinical Investigators ** At 2811 At 2808 Sponsors, Monitors, and Contract Research Organizations Clinical Investigators ** At 2811 At 2808, 42810 National Experts 42808, 42811 (0.4) National Experts 42808, 42811 (0.4) At 5808, 45811 6 Inspection of Medical Device Manufacturers 42845A,B,C 0.5 7 Inspection of Plasma Derivatives of Human Origin 42848A,F,G 1.1 2.2 3.3 (Team Biologies) *For BLT-DO to Assist & Coordinate ARC Information. ** All Domestic & Foreign Resources are planned under Domestic	4	Inspection of Licensed In-Vitro Diagnostic (IVD) Devices	42008A,F,G	1.3		0.7	2.0	42-9
5 Bioresearch Monitoring Programs ** Good Laboratory Practices (Nonclinical Labs) Institutional Review Boards Sponsors, Monitors, and Contract Research Organizations Clinical Investigators ** 42810 National Experts 42808, 42811 (4.0) National Experts 42808, 42811 (0.4) Inspection of Medical Device Manufacturers 42845A,B,C 7 Inspection of Plasma Derivatives of Human Origin 42848A,F,G 1.1 2.2 3.3 (Team Biologies) *For BLT-DO to Assist & Coordinate ARC Information. ** All Domestic & Foreign Resources are planned under Domestic	\dashv	Regulated by CBER (Team Biologics)						
Good Laboratory Practices (Nonclinical Labs) Institutional Review Boards Sponsors, Monitors, and Contract Research Organizations Clinical Investigators ** 42810 National Experts 42808, 42811 (0.4) National Experts 42808, 45811 6 Inspection of Medical Device Manufacturers 12845A,B,C 13.3 (Team Biologics) *For BLT-DO to Assist & Coordinate ARC Information. ** All Domestic & Foreign Resources are planned under Domestic	\dashv			0.5			0.5	
Institutional Review Boards	5	Bioresearch Monitoring Programs **		4.4			4.4	42-10
Sponsors, Monitors, and Contract Research Organizations Clinical Investigators ** 42811 (4.0) National Experts 42808, 42811 (0.4) 50 Inspection of Medical Device Manufacturers 61 Inspection of Plasma Derivatives of Human Origin 62845A,B,C 72 Inspection of Plasma Derivatives of Human Origin 63 Inspection of Plasma Derivatives of Human Origin 64 Inspection of Plasma Derivatives of Human Origin 65 Inspection of Plasma Derivatives of Human Origin 66 Inspection of Plasma Derivatives of Human Origin 67 Inspection of Plasma Derivatives of Human Origin 68 Inspection of Plasma Derivatives of Human Origin 69 Inspection of Plasma Derivatives of Human Origin 60 Inspection of Plasma Derivatives of Human Origin 60 Inspection of Plasma Derivatives of Human Origin 61 Inspection of Plasma Derivatives of Human Origin 62 Inspection of Plasma Derivatives of Human Origin 63 Inspection of Plasma Derivatives of Human Origin 64 Inspection of Plasma Derivatives of Human Origin 65 Inspection of Plasma Derivatives of Human Origin 66 Inspection of Plasma Derivatives of Human Origin 67 Inspection of Plasma Derivatives of Human Origin 68 Inspection of Plasma Derivatives of Human Origin 68 Inspection of Plasma Derivatives of Human Origin 69 Inspection of Plasma Derivatives of Human Origin 60 Inspection of Plasma Derivatives of Human Origin 60 Inspection of Plasma Derivatives of Human Origin 61 Inspection of Plasma Derivatives of Human Origin 61 Inspection of Plasma Derivatives of Human Origin 62 Inspection of Plasma Derivatives of Human Origin 62 Inspection of Plasma Derivatives of Human Origin 63 Inspection of Plasma Derivatives of Human Origin 64 Inspection of Plasma Derivatives of Human Origin 65 Inspection of Plasma Derivatives of Human Origin 66 Inspection of Plasma Derivatives of Human Origin 67 Inspection of Plasma Derivatives of Human Origin 68 Inspection of Plasma Derivatives of Human Origin 68 Inspection of Plasma Derivatives of Human Origin 69 Inspection of Plasma Derivatives of Human Origi	_	Good Laboratory Practices (Nonclinical Labs)	42808	*				
Clinical Investigators ** 42811 (4.0)		Institutional Review Boards	42809	*				
National Experts 42808, 42811 (0.4) 45808, 45811 6 Inspection of Medical Device Manufacturers 42845A,B,C 7 Inspection of Plasma Derivatives of Human Origin (Team Biologics) * For BLT-DO to Assist & Coordinate ARC Information. ** All Domestic & Foreign Resources are planned under Domestic	_	Sponsors, Monitors, and Contract Research Organizations	42810	*				
45808, 45811	_	Clinical Investigators **	42811	(4.0)				
6 Inspection of Medical Device Manufacturers 42845A,B,C 0.5 1.1 2.2 3.3 (Team Biologics) * For BLT-DO to Assist & Coordinate ARC Information. ** All Domestic & Foreign Resources are planned under Domestic		National Experts	42808, 42811	(0.4)				
7 Inspection of Plasma Derivatives of Human Origin 42848A,F,G 1.1 2.2 3.3 (Team Biologics)			45808, 45811					
(Team Biologics) (Team Biolog	6	Inspection of Medical Device Manufacturers	42845A,B,C	0.5			0.5	42-11
* For BLT-DO to Assist & Coordinate ARC Information. ** All Domestic & Foreign Resources are planned under Domestic	7	Inspection of Plasma Derivatives of Human Origin	42848A,F,G	1.1		2.2	3.3	42-12
** All Domestic & Foreign Resources are planned under Domestic		(Team Biologics)						
** All Domestic & Foreign Resources are planned under Domestic	\dashv							
** All Domestic & Foreign Resources are planned under Domestic	\dashv							
** All Domestic & Foreign Resources are planned under Domestic		* For DI T DO to Assist & Coordinate ADC Information						
	_							
FAC 42011. Foleign Resources to cover PPS 41, 42, 43.			 					-
	\dashv	PAC 42811. Foleign Resources to cover PPS 41, 42, 45.	-					
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	+							
NTER PROJECT MANAGER/TELEPHONE ORA PLANNER/TELEPHONE		PROJECT HANDER TELEPHONE						

	DGRAM/ASSIGNMENT TITLE			WORK! EAS	ALTERNATION PROPERTY OF THE PR	ECT NAME/NUM			0	ctober 1, 2012
Inspe	ction of Licensed and Unlicensed E	Blood Banks	(Domestic	& Foreign)	Blood and	Blood Produc	ets - 42			
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			E ODERAT	IONAL FTE PO	OUTIONS
	42001F,G,H						_	S. OPERA		SHIONS
	420017,0,1			X	ORA	CENTE	R		55.5	
\vdash	[6.	1	1	2	9	Т		-		
R E G - O Z	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	DOMESTIC INVESTI- GATIONS (Hours)	TECH ASST & COORDIN- ATION (Hours) OP CODE 92					
IN .	TOTAL FIELD	(1) 985	(2)	(3)	(4)		-	-		
	HEADQUARTERS	(b)(5)&(b)		2400	2040			+		
	REGIONAL STAFF		() (–)					-		
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE						50007			
	CHICAGO									
ı	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR					-				
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
1	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF DALLAS									
sw	DENVER							-		
3,1	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT					-		 		
	REGIONAL LAB									
	REGIONAL STAFF							 		
	LOS ANGELES									
PA	SAN FRANCISCO									
2000000	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS	PER OPERATION	47.9	42.0							
TOTAL	HOURS	47182	336	2400	2840					
	ERSION FACTOR	950	950	950	950					
TOTAL	OPERATIONAL FTES	49.67	0.35	2.53	2.99					

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 INSPECTIONS (1) 194 (b)(5)&(b) (7)(E)	4. WORK A	LLOCATION	PLANNED BY	Blood Produc		5. OPERAT	IONAL FTE PO	OSITIONS
194 (b)(5)&(b)	4. WORK A	_	-		R	5. OPERAT		OSITIONS
194 (b)(5)&(b)		_	-	-	R			
194 (b)(5)&(b)				CENTE			11.7	
194 (b)(5)&(b)								
194 (b)(5)&(b)								
(1) 194 (b)(5)&(b)								
194 (b)(5)&(b)								
(b)(5)&(b)								
(b)(5)&(b)								
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V								
N .								
58.3								
11310								
950			1					
11.91								
e:	11310 950 11.91	11310 950 11.91 stic/Foreign/Follow-up In	11310 950 11.91 stic/Foreign/Follow-up Inspections r PAC 42002F, use resources as i	11310 950 11.91 stic/Foreign/Follow-up Inspections/Investigation r PAC 42002F, use resources as needed to a	11310 950 11.91 stic/Foreign/Follow-up Inspections/Investigations, DSCs as r PAC 42002F, use resources as needed to accomplish thi	11310 950 11.91 stic/Foreign/Follow-up Inspections/Investigations, DSCs as needed. r PAC 42002F, use resources as needed to accomplish this complian	11310 950 11.91 stic/Foreign/Follow-up Inspections/Investigations, DSCs as needed. r PAC 42002F, use resources as needed to accomplish this compliance progra	11310 950 11.91

		F	Y 2013 ORA WORKPLA	THE RESERVE THE PERSON NAMED IN			October 1, 2012
	GRAM/ASSIGNMENT TITLE			2. PPS PROJE	ECT NAME/NUMBER		
Impo	rted CBER-Regulated Products			Blood and I	Blood Products - 42		
3. PR0	OGRAWASSIGNMENT CODE(S)		4. WORK ALLOCATIO	N PLANNED BY	100	5. OPERATIONAL	ETE POSITIONS
	07, 42R833, 42R824, 99R833, 41R	824, 45R824			CENTER		1.0
R	6. DISTRICT/	2		T			
Ε	SPECIALIZED	IMPORT		1		1 1	
G	LABORATORY	INVESTI- GATION	1	1		1 1	
0	1	HOURS		1		1 1	
N		(1)		-			
	TOTAL FIELD	3800					
		(b)(5)&(b)					
9	REGIONAL STAFF	$(7)(E)$ _					
NE	NEW ENGLAND NEW YORK			-			
INC	REGIONAL LAB					-	
	WEAC			-			
	REGIONAL STAFF						
	BALTIMORE					1	
	CHICAGO						
1	CINCINNATI						
CE	DETROIT						
	MINNEAPOLIS	_					
	NEW JERSEY						
	PHILADELPHIA FORENSIC CHEM. CTR					-	
	REGIONAL STAFF			+			
	ATLANTA					+	
SE	FLORIDA			1			
	NEW ORLEANS					1	
	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF	_					P1 - 1977 C-10 - 1970
C14/	DALLAS	_					
SW	DENVER	_					
	SOUTHWEST IMPORT DISTRICT			1			
	REGIONAL LAB			-	<u> </u>	+	
	REGIONAL STAFF			1	-	+	
	LOS ANGELES					1	
PA	SAN FRANCISCO		2.00			1	
	SEATTLE						
	PACIFIC REGIONAL LABORATORY-SW	_					
	PACIFIC REGIONAL LABORATORY-NW	,					
	S PER OPERATION						
	HOURS ERSION FACTOR	3800 950		-			
THE REAL PROPERTY.	OPERATIONAL FTES	4.00		 			
9. REM		4,00					
Plann Filer E and In Repor	ALL resources are planned under Pa ed Resources are to cover ALL Imp Evaluation 99R833 and any inspecti International Mail Facilities reviews.	port Operatio ions needed ate PAC and	ons: Entry Review 42 under the C.P. for P Operation Code,	R833; Follow AC 42007. F	Resources also includ	e time for Mail C	₹824; ourier
Note: and Ti	C.P. 7342.007 "Imported CBER-Re issue-Based Products (HCT/Ps)" pr	gulated Proc rovides produ	ducts," and Addendu uct specific guidance	im "Imported	Human Cells, Tissue	s, and Cellular	

1. PRO	GRAM/ASSIGNMENT TITLE		1 2013 3161	World Ditt	2. PPS PROJE	CT NAME/NUM	/BER			1000
Inspe	ction of Licensed In-Vitro Diagnost	ic (IVD) De	evices		Blood and	Blood Produ	cts - 42			
55	ated by CBER									1
	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	ONAL FTE PO	OSITIONS
	42008A,F,G Domestic & Foreig	n (1)		Х	ORA	CENTE	-R		2.5	
	42000M,I, d Domestie & Foreig	(1)			1 0101		-10		2.5	
	6.	1	1	2		1				
R E	DISTRICT/ SPECIALIZED	DOMESTIC	FOREIGN	DOMESTIC						
G	LABORATORY	INSPEC- TIONS	INSPEC- TIONS	INVESTI- GATIONS		ė.				1 1
0		TIONS	HONS	(Hours)			1	1		1 1
N				(2)						
	TOTAL FIELD	9	5	426	<u> </u>					
		(b)(5)&(b)	(/)(E)					-		
	REGIONAL STAFF					ļ	 			
	NEW ENGLAND						<u> </u>			
NE	NEW YORK REGIONAL LAB							-		
	WEAC							1		
	REGIONAL STAFF								1	
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS					-				
	NEW JERSEY					-				
	PHILADELPHIA FORENSIC CHEM. CTR								 	
	REGIONAL STAFF							1		
	ATLANTA									
SE	FLORIDA					1			1	
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF					ļ			1	<u> </u>
	DALLAS					-	-	+		
SW	DENVER					-	_	+	-	-
	KANSAS CITY SOUTHWEST IMPORT DISTRICT					 		-	 	
	REGIONAL LAB							1		1
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									-
_	PACIFIC REGIONAL LABORATORY-NW				,				ļ	+
-	S PER OPERATION	140.1 1261	132.8 664			 	 	+	+	_
	L HOURS ERSION FACTOR	950	950		•	<u> </u>	 		 	1
	L OPERATIONAL FTES	1.33	0.70			1				
	MARKS	7100	077							
	ram Tille CHANGED from Licensed	Viral Mark	er Test Kits	to: License	ed In-Vitro D	iagnostic (IV	D) Device	s.		
l' log	Tall Tille O. I. at old month in the						_ /			
(1) F	REVISED Titles, PACs: 42008A Pr	e-License I	nspections	- IVDs:						
	08F - Level 1 Inspection - Licensed									
	08G - Level 2 Inspection - Licensed									
PAC	42008 retired.									
No	separate resources are planned for	Pre-Licens	e Inspectio	ns, use abo	ove resource	es as neede	d.			
(2) -	Field Investigation time is for Distric	t support to	Team Biol	ogics. Field	d Investigati	on Hours ma	ay be used	for any		
Tea	m Biologics Program.									
Repo	ort accomplishments under appropri	ate PAC ar	nd Operatio	n Code.						
All In	spections will be performed by Tea	m Biologics	; .							
1										
1										
1										
1										

Personnel Types required: Investigator

(1) DOMESTIC INSPECTIONS	4. WORK	ALLOCATION			5, OPERA	TIONAL FTE PO	DEITIONE
INSPEC-		1		CENTER		0.5	201110140
12							
(b)(5)&(b)							
(7)(E)							
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		 	 	 		+	_
		1		1		1	+
RY-SW		1		1		+	
RY-NW			†				
39.7		1					
476							
950							
0.50							
priate PAC and O	peration Co	ode.			sources as ne	eeded.	
4 4	riate PAC and O	riate PAC and Operation C	riate PAC and Operation Code.	riate PAC and Operation Code.	riate PAC and Operation Code.	riate PAC and Operation Code.	12845A,B,C in FY05

	DGRAMASSIGNMENT TITLE action of Plasma Derivatives of Hum	an Origin				ECT NAME/NU Blood Produ				
inspe	enon of Frasina Derivatives of Hun	ian Origin			Diood and	Blood Produ	cts - 42			
3. PR0	OGRAM/ASSIGNMENT CODE(S)	12100	4. WORK	ALLOCATION	PLANNED BY	1 100		5 OPERAT	TIONAL FTE PO	OSITIONS
42	848A,F,G; 42848B,C,D Domestic	& Foreign (STATE AND ADDRESS OF STATE OF	X	ORA	CENT	EB	0. 0. 2.01	3.3	001110110
, , , , ,					j Olot	CENT	LIK		3.3	
R	6. DISTRICT/	DOMESTIC	1 FOREIGN					1		
Ε	SPECIALIZED	LICENSED	LICENSED			1			1	i
G	LABORATORY	INSPEC- TIONS	INSPEC- TIONS	ı		1				1
0		, nons	HONS	1		1	l	1		
N		-								
	TOTAL FIELD	8	10							
<u> </u>	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF					1000000				
	NEW ENGLAND									
NE	NEW YORK					ļ				
1	REGIONAL LAB WEAC									
_	REGIONAL STAFF					-				
	BALTIMORE									
	CHICAGO									
	CINCINNATI								-	
CE	DETROIT									
0.00000	MINNEAPOLIS					1				
	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							l		
	REGIONAL LAB							1		
	REGIONAL STAFF									
	LOS ANGELES								la constitución de la constituci	
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW S PER OPERATION	420.0	040.0							
	. HOURS	130.0 1040	210.0 2100							
	ERSION FACTOR	950	950							
	OPERATIONAL FTES	1.09	2.21							
9. REM		1.00	2.21		water to the same of the same					
	No separate resources are planned	for Pre-Lice	ense Insnect	tions use at	OVA recour	cos as nood	ad			
All res	sources are planned under PAC 42	848F. 42	848A Pre-l	icensed Ins	nection - Pl	sema Deriva	su.			
42848	BF Level 1 CGMP Inspection - Plas	ma Derivati	ive: 42848	G Level 2 C	GMP Inspe	ction - Diser	na Dorivati			
NEW	PACs in FY2011: 42848B Pre-Lice	ensed Inspe	ection - Reco	ombinant An	alounes.	ction - Flasi	na Denvau	ves.		
428	348C Level 1 CGMP Inspection - Re	ecombinant	Analogues:	:	alogado,					
	348D Level 2 CGMP Inspection - Re									
		over the second		100						
Repo	rt ALL Accomplishments under App	ropriate PA	C and Oper	ation Code.						
	spections will be performed by Tear									
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1									
Team	Biologics Compliance Program Ne	w in FY05 -	Inspection of	of Biological	Drug Produ	icts (CBFR)	previously	covered l	by DAC 420	106

Personnel Types required: Team Biologics

PROJECT SUMMARY SHEET FY 2013 1. PROGRAM CATEGORY 2. PPS PROJECT NAME/NUMBER Biologics Vaccines and Allergenic Products - 45 3. NO. 4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS 5. PROGRAM 6. OPERATIONAL FTE 7. TOTAL 8. PAGE ASSIGNMENT OPERATIONAL CODE DOMESTIC IMPORT FTEs TOTAL 10.2 3.0 13.2 Bioresearch Monitoring Programs * 7.0 7.0 45-14 Good Laboratory Practices (Nonclinical Labs) 45808 Institutional Review Boards 45809 Sponsors, Monitors, and Contract Research Organizations 45810 Clinical Investigators * 45811 (7.0)Licensed Allergenic Products 45848A,F,G 0.7 0.7 45-15 (Team Biologics) 3 Licensed Vaccine Products 45848B,C,D 2.5 3.0 5.5 45-16 (Team Biologics) * All resources are planned under PAC 45811.

Janet Ishimoto 301-827-6220 FORM FDA 2622 (10/09)

CENTER PROJECT MANAGER/TELEPHONE

Harriet R. Gerber 301-796-4396
PAGE NO.

ORA PLANNER/TELEPHONE

45-13

1. PRO	GRAM/ASSIGNMENT TITLE			HOIGH EATH	2. PPS PROJE	CT NAME/NUM	MBER		- 0	tober 1, 2012
GLPs	, IRBs, Sponsor/Monitor/CROs, Cl	inical Investig	ators		ACCESS OF SECURE ACCESSORS	nd Allergenie		- 45		
	FA Domestic & Foreign)		,41010		vaccines ai	id Anergenic	Troducts	- 4 3		
-					L					
	GRAM/ASSIGNMENT CODE(S)	D10 300 0	4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	SITIONS
4580	08-GLPs, 45809-IRBs, 45810-Spor 45811 Clinical Investigator	/Mon/CROs,		Х	ORA	CENTE	ER		7.0	
R	6. DISTRICT/	1								
E	SPECIALIZED	INSPEC-							l	
G	LABORATORY	TIONS (1)							l	
0		`'				l				
N										
	TOTAL FIELD	68								
	HEADQUARTERS	(b)								
1	REGIONAL STAFF	(5)&(b)								
NE	NEW ENGLAND NEW YORK	(7)(E)	-							
INE	REGIONAL LAB	-						-		
1	WEAC	_		7200				 		
	REGIONAL STAFF							 		
	BALTIMORE			19	7			 		
1	CHICAGO									
	CINCINNATI									
CE	DETROIT						r pa			
1	MINNEAPOLIS									
1	NEW JERSEY	_								
1	PHILADELPHIA	_		-	-					
-	FORENSIC CHEM. CTR REGIONAL STAFF	_								
1	ATLANTA	_						-		
SE	FLORIDA	_								
U.	NEW ORLEANS									
1	SAN JUAN				_					
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
sw	DENVER	_								
ı	KANSAS CITY	_								
1	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	-								
	REGIONAL STAFF	_								
1	LOS ANGELES	-					-			
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
\vdash	PACIFIC REGIONAL LABORATORY-NW				100000000000000000000000000000000000000					
	S PER OPERATION	97.8								
-	HOURS	6650								
	RSION FACTOR OPERATIONAL FTES	950 7.00								
9. REM		7.00								
Resor	Use above resources for Foreign In urces for PACs 45809, 45810, and ctions are to be conducted only what accomplishment hours under app	45811 are pla en assignmer	anned und its are rec	er PAC 458	311 Clinical	ions under (Investigator	Operation (Code 11.		
Perso	nnel Types required: Investigator									

1. PRO	GRAM/ASSIGNMENT TITLE	CONTROL OF THE CONTRO	1 2015 0101		2. PPS PROJE	ECT NAME/NUM	MBER			1000: 1, 2012
Inspe	ction of Licensed Allergenic Produc	ts (Post-Ma	rket & Pre-	License)	Vaccines as	nd Allergenic	Products	- 45		
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	8		5. OPERATIONAL FTE POSITIONS		
	45848A,F,G Domestic & Foreig	n (1)		X	ORA	CENTE	R		0.7	
R	6. DISTRICT/	1								
E G	SPECIALIZED LABORATORY	DOMESTIC INSPEC-						l .		
1		TIONS			1					
0 2										
*****	TOTAL FIELD	5								
	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
NE	NEW YORK	_								
	REGIONAL LAB	-				-				
	WEAC	-						-		
	REGIONAL STAFF	-				-				
	BALTIMORE CHICAGO									
	CINCINNATI					1		†		
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR	_								
	REGIONAL STAFF									
	ATLANTA	-						-		
SE	FLORIDA	-				-		-		
	NEW ORLEANS	-				-				_
	SAN JUAN REGIONAL LAB	-			-	 		 		
	REGIONAL STAFF	-								
	DALLAS					!		1	 	
sw	DENVER							1	1	
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				472					
	REGIONAL LAB	_								
	REGIONAL STAFF	_								
	LOS ANGELES	-						_		ļ
PA	SAN FRANCISCO	-				_				-
	PACIFIC REGIONAL LABORATORY-SW	-						+	-	-
	PACIFIC REGIONAL LABORATORY-NW	-				 	 	-	-	
HOUR	S PER OPERATION	133.0								
	HOURS	665								
CONV	ERSION FACTOR	950								
TOTAL	OPERATIONAL FTEs	0.70								
(1) - I appro 4584 4584 4584	Resources are planned under PAC opriate PAC and Operation Code (for 8A Pre-License Inspection - Allergo 8F Level 1 CGMP Inspection - Alle 8G Level 2 CGMP Inspection - Alle nspections will be performed by Te	oreign inspe enics; rgenics; ergenics.	ection is ope	es as needo	ed for dome e 11).	stic or foreig	n inspectio	ons, and re	port under	
Perso	onnel Types Required: Team Biolog	gics								

Inspec	GRAM/ASSIGNMENT TITLE ction of Licensed Vaccine Products Market)				PETERS OF THE PETERSON OF T	ECT NAME/NUMB			
					37	1 4 11			
					LV accines at	nd Allergenic F	roducts - 45		
					, accines a	de / mergeme i	roducts - 45		
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY		5. OPER	ATIONAL FTE P	OSITIONS
1	45848B,C,D Domestic & Foreign	gn (1)		X	ORA	CENTER		5.5	
					joint	OLIVIER	1	3.3	
	6.	1	1						1
R E	DISTRICT/ SPECIALIZED	DOMESTIC	FOREIGN		1	1 1	1		1
G	LABORATORY	INSPEC-	INSPEC-			1 1	- 1		
1		TIONS	TIONS			1 1	1		
ON		1				1 1			
"									
	TOTAL FIELD	10	13						
	HEADQUARTERS	(b)(5)&(b)((7)(E)						
	REGIONAL STAFF								
	NEW ENGLAND								
NE	NEW YORK								
	REGIONAL LAB							1	
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								t
	CHICAGO								<u> </u>
	CINCINNATI								
CE	DETROIT								
l	MINNEAPOLIS								—
	NEW JERSEY								1
	PHILADELPHIA								
1 1	FORENSIC CHEM. CTR								-
	REGIONAL STAFF								
	ATLANTA								
SE	FLORIDA								
	NEW ORLEANS								1
	SAN JUAN							1	
	REGIONAL LAB								
	REGIONAL STAFF								•
1	DALLAS								-
sw	DENVER								
1 [KANSAS CITY								-
1 [SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
I [LOS ANGELES								
PA	SAN FRANCISCO								
10000000	SEATTLE								-
1 [PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								†
HOURS	PER OPERATION	239.0	220.0						
TOTAL	HOURS	2390	2860			 			
CONVE	RSION FACTOR	950	950						
TOTAL	OPERATIONAL FTEs	2.52	3.01						1
9. REM.	ARKS								
Repor All Ins 45848 45848 45848	tesources are planned under PAC t Foreign Inspections under Opera pections will be performed by Tear B Pre-License Inspection - Vaccine C Level 1 CGMP Inspection - Vac D Level 2 CGMP Inspection - Vac	tion Code 1 n Biologics. es; ccines; ccines.	1.						
	eam Biologics Compliance Progra			ot Biologica	ai Drug Prod	aucts (CBER):	(Previously cove	ered by PAC	45002).

CENTER FOR DRUG EVALUATION AND RESEARCH RESOURCE SUMMARY FY 2013

		OPE	RATIONAL F	TES	TOTAL OPERATIONAL
PPS NO.	PROJECT TITLE	DOMESTIC	IMPORT	FOREIGN	FTEs
	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

		2. PPS PROJECT NAME/NUMBER							
	GRAM CATEGORY			R					
пиша	n Drugs	New Drug Eval	luation - 46						
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT		PERATIONAL	. FTE	7. TOTAL OPERATIONAL	8. PAGE		
		CODE	DOMESTIC	IMPORT	FOREIGN	FTEs			
	TOTAL		11.0		14.0	25.0			
1	NDA Pre-Approval Inspections/Investigations	46832/B/C	9.5			9.5	46-02		
	- Domestic (PDUFA)								
2	NDA Pre-Approval Inspections/Investigations	46832/B/C		- P	13.0	13.0	46-03		
	- Foreign (PDUFA)								
3	Pre-License Biotech (BLA) - (PDUFA)	46832M	1.0		1.0	2.0	46-04		
	Inspections/Investigations - Domestic/Foreign								
4	Positron Emission Tomography (PET) Pre-Approval	46832P	0.5			0.5	46-05		
<u> </u>	Inspections/Investigations	400321	0.5			0.5	40-00		
-	inspections/investigations	-							
-		_							
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				545 <u>-</u> 471 - 5					

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	100000								
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-									
OENTE	D DDO IECT MANACEDITE! FRUONE			ND4 51 1111					
Brian H	R PROJECT MANAGER/TELEPHONE asselbalch, HFD-320, (301) 796-3279; Diane Raccasi, HFD-320,	(301) 796-3927			R/TELEPHON Curdy 301-79				

FY 2013 ORA WORKPLAN October 1, 2012 I. PROGRAM/ASSIGNMENT TITLE 2. PPS PROJECT NAME/NUMBER											
. PRO	GRAM/ASSIGNMENT TITLE		10.50								
NDA	Pre-Approval Inspections/Investiga	ations - Don	nestic (PDIII	FA)	New Drug I	Evaluation -	46				
			(120)	Tien Diag I	Evaluation -	-10				
B. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	TIONAL FTE PO	OSITIONS	
	46832, 46832B, 46832C, 46R	845		X	ORA	CENT	FR		9.5		
	, , , , , , , , , , , , , , , , , , , ,	70.00							7.3		
	6.	1	1	3	7						
R	DISTRICT/ SPECIALIZED		CHEMIST	DOMESTIC	DOMESTIC SAMPLES	1	1	1	1		
G	LABORATORY	INSPECTIONS		SAMPLE	TOBE	1		1			
1			(Hours)	COLL	ANALYZED	l	l.	1	1	l	
ON		1	(1)	CHEM	PROFILE			1			
			-		CHEM		 	 			
	TOTAL FIELD	141 (b)(5)2 (b)	703	17	35						
	HEADQUARTERS	(b)(5)&(b)(
	REGIONAL STAFF	4									
	NEW ENGLAND	-									
	NEW YORK										
-	REGIONAL LAB	_									
	WEAC	-									
	REGIONAL STAFF										
ļ	BALTIMORE								(9)		
	CHICAGO										
	CINCINNATI										
	DETROIT										
ļ	MINNEAPOLIS										
	NEW JERSEY										
- 1	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF									10.100.10	
- 1	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
-	REGIONAL LAB						-10,000				
	REGIONAL STAFF										
	DALLAS										
	DENVER	1									
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
$\overline{}$	REGIONAL LAB	ŀ									
-	REGIONAL STAFF										
-	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE						_				
	PACIFIC REGIONAL LABORATORY-SW										
COLUMN TWO IS NOT THE OWNER.	PACIFIC REGIONAL LABORATORY-NW			- 1							
	PER OPERATION	55.8		7.1	11.8			_			
	HOURS	7868	703	121	413						
	RSION FACTOR OPERATIONAL FTEs	950 8.28	950 0.74	950	1180						
. REM.		0.20	0.74	0.13	0.35						
000	ncludes Microbiologists on Inspec atory allocations were planned by										
	EDA 2621a /10/09\	004	WORKE		IC SHEE.	- 10					

	OGRAM/ASSIGNMENT TITLE	`	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46									
INDA	Pre-Approval Inspections/Investigat	iions - Fore	eign (PDUFA	.)	New Diag Evaluation - 40							
3. PRO	OGRAM/ASSIGNMENT CODE(S)	- 1000	4. WORK	ALLOCATION	PLANNED B	Υ		5. OPERAT	IONAL FTE PO	OSITIONS		
	(1) 46832, 46832B, 46832C, 468	332D		X	ORA	CENT	ER		13.0			
					T							
R E G	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	CHEMIST ON INSPECTIONS (Hours)				6					
0						1						
N		(2)	(3)			+	 	 				
-	TOTAL FIELD	98 (b)(5)&(b			-	+	 	-				
\vdash	HEADQUARTERS REGIONAL STAFF		\(\(\C)		1	+	1					
	NEW ENGLAND				 		1	1				
NE	NEW YORK											
	REGIONAL LAB											
	WEAC							-				
	REGIONAL STAFF				-							
	BALTIMORE CHICAGO				-			1				
	CINCINNATI					1		1				
CE	DETROIT				<u> </u>							
"-	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
	REGIONAL STAFF				<u> </u>		 					
0.5	ATLANTA			_			 		-			
SE	FLORIDA NEW ORLEANS				 	+	 	 	-			
	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
SW	DENVER							_				
	KANSAS CITY				-		-					
	SOUTHWEST IMPORT DISTRICT				ļ				-			
-	REGIONAL LAB REGIONAL STAFF				 		 					
	LOS ANGELES				<u> </u>		 	†				
PA	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW											
	PACIFIC REGIONAL LABORATORY-NW											
_	S PER OPERATION	70.2			-	+	-	+		-		
	HOURS	6880 950			 		1	+	 	 		
	ERSION FACTOR L OPERATIONAL FTEs	7.24						1	 			
	MARKS								A			
	Use PAC 46832D to report work or Report as follows: Insps./Chem o							EPFAR).				
	M. Valid 46832; Profile ISCs & IS	As - 46832	2B; Biotest I	SCs & ISA	s (not plan	ned) if collec	ted - 4683	2C.				
(3) -	Includes Microbiologists on Inspec	tions.										
Labo	oratory allocations were planned by	DFFI.										

OGRAM/ASSIGNMENT TITLE Licensed Biotech (BLA) Inspections/				2. PPS PROJ	ECT NAME/NU	MRED							
icensed Biotech (BLA) Inspections/								2. PPS PROJECT NAME/NUMBER					
nochibed Dieteen (DLII) Inopections	Investigatio	ns -		New Drug Evaluation - 46									
estic and Foreign (PDUFA)													
OGRAM/ASSIGNMENT CODE(S)		4 WORK	ALLOCATION	DI ANNED BY	,		E ODEDAT	TONAL ETE D	001710110				
		4. WORK	even acroserance				5. OPERA		OSITIONS				
46832M			X	ORA	CENT	ER		2.0					
6.	1	1					-						
	INSPECTIONS	NERECTIONS			ı	1	1						
LABORATORY	Domestic	Foreign					l						
	(4)			v.		1	1	l .					
	(1)												
TOTAL FIELD	6	9											
		W - 1 / 1				_							
REGIONAL STAFF													
NEW ENGLAND													
NEW YORK													
						-							
MINNEAPOLIS													
NEW JERSEY													
PHILADELPHIA							2						
FORENSIC CHEM. CTR					111.754								
REGIONAL STAFF													
			-										
													
DALLAS													
DENVER													
KANSAS CITY													
PACIFIC REGIONAL LABORATORY-NW													
	152.9	110.2											
	917	992											
	0.97	1.04					L						
Includes Microbiologists on Inspect	ions.												
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3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. DOMESTIC		L FTE FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE						
	TOTAL	OODE	62.9		24.5	87.4							
1	In Vivo Biocquivalence - ANDAs & NDAs	48001, A	6.5			6.5	48-07						
	PDUFA (NDAs)		(3.3)										
	Foreign Inspections (In Vivo Bioequivalence,	48001, A;			7.2	7.2	48-08						
	GLPs)*	48808											
	* Foreign Inspections PEPFAR (AIDS Relief)	48001D, E;					The state of the s						
	(planned under 48001A and 48001)	48808, 48811D											
2	Bioresearch Monitoring						48-09						
	Good Laboratory Practices (Non-Clinical Lab)	48808	3.1			3.1							
	National Experts		(0.1)										
	** Institutional Review Board	48809, 48809A	10.0			10.0							
	Sponsors, Contract Research Organizations,	48810	6.3			6.3	0.000						
	and Monitors												
3	Clinical Investigators	48811, F	37.0		17.3	54.3	48-10						
	National Experts		(0.1)		(2.2)								
	* - PEPFAR work is not planned separately, NDA PEPFAR	resources are planned u	ınder 48001	A and AND	A PEPFAR								
	resources are planned under 48001.												
	** - Resources in the Radioactive Drug Research Committee	(48809A) have been o	collapsed in	o Institution	al Review Bo	oard (48809).							
			***************************************				The p						
	A CONTRACTOR OF THE CONTRACTOR												
	R PROJECT MANAGER/TELEPHONE Salewski, HFD-45, (301) 796-3395				ER/TELEPHON Curdy 301-79								
	Service Annual Control of the Contro					oseph Salewski, HFD-45, (301) 796-3395 Anita T. McCurdy 301-796-4395							

1. PRC	OGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER							
In Vi	vo Bioequivalence - Pre-Approval (I		Bioresearch Monitoring: Human Drugs - 48							
3. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	TION PLANNED BY 5. OPERATIONAL FTE POSITIONS					
	48001 (ANDAs), 48001A (N	DAs)		X	ORA	CENT	ER		6.5	
R E G - O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPECTIONS	1 48001A NDA INSPECTIONS							
N	TOTAL FIELD	36	37							
	HEADQUARTERS	(b)(5)&(b)	(7)(E)						1	
	REGIONAL STAFF					1				
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC					1				
	REGIONAL STAFF									2001-000
	BALTIMORE									
	CHICAGO									
1220-20	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
22 2	FORENSIC CHEM. CTR							-	-	
	REGIONAL STAFF					-				
SE	ATLANTA FLORIDA							-		
SE	NEW ORLEANS							_		
	SAN JUAN					-		-		
	REGIONAL LAB					-		-		
	REGIONAL STAFF								 	
	DALLAS							-		
sw	DENVER				-	1		+		
	KANSAS CITY				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	†		1		
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW					A	(3)			
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION	85.4	84.3							
	HOURS	3074	3119							
	ERSION FACTOR	950	950							
REM	OPERATIONAL FTES	3.24	3.28							
Assigi	nments issued by the Center will id timate of percentage of time for ear				_			DA) 55%.		
Please	e note: District inspection allocation	n may be si	ubject to ch	ange as a i	result of CE	DER's final si	ite selectio	ns.		

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJECT NAME/NUMBER					
Foreig	n Inspections (NDA - PDUFA; AN	NDA - PRE	-APPROVA	L)	Bioresearch	Monitoring:	Human Di	ugs - 48		
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	ONAL FTE PO	SITIONS
		1110	0 00000000	Х		CENTE		7.2		
	48001,A; 48808; 48001D,E, 488 NDA & ANDA (1)	IID		^	JORA	CENTE	:K		1.2	
	6.	1	1							
R E G - O Z	DISTRICT/ SPECIALIZED LABORATORY	FOREIGN 48001A NDA INSPECTIONS (PDUFA)	FOREIGN 48001 ANDA INSPECTIONS (PRE-APPVL)							
	TOTAL FIELD	33	32							
	HEADQUARTERS	(b)(5)&(b))(7)(E)							
	REGIONAL STAFF									
1	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF						1,000			
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB					H 28° - 22°				
	REGIONAL STAFF						500 00000000000000000000000000000000000			
	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									
HOUR	S PER OPERATION	108.0	102.8							
TOTAL	HOURS	3564	3290							
CONV	ERSION FACTOR	950	950							
TOTAL	OPERATIONAL FTEs	3.75	3.46							

(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.

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.

TOTAL HOURS

HOURS PER OPERATION

CONVERSION FACTOR

TOTAL OPERATIONAL FTES

PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW

NEW

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

118.8

21028

950

22.13

102

950

0.11

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

119.1

14054

950

14.79

94.0

950

17.32

16450

FY 2013

		FY 2013				TO THE REAL PROPERTY AND A STREET OF THE PERSON OF THE PER	
	GRAM CATEGORY n Drugs	2. PPS PROJECT Generic Drug I					
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. C	PERATIONAL	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL		8.4	IIIII OTT	12.0		
1	ANDA Pre-Approval Domestic	52922 B C	*		12.0		
4000		52832, B, C	5.0			5.0	52-12
2	ANDA Pre-Approval Inspections/Investigations - Foreign	52832, B, C, E			12.0	12.0	52-13
3	Positron Emission Tomography (PET) Pre-Approval	52832P	2.4				
3		32832P	3.4			3.4	52-14
	Inspections/Investigations						
	6						
							- Interior
							-
	The state of the s						
-							
							10
		_					
1							
		-					
ENTER	PROJECT MANAGER/TELEPHONE		C	DRA PLANNE	R/TELEPHON	E	*****
rian H	asselbalch, HFD-320, (301) 796-3279; Diane Raccasi, HFD-320,	(301) 796-3927	1	Anita T. McC	Curdy 301-79	6-4395	

			FY 2013 ORA	WORKPLAN					0	ctober 1, 2012
	OGRAM/ASSIGNMENT TITLE					ECT NAME/NU				
AND	A Pre - Approval Inspections/Inves	stigations - I	Domestic		Generic Dr	ug Evaluatio	n - 52			
3 PR(OGRAM/ASSIGNMENT CODE(S)		4 MORK	ALLOCATION	DI ANNED DY			Te openie		
0.11			4. WORK	4. WORK ALLOCATION PLANNED BY				5. OPERA	TIONAL FTE P	DSITIONS
	52832, B, C			X	ORA	CENT	ER		5.0	
\vdash	[6.	1	3	7	7			+		
R	DISTRICT/	l		DOMESTIC	DOMESTIC	l		1	1	
E G	SPECIALIZED LABORATORY	ANDAS TO INSPECT	DOMESTIC SAMPLE	SAMPLES TO BE	SAMPLES TO BE	1	1	1		
1		10 Million 201	COLL	ANALYZED	ANALYZED	l			1	
O		1 1		PROFILE CHEM	BIOTEST		l		1	
"	TOTAL FIGUR	 			CHEM			+		
	TOTAL FIELD	66	35	13	22					
	HEADQUARTERS	(b)(5)&(b)	(/)(⊏)							
	REGIONAL STAFF NEW ENGLAND									
NE	NEW YORK									
INE	REGIONAL LAB									
	WEAC							-		
	REGIONAL STAFF							 	 	
	BALTIMORE							 	 	
	CHICAGO							1		
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS							1		
	NEW JERSEY									
	PHILADELPHIA							0.000000		
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	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 NIV									
HOUR	PACIFIC REGIONAL LABORATORY-NW S PER OPERATION	E2.4	0.7	50.0	20.5					
	HOURS	53.1 3505	6.7 235	50.0 650	28.5 627					
	ERSION FACTOR	950	950	1180	1180			_		
	OPERATIONAL FTEs	3.69	0.25	0.55	0.53					
	IARKS									
abor	atory allocations were planned by I	756								
Labor	atory anocations were planned by t	Jrs.								
0000	ED A 2004 - (40/00)	ODA	MODE	I ALIAHAA IC	G SHEE	T (C == 1"	- N			
OKM	FDA 2621a (10/09)	UKA	WUKKE	LANNIN	G OHEE	ı (Contir	med)		PAGE NO.	52-12

FY 2013 ORA WORKPLAN

		1	Y 2013 ORA						. Oc	tober 1, 2012
1. PRC	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NUM	BER			
AND	A Pre - Approval Inspections/Inves	tigations - Fe	oreign		Generic Dru	ig Evaluation	- 52			
3. PRC	GRAM/ASSIGNMENT CODE(S)	4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	SITIONS	
	52832, 52832B ,52832C, 52832E			X ORA CENTER 12				12.0		
	J2032, J2032D ,J2032C, J200	,	1		0.01		,			
R E G	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 CHEMIST INSPECTIONS	2 INVESTI-	4 IMPORT SAMPLE	8 IMPORT SAMPLES TO BE	8 IMPORT SAMPLES TO BE			
- 0 z		(1) (Foreign) (2)	(Hours) (Foreign) (3)	GATIONS (Hours)	COLL (4)	ANALYZED PROFILE CHEM (5)	ANALYZED BIOTEST CHEM (5)			
	TOTAL FIELD	83	2200	147	151	75	76			
	HEADQUARTERS	(b)(5)&(b)	(7)(ヒ)							
	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									
L	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW						100000	,		
	S PER OPERATION	79.7			3.0					
	HOURS	6615	2200	147	453		1178	-		
	ERSION FACTOR	950	950	950			1180			
_	OPERATIONAL FTEs	6.96	2.32	0.15	0.48	1.07	1.00			
9. REM	MARKS									

- (1) Report as follow: Insps./Chem on Insps. under foreign operation code 11 Pac Code 52832;
- (2) PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

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

- (3) Includes microbiologists on inspections
- (4) Samples are collected at foreign manufacturers.
- (5) NRL analyzes all Profile/Biolest ISCs and methods development ISAs.

Laboratory allocations were planned by DFS. Chem-On foreign inspsections planned by DFFI.

1. PRO	GRAM/ASSIGNMENT TITLE		I 1 2013 OKA WORKFLA	_	JECT NAME/NU	MRER			lober 1, 2012		
					Generic Drug Evaluation - 52						
	on Emission Tomography (PET) Pr	e-Approvai		Generic D	rug Evaluatio	n - 52			1		
Inspe	ctions/Investigations				Control of the Contro				- 1		
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK ALLOCATION PLANNED BY				5 OPERAT	IONAL FTE PO	SITIONS		
	52832P			X ORA X CENTER			0.012.01				
	328321		-	A ONA A CENTER				3.4			
\vdash	6.	1			T	1					
R E	DISTRICT/ SPECIALIZED	ANDA	l l	1	1				1		
G	LABORATORY	PET		1					1		
1		INSPEC-		1	1						
0 0		TIONS (1)		1							
2.500	TOTAL FIELD	150									
	HEADQUARTERS	(b)									
	REGIONAL STAFF	(5)&(b)									
	NEW ENGLAND	(7)(E)									
NE	NEW YORK	(1)(L)									
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
	BALTIMORE		0.75	700							
	CHICAGO		a management and		A construction of						
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS										
l	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS			+							
SW	DENVER				<u> </u>						
SE	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB			+	 						
	REGIONAL STAFF										
	LOS ANGELES			+					-		
PA	SAN FRANCISCO			+							
	SEATTLE			 							
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW			+							
HOUSE	PER OPERATION	21.5		+							
	HOURS	3225		1							
	RSION FACTOR	950		+							
	OPERATIONAL FTEs	3.39		1					-		
9 REM		0.00									

(1) - Inspections are to determine compliance of establishments with GMPs prior to approval of pending ANDAs. ANDA bulk products are collected for profile analysis.

FY 2013

	GRAM CATEGORY n Drugs	2. PPS PROJECT Postmarketing			niology: U.	ıman Druge 52	
3. NO.	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM		PERATIONAL	35330	7. TOTAL	8. PAGE
	a	ASSIGNMENT CODE	DOMESTIC	IMPORT	LEOREIGN	OPERATIONAL FTEs	
	TOTAL		9.8	IIVII OITT	1.0		
1	Enforcement of the Adverse Drug	53001A	7.7				53-16
	Experience Reporting Regulation (Domestic/Foreign)		,		1	6.7	33-10
2	Experience Reporting Regulation REMS (PDUFA)	52001C	2.1				
	Experience Reporting Regulation REMS (FDOFA)	53001C	2.1			2.1	53-17
							-
A							
				6. (6.00) 2.	100		

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		_					
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1	7,000						
\dashv							
\dashv							
\dashv		_					
	220 1507 1111 052 751 521 017						
	PROJECT MANAGER/TELEPHONE Barone, HFD-330, (301) 796-3224		9	ORA PLANNE	NAL FTE	IE 06_4305	
	DA 0000 (40/00)			mu 1. WIC	July 301-75	- 1 373	

				October 1, 20 2. PPS PROJECT NAME/NUMBER						
ement of the Adverse Drug Experi	ence Report	ing Regulation	on	Postmark	eting Surveill	ance and l	Epidemiolog	y: Human I	Orugs - 53	
RAM/ASSIGNMENT CODE(S)		4. WORK A	LLOCATION	N PLANNED	BY		5 OPERA	TIONAL FTE F	POSITIONS	
					Transaction and the second	TER	O. O. E.O.		001110143	
5500111(1)		335-77] 0.00		ILIX		0.7		
DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS								
TOTAL FIELD	03	15		┼──	+	+-	_	 	-	
	(b)(5)&(b)	(7)(E)		_	+	+-	+		+	
						1	_		 	
				1		1	1			
IEW YORK							+-			
			W 177 H 3					-		
VEAC										
EGIONAL STAFF										
ALTIMORE			N 15850							
CHICAGO									1	
CINCINNATI				10571100						
ETROIT										
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		-		_						
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The second secon		-		-				L		
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		-						1		
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EGIONAL STAFF										
OS ANGELES										
									1	
EATTLE										
ACIFIC REGIONAL LABORATORY-SW					20 (20				100000	
ACIFIC REGIONAL LABORATORY-NW										
PER OPERATION	78.6	63.5								
	7310	953								
	950		the factor of							
PERATIONAL FTES RKS	7.69	1.00								
	SPECIALIZED	DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD EADQUARTERS EGIONAL STAFF IEW ENGLAND IEW YORK REGIONAL LAB VEAC EGIONAL STAFF INLIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS IEW JERSEY CHILADELPHIA CORENSIC CHEM. CTR EGIONAL STAFF ITLANTA LORIDA IEW ORLEANS IAN JUAN REGIONAL LAB EGIONAL LAB EGIONAL LAB EGIONAL STAFF CALLAS DENVER EANSAS CITY COUTHWEST IMPORT DISTRICT IEGIONAL LAB EGIONAL STAFF OS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW DER OPERATION OURS 5100 FACTOR 78.6 7310 950	DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD EADQUARTERS EGIONAL STAFF IEW ENGLAND IEW YORK REGIONAL LAB VEAC EGIONAL STAFF IALTIMORE HICAGO CINCINNATI DETROIT HINNEAPOLIS IEW JERSEY PHILADELPHIA ORENSIC CHEM. CTR EGIONAL STAFF IALLANTA LORIDA LEW ORLEANS EAN JUAN REGIONAL LAB EGIONAL STAFF OCHEM. CTR EGIONAL STAFF OC	DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD TOTAL FIELD BAS 15 EADQUARTERS EGIONAL STAFF INEW ENGLAND IEW YORK REGIONAL LAB VEAC EGIONAL STAFF INITIANORE CHICAGO CINCINNATI DETROIT MININEAPOLIS IEW JERSEY PHILADELPHIA ORENSIC CHEM. CTR EGIONAL STAFF ITLANTA LORIDA IEW ORLEANS IAN JUAN IEGIONAL LAB EEGIONAL LAB EEGIONAL LAB EEGIONAL LAB EEGIONAL LAB EEGIONAL STAFF OALLAS IEW ORLEANS IAN JUAN IERONAL STAFF OS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-NW PER OPERATION 78.6 63.5 OURS 7310 953 SION FACTOR 950 950	DISTRICT/ SPECIAL IZED LABORATORY DOMESTIC INSPECTIONS TOTAL FIELD EADQUARTERS EGIONAL STAFF JIEW ENGLAND JIEW YORK REGIONAL LAB VEAC EGIONAL STAFF JALTIMORE HICAGO CINCINNATI JETROIT MINNEAPOLIS JEEW JERSEY PHILADELPHIA ORENSIC CHEM. CTR EGIONAL STAFF JILLANTA LORIDA LEW ORLEANS JAN JUAN LEGIONAL LAB EGIONAL LAB EGIONAL STAFF JALLAS JEW ORLEANS JEW ORLEANS JAN JUAN LEGIONAL LAB EGIONAL STAFF ANLAS ANSAS CITY OUTHWEST IMPORT DISTRICT JEEGIONAL LAB EGIONAL STAFF OS ANGELES AN FRANCISCO EATTLE ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-SW ACIFIC REGIONAL LABORATORY-NW PER OPERATION 78.6 63.5 OURS 7310 953 SION FACTOR 950 950	DISTRICT/ SPECALIZED LABORATORY TOTAL FIELD BADQUARTERS EGIONAL STAFF IJEW ENGLAND IEW YORK REGIONAL STAFF IJALTIMORE HIGHORE HIGHOR	DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD BASSEC-TIONS TOTAL FIELD EADQUARTERS EGIONAL STAFF SIEW ENGLAND SEEGIONAL STAFF SIEW ENGLAND SEEGIONAL STAFF SEIGNAND SEEGIONAL STAFF SEIGNAND SEEGIONAL STAFF SEIGNAND SEEGIONAL STAFF SEIGNAND SEEGIONAL STAFF SEIGNINNATI SETROIT SETROIT SETROIT SETROIT SETROIT SEEW JERSEY HILLADELPHIA ORENSIC CHEM CTR SEGIONAL STAFF STLANTA LORIDA SEEGIONAL STAFF STLANTA LORIDA SEGIONAL STAFF SEIGNAN SIAFF SEIGNAN	S3001A (1) DISTRICT/ SPECIAL ZED LABORATORY DOMESTIC INSPEC.	S3001A (1) X ORA X CENTER 8.7	

	GRAM/ASSIGNMENT TITLE Evaluation and Mitigation System ()	PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53								
BBO	GRAM/ASSIGNMENT CODE(S)		4 WORK ALLOCATIO							
. PRO	53001C		4. WORK ALLOCATION PLANNED BY ORA X CENTER				5. OPERATIONAL FTE POSITIONS 2.1			
R	6. DISTRICT/	1		Т			Т			
EG-ON	SPECIALIZED LABORATORY	INSPEC- TIONS (1)		,						
14	TOTAL FIELD	27								
	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)			 					
NE	NEW ENGLAND NEW YORK	-		-	 			-		
NE	REGIONAL LAB	_			 		_			
	WEAC	_								
	REGIONAL STAFF									
	BALTIMORE	_								
	CHICAGO				 		_			
or.	CINCINNATI			-	 					
CE	DETROIT MINNEAPOLIS				 					
	NEW JERSEY							1		
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	_						-		
SE	FLORIDA	_		-	 			-		
	NEW ORLEANS				 			-		
	SAN JUAN REGIONAL LAB	-		-	 					
	REGIONAL STAFF			1			+			
	DALLAS	_		1				 		
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT	_		1				-		
	REGIONAL LAB	_			-			+		
	REGIONAL STAFF	_			 					
PA	LOS ANGELES SAN FRANCISCO	_								
PA	SEATTLE			1				1		
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	72.6								
	HOURS	1960								
	ERSION FACTOR	950								
	OPERATIONAL FTES	2.06		1						
(1) - i	Because of the complexity and indinspection. Forward EIRs directly to see note: District inspection allocation	CDER's Divi	ision of Safety Com	pliance (CDE	ER/OC/OSI).		nducting			

FY 2013

1. PROGRAM CATEGORY 2. PPS PROJECT NAME/NUMBER Human Drugs Drug Quality Assurance - 56 3. NO. 4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS 5. PROGRAM 6. OPERATIONAL FTE 7. TOTAL 8. PAGE **ASSIGNMENT** OPERATIONAL CODE DOMESTIC IMPORT FOREIGN **FTEs** TOTAL 115.5 49.0 74.0 238.5 Drug Process Inspections - Domestic 56002A,B,D* 48.0 48.0 56-19 2 Foreign Drug Process Inspections 56002A-D* 62.0 62.0 56-20 3 Drug Process Inspections - Gas Manufs. 56002E 12.0 12.0 56-21 Drug Process Inspections - API Manufs. (Domestic/Foreign) 4 3.0 56002F, L* 10.0 13.0 56-22 5 Drug Process Inspections - Biotech Manufacturers 56002M 6.0 6.0 56-23 Positron Emission Tomography (PET) Pre-Approval 56002P, Q* 2.0 2.0 56-24 Inspections/Investigations 7 Drug Quality Sampling and Testing Program 56008A, L 18.0 18.0 56-25-26 Drug Product Surveillance - Import Drugs 8 56008H*** 49.0 49.0 56-27 9 Drug Quality Reporting System - DQRS 56021A, B 4.5 4.5 56-28 Enforcement of Rx Drug Marketing Act (PDMA) 10 56022, A 2.0 2.0 56-29 11 Post-Approval Inspections/Investigations - Domestic 56843 2.0 2.0 56-30 12 Post-Approval Inspections/Investigations - Foreign 56843 2.0 2.0 56-31 Pharmacy Compounding Assignments 13 56D015 2.0 2.0 56-32 14 DPI - Global Parity Initiative 56R010 4.0 4.0 56-33 15 DPI - OEI Clean Up 56R011 2.0 2.0 56-34 16 Forensic Evaluation and Sample Analysis 56R838**** 10.0 10.0 56-35 * 56002H-L Q (Abbreviated); Additional 56832, 56R359 *** 56R824, 56R833, 99R833 **** 56R831 CENTER PROJECT MANAGER/TELEPHONE ORA PLANNER/TELEPHONE Kathleen Anderson, HFD-310, (301) 796-3309 Anita T. McCurdy 301-796-4395

TOTAL HOURS

REGIONAL LAB
REGIONAL STAFF
LOS ANGELES
SAN FRANCISCO
SEATTLE

HOURS PER OPERATION

TOTAL OPERATIONAL FTES

CONVERSION FACTOR

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

1900

950

2.00

2499

950

2 63

1200

950

1 26

76.2

950

34.97

33223

(2) - DSCs not analyzed are documentary samples.

PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW

(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.

NEW

* The following PACS are for Abbreviated Inspections

56002H - ABBREVIATED DRUG PROCESS INSPECTIONS (DPI)

560021 - ABBREVIATED DPI / SMALL VOLUME PARENTERALS

56002J - ABBREVIATED DPI / DRUG REPACKERS AND RELABELLERS

56002K - ABBREVIATED DPI / RADIOACTIVE DRUGS

Laboratory allocations were planned by DFS.

7.9

1548

950

1.63

36.8

5741

1180

4.87

18.0

720

1180

0.61

1. PRO	GRAM/ASSIGNMENT TITLE		1 1 2013 OKA	WORKITAN		DJECT NAME/NUI	MBER	92 - 500		100er 1, 2012
	gn Drug Inspections					ality Assurance				
rorei	gn Drug mspections				Diug Qua	ility Assurance	- 50			
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK A	LLOCATION	PLANNED BY	Y		5. OPERAT	IONAL FTE PO	SITIONS
	56002, A, B, C, D, 56832, 56	R359		X	ORA	CENTE	ER		62.0	
					-					
R	6. DISTRICT/	1	1							
E	SPECIALIZED	FOREIGN	CHEMIST ON							
G	LABORATORY	INSPEC-	INSPECTIONS FOREIGN			1			i	
0		TIONS	(Hours)		1			1		
Ň		(1)	(2)							
	TOTAL FIELD	659	7200							
	HEADQUARTERS	(b)(5)&(b)(7))(E)							
	REGIONAL STAFF									
	NEW ENGLAND			100.7579.050	A 741 462 - 144					
NE	NEW YORK									
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	REGIONAL STAFF								-	
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	CHICAGO									
	CINCINNATI							_		
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	MINNEAPOLIS				-			-		
	NEW JERSEY									
	PHILADELPHIA							-		
├	FORENSIC CHEM. CTR				-			-		
	REGIONAL STAFF				-	+		-		100 - 0.000
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***************************************	KANSAS CITY									
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	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE				ļ					
	PACIFIC REGIONAL LABORATORY-SW				-			-	-	
_	PACIFIC REGIONAL LABORATORY-NW	70.51			+			+	-	_
	S PER OPERATION	78.5 51732	7200			+		+	-	
	. HOURS ERSION FACTOR	950	950					+	 	
-	OPERATIONAL FTEs	54.45	7.58		 				 	
	MARKS	510	00			-		_		
(1) -	Report time under appropriate PAC					nder operation	11.			
5 10	gn Inspections include the Foreign			Joiologiot	×1					

Laboratory allocations were planned by DFFI.

			FY 2013 ORA						0	ctober 1, 2012
1. PR	OGRAM/ASSIGNMENT TITLE				2. PPS PROJ	ECT NAME/NU	MBER	1.83		
Drug	Process Inspections - Gas Manufac	turers (Dom	estic)		Drug Ouali	ty Assurance	- 56			
"			,			., resourcino	5 50			
-										
3. PR	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	•		5. OPERAT	IONAL FTE PO	OSITIONS
1	56002E			X	ORA	CENT	FR		12.0	
1									12.0	
	6.	1								
R	DISTRICT/ SPECIALIZED	INSPEC-						1		
G	LABORATORY	TIONS				1	l			
1		MEDICAL				1	1	1	1	
O N		GAS (1)							l	
	TOTAL CIELD							+		
\vdash	TOTAL FIELD	295								
	HEADQUARTERS	(b)								
1	REGIONAL STAFF	(5)&(b)								
NE	NEW ENGLAND	(7)(E)								
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l	REGIONAL LAB									
\vdash	WEAC REGIONAL STAFF									
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	CINCINNATI									
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	MINNEAPOLIS									
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	PHILADELPHIA	·								
1	FORENSIC CHEM. CTR	1								
	REGIONAL STAFF	†						-		
l	ATLANTA							┼──	ļ	
SE	FLORIDA									
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ı	SAN JUAN	:						_		
	REGIONAL LAB	-						 		
	REGIONAL STAFF	-				-		 		
1	DALLAS	1								
sw	DENVER									
7442	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES					2. 12				
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION	38.6								
	HOURS	11387					_			
	ERSION FACTOR	950								
	OPERATIONAL FTES	11.99							3.000.000	
9. REN	MARKS									
(1) - 7	Fotal number of planned gas inspec	ctions in the	Program fo	or FY 2013.						
	EDA 2624 - (40/00)	ODA	MODED	I ANIAUNI	0.011==	= (0 ::	- 13			

FY 2013 ORA WORKPLAN

	GRAM/ASSIGNMENT TITLE					JECT NAME/NU				
Drug	Process Inspections - Active Pharma	aceutical Ingre	dients (API	s) -	Drug Qua	lity Assurance	e - 56			
(Dom	estic and Foreign)									
_	GRAM/ASSIGNMENT CODE(S)		4 WORK ALL	OCATION PLA	ANNED BY			5. OPERAT	IONAL FTE PO	OSITIONS
J. FILC		1	1. 1101011100		-	CENT	ED.	0.0.2.0	13.0	
	56002F, 56002L*	1		X	ORA	CENT	ER		13.0	
	6.	1	1	T	T					
R	DISTRICT/ SPECIALIZED	DOMESTIC	FOREIGN		1	1				1 1
E G	LABORATORY	INSPEC-	INSPEC-		1	1	1			
1		TIONS	TIONS	1	1			1		
ON										
	TOTAL FIELD	45	13	8						
	HEADQUARTERS	(b)(5)&(b)(7)					1			
	REGIONAL STAFF				1		1			
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC							-	_	-
	REGIONAL STAFF			_	-	1	-			
	BALTIMORE			1.75578	-	1	1			
	CHICAGO CINCINNATI				†	1	1			
CE	DETROIT					1				
0.	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM, CTR						-			
	REGIONAL STAFF						-			
	ATLANTA				 		+			
SE	FLORIDA				 	 	+	+		
	NEW ORLEANS SAN JUAN				 	+	1	_	 	
	REGIONAL LAB					1	1			1
	REGIONAL STAFF									
	DALLAS									
sw	DENVER									
	KANSAS CITY				1	4	-			
1	SOUTHWEST IMPORT DISTRICT				-					
	REGIONAL LAB				-		+	+	├──	+
	REGIONAL STAFF LOS ANGELES				1		 		<u> </u>	
PA	SAN FRANCISCO						1	1		
1 '	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW					3 - 37				
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION	63.4	68.							
	HOURS	2853	945				-			
CONV	ERSION FACTOR	950 3.00	9.9				+	-	-	+
	OPERATIONAL FTES	3.00	3.3	3						
9. RE	MARKS									
(b)(5))&(b)(7)(E)									
(/ (-										
			Sept. 1							
* 7	he following PAC is for Abbreviated	d Inspections:	NEWS							
l	56002L - ABBREVIATED ACTIV	E PHARMAC	EUTICAL II	NGREDIEN'	T PROCES	S INSPECTION	ONS			
1										

				PROJECT NAME/NUMBER		
Process Inspections - Positron Emis	sion Tomogra	phy (PET)	Drug (Quality Assurance - 56		
ections/Investigations						
		4. WORK ALLO	CATION PLANNED B	Y	5. OPERATIONAL ETE POSI	ITIONS
			(C)		Bonney or recommended States and Printers	
56002P, 56002Q**			X ORA	X CENTER	2.0	
6.	1			T		
DISTRICT/	INSDEC	1	1		1 1 1	
LABORATORY	TIONS		- 1		1 1 1	
	(4)		1		1 1 1	
	(1)					
TOTAL FIELD	51					172
HEADQUARTERS						-##W
REGIONAL STAFF	(7)(E)					
NEW ENGLAND						
NEW YORK						
		-				
					- - 	
					 	
						100 Marie 1100 Marie 1
PHILADELPHIA						
FORENSIC CHEM. CTR					3.000.00	
REGIONAL STAFF						
ATLANTA						
SOUTHWEST IMPORT DISTRICT						
REGIONAL LAB						
REGIONAL STAFF						
					1 1 1	
	37.5					
	1913					
	950					
L OPERATIONAL FTEs	2.01					
Inspections are to evaluate the con	ditions under USP <823>;	which drug p 21 CFR Part	roducts are mand 212 (effective De	ufactured, tested, pack ecember 2011).	aged and held.	
	DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD 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 LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW RS PER OPERATION LHOURS VERSION FACTOR LOPERATIONAL FTES MARKS	OGRAM/ASSIGNMENT CODE(S) 56002P, 56002Q* 6. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD 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 LAB REGIONAL LAB REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW RS PER OPERATION 37.5 L HOURS Inspections are to evaluate the conditions under	DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD HEADQUARTERS (1) 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 LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-NW RS PER OPERATION L HOURS JERSEY PAGE LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-NW RES PER OPERATION L HOURS JERSEY P50 JERSEY JOHN JA7.5 L HOURS JOHN JA7.5 JA	A. WORK ALLOCATION PLANNED B 56002P, 56002Q* B. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD TOTAL FIELD HEADQUARTERS REGIONAL STAFF NEW PORK REGIONAL LAB WEAC CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM, CTR REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF LORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF LORIDA REGIONAL STAFF LORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF LORIDA REGIONAL STAFF LORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF LORIDA REGIONAL STAFF LORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-NW REPROPERATION SPER OPERATION SPER OPERATION JOS	A. WORK ALLOCATION PLANNED BY	OGRAMASSIGNMENT CODIES \$6002P, \$6002Q* \$0002P, \$6002Q* \$1 B. DISTRICT SPECIAL ED LABORATORY TOTAL FIELD HEADQUARTERS (1) HEADQUARTERS REGIONAL STAFF NEW PENCLAND NEW YORK REGIONAL STAFF BALTMORE CHICAGO CINCARNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FLORIDA FLOR

		f	FY 2013 ORA	WORKPLAN	1				Oc	tober 1, 2012
1. PRO	OGRAM/ASSIGNMENT TITLE				2. PPS PROJ	ECT NAME/NU	JMBER	-		1,20,2
Drug	Quality Sampling and Testing Progr	ram			Drug Quali	ity Assurance	e - 56			
	, , , , , , , , , , , , , , , , , , , ,					.,				
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	N PLANNED BY	/		5 OPERAT	IONAL FTE PO	SITIONE
	56008A, L(1)			X	ORA	X CENTI	CD.	U. OF LIGHT		
	3000371, E (1)			_^_] 0100	_ ^ CENTI	EK		10.0	[3.7]
REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	3 DOMESTIC IMPORT SAMPLE COLL 56008L (1)	DOMESTIC IMPORT SAMPLE COLL CHEM SCOOSL	DOMESTIC IMPORT SAMPLE COLL MICRO 56008L	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	219	36	20	16			-	20	10
	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									
1	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
IOUE:	PACIFIC REGIONAL LABORATORY-NW		2 2			-				
	S PER OPERATION - HOURS	219	6.3			5.5 2090			51.6	21.9
UIAL	, HOURS	4191	221	Sparrier of the Control of the Park	A DECEMBER AND PROPERTY OF	2090	PROPERTY AND DESCRIPTION OF THE PERSON OF TH	A STREET, SQUARE, SQUA	1032	219

CONVERSION FACTOR

TOTAL OPERATIONAL FTES

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.

950

0.23

950 0.24

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

Laboratory allocations were planned by DFS.

950

1180

1180

0.19

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PR	OJECT NAME/NU	JMBER	1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1		
Drug	Quality Sampling and Testing Progr	am			Drug Qu	ality Assuranc	e - 56			
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED	BY		5. OPERAT	IONAL FTE PO	OSITIONS
0.1710	56008A, L (1)			X		X CENT	FR			[14.3]
	5000071, E (1)				0.01	_ X _ OEIV			70.0	[11.5]
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)							
	REGIONAL STAFF									
	NEW ENGLAND						-	_		
NE	NEW YORK									
	REGIONAL LAB						 			
	WEAC							_		
	REGIONAL STAFF						1	_		
	BALTIMORE CHICAGO						1			
	CINCINNATI						1			
CE	DETROIT									
02	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
200000	ATLANTA						-	-		
SE	FLORIDA					+				
	NEW ORLEANS				_		-	-		-
	SAN JUAN						+	+	 	
-	REGIONAL LAB						1	-		
	REGIONAL STAFF DALLAS						+	 	 	
SW	DENVER						1	-	1	
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE						+			
	PACIFIC REGIONAL LABORATORY-SW				_		+	+		
	PACIFIC REGIONAL LABORATORY-NW	20.0	46.5	1			+	+	 	
	S PER OPERATION	36.3 10890	16.5 1320				2000000	+		
	HOURS ERSION FACTOR	1180	1180		_	1		+	<u> </u>	
	OPERATIONAL FTES	9.23	1.12					+		
	MARKS								A	
,	Reporting Guidance: Report domes ALL domestic-import sample colle Methods Validation/Development ho	ections and	d sample a	nalyses sh	ould be i	reported und	er NEW PA			
Labo	ratory allocations were planned by [OFS.								

1 PRO	GRAM/ASSIGNMENT TITLE				2 DDC DDO ID	CT NAME/NUM	ADED.			10001 1, 2012
100					l					
Drug	Product Surveillance - Imported Dr	ugs			Drug Qualit	y Assurance	- 56			
					İ					
3 PRC	OGRAM/ASSIGNMENT CODE(S)		4 WORK	ALL OCATION	PLANNED BY			E OBERATI	ONAL FTE PO	PITIONS
0.110		000000	4. WORK		•			5. OPERATI		31110145
1	56008H, 56R833, 56R824, 9	9K833		X	ORA	CENTE	R		49.0	
\vdash	16.	2	2	6	2	2	,	8		
R	DISTRICT/	1 '	•	۰	INTERNATIONAL	MAIL	•	IMPORT	8 IMPORT	
E	SPECIALIZED	IMPORT	IMPORT	IMPORT	MAIL FACILITY	COURIER	IMPORT	SAMPLES	SAMPLES	
G	LABORATORY	ENTRY REVIEW	INVESTIGA- TIONS	FIELD	REVIEWS	REVIEWS	COLL	TO BE ANALYZED	TO BE ANALYZED	
0		HOURS	HOURS	HOURS	INV HOURS	INV HOURS	COLL	API	FIN-DOSAGE	
N			(1)					CHEM	CHEM	
	TOTAL FIELD	14780	4523	7156	15901	1710	393	155	178	
	HEADQUARTERS	(b)(5)&(b)	(了)(E)							
1	REGIONAL STAFF									
ı	NEW ENGLAND									
NE	NEW YORK									
1	REGIONAL LAB									
	WEAC									
1	REGIONAL STAFF									
1	BALTIMORE									
1	CHICAGO									
	CINCINNATI									
CE	DETROIT									
1	MINNEAPOLIS									
ı	NEW JERSEY									
1	PHILADELPHIA									
	FORENSIC CHEM. CTR									
1	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
i	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
l	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
1	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
_	REGIONAL LAB									
1	REGIONAL STAFF									-
١.,	LOS ANGELES									
PA	SAN FRANCISCO									_
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION			1.0			n -l	I		
	HOURS	14780	4523	7156	45004	4740	2.7	20.1	13.5	
	ERSION FACTOR	1200	4523 950	950	15901 950	1710	1061	3116	2403	
	OPERATIONAL FT'Es	12.32	4.76	7.53	16.74	950 1,80	950 1.12	1180 2.64	1180 2.04	
-	ADVE	12.02	4.70	7.00	10.74	1.00	1.12	2.04	∠.04	

Reporting Guidance:

- Import Entry Reviews (electronic and manual-- operation code 14) PAC 56R833;
- Filer Evaluations (operation code 95) PAC 99R833;
- Follow-Up to Refusals 56R824, 63R824
- Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001, 63002;
- Report finished dosage form drugs and APIs collected at the site of entry under 56008H.
- (1) Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

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

Laboratory allocations were planned by DFS.

56-27

	GRAM/ASSIGNMENT TITLE	2, PPS PROJECT NAME/NUMBER								
Drug	Quality Reporting System (DQRS)/	NDA-Field	Alert Repor	ting	Drug Qualit	y Assurance	- 56			
3 PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	OSITIONS
J. 1 144	56021A, 56021B			X		CENTE	R		4.5	
R E G	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 DORS FARS INVESTI-	3 DOMESTIC SAMPLES	7 DOMESTIC SAMPLES TO BE					
0			(Hours)	(Hours)	ANALYZED (Hours)					
N	TOTAL FIELD	46	1425	17	<u>СНЕМ</u> 28					
	HEADQUARTERS	(b)(5)&(b)		.,,						
	REGIONAL STAFF		(
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC						00.00 0.00			
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY							 		
	PHILADELPHIA								-	
	FORENSIC CHEM. CTR								-	
	REGIONAL STAFF									
C.F.	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									
	S PER OPERATION	37.6		7.4				 		
TOTA	L HOURS	1730	1425					-		-
CON	YERSION FACTOR	950 1.82	950 1.50	950 0.13				 	 	
	L OPERATIONAL FTEs	1.02	1.50	0.13	1.02					
	MARKS Pratory allocations were planned by	DFS.								

	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NU	MBER			
Enfor	cement of the Prescription Drug Ma	rketing Act (PDMA)		Drug Qualit	ty Assurance	- 56			
3. PRC	OGRAM/ASSIGNMENT CODE(S)	1,000, 4,000	4. WORK	ALLOCATION	PLANNED BY	į		5. OPERAT	IONAL FTE PO	OSITIONS
	56022, 56022A			X	_	CENT	ĒR		2.0	33.710110
	6.	1	2	3	7					
R	DISTRICT/ SPECIALIZED	INSPEC-	INVESTI-	DOMESTIC	DOMESTIC					
G	LABORATORY	TIONS	GATIONS	SAMPLES COLL	SAMPLES TO BE			· ·		
0			(Hours)	(Hours)	ANALYZED	l .				
N					CHEM					
	TOTAL FIELD	21 (b)(5) 8 (b)(294	27	34	l				
_	HEADQUARTERS	(b)(5)&(b)(7	/)(L)							
	REGIONAL STAFF NEW ENGLAND							_		
NE	NEW YORK									
'''-	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI DETROIT							-		
٦٠	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA								0.000 (0.0	
	FORENSIC CHEM. CTR						-			
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA NEW ORLEANS									
1	SAN JUAN									-
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
sw	DENVER									
	KANSAS CITY SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB							1		
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE							ļ		
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	60.7		2.5	11.0					
	HOURS	1275	294	68						
CONV	ERSION FACTOR	950	950	950					1000000	
TOTAL 9. REM	OPERATIONAL FTES	1.34	0.31	0.07	0.32	L	L			
Labor	ratory allocations were planned by	DFS.								
	4									

B. PROGRAM/ASSIGNMENT CODE(S) 56843 6. DISTRICT/ SPECIALIZED G LABORATORY O N TOTAL FIELD HEADQUARTERS REGIONAL STAFF NEW ENGLAND NE NEW YORK	1 INSPEC- TIONS 44 (b) (5)&(b)	4. WORK		PLANNED BY	CENTE		5. OPERATI	ONAL FTE PC 2.0	SITIONS
R DISTRICT/ E SPECIALIZED G LABORATORY O N TOTAL FIELD HEADQUARTERS REGIONAL STAFF NEW ENGLAND NE NEW YORK	44 (b)								
HEADQUARTERS REGIONAL STAFF NEW ENGLAND NE NEW YORK	(b)								
REGIONAL STAFF NEW ENGLAND NE NEW YORK			1						
NEW ENGLAND NE NEW YORK	(5)&(b)								
NE NEW YORK		-0.5							
	(7)(E)								
DECIONAL LAB			-				_		
REGIONAL LAB									
REGIONAL STAFF	-								
BALTIMORE									
CHICAGO									
CINCINNATI									
CE DETROIT									
MINNEAPOLIS									
NEW JERSEY									
PHILADELPHIA									
FORENSIC CHEM. CTR		10000							
REGIONAL STAFF ATLANTA									
SE FLORIDA									,
NEW ORLEANS									
SAN JUAN									
REGIONAL LAB						- Assessment French			
REGIONAL STAFF									
DALLAS				-					
SW DENVER			ļ	 					
KANSAS CITY	NOT								
SOUTHWEST IMPORT DISTR	-			1	 				
REGIONAL STAFF									
LOS ANGELES						-			
PA SAN FRANCISCO								***	
SEATTLE									
PACIFIC REGIONAL LABORA									
PACIFIC REGIONAL LABORA									
HOURS PER OPERATION	43.1								
TOTAL HOURS	1896 950								
CONVERSION FACTOR TOTAL OPERATIONAL FTES	2.00			-					
9, REMARKS	2.001								

	OGRAM/ASSIGNMENT TITLE Approval Inspections/Investigations	- Foreign		- 1		ECT NAME/NU ty Assurance				
3. PR(OGRAM/ASSIGNMENT CODE(S) 56843		4. WORK ALL	OCATION		CENTI	ΕR	5. OPERAT	ONAL FTE PO	OSITIONS
R II G - O Z	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS								
	TOTAL FIELD	53								
	HEADQUARTERS	(b)								
	REGIONAL STAFF	(5)&(b)								
NE	NEW ENGLAND NEW YORK	$(7)(E)$ _								
INE	REGIONAL LAB	-								_
	WEAC	_								
	REGIONAL STAFF	_								
	BALTIMORE CHICAGO	-								
	CINCINNATI	-						-		
CE	DETROIT			1						
	MINNEAPOLIS	_					-			
	NEW JERSEY PHILADELPHIA	-								
	FORENSIC CHEM. CTR	-								
	REGIONAL STAFF									
	ATLANTA	_								
SE	FLORIDA NEW ORLEANS	-								
	SAN JUAN	-								
	REGIONAL LAB									
	REGIONAL STAFF	_								
sw	DALLAS DENVER	-			_					
J.,,	KANSAS CITY	_								
	SOUTHWEST IMPORT DISTRICT									
_	REGIONAL LAB	_								
	REGIONAL STAFF LOS ANGELES	-		-						
PA	SAN FRANCISCO	-								
	SEATTLE								. 1757	
	PACIFIC REGIONAL LABORATORY-SW	_								
HOUR	PACIFIC REGIONAL LABORATORY-NW S PER OPERATION	36.1								
	HOURS	1913								
	ERSION FACTOR	950								
	OPERATIONAL FTEs	2.01								
9. REN	MARKS									

I. PROC	RAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NUMBE	R			
Pharma	acy Compounding				Drug Qualit	y Assurance -	56			
3. PROG	RAM/ASSIGNMENT CODE(S)		4. WORK AL	LOCATION P	LANNED BY			5. OPERATIO	ONAL FTE POSI	ITIONS
	56D015				ORA	CENTER	2		2.0	
	302013			_ ^	I OIVA	CENTE	Mi Total one of the control of the c		2.0	
	6.	1								
R E	DISTRICT/ SPECIALIZED LABORATORY	INSPEC-	- 1			1				1 1
G	LABORATORY	TIONS				1				1 1
0		1 1	- 1			1		1		1 1
N										
	TOTAL FIELD	24								
	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND	-								
NE	NEW YORK	-								
1	REGIONAL LAB WEAC	-				-				
	REGIONAL STAFF	-			-			-		
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA	-								
	FORENSIC CHEM. CTR	_								
	REGIONAL STAFF	-				-		-	-	
CF.	ATLANTA FLORIDA	-				-		-	 	1
SE	NEW ORLEANS	-				+		-		1
	SAN JUAN				, 10 10 10 10 10 10 10 10 10 10 10 10 10					
	REGIONAL LAB									
	REGIONAL STAFF	_								
	DALLAS									
SW	DENVER									
	KANSAS CITY								1	
	SOUTHWEST IMPORT DISTRICT									
_	REGIONAL LAB REGIONAL STAFF	-						-	-	
	LOS ANGELES	-				-			 	1
PA	SAN FRANCISCO	-		720 120 100 100 100	1			1	1	1
F.A.	SEATTLE	-						1	1	1
	PACIFIC REGIONAL LABORATORY-SW	_			†					1
	PACIFIC REGIONAL LABORATORY-NW									
	PER OPERATION	80.6								
	HOURS	1934								
CONVE	RSION FACTOR	950								
	OPERATIONAL FTES	2.04								
	urces for collection and analysis of	any samples	under this p	program s	hould be ta	ken from Dru	g Quality S	ampling ar	nd	
Testi	ng Program (56008A).									
1										
1										
1										
1										

FY 2013 ORA Workplan

October 1, 2012

	OGRAM/ASSIGNMENT TITLE Process Inspections - Global Parity 1	Initiative	NEW Z			DJECT NAME/NU				october 1, 20
Jug	Process hispections - Giovai rainty i	Initiative -7	1/1/2_		Drug Quai	lity Assurance	e - 36			
. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK A		PLANNED B	JΥ		5. OPERAT	TIONAL FTE PO	OSITIONS
_	56R010			X	ORA	CENT	ER		4.0	
R E G - O N	6. DISTRICT/ SPECIALIZED LABORATORY	Desk Audits INVESTIG- ATIONS (Hours)								
	TOTAL FIELD	3800								
	HEADQUARTERS	(D)								
!		(5)&(b)	\rightarrow			+	+	+		
NE	NEW YORK	(7)(E)	-			+	+	+	-	
1.12	REGIONAL LAB							+		
	WEAC									
	REGIONAL STAFF									
/	BALTIMORE	4								
/	CHICAGO									
CE	DETROIT						-	+		-
UE ,	MINNEAPOLIS					_		+		
	NEW JERSEY					1		1		
	PHILADELPHIA							1		
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
25	ATLANTA EL ORIDA		-+			-	-	-		
SE	FLORIDA NEW ORLEANS		\rightarrow			+	+			
1	SAN JUAN					+	+	+		
!	REGIONAL LAB									-
	REGIONAL STAFF									
1	DALLAS									
SW	DENVER									
	KANSAS CITY									
1	SOUTHWEST IMPORT DISTRICT REGIONAL LAB		$\overline{}$			+		-		-
	REGIONAL STAFF					+	+	+		-
	LOS ANGELES					1		1		
	SAN FRANCISCO									
1	SEATTLE									
J	PACIFIC REGIONAL LABORATORY-SW	A	\rightarrow							
	PACIFIC REGIONAL LABORATORY-NW		\rightarrow					<u> </u>		—
	S PER OPERATION . HOURS	3800	\rightarrow			+		+		
	ERSION FACTOR	950	$\overline{}$	-		+	\vdash	+		-
	OPERATIONAL FTEs	4.00						+		
he G	MARKS Global Parity Initiative is a new collal al Product Safety and Quality" initiati rity inspections. The program will u	tive. Specifica	ally, this pr	rogram will	Il support o	our aim to leve	erage fore	ign regulat	lory	

1. PRO	GRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER							
Drug	Process Inspections - OEI Clean Up				Drug Quali	ty Assurance	- 56			
3. PRC	GRAM/ASSIGNMENT CODE(S) 56R011		4. WORK	ALLOCATION	PLANNED BY	CENTE		5. OPERAT	IONAL FTE PO	SITIONS
	501011				1 0.00				2.0	
R E G I ON	6. DISTRICT/ SPECIALIZED LABORATORY	Desk Audits INVESTI- GATIONS (Hours)								
	TOTAL FIELD	1900								
	HEADQUARTERS	(b)								
	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	(7)(E)						-		
NE	NEW YORK	-						-		-
	REGIONAL LAB WEAC	-						 	-	
-	REGIONAL STAFF	-								
	BALTIMORE									
	CHICAGO									
1	CINCINNATI									
CE	DETROIT							-		
	MINNEAPOLIS	-			-					
	NEW JERSEY	-								
	PHILADELPHIA FORENSIC CHEM. CTR	-						-		
	REGIONAL STAFF	-								
	ATLANTA									
SE	FLORIDA	Ī								
	NEW ORLEANS									
	SAN JUAN									
_	REGIONAL LAB	-						-		
	REGIONAL STAFF DALLAS	-						-		
sw	DENVER	-				†				
J ""	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF	-				-				
	LOS ANGELES	-						-		
PA	SAN FRANCISCO	-			-			-	-	
1	SEATTLE PACIFIC REGIONAL LABORATORY-SW	-				-		 		
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	i							-	
TOTAL	LHOURS	1900								
CONV	ERSION FACTOR	950								
	L OPERATIONAL FTEs	2.00					<u> </u>			
	MARKS stigation hours are to help address	the foreign	inventory ac	ccuracy, co	ontact inform	nation, regist	ration, and	d related π	naintenance	

	\$	4. WORK			lity Assurance	e - 56	5. OPERAT	IONAL ETE PO	OSITIONS
56R838, 56R831		4. WORK		N PLANNED B	SY.		5. OPERAT	IONAL ETE PO	OSITIONS
		4. WORK ALLOCATION PLANNED BY X ORA CENTER			ER	5. OPERATIONAL FTE POSITIONS 10.0			
6. DISTRICT/ E SPECIALIZED G LABORATORY I O									
	FORENSIC EVALUATION								
TOTAL FIELD	12050								
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				-	+		+		
RK	(7)(E) =				1		 		
L LAB	_			1			1		
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L STAFF									
RE	_								
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ATI	_								
21.10	_			-					
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EANS									
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L LAB	_								
STAFF				-					
	_						-		
OLTV	-			-	+	-	_	-	
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STAFF	_								-
ELES									
VCISCO			notes encountries						
	_				10000				
	_								
THE RESERVE THE PERSON NAMED IN COLUMN 2 IS NOT THE OWNER.									
RATION			_						
CTOR				-			-		
			 		+		-		
JIANE I IEO	10.00								
	RTERS STAFF LAND K LAB STAFF RE TI DLIS SEY PHIA CCHEM. CTR STAFF EANS LAB STAFF ETTY ST IMPORT DISTRICT LAB STAFF ILES CISCO EGIONAL LABORATORY-SW EGIONAL LABORATORY-NW RATION CTOR NAL FTES	RTERS (b) STAFF (5)&(b) LAND (7)(E) K LAB STAFF RE TI DLIS SEY PHIA C CHEM CTR STAFF EANS LAB STAFF EANS LAB STAFF EITY ST IMPORT DISTRICT LAB STAFF LES CISCO EGIONAL LABORATORY-SW EGIONAL LABORATORY-NW RATION 12050 CTOR 1205 NAL FTES ned above are estimates. Report Forem code 03, Petition Evaluation, Method	RTERS (b) STAFF (5)&(b) LAND (7)(E) K LAB STAFF RE TI DLIS SEY PHIA C CHEM CTR STAFF EANS LAB STAFF STAFF EANS CITY ST IMPORT DISTRICT LAB STAFF LES CISCO EGIONAL LABORATORY-SW EGIONAL LABORATORY-NW RATION 12050 CTOR 1205 NAL FTES ned above are estimates. Report Forensic active code 03, Petition Evaluation, Methods Develo	RTERS (b) STAFF (5)&(b) K LAND (7)(E) K LAB STAFF RE TI DUIS SEY PHIA C CHEM. CTR STAFF EANS LAB STAFF EANS LAB STAFF CITY ST IMPORT DISTRICT LAB STAFF LES CISCO EGIONAL LABORATORY-SW EGIONAL LABORATORY-NW RATION 12050 CTOR 1205 NAL FTES 10.000 Ined above are estimates. Report Forensic activities under a code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 03, Petition Evaluation, Methods Development or laboration and code 04, Petition Evaluation, Methods Development or laboration and code 04, Petition Evaluation, Methods Development or laboration and code 04, Petition Evaluation, Methods Development or laboration and code 04, Petition Evaluation, Methods Development or laboration and code 04, Petition Evaluation, Methods Development or laboration and code 04, Petition Evaluation and code 0	RTERS (b) STAFF (5)&(b) LAND (7)(E) K LAB STAFF RE TI DUIS SEY PHIA C CHEM CTR STAFF EANS LAB STAFF STAFF STAFF STAFF STAFF STAFF CITY ST IMPORT DISTRICT LAB STAFF LES CISCO EGIONAL LABORATORY-SW EGIONAL LABORATORY-NW RATION 12050 CTOR 1205 NAL FTES 10.00 The dabove are estimates. Report Forensic activities under the appropriate code 03, Petition Evaluation, Methods Development or Forensic Experience of the code o	RTERS (b) STAFF (5)&(b) K LAND (7)(E) K LAB STAFF REE TI DUIS SEY PHIA CHEM.CTR STAFF EANS LAB STAFF STAF	RTERS (b) STAFF (5)8(b) K LAND (7)(E) K LAB STAFF (EE TI TI TI DUIS SEY PHIA CHEM CTR STAFF EANS LAB STAFF EANS LAB STAFF EANS LAB STAFF EANS LIAB STAFF EST MPORT DISTRICT LAB STAFF LES CISCO EGIONAL LABORATORY-SW EGIONAL LABORATORY-NW RATION 12050 DTOR 1205 NAL FTES 10.00 ned above are estimates. Report Forensic activities under the appropriate PAC 56R838;	RTERS (b) (5)&(b) (T)(E) RTERS (b) (5)&(b) (5)&(b) (7)(E) (7)(E) (7)(E) (7)(E) (8) (8) (8) (8) (8) (9) (8) (9) (9) (9) (9) (9) (9) (9) (9) (9) (9	

		FY 2013				-View - Inc.	
	GRAM CATEGORY in Drugs	2. PPS PROJECT Unapproved an			Human Dru	ıgs - 63	
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. C	PERATIONAL IMPORT	L FTE FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE
	TOTAL	IN ACCURATION	15.9			15.9	
1	Internet, Health Fraud, & OTC Monographs	63001A,	11.4			11.4	63-37
<u> </u>	interior, from that, to one menographs	63D012	11.7			11.4	03-37
2	Ni Duran Du Not Coursed by Assessed NDA		4.5	<u> </u>		1.5	
	New Drugs Rx Not Covered by Approved NDAs	63002	4.5			4.5	63-38
				-			
		_			ļ		
	SERVICE OF ARRANGE AND ARRANGE						
					W. 1996 KH20100765.199		
						 	
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	He was a state of the state of						
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\vdash							
CENTE	R PROJECT MANAGER/TELEPHONE			ORA PLANNI	ER/TELEPHOI	NE	
Kathlee	n Anderson, HFD-310, (301) 796-3309			Anita T. Mc	Curdy 301-7	96-4395	

101 101 15	ogram/assignment title net, Health Fraud, & OTC Monogra	phs			Unapprove			gs - 63		
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	,		5. OPERAT	IONAL FTE PO	SITIONS
	63001A, 63D012			X	ORA	CEN	TER		11.4	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL (1)					7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	
1031	TOTAL FIELD	79	2252	269					199	
	HEADQUARTERS	(b)(5)&(b))(7)(E)				•			
	REGIONAL STAFF									
	NEW ENGLAND	-								
NE	NEW YORK REGIONAL LAB	-								
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	DETROIT DETROIT	-								
U.E.	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
<u> </u>	FORENSIC CHEM. CTR									
	REGIONAL STAFF ATLANTA									
SE	FLORIDA									
	NEW ORLEANS	1								
	SAN JUAN									
<u> </u>	REGIONAL LAB									
	REGIONAL STAFF DALLAS									
sw	DENVER									
1,500,000,00	KANSAS CITY	i								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF LOS ANGELES									
PA	SAN FRANCISCO									
50000	SEATTLE	ĺ								
	PACIFIC REGIONAL LABORATORY-SW									
LICHE	PACIFIC REGIONAL LABORATORY-NW S PER OPERATION	42.4								
	HOURS	43.4 3429	2252	5.5 1480			-		22.8 4537	
CONV	ERSION FACTOR	950	950						1180	
TOTAL 9. REN	OPERATIONAL FTES	3.61	2.37	1.56					3.85	
Repo Repo	Not all samples collected will requirent Health Fraud and OTC Monograph to Internet Drugs work to PAC 63D0 ratory allocations were planned by	ph work to 1012.			for docume	entary and I	abel reviev	v.		
FORM	FDA 2621a (10/09)	ORA	A WORK	PLANNII	IG SHEE	T (Cont	nued)		PAGE NO.	63-37

FY 2013 ORA WORKPLAN

October 1, 2012

	GRAM/ASSIGNMENT TITLE Drugs (Prescription) Without Appro	ved NDAs				ect NAME/NU d and Misbra		gs - 63		
			A WORK	ALL OCATION	PLANNED BY				ON A FTE D	
s. PRO	GRAM/ASSIGNMENT CODE(S) 63002		4. WURK	X	21	CENT	ER	5. OPERAT	IONAL FTE PO	SHIONS
	6.	1 1	2							
R E G - O Z	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	INVESTI- GATIONS (Hours)							
	TOTAL FIELD	82	200							
	HEADQUARTERS	(b)(5)&(b)	(/)(E)							
	REGIONAL STAFF								ļ	
NE	NEW ENGLAND NEW YORK					 		-		
NE	REGIONAL LAB					 	1			
	WEAC	1				†				
	REGIONAL STAFF									
İ	BALTIMORE									15
	CHICAGO			0.000						
	CINCINNATI									
CE	DETROIT							-		
	MINNEAPOLIS				-			-		
	NEW JERSEY PHILADELPHIA				ļ	1	1	+	 	
	FORENSIC CHEM. CTR						1	1		
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS							-		
	SAN JUAN					-		-		
-	REGIONAL LAB					-	_	-	 	
	REGIONAL STAFF DALLAS					 	-	+	 	
sw	DENVER						 	 	-	
	KANSAS CITY					1		1		
	SOUTHWEST IMPORT DISTRICT			A202 (MI) (80-20)	- 50					
	REGIONAL LAB									
	REGIONAL STAFF				ļ				ļ	
	LOS ANGELES					-		 	-	-
PA	SAN FRANCISCO SEATTLE				-	 	 	1		-
	PACIFIC REGIONAL LABORATORY-SW					1				
	PACIFIC REGIONAL LABORATORY-NW									
IOUR!	S PER OPERATION	49.6								
	HOURS	4067	200							
	RSION FACTOR	950	950							
	OPERATIONAL FTES	4.28	0.21							
	IARKS rt work under New Drugs (Rx) with	oul Approve	ed NDAs (fo	rmerly PA	C 52002) to	PAC 63002	r.			

FY 2013

4 555	ODALI OLITEOODY	0 000 000					
	GRAM CATEGORY n Drugs	2. PPS PROJECT			20) 00		
riuma	וו סומצי	ICA (Interagen	cy Cooperati	ve Activition	es) - 88		
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT	•	PERATIONAL		7. TOTAL OPERATIONAL	8. PAGE
		CODE	DOMESTIC	IMPORT	FOREIGN	FTEs	
	TOTAL		12.0			12.0	
1	Shelf Life Extension Projects	*	12.0			12.0	88-40
	*See Data Codes Manual for appropriate						
	project reporting PACs.						
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		di li in in ancie i					
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		No. 1991 Acres					
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y.							

	R PROJECT MANAGER/TELEPHONE			ORA PLANNE	ER/TELEPHO!	NE .	
	A. Porter, HFC-140; 301-827-2757			Anita T. Mo	Curdy 301-7	96-4395	00.00

		F	Y 2013 ORA	WORKPLAN					Oc	tober 1, 2012
1	GRAM/ASSIGNMENT TITLE				2. PPS PRO	JECT NAME/NU	MBER			
Shelf	Life Extension Projects				Interagenc	y Cooperative	e Activitie	s - 88		
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED B	Y		5. OPERAT	IONAL FTE PO	OSITIONS
	All Appropriate PACs			Х	•	CENT	ER	0.012.01	12.0	201110145
	16.	7 7						+		
R	DISTRICT/	DOMESTIC				1				
E G	SPECIALIZED LABORATORY	SAMPLES TO BE					l	1		
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ON		CHEM						1	1	
"	TOTAL SISLE					 	_	+		
	TOTAL FIELD	14160 (b)						-		
	HEADQUARTERS	(5)&(b)								
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NE	NEW ENGLAND	(7)(E)				-				
NE	NEW YORK REGIONAL LAB	-				-				
1	WEAC .	-					-	-		
	REGIONAL STAFF	-					_	-		
1	BALTIMORE	-				1		_		
1	CHICAGO	-				 		_		
1	CINCINNATI							1		_
CE	DETROIT					 		+		
1	MINNEAPOLIS					1		_		
	NEW JERSEY									
1	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
1	ATLANTA				215					
SE	FLORIDA									
1	NEW ORLEANS	_		1						
1	SAN JUAN	_			10 to 100					
	REGIONAL LAB	_								
1	REGIONAL STAFF	_								
	DALLAS	_								
sw	DENVER	-						-		
1	KANSAS CITY SOUTHWEST IMPORT DISTRICT	-								
	REGIONAL LAB	-				1		-		
	REGIONAL STAFF	_						_		
	LOS ANGELES							1		
PA	SAN FRANCISCO							1		
	SEATTLE									32
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION									
	HOURS	14160								
	ERSION FACTOR	1180								
9. REN	OPERATIONAL FTES	12.00								
Sever	FTEs are assigned to this Program additional FTEs are assigned to the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as a supplication of the additional FTEs are as	his Program	s reimburse using dolla	ed by DOD ars reimbur	sed by the	Department	of Homel	and Securi	ty.	
FORM	FDA 2621a (10/09)	ORA	WORKE	DI ANNIN	IC SHEE	ET (Conti	nuod)		PAGE NO	20.40

CENTER FOR VETERINARY MEDICINE RESOURCE SUMMARY FY 2013

		OPE	RATIONAL F	TES	TOTAL OPERATIONAL
PPS NO.	PROJECT TITLE	DOMESTIC	IMPORT	FOREIGN	FTEs
	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

FY 2013									
	GRAM CATEGORY	2. PPS PROJECT I			9074.3	B IS STATED IN			
Anima	al Drugs and Feeds	Pre-Approval E	valuation of	Animal Dr	ugs and Foo	d Additives - 6	8		
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT		PERATIONAL		7. TOTAL OPERATIONAL	8. PAGE		
	MOTAL	CODE	DOMESTIC	IMPORT	FOREIGN	FTEs			
	TOTAL	NAMES OF THE PARTY	6.3		3.8	10.1			
l	NADA Pre-Approval Inspection	68001, 68001G	1.1		3,4	4.5	68-2		
2	Bioresearch Monitoring		5.2		0.4	5.6	68-3		
	(Pre-Market) GLP	68808, 68808G	(2.5)		(0.2)	(2.7)			
	* (Pre-Market) Spon/Mon/Con	68810, 68810G							
	(Pre-Market) Clinical Investigators	68811, 68811G	(2.7)		(0.2)	(2.9)			
					-				
			-						
	* 68810 is planned under 68808								
	00010 to planies and 00000								
		3 700 300							
		_							
		-							
		+							
		 							
-				Y			20 00 00		
CENTE	R PROJECT MANAGER/TELEPHONE			ORA PLANNI	ER/TELEPHOI	L			
	Robbi 240-276-9227			Kristen Kam	as 301-796-4:	391			

FORM FDA 2622 (10/09) PAGE NO. 68-1

1. PRO	OGRAM/ASSIGNMENT TITLE	the Alberta Control of the Control o		WORKI LAN		ECT NAME/NU	MREC		00	tober 1, 2012
NAD	A Pre-Approval Inspections									- 1
IVAD	A Tre-Approval hispections				Pre-Appro	val Evaluatio	n of Anima	l Drugs an	d Food Add	itives - 68
3. PR0	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	Y		5. OPERAT	IONAL FTE PO	SITIONS
	68001, 68001G			X	ORA	X CENT	ED		4.5	
					, 0.00	_ X JOERT		ĺ	4.5	1
R	6. DISTRICT/	f FOREIGN	1	1		T				
E	SPECIALIZED	INSPEC-	DOMESTIC INSPEC-	CHEMIST ON		1				
G	LABORATORY	TIONS	TIONS	INSP		1				1
0		1 1			1		l .			1
N		(1)	(2)							
	TOTAL FIELD	40	5	850						
	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				500 85 10					
	REGIONAL STAFF									
	LOS ANGELES							, and the second		
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION	80.0	50,0							
	HOURS	3200	250	850						
	ERSION FACTOR	950	950	950						
TOTAL	OPERATIONAL FTEs	3.37	0.26	0.89						

- (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".)

GLPs Sponsor-Monitors, Clinical Investigators (Pre-Market) Pre-Approval Evaluation of Animal Drugs and Food Additives	1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUMBER		· ·	100er 1, 2012
PACS 68808, G, 68810, G, 68811, G R B. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD NEW PORICA REGIONAL STAFF REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI MINEAPOLIS MINEAPOL			gators (Pre-	Market)		1		nal Drugs and	l Food Addi	tives - 68
PACS 68808, G, 68810, G, 68811, G R B DISTRICTY SPECIALIZED LABORATORY TOTAL FIELD HEADQUARTERS REGIONAL STAFF REGIONAL STAFF CHICAGO CINCINNATI OETROT MINNEAPOLIS NEW PACS DETROIT MINNEAPOLIS NEW GRESP PHILADELPHIA FOREISCH CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA SE REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA SE REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF ATLANTA FOREISC CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL STAFF AND CHEM GTR REGIONAL LAB REGIONAL CHEM CHEM CHEM CHEM CHEM CHEM CHEM CHEM	3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALL OCATION	PI ANNED BY		E ODEDATI	ONAL ETE DO	OFFICIAL
Color			1 G	4. Work				5. OPERATI		SITIONS
B DISTRICT/ E SPECIALIZED LABORATORY TOTAL FIELD MEADQUARTERS REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL STAFF BALTIMORE CHICAGO CHICINNATI CE DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF ATLANTA FLORIDA FLORIDA NEW ORLEANS SAN JUAN REGIONAL STAFF REGIONAL STAFF REGIONAL STAFF REGIONAL STAFF ATLANTA FLORIDA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF ATLANTA REGIONAL STAFF DALLAS SOUTHWEST IMPORT DISTRICT REGIONAL STAFF LOS ANGELES AND FLORIDA REGIONAL STAFF LOS ANGELES AND SAN FRANCISCO SEATHE PACIFIC REGIONAL LABORATORY-SW			.,, 0		^_	ONA	CENTER		5.6	
TOTAL FIELD 2 3 50 44	E G I O	DISTRICT/ SPECIALIZED	INSPEC- TIONS	FOREIGN INSPEC- TIONS	INSPEC- TIONS 68808	INSPEC- TIONS				
MEADQUARTERS REGIONAL STAFF REGIONAL STAFF REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETEROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF ATLANTA SE FLORIDA REGIONAL STAFF DALLAS SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW		TOTAL FIELD	2	2		44		++		
REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL LAB WEAG REGIONAL STAFF BALTIMORE CHICAGO CINICINATI CE DETROIT MINIBEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL STAFF DAILAS SW DENVER REGIONAL STAFF DOLLAS REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL STAFF DOLLAS SW DENVER REGIONAL STAFF DOLLAS SW DENVER REGIONAL STAFF DOLLAS SW SW DENVER REGIONAL LAB REGIONAL STAFF DOLLAS SOUTHWEST IMPORT DISTRICT REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW			(b)(5)&(b)	(7)(E)	30	44	 			
NEW PRICIAND NEW YORK				/(- /(-/						
NEW YORK REGIONAL LAB										
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WEAC REGIONAL STAFF	142									
REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF ATLANTA SEE FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF DALLAS SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW										
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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 STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW										
MINNEAPOLIS NEW JERSEY	CE							+		
PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL LAB REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW										
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REGIONAL STAFF		PHILADELPHIA								
ATLANTA SE FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW		FORENSIC CHEM, CTR								
SE		REGIONAL STAFF								
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		ATLANTA								
SAN JUAN REGIONAL LAB REGIONAL STAFF DALLAS SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW	SE	FLORIDA								
REGIONAL LAB REGIONAL STAFF DALLAS DALLAS SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-SW		NEW ORLEANS								
REGIONAL STAFF DALLAS SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW		SAN JUAN								
DALLAS SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW		REGIONAL LAB								
SW DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW										-
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SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF LOS ANGELES PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW	SW									
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REGIONAL STAFF LOS ANGELES PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW										
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PA SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW										
SEATTLE PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-SW	PA									
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								-		
CONVERSION FACTOR 950 950 950 950 TOTAL OPERATIONAL FTES 0.19 0.19 2.53 2.69								-		
7. REMARKS	THE RESERVE		0.10	0.13	2.33	2.09				

(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").

FY 2013

	GRAM CATEGORY al Drugs and Feeds	2. PPS PROJECT I Monitoring of M			Feeds, and	Devices - 71	
3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT		PERATIONAL		7. TOTAL OPERATIONAL	8. PAGE
	TOTAL	CODE	DOMESTIC	IMPORT	FOREIGN	FTEs	
,			115.5	17.7	1.9	135.1	
1	Animal Drug Manufacturing Inspections	71001	10.5	0.1	1.7	12.3	71-5
2	Feed Contaminants*	71003A-K	25.7	6.4		32.1	71-6-8
3	Feed Manufacturing	71004,A	5.0		0.2	5.2	71-9
	Illegal Drug Residues in Meat and Poultry	71006,M	39.5			39.5	71-10
	Ruminant Feed Ban Rule (BSE) Program**	71009,71R843	19.8	11.2		31.0	71-11-13
6	FY 13 High Risk Feed Inspection Pilot Assignment (FSMA)	71V030	6.3			6.3	71-14
7	Methods Validation/Development Program	71R816	5.0			5.0	71-15
8	Forensic Evaluation and Sample Analysis	71R838	1.0			1.0	71-16
9	Center Initiated Assignments***	71V800	2.7			2.7	71-17
	*Includes 2.75 FTE's for selected research projects						
	**Includes: 71R833, 71R844, 99R833, and 71R824						
	***Includes a pool of resources to investigate adverse events.			100000			

							-
							*
	10000 10000 10000						
	PROJECT MANAGER/TELEPHONE			RA PLANNE			
reremy l	Robbi 240-276-9227		K	risten Kamas	301-796-43	91	

1. PRO	OGRAMASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NUI	MRER		Uc	lober 1, 2012
Anim	al Drug Manufacturing Inspection/	Type A Me	dicated Artic							
Amm	at Drug Manufacturing hispection	Type A Me	ulcated Armo	ries	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71					
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATI	ONAL FTE PO	SITIONS
	PACs 71001, A, B, 71005, A	A		X	ORA	X CENTE	ъ			
			1		Oret	A CLIVIE	.IX	12.3		
R	6. DISTRICT/	1 FOREIGN	1	1	2	3	3	6	7	
E	SPECIALIZED	INSPEC-	DOMESTIC INSPEC-	CHEM	INVESTI- GATIONS	DOMESTIC SAMPLE	DOMESTIC	IMPORT	DOMESTIC	
G	LABORATORY	TIONS	TIONS	INSPEC	on none	COLL	COLL	FIELD EXAMS	SAMPLES TO BE	
0		1 1		(Hours)	(House)				ANALYZED	1
N		(1)	(2)	(nours)	(Hours)	(3)	CHEM		CHEM	
	TOTAL FIELD	33	205	600	250	50	20	100	20	
	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									
1	PHILADELPHIA	4								
-	FORENSIC CHEM. CTR									
1	REGIONAL STAFF	-								
	ATLANTA	-								
SE	FLORIDA									
	NEW ORLEANS SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
sw	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB	1								
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									-
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
_	S PER OPERATION	49.0	40.0			7.0		0.8	35.0	
TOTAL	HOURS	1617	8200	600	250	350	National States	80	700	
	ERSION 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	

- (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. PRO	GRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER							
	Contaminants- Domestic					of Marketed		nge Feede	and Device	ac. 71
T.CCC	Comaninants- Domestic				1410IIIIUI IIIg	OI WIGINGICU	Animai Di	ugs, reeds	and Device	28 - /1
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATI	ONAL FTE PO	SITIONS
	71003 A,B,C,E,G-K			X	ORA	CENTE	D			
	/1005 A,D,C,L,O-K				UNA	CENTE			32.1	[8.1]
R H G - O	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL Metals 71003B	3 DOMESTIC SAMPLE COLL Myco 71003C	DOMESTIC SAMPLE COLL Micro 71003E	3 DOMESTIC SAMPLE COLL Micro 71803E	3 DOMESTIC SAMPLE COLL Chem 71003A	DOMESTIC SAMPLE COLL Dioxin 71003G	3 DOMESTIC SAMPLE COLL Antiblotics 71003K
N	TOTAL FIELD	(1)	1615	60	395	(2) (a) 600	(b)	200	(c)	(3)
	HEADQUARTERS	(b)(5)&(b		QU-	282	600	100	290	150	2
	REGIONAL STAFF		/(
NIE.	NEW YORK									
NE	NEW YORK REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
CE										
	MINNEAPOLIS NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
_	REGIONAL STAFF									
	DALLAS									
sw	DENVER									
1	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUF	RS PER OPERATION	25.0	4.2		Section Append	Approximately the		1000000		
	L HOURS	925	6783							
	ERSION FACTOR	950	950		2001	3.3 3.3 3.3 3.5	ENGLES E	District the	**************************************	
	L OPERATIONAL FTEs	0.97	7.14		Service Lines		No. 10 to 10	47.105975.350		

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".

			FY 2013 ORA	WORKPLAN	l				Or	ctober 1, 2012
1. PRC	OGRAM/ASSIGNMENT TITLE			- 30	2. PPS PROJE	ECT NAME/NUI	MBER	***		
Feed	Contaminants- Domestic				Monitoring	of Marketed	Animal Dr	ugs, Feeds	, and Devic	es - 71
3. PR0	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	,		5 OBERAT	TONAL ETE D	2017:0110
100 to 100	71003 A,B,C,E,G-K				- Contract - Contract			5. UPERAT	IONAL FTE PO	- 1
_	71003 A,B,C,E,G-K	-		X		CENTE	ER		32.1	[17.6]
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED Metals 71003B	DOMESTIC SAMPLES TO BE ANALYZED Myco 71003C	7 DOMESTIC SAMPLES TO BE ANALYZED Micro 71003E	7 DOMESTIC SAMPLES TO BE ANALYZED Micro 71003E	7 DOMESTIC SAMPLES TO BE ANALYZED Chem 71003A	7 DOMESTIC SAMPLES TO BE ANALYZED Dioxin 71003G (4)	7 DOMESTIC SAMPLES TO BE ANALYZED Antibiotics 71003K	9 METHODS VAL/DEV CONTAM ID CHEM (Hours) 71093A (5)	9 METHODS VAL/DEV MICRO (Hours) 71003E
	TOTAL FIELD	60	395	300	100					(6)
	HEADQUARTERS	(b)(5)&(b)					130	201	2065	1180
	REGIONAL STAFF		(1-)(-)							
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
1	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	1								
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW	1								
HOURS	S PER OPERATION	18.0	11.0	13.0	13.0	6.6	30.0	23.0		
TOTAL	HOURS	1080	4345	3900			4500			1180
	ERSION FACTOR	1180	1180	1180						
TOTAL	OPERATIONAL FTES	0.92	3.68	3.31	1.10		3.81		1.75	
7 REM	ARKS			-						

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. PRO	PROGRAM/ASSIGNMENT TITLE					2. PPS PROJECT NAME/NUMBER							
	Contaminants- Import		Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71										
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5 OPERATI	ONAL FTE P	PACITIONS			
	71003 A,B,C,E,G-K			X	ORA	X CENTER			32.1	[6.4]			
К ш О − O Z	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL (7)	IMPORT SAMPLE COLL Chem	4 IMPORT SAMPLE COLL Micro 71003E	4 IMPORT SAMPLE COLL Antibiotics	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES TO BE ANALYZED Chem	B IMPORT SAMPLES TO BE ANALYZED Micro (7)	8 IMPORT SAMPLES TO BE ANALYZED Antibiotics				
	TOTAL FIELD	550	250	280	20	300	250	D. SPECIAL DESIGNATION OF THE PARTY OF THE P	20				
	HEADQUARTERS	(b)(5)&(b)	Committee of the latest termination of the l	200	Ευ	300	250	1 200	20	Marie and the second second			
	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	-											
HOUD	S PER OPERATION	2.5				0.6		100		_			
	HOURS	1375		14271551151555		0.6 180							
	ERSION FACTOR	950				950	And the second second						
TOTAL	OPERATIONAL FTES	1.45				0.19							
	MARKS	diameter and the second		Commence of the Control of the Contr				2000					
	shaded area serves as a guideline	for districts	on the spec	cific types o	of samples t	hat should b	e collected	d in order t	to match				
samo	oles expected by the laboratories for	or analysis.											
	, ,												
	mport Sample Collections and Ana animal feed ingredients.	alyses: 7100	03E, sample	e collection	is are for pig	ears, pet tr	eats, and p	oet foods a	as well as				
Labo	ratory allocations were planned by	DES											
Labo	ratory allocations were planned by	DF3.											
l													

1. PRO	GRAM/ASSIGNMENT TITLE	and the same of the same of			2. PPS PROJE	CT NAME/NUN	MBER		00	10ber 1, 2012	
Feed	Manufacturing				1						
l' cca	Transitation in S				Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK	ALLOCATION	PLANNED BY			5. OPERATIONAL FTE POSITIONS			
	PACs 71004, A			X	ORA	X CENTE	R		5.2		
							5.2				
R E G	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPEC- TIONS	DOMESTIC INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE					
0 2					GUIDANCE (CHEM)	ANALYZED CHEM					
	TOTAL FIELD	5	141	60	15	15					
	HEADQUARTERS	(b)(5)&(b)			Patricular Control (Proprior C		-				
	REGIONAL STAFF									_	
	NEW ENGLAND										
NE	NEW YORK							1			
	REGIONAL LAB							1			
	WEAC							1	-		
	REGIONAL STAFF							1			
1	BALTIMORE										
	CHICAGO										
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS							1			
ł	NEW JERSEY							1			
l	PHILADELPHIA							1			
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
1	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										
HOUR	S PER OPERATION	50.0	28.0	7.8		25.0					
	HOURS	250	3948	468		375	134344				
CONV	ERSION FACTOR	950	950	950		1180					
TOTAL	OPERATIONAL FTEs	0.26	4.16	0.49		0.32					

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.

1 000	GRAM/ASSIGNMENT TITLE		1 ZOIS ORA		2 PDC PDQ I	OT NAME OF B	10.55		Uci	lober 1, 2012	
10000 7500					Company of the compan	CT NAME/NUM					
Illega	l Residues in Meat & Poultry				Monitoring	of Marketed	Animal Dr	ugs, Feeds	, and Device	es - 71	
			1, ,,,,,,,,,,								
3. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	ONAL FTE PO	SITIONS	
	71006, M			X	ORA	X CENTE	R		39.5		
R E G	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE	9 METHODS VAL/DEV CHEM	9 TECH SUPPORT				
1 0 N			(1)	MILK (2)	ANALYZED CHEM (3)	(Hours) (4)	(Hours)				
	TOTAL FIELD	600	930	400	580	360	1900				
	HEADQUARTERS	(b)(5)&(b)	(7)(E)								
	REGIONAL STAFF	() () ()									
	NEW ENGLAND										
NE	NEW YORK										
1	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
1	BALTIMORE										
1	CHICAGO										
	CINCINNATI										
CE	DETROIT										
65,011	MINNEAPOLIS										
l	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF									V	
	ATLANTA										
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
SW	DENVER										
1	KANSAS CITY										
1	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES							NO. CORP. CORP. NO.			
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOUR	S PER OPERATION	39.0	7.0	2.5	9.4						
TOTA	HOURS	23400	6510	1000	5452	360	1900				
CONV	ERSION FACTOR	950	950	950	1180	1180	950	-			
TOTA	OPERATIONAL FTEs	24.63	6.85	1,05	4.62	0.31	2.00				

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.

			FY 2013 ORA 1	WORKPLAN					Or	tober 1, 2012
1. PR	OGRAM/ASSIGNMENT TITLE					ECT NAME/NUI	MBER			UDC: 1, 2012
Rumi	inant Feed Ban Rule/BSE Program				Monitoring	of Marketed	Animal D	rugs, Feeds	, and Devic	es - 71
								27. 2		
3. PR	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5 OPERAT	IONAL FTE PO	PITIONS
	71009, 71R844, 71R843		22 320000	X				J. OF ERATI		
	(99R833, 71R833, 71R824))			ORA	X CENTE	:R		31.0	[27.9]
	6.	1	2	2	2	3	4	6	7	7
Ŕ	DISTRICT/ SPECIALIZED	DOMESTIC INSPEC-	DOMESTIC INVESTI-	IMPORT	IMPORT	DOMESTIC	IMPORT	IMPORT	DOMESTIC	DOMESTIC
G	LABORATORY	TIONS	GATIONS	ENTRY REVIEW	INVESTI- GATIONS	SAMPLE COLL	SAMPLE COLL	FIELD EXAMS	SAMPLES	SAMPLES
0	Committee and Co					0022	COLL	EAAMS	TO BE ANALYZED	TO BE ANALYZED
N		(1)	(Hours) (2)	(Hours) (3)	(Hours) (4)				CHEM	MICRO
	TOTAL FIELD	1205	1000	8440	1530	640	200	2000	(5)	(5)
	HEADQUARTERS	(b)(5)&(b		0440	1530	640	200	3200	425	215
	REGIONAL STAFF	(D)(S)&(D	八/八二)							
ı	NEW ENGLAND	1								
NE	NEW YORK	1								
Accept	REGIONAL LAB	1								
	WEAC	1								
	REGIONAL STAFF	1								
	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	l .								
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO	ŀ								
	SEATTLE	-								
	PACIFIC REGIONAL LABORATORY-SW	-								
	PACIFIC REGIONAL LABORATORY-NW		_							
	S PER OPERATION	8.5				4.0	2.5	0.4	6.0	4.0
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	HOURS	10243	1000	8440	1530	2560	500	1280	2550	860
	ERSION FACTOR	950	950	1200	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

- (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. PRO	GRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER									
Rumi	nant Feed Ban Rule/BSE Program		Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71									
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED B	Y		5. OPERATIONAL FTE POSITIONS				
	PACs 71009, 71R844, 71R84	3			ORA				31.0 [3,1]			
	(99R833, 71R833, 71R824)				i managa				51.0	[5,1]		
Z = 0 - 0 Z	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED CHEM	9 TECHNICAL SUPPORT (Hours) (6)									
	TOTAL FIELD	200	2248									
	HEADQUARTERS	(b)(5)&(b)	(7)(E)									
	REGIONAL STAFF											
	NEW ENGLAND											
NE	NEW YORK											
	REGIONAL LAB											
	WEAC											
	REGIONAL STAFF											
	BALTIMORE						-	-				
	CHICAGO					+						
05	CINCINNATI					-		-				
CE	DETROIT MINNEAPOLIS			-		-	 	-				
	NEW JERSEY						ļ	-				
	PHILADELPHIA				 	 		-		+		
	FORENSIC CHEM. CTR				 	+	†	1		+		
	REGIONAL STAFF					—	 	+		-		
	ATLANTA							1		+		
SE	FLORIDA									1		
	NEW ORLEANS									+		
1	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF					777						
	DALLAS											
SW	DENVER					-						
1	KANSAS CITY						ļ					
	SOUTHWEST IMPORT DISTRICT											
-	REGIONAL LAB REGIONAL STAFF				<u> </u>		+	+				
l	LOS ANGELES				 	+	-	-	 			
PA	SAN FRANCISCO				 		 	_	 			
1.24	SEATTLE				†			—				
l	PACIFIC REGIONAL LABORATORY-SW					1			 			
	PACIFIC REGIONAL LABORATORY-NW											
HOUR	S PER OPERATION	4.3										
TOTAL	HOURS	860	2248									
CONV	ERSION FACTOR	1180	950									
_	OPERATIONAL FTEs	0.73	2.37									
	MARKS											
(6) -	Technical support hours include su	pporting st	ate activities	s under the	Ruminant	Feed Ban R	egulation a	and suppor	ting state	activities		
unde	r the Feed Manufacturing Program	, 71004. T	hese hours	also includ	de resource	es for audits	of state co	ntract insp	ections.			
Labo	ratory allocations were planned by	DFS.										
1												
1												
1												
1												
1												
1												
1												
1												

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 classifed 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 priotitizing 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
- Prolein 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)

practices, flagged with a risk identifier, and a newly established PAC- 71V030 for FY13.

4 804			FY 2013 ORA	WORKPLAN					Or	tober 1, 2012
	OGRAM/ASSIGNMENT TITLE					ECT NAME/NU				
Metn	ods Validation				Monitoring	g of Marketed	d Animal D	rugs, Feed	s, and Devic	es - 71
3. PRO	OGRAM/ASSIGNMENT CODE(S)	· · · · · · · · · · · · · · · · · · ·	4. WORK	ALLOCATION	PLANNED BY	,		5. OPERATIONAL FTE POSITIONS		
	71R816		III WORK		ORA	CENT	ED	The Industrial Control of the Contro		
					JOICA	CENT	EK		5.0	
R	6. DISTRICT/	9 METHODS	9 APPLIED							
E G	SPECIALIZED LABORATORY	VAL/DEV CHEM	TECHNOLOGY					1		
0	0.779469633.979439.000.00770.75063067		CHEM					l		
Ň		(Hours)	(Hours)					1		
	TOTAL FIELD	1205	4720							
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF NEW ENGLAND									
NE	NEW YORK					<u> </u>	-		-	
	REGIONAL LAB						-	 		
	WEAC							1		
	REGIONAL STAFF									
	BALTIMORE CHICAGO									
	CINCINNATI									
CE					-			 		
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR REGIONAL STAFF									
	ATLANTA					-				
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB REGIONAL STAFF									
	DALLAS									
sw	DENVER							1		
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
HOLIR	PACIFIC REGIONAL LABORATORY-NW S PER OPERATION	·								
	HOURS	1205	4720				l			
CONV	ERSION FACTOR	1205	1180							
	OPERATIONAL FTEs	1.00	4.00							
7. REM										
vvork	load Source - Determined by Division	on of Field :	Science, Ol	RO						

	GRAM/ASSIGNMENT TITLE sic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Dev							es - 71
3. PRO	GRAM/ASSIGNMENT CODE(S) 71R838		4. WORK	ALLOCATION		X CENTI	ĒR	5. OPERATI	ONAL FTE PO	SITIONS
R E G L O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	1205								
	HEADQUARTERS	(b)								
	REGIONAL STAFF	(5)&(b)								
	NEW ENGLAND	(7)(E)								
NE	NEW YORK						-			
	REGIONAL LAB WEAC			 			-			
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE.	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA						-			
<u> </u>	FORENSIC CHEM. CTR REGIONAL STAFF			 			-	_		
	ATLANTA						 	_		
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
L_	REGIONAL LAB		100							
	REGIONAL STAFF									
	DALLAS									
SW	DENVER	-			-					
	KANSAS CITY SOUTHWEST IMPORT DISTRICT	-			 		-			ļ
	REGIONAL LAB				 		1			
	REGIONAL STAFF						1			
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW				-					
_	PACIFIC REGIONAL LABORATORY-NW			-	-		+-			
	S PER OPERATION L HOURS	1205		+	1		-			
	ERSION FACTOR	1205								
	L OPERATIONAL FTEs	1.00		 	1		1			
7. REN	MARKS kload Source - Determined by Divisi	ion of Field	Science, C	DRO						

		1	Y 2013 ORA	WORKPLAN					(otober 1, 2012	
1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NU	MBER			1, 2012	
Cente	r Initiated Assignments				Monitoring	of Marketed	I Animal D	rugs, Feed	ls, and Devi	ces - 71	
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	,		5. OPERATIONAL FTE POSITIONS			
	71V800, 71V022			X	ORA	X CENT	ER	J. OFERA	2.7		
R E	6. DISTRICT/ SPECIALIZED	DOMESTIC INSPEC-	3 INVESTI- GATIONS	7 DOMESTIC LAB	DOMESTIC LAB						
G 0	LABORATORY	71V022	(Hours)	ANALYST CHEM	ANALYST MICRO						
N	TOTAL FIELD	(1)	950	295	590			-	+	-	
	HEADQUARTERS	(b)(5)&(b)	Carting the Contract of the Co		380			+	+	_	
	REGIONAL STAFF							1-	+	+	
	NEW ENGLAND							1	1	-	
NE	NEW YORK							-	1	1	
	REGIONAL LAB							1	 		
	WEAC									†	
	REGIONAL STAFF							1			
	BALTIMORE							—		 	
	CHICAGO									1	
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR						10000				
	REGIONAL STAFF										
	ATLANTA								T		
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
SW	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL CASE							-			
	REGIONAL STAFF LOS ANGELES						-	 			
PA	SAN FRANCISCO						-				
FA	SEATTLE							-	-	-	
	PACIFIC REGIONAL LABORATORY-SW								+	+	
	PACIFIC REGIONAL LABORATORY-NW							+	+	+	
HOUR	PER OPERATION	10.0						+	+	+	
	HOURS	900	950	295	590			 	+	-	
	RSION FACTOR	950	950	1180	1180			+	+	1	
	OPERATIONAL FTEs	0.95	1.00	0.25	0.50			 		+	
7. REM										1	
They 71V8((1) - T	e resources include time for investi- also may be applied to sample coll 00 Workload Source: Based the Fe the FY13 Poultry Hatchery Assignment	ections and eed Manufac nent instruc	I analyses v cluring, Fee ts the Field	when invest ed Contami to inspect	igating advi nants and F designated	erse events Pre-Approva poultry hato	I program	inventorie	es.		
possil	ole misuse/extralabel use of antimi atory allocations were planned by	crobials. Re	port Inspec	ctions unde	r PAC 71V0	022 Op 12.	,		e conservation of the last		
	and a market of the control of the c	_, 0,									

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH RESOURCE SUMMARY FY 2013

		OPE	RATIONAL F	TES	TOTAL OPERATIONAL
PPS NO.	PROJECT TITLE	DOMESTIC	IMPORT	FOREIGN	FTEs
	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

PROJECT SUMMARY SHEET FY 2013 1. PROGRAM CATEGORY 2. PPS PROJECT NAME/NUMBER Medical Devices and Radiological Health Postmarket Assurance: Devices - 81 5. PROGRAM ASSIGNMENT 4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS 3. NO. 6. OPERATIONAL FTE 7. TOTAL OPERATIONAL 8. PAGE DOMESTIC IMPORT FOREIGN CODE FTEs TOTAL 1.0 1.0 Medical Device Problem Reporting - MDR Follow-Up 81010 1.0 1.0 81-2

Thomas P. Gross 301-796-5997 FORM FDA 2622 (10/09)

CENTER PROJECT MANAGER/TELEPHONE

ORA PLANNER/TELEPHONE

John Aydinian 301-796-4394

1. PRC	GRAM/ASSIGNMENT TITLE			2. PPS PROJ	ECT NAME/NU	MBER			1,2012	
Medi	cal Device Problem Reporting - MI	OR Follow-U	Jр		Postmarket	Assurance: 1	Devices - 8	1		
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	,		5. OPERAT	IONAL FTE PO	SITIONS
	81010			X	ORA	CENTE	P		1.0	111111111111111111111111111111111111111
l	57515				0101		-11		1.0	
R E G - O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL STER	3 DOMESTIC SAMPLE COLL 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	1	
_	HEADQUARTERS	(b)(5)&(b)				· · · · ·				
—	REGIONAL STAFF		/(
	NEW ENGLAND									
NE	NEW YORK									
1	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
1	CINCINNATI									
CE	DETROIT									
"-	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM, CTR									
· ·	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
1	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									
HOUR:	S PER OPERATION	18.4 828		8.0	8.0	8.0	36.0	20.0	37.0	
	HOURS	30	8	8	8	36	20	37		
	ERSION 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	

- (1)-Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.
- (2)-Investigational hours for MDR followup at medical facilities.
- (3)-Performance testing of chemical and serological test kits.
- (4)-Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.
- (5)-MDR samples to confirm reported defects.

PROJECT SUMMARY SHEET

FY 2013

1. PROGRAM CATEGORY
2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health
Compliance: Devices - 82

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT		PERATIONAL	.FTE	7. TOTAL OPERATIONAL	8. PAGE	
		CODE	DOMESTIC	IMPORT	FOREIGN	FTEs		
	TOTAL		108.6		29.2	190.9	Latings-	
	Monitoring Devices of Foreign Origin - Import	82008*		44.0		44.0	82-4-5	
2	Inspection of Medical Device Manufacturers:		101.0		29.2	130.2	82-6-8	
	GMP Inspections	82845A-S	(100.3)		(29.2)	(129.5)		
	Accredited Persons Audit Investigations	82845J	(0.2)			(0.2)		
	Accredited Persons Audit Inspections	82845P	(0.5)	- v		(0.5)		
	Condom Assignment	82Z002		3.6		3.6	82-9	
4	Manufacturers and Importers of Surgical/Examination Gloves	82Z003		5.5		5.5	82-10	
5	Center Initiated Assignments	82Z800	5.3			5.3	82-11	
6	Methods Validation/Development Program	82R816	2.0			2.0	82-12	
7	Forensic Evaluation & Sample Analysis	82R838	0.3			0.3	82-13	
	- 1						**	
	* In addition to PAC 82008, includes reporting							
	PACs 82R824, 82R833, and 99R833.						** *** **** **** **** **** **** **** ****	
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	R PROJECT MANAGER/TELEPHONE Gliverman 301-796-5500				R/TELEPHON n 301-796-43			

FORM FDA 2622 (10/09) PAGE NO. 82-3

			FY 2013 ORA	WORKPLAN					Oc	tober 1, 2012
1. PRC	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUI	MBER			
Moni	oring Devices of Foreign Origin - I	mport			Compliance	e: Devices - 8	32			
3 PRC	GRAM/ASSIGNMENT CODE(S)		4 WORK	ALL OCATION	PLANNED BY			5 OPERAT	IONAL FTE PO	SITIONS
0.1710		022	i. Wordt	ATTENDED OF THE PERSON OF THE			_	J. OF LIKAT		
	82008, 82R824, 82R833, 99R	833		X	ORA	CENTE	R		44.0	[43.2]
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 ENTRY REVIEW (Hours)	2 IMPORT INVESTI- GATION HOURS (1)	MAIL COURIER REVIEW	2 INTERNATIONAL MAIL FACILITY REVIEW	4 IMPORT SAMPLE COLL (Physical) MICRO (2)	4 IMPORT SAMPLE COLL (Physical) ENG	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES TO BE ANALYZED MICRO (3)	8 IMPORT SAMPLES TO BE ANALYZED ENG
	TOTAL FIELD	26062	4037	2200	300	60	120	20900	60	150
	HEADQUARTERS	(b)(5)&(b)					,_,_,			100
	REGIONAL STAFF	(2)(2)2.(2)								
1	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
1	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1								
L	CHICAGO									
	CINCINNATI									
CE	DETROIT	1								
CE	MINNEAPOLIS	1								
	NEW JERSEY	1								
1	PHILADELPHIA	1								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF	1								
	ATLANTA									
SE	FLORIDA	1								
J.	NEW ORLEANS									
	SAN JUAN	1								
	REGIONAL LAB	1								
\vdash	REGIONAL STAFF									
	DALLAS									
sw	DENVER	1								
J	KANSAS CITY									
1	SOUTHWEST IMPORT DISTRICT	1								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
1.0	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	PER OPERATION		T			2.2	2.2	0.4	30.4	30.4
	HOURS	26062	4037	2200	300	132	264	8360	1824	4560
	ERSION FACTOR	1200	950	950	950	950	950	950	1180	1180
	OPERATIONAL FTEs	21.72	4.25	2.32	0.32	0.14	0.28	8.80	1.55	3.86
-								0.00	1.00	0.00

- (1)-Import investigation hours are for filer evalutions, 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.

. PROG	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATI	PERATIONAL FTE POSITIONS		
	82008, 82R824, 82R833, 99R8	333		X	ORA [CENTE	R		44.0	[8.0]	
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED CHEM									
	TOTAL FIELD	30									
	HEADQUARTERS	(b)									
	REGIONAL STAFF	(5)&(b)									
	NEW ENGLAND	(7)(E)									
-	NEW YORK	-									
_	REGIONAL LAB	-									
	WEAC REGIONAL STAFF	-									
	BALTIMORE	-									
-	CHICAGO										
_	CINCINNATI										
	DETROIT										
-	MINNEAPOLIS										
	NEW JERSEY	_									
	PHILADELPHIA	,			-						
	FORENSIC CHEM. CTR	-			\vdash						
	REGIONAL STAFF	-			-						
	ATLANTA FLORIDA	-									
_	NEW ORLEANS	-									
	SAN JUAN										
-	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER	_									
	KANSAS CITY	-									
	SOUTHWEST IMPORT DISTRICT	-								_	
	REGIONAL LAB REGIONAL STAFF	-						<u> </u>			
٠,	LOS ANGELES										
	SAN FRANCISCO	-	- IMPORT								
	SEATTLE	-									
- 1	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
OURS	PER OPERATION	30.5									
	HOURS	915									
ONVE	RSION FACTOR OPERATIONAL FTES	1180 0.78								-	
REM	UPERATIONAL FTES										

			FY 2013 ORA	WORKPLAN					Oc	ctober 1, 2012
1. PRC	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUM	MBER			
Inspe	ction of Medical Device Manufactur	rers			Compliance	e: Devices - 8	2			
3. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	SITIONS
0	82845A,B,C,G,H,J,K,P,S,81845R,7	T 91011	35% Galacticate				7.0%	0. 0. 2		
		1,01011			ORA	CENTE	.R		130.2	[126.1]
R H G - O Z	6. DISTRICT/ SPECIALIZED LABORATORY	INSPECTIONS LEVEL I DOMESTIC 82845A	INSPECTIONS LEVEL II DOMESTIC 82845B	INSPECTIONS LEVEL III COMPLIANCE DOMESTIC 82845C	1 INSPEC- TIONS FOREIGN 82845B	1 INSPECTIONS FOR CAUSE DOMESTIC 82845G	INSPECTIONS FOR CAUSE HIGH RISK DOMESTIC 82845H	1 INSPEC- TIONS FOR CAUSE HIGH RISK FOREIGN 82845H	1 INSPECTIONS ACCRED PERSONS DOMESTIC 82845P	2 INVESTI- GATIONS (Hours) 82845B
	TOTAL FIELD	782	530	115	368	113	43	38	9	1494
	HEADQUARTERS	(b)(5)&(b)								, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	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									
9	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	S PER OPERATION	39.6	63.1	115.0	65.0	72.3	99.9	100.0	53.0	100
TOTAL	HOURS	30967	33443	13225	23920	8170	4296	3800	477	1494
CONVE	ERSION FACTOR	950	950	950	950	950	950	950	950	950
TOT.	ODEDATIONAL ETE-	20.00	25.00	40.00	05.40					

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.

TOTAL HOURS
CONVERSION FACTOR

TOTAL OPERATIONAL FTES

Accredited Person Audits are conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO.

190

950

0.20

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.

252

950

72

950

0.08

71

950

0.07

1 000	GRAM/ASSIGNMENT TITLE				0 DDC DDO II	OT MALIE AUG	IDED			100er 1, 2012
I. PRO	GRAWASSIGNMENT TITLE					ECT NAME/NUM				
Inspe	ction of Medical Device Manufactur	rers			Compliance	: Devices - 8	32			
0.000	ODANIA COLONINENIA CODECO		4. 14/001/		D					
	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	SITIONS
	82845A,B,C,G,H,J,K,P,S,81845R,7	Г,81011		X	ORA	CENTE	130.2			[3.5]
R	6. DISTRICT/	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC	7 DOMESTIC			
E	SPECIALIZED	SAMPLES	SAMPLES	SAMPLES	SAMPLES	SAMPLES	SAMPLES			
G	LABORATORY	TO BE	TO BE	TO BE	TO BE	TO BE	TO BE			
0		ANALYZED ENG	ANALYZED MICRO	ANALYZED CHEM	ANALYZED	ANALYZED	ANALYZED	1		
N		82845C	82845C	82845C	ENG 82845H	BIOBURDEN 82845\$	STERILITY 82845S			
	TOTAL FIELD	10	26	6	12	10	5			
	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	80.0	62.0	38.0	88.3	25.0	29.5			
TOTAL	HOURS	800	1612	228	1060	250	148			
	DNVERSION FACTOR 1180			1180	1180	1180	1180			
TOTAL	OPERATIONAL FTEs	0.68	1.37	0.19	0.90	0.21	0.13			
9. REM	ARKS									

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 Reagant Testing to support GMP observations at WEAC; Sporicidal and Tuberculocidal at WEAC and DEN Lab.

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJECT NAME/NUMBER					
	om Assignment				Compliance	: Devices - 8	2			
Condo					Compilation					
			V CONTRACTOR							
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	\		5. OPERATIONAL FTE POSITIONS		
	82Z002			X	ORA	CENTE	R		3.6	
R	6. DISTRICT/	1	4	4	8 IMPORT	8 IMPORT				
E	SPECIALIZED	INSPEC-	IMPORT	IMPORT	SAMPLES	SAMPLES			1	1
G	LABORATORY	TIONS	SAMPLE	SAMPLE	TO BE ANALYZED	TO BE ANALYZED				
0			(Physical)	(Physical)	(Physical)	(Physical)				
N			CHEM	ENG	CHEM	ENG				
	TOTAL FIELD	1	197	127	197	127				
		(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF							`		
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI DETROIT									
CE	MINNEAPOLIS									
	NEW JERSEY						-			
	PHILADELPHIA								-	
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA						***************************************			
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									N. 200 L. 100 L.
SW	DENVER									
	KANSAS CITY									
]	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES							-		
PA	SAN FRANCISCO							1		
1	SEATTLE							 		
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	29.0	2.9	2.9	9.5	9.5		1	-	
	HOURS	29.0	571	368	1872	1207		1		
	ERSION FACTOR	950	950	1180	1180		1	†	-	
	OPERATIONAL FTES	950 0.03	0.60	0.39	1.59	1.02				
9. REM										

Import Samples are estimated and should be collected to cover the districts' workload.

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

1. PRC	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NUM	IBER			
Manu	facturers and Importers of Surgical/	Examinatio	n Gloves		Compliance	e: Devices - 8	32			
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	- 10 to to		5. OPERAT	IONAL FTE PO	DSITIONS
	82Z003			X	ORA	CENTE	R		5.5	
R E G - 0 Z	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL (Physical) CHEM	4 IMPORT SAMPLE COLL (Physical) ENG	8 IMPORT SAMPLES TO BE ANALYZED (Physical) CHEM	8 IMPORT SAMPLES TO BE ANALYZED (Physical) ENG	9 OTHER OPERATIONS (Hours) ENG				
	TOTAL FIELD	360	303	360	303	1180				
	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF									
	NEW ENGLAND							CONTRACTOR OF THE PARTY OF THE		
NE	NEW YORK .									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
1	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
l	NEW JERSEY									
	PHILADELPHIA									
ı	FORENSIC CHEM. CTR									
	REGIONAL STAFF							1		
1	ATLANTA							1		
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									
HOUR	S PER OPERATION	2.3	2.3	5.2	5.2					
TOTAL	HOURS	828	697	1872	1576	1180	11.00			
	ERSION FACTOR	950	950	1180	1180	1180				
TOTAL	OPERATIONAL FTES	0.87	0.73	1.59	1.34	1.00	505 38453500		V 312 12 COMMON	

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. PRC	GRAM/ASSIGNMENT TITLE	(6)	I I ZUIJ ORIT		2. PPS PROJE	ECT NAME/NUM	//BER			1,2012
	r Initiated Assignments				Compliance	: Devices - 8	22			
Conto	minated Assignments				Compilance	. Devices - 6	12			
\vdash										
3. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATIONAL FTE POSITIONS		
	82Z005, 82Z800			X	ORA	ORA CENTER			5.3	
R E G I O	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS CENTER- INITIATED	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	DOMESTIC SAMPLES TO BE ANALYZED STERILITY (3)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	7 DOMESTIC SAMPLES TO BE ANALYZED ENG	9 OTHER OPER- ATIONS (Hours)		
N		82Z800	(1) 82Z800	82Z800	82Z800	82Z800	82Z800	ENG (5) 82Z800		
	TOTAL FIELD	31	50	5	11	15	11	1600	1181	
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
1	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
l	NEW JERSEY									
l	PHILADELPHIA									
L	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
l	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
Į.	SAN JUAN									
L	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									
	S PER OPERATION	43.2	8.0	15.0			100.0			
	HOURS	1339	400	75	-		1100			
-	ERSION FACTOR	950	950	1180	1180		1180	1180		
TOTAL	OPERATIONAL FTEs	1.41	0.42	0.06	0.47	0.64	0.93	1.36		

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	FY 2013 ORA	WORKPLAN					Oc	tober 1, 2012
1. PRC	OGRAM/ASSIGNMENT TITLE					JECT NAME/NU	MBER		- 0,	AUDEI 1, 2012
	ods Validation/Development Program	m				e: Devices - 8				
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALL OCATION	PLANNED B	Υ		5. OPERATIONAL FTE POSITIONS		
0	82R816		- Work	7	X ORA CENTER			J. OFEINI	2.0	ZOTTIONS
	8210				ORA CENTER				2.0	
_	6.	9	9							
R	DISTRICT/ SPECIALIZED	METHODS	METHODS							
G	LABORATORY	VAL/DEV	VAL/DEV			1				
0		CHEM (Hours)	MICRO (Hours)			1		1		
N		***************************************								
	TOTAL FIELD	1205	1205					, , , , , , , , , , , , , , , , , , ,		
	HEADQUARTERS	(b)(5)&(b))(/)(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								 		
	NEW ORLEANS				<u> </u>					
	SAN JUAN			30000			<u> </u>			
	REGIONAL LAB									
	REGIONAL STAFF									ATTENNESS INC.
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
	REGIONAL STAFF					 				
	LOS ANGELES								****	
PA	SAN FRANCISCO									
	SEATTLE									
9	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	S PER OPERATION									
	HOURS	1205	1205			_				
	ERSION FACTOR OPERATIONAL FTES	1205 1.00	1205 1.00			 		 		
		1.00	1.00							
9. REM	ARKS									

sic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82									
and Brandanian and Sample 11111, 111				00.11						
OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	SITIONS	
82R838			X	ORA	CENTE	R	0.3			
6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC ANALYSIS CHEM (Hours)									
TOTAL FIELD	360									
		and the second								
REGIONAL STAFF	(7)(E)									
	-									
	_									
WEAC										
REGIONAL STAFF	_									
	_				-					
	-							33300		
MINNEAPOLIS										
	_									
	_			<u> </u>						
	_									
ATLANTA										
FLORIDA	_									
	_				-					
		1998 1908 V								
REGIONAL STAFF	_									
DALLAS										
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	_									
REGIONAL STAFF										
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	-									
	_									
PACIFIC REGIONAL LABORATORY-NW										
					-		<u> </u>			
OPERATIONAL FTEs	0.30	· · · · · · · · · · · · · · · · · · ·								
MARKS										
	BORRAM/ASSIGNMENT CODE(S) 82R838 6. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD 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 LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW	B. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD TOTAL FIELD 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 LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-NW IS PER OPERATION L HOURS GERSION FACTOR L OPERATIONAL FTES O .30 PERSION FACTOR L OPERATIONAL FTES O .30	B. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD TOTAL F	DGRAM/ASSIGNMENT CODE(S) 82R838 E. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD TOTAL FIELD MEADQUARTERS REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL LAB WEAC REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF BALTIANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL LAB REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATILE LOS ANGELES SAN FRANCISCO SEATILE PACIFIC REGIONAL LABORATORY-NW SPER OPERATION L HOURS 360 LESSION FACTOR 1205 LOPERATIONAL FTES 0.300	B. DISTRICT/ SPECIALIZED LABORATORY TOTAL FIELD FORMSIC ANALYSIS CHEM (Mours) TOTAL FIELD S60 HEADQUARTERS (b) (5) & (b) REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL LAB WEAC CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL LAB REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LABORATORY-NW RESPION FACTOR 1205 LOVERSTON BANGELES SAN FRANCISCO SEATTLE REGIONAL LABORATORY-NW REPROPERATION LHOURS 360 LHOURS LHOURS 1205 LOVERSTON BANGELES SAN FRANCISCO SEATTLE REGIONAL LABORATORY-NW REPROPERATION LHOURS 1205 LOVERSTON BANGELES 1205 LOV	SZR838	S2R838 8. WORK ALLOCATION PLANNED BY 82R838 8. DISTRICT/ SPECIAL/ZED LABORATORY TOTAL FIELD 10. S60 HEADQUARTERS (D)(5)&(0) REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL STAFF BALTIMORE CHICAGO	DGRAM/ASSIGNMENT CODE(S) 82R838 4. WORK ALLOCATION PLANNED BY 82R838 5. DISTRICT/ SPECAL/IZED AMALYSIG CHEM (Reurs) HEADQUARTERS (b)(5)(6)(b) HEADQUARTERS (c)(5)(5)(c) HERM (Reurs) HEM VORK REGIONAL STAFF (7)(E) NEW FINGLAND NEW YORK REGIONAL STAFF BALTIMORE CHICARGO CINICINATI DETROIT MINNEAPOLIS MINNEAPOLIS MINNEAPOLIS MINNEAPOLIS MINNEAPOLIS NEW GRICANS TORRESSEY PHALDELPHIA FORENSIC CHEM CTR REGIONAL STAFF ATLANTA FLORIDA NEW GRICANS NEW GRICANS NEW GRICANS SAN JUAN REGIONAL STAFF DALLAS DENVER LANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL STAFF LOS AN GRICANS SAN FRANCISCO SEATTLE REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-WW SPEC OPERATION LHOURS 360 100 100 100 100 100 100 100 100 100	S. DISTRICT/ SPECIALIZED S. OPERATIONAL FTE PC	

PROJECT SUMMARY SHEET

FY 2013

1. PROGRAM CATEGORY
2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health
Product Evaluation: Devices - 83

NO.	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT	6. OPERATIONA			7. TOTAL OPERATIONAL	8. PAGE
	TOTAL	CODE	DOMESTIC	IMPORT	FOREIGN	FTEs	
			29.4		4.5	33.9	
1	Medical Device Premarket Approval and Postmarket Inspections:		6.2		2.5	8.7	83-15
	MDUFMA User Fee	83001	(5.0)			(5.0)	
	PreMarket Approval Inspections	83001			(1.6)	(1.6)	
	Postmarket Approval Inspections	83001A	(1.2)		(0.9)	(2.1)	
2	Bioresearch Monitoring	83808-11	23.2		2.0	25.2	83-16
					-		
1							
1							
TEF	R PROJECT MANAGER/TELEPHONE Foreman 301-796-6382			ORA PLANNE	ER/TELEPHON in 301-796-43	IE	

FORM FDA 2622 (10/09)

	INEW ENGLAND								
NE	NEW YORK								1
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
CE	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY	1							
	PHILADELPHIA	1						 	
	FORENSIC CHEM. CTR	1							
	REGIONAL STAFF	1							
	ATLANTA	1							
SE	FLORIDA	1							
	NEW ORLEANS	1				AND ADDRESS OF THE PARTY OF THE			
	SAN JUAN	1							
	REGIONAL LAB	1							
	REGIONAL STAFF	1							
	DALLAS								
SW	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT	1							
	REGIONAL LAB								
	REGIONAL STAFF						-		
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOUR	S PER OPERATION	70.9	49.0	33.8	45.0				
TOTAL	HOURS	4750	1519	1149	855				
CONV	ERSION FACTOR	950	950	950	950				
TOTAL	OPERATIONAL FTEs	5.00	1.60	1.21	0.90	S - 20 N - 10			

NEW ENGLAND

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

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

1 PRO	GRAM/ASSIGNMENT TITLE		F 1 2013 OKA	WORKI LAN	_	ROJECT NAME/NU	IMBER		00	100ci 1, 2012	
					I					- 1	
A SHARE THE PARTY OF	search Monitoring				Product	Evaluation: De	evices - 83			- 1	
(Pre-N	Market)										
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED) BY		5. OPERATIONAL FTE POSITIONS			
	83808, 83809, 83810, 83811	Ĺ		X	ORA	CENT	ΓER	25.2			
	27 0 1				-						
R E G - O Z	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN								
1.0	TOTAL FIELD	300	25								
	HEADQUARTERS	(b)(5)&(b)	The second second second		\vdash	-	+	_			
	REGIONAL STAFF	(5)(5)&(5)	(1)(-)				—				
	NEW ENGLAND						1				
NE	NEW YORK				1						
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
'	BALTIMORE										
	CHICAGO										
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS						_		\vdash		
	NEW JERSEY										
	PHILADELPHIA				-		+	-	—		
	FORENSIC CHEM. CTR						+	 	 		
	REGIONAL STAFF				+	_	+			 	
\ <u></u>	ATLANTA				-		1			 	
SE	FLORIDA NEW ORLEANS						+				
	SAN JUAN						+	+			
	REGIONAL LAB				 						
	REGIONAL STAFF										
	DALLAS										
sw	DENVER								983399		
	KANSAS CITY										
1	SOUTHWEST IMPORT DISTRICT			-							
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	LOS ANGELES				-			+			
PA	SAN FRANCISCO				₩						
	SEATTLE							+			
1	PACIFIC REGIONAL LABORATORY-SW				-		+	+	-		
<u> </u>	PACIFIC REGIONAL LABORATORY-NW	70.5	75.		+			+			
	S PER OPERATION	73.5 22050			\vdash			+	1		
	L HOURS ÆRSION FACTOR	950			-			-			
	L OPERATIONAL FTEs	23.21	1.99		+		+	+			
9. REM Devid	MARKS the Bioresearch Monitoring inspection Cause with 30-day due dates;				ng to the f	following sche	me:				
	cted data audit for expedited PMA;	Į.									
	cted data audit for expedited PMA; cted data audit for non-expedited P										
	Cause with 60-90 day due dates;	IVIA,									
-Por	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.

	GRAM CATEGORY cal Devices and Radiological Health			2. PPS PROJECT NAME/NUMBER Science: Devices - 84								
NO.		5. PROGRAM	WHEEL THE TAX	PERATIONAL	7. TOTAL	8. PAG						
		ASSIGNMENT CODE	DOMESTIC	IMPORT	FOREIGN	OPERATIONAL FTEs	0. FAG					
	TOTAL		5.7			5.7						
1	Test Method Development and Evaluation	84Z002	3.7			3.7	84-18					
2	Methods Validation/Development Program	84R816	2.0			2.0	84-19					
-												
\dashv	2											

9.	REMARKS
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TOTAL HOURS

SAN JUAN
REGIONAL LAB
REGIONAL STAFF
DALLAS
DENVER
KANSAS CITY

REGIONAL LAB
REGIONAL STAFF
LOS ANGELES
SAN FRANCISCO
SEATTLE

HOURS PER OPERATION

CONVERSION FACTOR
TOTAL OPERATIONAL FTES

SOUTHWEST IMPORT DISTRICT

PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW

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

4390 1180

3.72

. PRC	GRAM/ASSIGNMENT TITLE				2. PPS PRO	DJECT NAME/NU	MBER			tober 1, 201	
Metho	ods Validation/Development Progra	m			Science: 1	Devices - 84					
B. PRC	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATIO	N PLANNED I	BY		5. OPERATIONAL FTE POSITIONS			
	84R816		X ORA CENTER				ER	2.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 APPLIED TECHNOLOGY CENTER (Hours) MICRO									
	TOTAL FIELD	2360									
	HEADQUARTERS	(b)									
NE	REGIONAL STAFF NEW ENGLAND NEW YORK	(5)&(b) (7)(E)									
	REGIONAL LAB WEAC	-			+	+		-			
	REGIONAL STAFF BALTIMORE	-									
	CHICAGO	_									
CE	CINCINNATI DETROIT	-						1000			
	MINNEAPOLIS	_									
	NEW JERSEY	-			-						
	PHILADELPHIA	-			├			-			
-	FORENSIC CHEM. CTR	-			-	-		+			
	REGIONAL STAFF ATLANTA	-		 	+			+			
SE	FLORIDA	-			 			 			
JL.	NEW ORLEANS	-		 	1	1		†			
	SAN JUAN	_			1			1			
	REGIONAL LAB										
	REGIONAL STAFF DALLAS										
SW	DENVER	_									
	KANSAS CITY	-						-			
	SOUTHWEST IMPORT DISTRICT	_		-		_		-			
	REGIONAL LAB REGIONAL STAFF	-			+	+		-	-		
	LOS ANGELES	-			+		<u> </u>	 			
PA	SAN FRANCISCO	-						 			
I A	SEATTLE	-			1						
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW	_									
HOLIR	S PER OPERATION				1		1	_			
	HOURS	2360									
	ERSION FACTOR	1180									
	OPERATIONAL FTEs	2.00					les esta				

PROJECT SUMMARY SHEET

4 DDC	GRAM CATEGORY	FY 2013 2. PPS PROJECT NAME/NUMBER								
Medi	cal Devices and Radiological Health	Mammography			s (MQSA) A	uthority - 85				
3. NO	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. O	PERATIONA IMPORT	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. PAGE			
	TOTAL		14.5		0.1					
I	Mammography Facilities Inspection Program	85014 A,C,F	14.5		0.1	14.6	85-21-22			
							-			

CENTE	R PROJECT MANAGER/TELEPHONE L. Rice 240-276-3209	31		ORA PLANNI Kristen Kam	ER/TELEPHON as 301-796-43	NE 391				

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NUM	/BER			1, 2012
Mamr	nography Facilities Inspection Progr	ram			Mammogra	phy Quality	Standards A	ct (MOSA) Authority	- 85
	8 7 7					p.,5 <		(,	0.5
2 000	GRAM/ASSIGNMENT CODE(S)	-20040, 1500 N	L WORK	ALL COATION	DI ANNED DIV					
S, PKU	A (50)		4. WORK	_	N PLANNED BY			5. OPERATION	ONAL FTE PO	
	85014 A,C,F			X	ORA	CENTE	R		14.6	[11.0]
	6.	1	1	1	1	1	1	2 1	9	9
R E	DISTRICT/						CONTROL CONTROL		OTHER	OTHER
G	SPECIALIZED LABORATORY	INSPEC- TIONS	INSPEC- TIONS	INSPEC- TIONS	INSPEC- TIONS	INSPEC- TIONS	INSPEC- TIONS	INVESTI- GATIONS	OPERA- TIONS	OPERA- TIONS
1		1001900000	FOREIGN					(Hours)	(Hours)	(Hours)
0 0		85014 (1)	85014 (2)	85014 (3)	85014 (4)	85014F (5)	85014F (6)	85014A (7)	85014C (8)	85014C (9)
	. TOTAL FIELD	541	15	119		9	9		3374	
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
. 1	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									
İ	LOS ANGELES									
PA	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	Г		
	HOURS	4328	120	952	360	99	99	2211	3374	1200
	RSION FACTOR	1160	1160	1160	1160	1160	1160	1160	1160	1200
	OPERATIONAL FTES	3.73	0.10	0.82	0.31	0.09	0.09	1.91	2.91	1.00
Control of the last	ADKS								2.01	50

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					2. PPS PROJECT NAME/NUMBER						
Mamr	nography Facilities Inspection Progr	am			Mammogra	phy Quality	Standards .	Act (MQS	A) Authorit	y - 85	
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	,		5. OPERATIONAL FTE POSITIONS			
	85014 A,C,F			Х	ORA	CENTE	ER		14.6	[3.6]	
K m G - O Z	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERA- TIONS (Hours) 85014C (10)	9 OTHER OPERA- TIONS (Hours) 85014C (11)								
	TOTAL FIELD	4164	59								
	HEADQUARTERS	(b)(5)&(b)	(7)(E)	PRODUCTION OF THE PROPERTY OF							
	REGIONAL STAFF										
1	NEW ENGLAND										
NE	NEW YORK										
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF						100				
	ATLANTA										
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB									700	
	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										
HOUR:	S PER OPERATION					1					
	HOURS	4164	59								
	ERSION FACTOR	1160	1160								
-	OPERATIONAL FTES	3.59	0.05			1					
7. REN	IARKS RS SHOULD REPORT ALL TECHN	IICAL ASS	ISTANCE &	COORDIN	NATION HO	URS					

(10) - Technical Assistance and Coordination Activities: non-RRHRs. (11) - Compliance Activities: Warning Letters.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY 2. PPS PROJECT NAME/NUMBER Medical Devices and Radiological Health Radiation Control and Health Safety Act (RCHSA) Authority - 86 4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS 3. NO. 5. PROGRAM 6. OPERATIONAL FTE 7. TOTAL 8. PAGE ASSIGNMENT OPERATIONAL CODE DOMESTIC IMPORT FOREIGN FTEs TOTAL 30.9 20.6 8.1 2.2 Inspection and Field Testing of Radiation-Emitting 5.1 0.9 6.0 86-24-25 Electronic Products: 86001 Inspection of Manufacturers of Laser Products (4:3)(0.9)(5.2)Field Implementation of the Sunlamp & Sunlamp 86002 (0.3)(0.3)Products Performance Standard as Amended Field Compliance Testing of Cabinet X-Ray Equipment 86004 (0.5)(0.5)2 Inspections of Manufacturers (Foreign and Domestic) and 86003 7.7 1.0 8.7 86-26-32 Field Compliance Testing of Diagnostic X-Ray Equipment 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 86008 Medical Device and Radiological Health Use (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 ORA PLANNER/TELEPHONE ynne L. Rice 240-276-3209 Kristen Kamas 301-796-4391

SUIT OF THE PERSON NAMED IN			F1 2013 ORA	WURKPLAN					- 00	ctober 1, 2012
1. PRO	OGRAM/ASSIGNMENT TITLE				2. PPS PROJE	ECT NAME/NUM	MBER			
Inspe	ection and Field Testing of Radiation	n-Emitting E	lectronic		Radiation C	Control and H	lealth Safet	y Act (RC)	HSA)	
Produ	acts	on any			Authority -					
3. PRO	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5 OPERAT	IONAL FTE PO	SUDITIONS
	1666-1677-1671 - 167-167-1671-177-177-177-177-177-177-177				_			J. OF LIVE		0.100
	86001, 86002, 86004			X	ORA	CENTE	:R		6.0	[4.7]
	6.	1	1	1	1	2	2	3	5	5
R	DISTRICT/	l webse								
E G	SPECIALIZED LABORATORY	INSPEC- TIONS	INSPEC- TIONS	INSPEC- TIONS	INSPEC- TIONS	INVESTI- GATIONS	INVESTI- GATIONS	DOMESTIC SAMPLE	FIELD EXAMS/	FIELD EXAMS/
1		1 1	FOREIGN		1000000000	(Hours)	(Hours)	COLL	TESTS	TESTS
0 N		86001	86001 (2)	86002 (3)	86004 (4)	86001 (5)	86004	86001	86001 (6)	86002
	TOTAL FIELD	105	30	3			31	5	Name and Address of the Owner, where	(7)
	HEADQUARTERS	(b)(5)&(b)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
0000000	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	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									
\vdash	REGIONAL LAB REGIONAL STAFF									
PA	LOS ANGELES SAN FRANCISCO									
PA	SEATTLE SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION	17.3	36.0	36.0	20.0			3.0	5.0	- 47
	HOURS	1817	1080	108	440	658	31	15	5.0 375	132
	ERSION FACTOR	950	1180	950	950	950	950		950	950
OOITT	OPERATIONAL FTEs	1,91	0.92	0.11	0.46	0.69	0.03		0.39	

7 REMARKS

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

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

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

1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJ	ECT NAME/NU	MBER			
Inspec	ction and Field Testing of Radiation	-Emitting El	lectronic		Radiation Control and Health Safety Act (RCHSA)					
Produ		-			Authority - 86					
			4 WORK	ALLOCATION	ON PLANNED BY 5. OPERATIONAL FTE POSITIONS					OCITIONS
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	-				5. OPERAT		
	86001, 86002, 86004			X	ORA	CENTE	ER .	1	6.0	[1.3]
	6.	9	9							
R H G - 0 Z	DISTRICT/ SPECIALIZED LABORATORY	OTHER OPERA- TIONS (Hours) 86001 (8)	OTHER OPERA- TIONS (Hours) 86002							
	TOTAL FIELD	1197	75							
	HEADQUARTERS	(b)(5)&(b)					<u> </u>			
	REGIONAL STAFF	(0)(0)(0)	(1)(L)							-
	NEW ENGLAND				-					
NE	NEW YORK									
1,,,	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	DETROIT			1			No. 25			
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									-
SE	FLORIDA									-
	NEW ORLEANS						<u> </u>		<u> </u>	-
	SAN JUAN									-
<u> </u>	REGIONAL LAB					_		_		
	REGIONAL STAFF				ļ			-		-
sw	DALLAS DENVER							1		+
SVV	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT							1		1
	REGIONAL LAB						100000			
\vdash	REGIONAL STAFF									1
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW					00,000	10000			
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION									
TOTAL	HOURS	1197	75							
CONV	ERSION FACTOR	950	950							
_	OPERATIONAL FTEs	1.26	0.08						L	
7. REN	MARKS									
Lase	r 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.

			FY 2013 ORA	WORKPLAN	<u> </u>				Or	ctober 1, 2012
1. PR	OGRAM/ASSIGNMENT TITLE				2. PPS PROJ	JECT NAME/NUI	MBER			
Inspe	ections of Manufacturers (Foreign an	nd Domestic) and		Radiation (Control and H	Health Safet	ty Act (RC	HSA)	
Field	Compliance Testing of Diagnostic	X-ray Equip	oment		Authority -		/ *************************************			7
	OGRAM/ASSIGNMENT CODE(S)			ALLOCATION	N PLANNED BY			- ODERAT	TIONAL FTE PO	PINOTEON
3.11			4 110111					5. UPERATI		
	86003			L X	ORA	X CENTE			8.7	[7.7]
R	6. DISTRICT/	1 1	1	1	1	2	2	5	5B	5
R E	SPECIALIZED	INSPEC-	INSPEC-	INSPEC-	INSPEC-	INVESTI-	INVESTI-	FIELD	AUDITS	FIELD
G I	LABORATORY	TIONS DOMESTIC	TIONS	TIONS	TIONS	GATIONS	GATIONS	EXAMS/	1	EXAMS/
0	1	DOMESTIC	FOREIGN	DIRECTED	4 '	(Hours)	(Hours)	TESTS	1 1	TESTS ENG
N		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(7)	Ente
	TOTAL FIELD	52		5	18	884	1051	345	30	50
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
ı	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									
1 /	SEATTLE									
1 /	PACIFIC REGIONAL LABORATORY-SW									
· VOLID	PACIFIC REGIONAL LABORATORY-NW	50.0	85.0	50.0	40.0					-
	S PER OPERATION	50.0	65.0				1054	3.0		
	HOURS ERSION FACTOR	2600 950	975	250			1051	1	120	-
	OPERATIONAL FTEs	2.74	950 1.03	950 0.26						
		4 4 7	1.00	U.EUF	4 0.007	4 0.50	4 1.11	1.037	4 0.13*	4 10.15

- (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.

1.11

1.09

0.13

0.13

			1 2013 OICA							100Cl 1, 2012
1. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJI	ECT NAME/NUI	MBER			
Inches	ctions of Manufacturers (Foreign and	d Domestic)	and		Radiation (Control and H	lealth Safet	v Act (RC)	HSA)	- 1
							carm barer	y mor (nec	15/1/	
Field	Compliance Testing of Diagnostic X	-ray Equipi	nent		Authority -	86				
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY	•		5. OPERATI	ONAL FTE PO	SITIONS
	86003		1	X	ORA	X CENTE	-R		8.7	[1.0]
	00003				0.01	L A J OLIVII	-11		0.7	[]
	6. 9									
R E	DISTRICT/ SPECIALIZED	OTHER						1 1		
G	LABORATORY	OPERA-								
1		TIONS				1		1 1		
0 N		(Hours) (8)				1		1 1		
100										
	TOTAL FIELD	965				-				
\vdash	HEADQUARTERS	(b)	·			 		-		
	REGIONAL STAFF	(5)&(b)				 				
	NEW ENGLAND	(7)(E)								
NE	NEW YORK					-	_	-		
	REGIONAL LAB			-		 	 	_		
-	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO					-				
	CINCINNATI			 		 		_		
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY					-				
	PHILADELPHIA									
	FORENSIC CHEM. CTR					ļ				
	REGIONAL STAFF			ļ		 				
	ATLANTA									
SE	FLORIDA					 				
	NEW ORLEANS					-		-		-
	SAN JUAN					 				
_	REGIONAL LAB									
	REGIONAL STAFF DALLAS				 	-		_		
CIA					 	 				
sw	DENVER KANSAS CITY				—	 				
			***					-		
	SOUTHWEST IMPORT DISTRICT				-	-	-			
<u> </u>	REGIONAL LAB REGIONAL STAFF			1	-	 				
	LOS ANGELES						l			
	SAN FRANCISCO					1		-	-	
PA	SEATTLE					-		 		
	PACIFIC REGIONAL LABORATORY-SW					 		_		
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION					 				
	HOURS	965								
	ERSION FACTOR	950				 				
	OPERATIONAL FTES	1.02				†				
7. REN		1.02				-			Annual Control of the	-
(8) - (Coordination/technical assistance h	nours for fie	ld test activ	ities.						
(0,-)	CONTRIBUTION CONTINUE GOOD CONTINUE T									

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

NEW ENGLAND DISTRICT

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

NEW YORK DISTRICT

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

CE REGIONAL STAFF (STATES IN BALTIMORE DISTRICT)

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

PAGE NO. <u>86-28</u>

CE REGIONAL STAFF (STATES IN CHICAGO DISTRICT)

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

CE REGIONAL STAFF (STATES IN CINCINNATI DISTRICT)

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

CE REGIONAL STAFF (STATES IN DETROIT DISTRICT)

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

CE REGIONAL STAFF (STATES IN MINNEAPOLIS DISTRICT)

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

CE REGIONAL STAFF (STATES IN NEW JERSEY DISTRICT)

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

CE REGIONAL STAFF (STATES IN PHILADELPHIA DISTRICT)

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

ATLANTA DISTRICT

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

FLORIDA DISTRICT

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

NEW ORLEANS DISTRICT

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

SAN JUAN DISTRICT

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

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

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

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

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

PAGE NO. 86-31

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

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

LOS ANGELES DISTRICT

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

SAN FRANCISCO DISTRICT

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

SEATTLE DISTRICT

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

PAGE NO. <u>86-32</u>

1. PRO	GRAM/ASSIGNMENT TITLE			The second second second	2. PPS PROJE	ECT NAME/NUM	MBER			
	liance Testing of Electronic Product	ts at WEAC			Radiation C	Control and H	ealth Safet	v Act (RC	HSA)	
Comp	mande resting of according frouder				Authority -			, (ACC)		
-		****	To some					T		
3. PRO	GRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERAT	IONAL FTE PO	SITIONS
	86006 A,D,E				ORA	X CENTE	R		3.1	
		1	7	7	7	7		-		
R	6. DISTRICT/	FOREIGN	DOMESTIC	DOMESTIC	DOMESTIC	DOMESTIC				
E	SPECIALIZED LABORATORY	INSPEC- TIONS	SAMPLES TO BE	SAMPLES TO BE	SAMPLES TO BE	SAMPLES TO BE				
G	LABORATORT	PL 90- 602	ANALYZED	ANALYZED	ANALYZED	ANALYZED				
0		STANDARD	MICROWAVE	X-RAY WHOLE	NON-MED	SUN LAMPS				
N				WHOLE	LASERS					
	TOTAL FIELD	(b)(5) 9 (b)	(7)/=)	4	42	10				
<u> </u>	Control of the Contro	(b)(5)&(b)	(/)(⊏)							
	REGIONAL STAFF NEW ENGLAND									
NE	NEW YORK									
1	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
1	CINCINNATI									
CE	DETROIT							-		
1	MINNEAPOLIS								-	
	NEW JERSEY							-		
1	PHILADELPHIA FORENSIC CHEM. CTR							 	-	
	REGIONAL STAFF							1		
	ATLANTA						20.00.000000000000000000000000000000000			
SE	FLORIDA									
1,000	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB								ļ	
	REGIONAL STAFF									
	DALLAS							 	 	
sw	DENVER KANSAS CITY							_		
	SOUTHWEST IMPORT DISTRICT							1		
	REGIONAL LAB									
	REGIONAL STAFF									
1	LOS ANGELES									
PA	SAN FRANCISCO									
1	SEATTLE							-		
1	PACIFIC REGIONAL LABORATORY-SW							-		
LIOUE	PACIFIC REGIONAL LABORATORY-NW	68.0	18.0	345.0	15.0	25.0		 	_	-
	S PER OPERATION HOURS	340	1098					1		
	ERSION FACTOR	1180	1180						1	
	OPERATIONAL FTES	0.29	0.93			-				
The second second	MARKS									
Work	plan includes both foreign inspecti	ion and lab	oratory testi	ing activitie	s for electro	nic products				
	(b)(7)(E)						any inspe			
emitt	ing medical device manufacturers,	a joint QSI	T and elect	ronic produ	ict radiation	control inspe	ection sho	uld be con	ducted by a	ì
	ed investigator. Instructions for per	forming ins	pections are	e provided	in Complian	ce Program	7 386.001,	with time	reported un	ider
PAC	86006.									
Repo	ort time for specific lab analyses un	ider PAC 80	6006, using	the approp	priate colum	n and an acc	urate des	cription of	the type of	
prod	uct tested (e.g. hand-held laser pro	duct, mobil	le diagnosti	c x-ray sys	tem, househ	nold microwa	ve oven) i	n FACIS.		
1.		DEC								
Labo	ratory allocations were planned by	DF5.								

1. PRO	OGRAM/ASSIGNMENT TITLE		. 2015 OKIT		2 PPS PROJE	CT NAME/NUM	MRER			100¢1 1, 2012
				8						
Impo	rted Electronic Products			1	Radiation C	ontrol and H	ealth Safe	ty Act (RC	HSA)	
					Authority -	86				
3. PR0	OGRAM/ASSIGNMENT CODE(S)		4. WORK A	LLOCATION	PLANNED BY		0.0000000000000000000000000000000000000	5 OPERAT	IONAL FTE PO	SITIONS
	86007, 86R824, 86R833, 99R8	22	1				_	J. Of LIVE		201110143
	80007, 80K824, 80K833, 99K8	333		X	ORA	CENTE	:R		8.1	
_	[6.	2	2	4	4	8				
R E	DISTRICT/ SPECIALIZED	IMPORT ENTRY	IMPORT	IMPORT		IMPORT		1		
G	LABORATORY	REVIEW	INV	FIELD	IMPORT SAMPLE	SAMPLES TO BE				
1		(Hours)	(Hours)		COLL	ANALYZED				
O N			(1)			ENG		1		
	TOTAL FIELD	6515	1400	400	25	25		 	 	
_	HEADQUARTERS	(b)(5)&(b)		400				 	-	
	REGIONAL STAFF		(1)(二)					!		
	NEW ENGLAND						-			
NE	NEW YORK							 		
,,,,	REGIONAL LAB							 		
	WEAC									
<u> </u>	REGIONAL STAFF									
	BALTIMORE							 		
	CHICAGO							1		
	CINCINNATI							1	——	
CE	DETROIT									
"-	MINNEAPOLIS								—	-
	NEW JERSEY							 		
	PHILADELPHIA							1	†	
	FORENSIC CHEM. CTR							1		
	REGIONAL STAFF									
	ATLANTA							 		
SE	FLORIDA							_		
	NEW ORLEANS							1		
	SAN JUAN									
	REGIONAL LAB							1		
	REGIONAL STAFF									
	DALLAS									
sw	DENVER							1		
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION			0.7	5.7	34.0				
TOTAL	HOURS	6515	1400	280	143	850				
CONV	ERSION FACTOR	1200	950	950	950	1180	100000000000000000000000000000000000000			
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. PRO	GRAM/ASSIGNMENT TITLE				2. PPS PROJE	CT NAME/NUM	/BER			
Radio	logical Health Control Activities	cal Health Control Activities Radiation Control and Health Safety Act (RCHSA)								
					Authority -					- 1
			T							
3. PRO	PROGRAM/ASSIGNMENT CODE(S) 4. WORK ALLOCATION PLANNED BY 5. OPERATIONAL FTE POSITIONS						ISITIONS			
86008, 86009 ORA X CENTER 5.0				5.0	- 1					
		9	9							
R	6. DISTRICT/		TECHNICAL							
E G	SPECIALIZED LABORATORY	MISC (Hours)	ASSISTANCE (Hours)							
ı	EABORATORT	RRHR	RRHR							
0		86008	86009							
N		(1)	-							
	TOTAL FIELD	3600								
	HEADQUARTERS	(b)(5)&(b)	(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB					$\overline{}$				
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO							350.500		
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR								1	
	REGIONAL STAFF									
1	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
l	SAN JUAN									
1	REGIONAL LAB									
	REGIONAL STAFF								110000-000-000-000-000-000-000-000-000-	
1	DALLAS									
sw	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
1	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
1	PACIFIC REGIONAL LABORATORY-SW									
1	PACIFIC REGIONAL LABORATORY-NW									
HOUR	S PER OPERATION									
	. HOURS	3600	2400							
CONV	ERSION FACTOR	1200								
TOTAL	OPERATIONAL FTEs	3.00	2.00							
	MARKS Continuation Sheet for footnotes, g	uidance, e	lc.							

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.

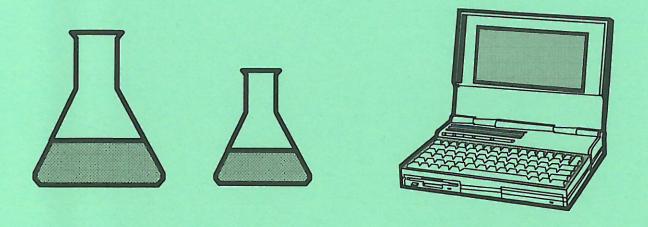
CENTER FOR TOBACCO RESOURCE SUMMARY FY 2013

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

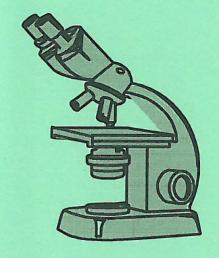
		1	Y 2013 UKA	WORKPLAN					Uc	tober 1, 2012
1. PRO	OGRAM/ASSIGNMENT TITLE	100			2. PPS PROJE	CT NAME/NUM	IBER			
Regu	lated Tobacco Products: Domestic as	nd Import			Tobacco - 9	6				
		00 000000000 2000 1 000000000000000000000000000000000				•				- 1
3. PRC	OGRAM/ASSIGNMENT CODE(S)		4. WORK	ALLOCATION	PLANNED BY			5. OPERATI	ONAL FTE PO	SITIONS
	96R800, 96T800, 96R824, 96R	922			ORA	OFNE				
	90K800, 901800, 90K824, 90K	023		X	ORA	CENTE	К		21.0	[13.8]
	6.	1	1	1	2	2	2	3	4	7
R	DISTRICT/ SPECIALIZED	PRE- APPROVAL	INSPEC- TIONS	INSPEC- TIONS	INVESTI- GATIONS	IMPORT INVESTI-	IMPORT ENTRY	DOMESTIC SAMPLE	IMPORT SAMPLE	DOMESTIC SAMPLES
Ğ	LABORATORY	INSPEC-		ASSIGN-	(Hours)	GATIONS	REVIEW	COLL	COLL	TO BE
1		TIONS	DOMESTIC	MENTS		(Hours)	(Hours)			ANALYZED
O N		DOMESTIC (1)	(2)	DOMESTIC (1)	(3)	(4)		(5)		CHEM
	TOTAL FIELD	10	50	10	1425	2000	2500	120	60	60
	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									
l	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
200000000	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
l	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
ı	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
116:16	PACIFIC REGIONAL LABORATORY-NW		07.0	07.0						
	S PER OPERATION	87.0 87.0	87.0	87.0 870		0000	otas	6.0	6.0	
	L HOURS	950	4350 950	950	1425	2000	2500	720	360	594
-	ERSION FACTOR	0.92	4 58	0.92	950 1.50	950	1200	950 0.76	950	1180

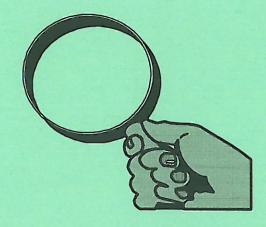
- (1) The Domestic Pre- Approval and Inspection Assignment columns represent the Center's potential need for Inspections. There may not be any Pre-Approval Inspections conducted in FY 2013.
- (2) Represents the locations of half the registered tobacco facilities. FDA is required to inspect each registered 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.
- (3) Represents assignments that include complaint follow-up, smokeless free sample events, and other similar investigative assignments.
- (4) Includes Import Label Exams.
- (5) Represents samples that may be collected during an Inspection, Investigation, or Sample Assignments.

ERATIONAL FTE POSITIONS 21.0 [7.2]
21.0 [7.2]
-



OPERATIONS





\/F\9 (\\/7\\F\)	
)(5)&(b)(7)(E)	

(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)	

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

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

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

Date: 07-SEP-2012 Time:7:06:22 AM

WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

Report: FWF118C Page 22 of 120

Report Type: Complete

POMESTICT NATE POMESTIC N	Region: NE REGN	1		2		3		4		5	
REGION TOTAL 1833 87.93 0 70.60 1172 7.75 7742 18.16 498 0.73		DOMESTIC IN	SPECTIONS	INVESTIGA	ATIONS	DOM SAMI	PL COLL	IMP SAMP	L COLL	FIELD EXA	M/TESTS
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 12.90 10.4 04 0 0 0.00 0 0 32.9 310 14.0 907 196 10 0.01 07 0 0.00 0 0 0.00 79 0.33 1194 0.41 0 0.00 09 0 0 0.00 0 0 16 20 0.00 0 32.5 0.48 0 0.00 18 0 0.00 0 0 16 20 0.09 9.0 0.00 0 0.00 21 0 0 0.00 0 0 0.16 20 0.09 9.0 0.00 0 0.00 21 0 0 0.00 0 0 0.26 77 0.35 377 0.57 202 0.09 22 13 0 0.00 0 0 0.00 29 0.11 88 0.14 0 0.00 BIOLOGICS 192 10.44 0 0 0.84 0 0.00 0 0 0.00 0 0.00 41 87 444 0 0 0.84 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 42 88 52.5 0 0.84 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 45 77 0.72 0 0.00 0.84 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 HUMANDRUGS 273 19.46 0 14.43 112 0.71 109 0.32 0 0.00 46 20 1.17 0 0.72 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 48 58 608 0 0.00 0 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 52 25 25 0.80 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0.00 52 2 180 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 52 2 180 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 52 2 180 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 53 22 180 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 54 70 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 55 12 5 0.80 0 0.00 0 0 0.00 0 0 0 0.00 0 0 0.00 0 0.00 56 126 8.52 0 0 14.30 777 0.50 86 0.24 0 0.00 58 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		· OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S			OPRNS	OPR FTE'S
POOD SAFETY/COS											
03	REGION TOTAL	1833	87.93	0	70.60	1172	7.75	7742	18.16	498	0.73
04	FOOD SAFETY/COS	801	32.90	0	46.25	718	5.09	7131	16.46	341	0.23
07 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	03	788	32.67	0	42.55	203	2.82	5240	12.90	129	0.14
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 0.00 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 46 20 1.17 0 0.00 2 0.71 109 0.32 0 0.00 48 58 6.08	04	0	0.00	0	3.29	310	1.40	907	1.96	10	0.01
18		0	0.00	0	0.00	79	0.33	194	0.41	0	
21	09	0	0.00	0	0.00	0	0.00	325		0	
BIOLOGICS 192 10.41 0 0.84 0 0.00 0 0.00 0 0.00 0	18	0	0.00	0	0.16	20	0.09	0	0.00		
BIOLOGICS 192 10.41 0 0.84 0 0.000 0 0.000 0 0.00 0 0.000 41 87 444 0 0 0.00 0 0.00 0 0.00 0 0 0.00 0 0 0.00 42 98 5.25 0 0.84 0 0.00 0.00 0 0.00 0 0.00 0 0.00 0 0.00 45 7 7.072 0 0.00	21	0	0.00	0	0.26	77	0.35	377	0.57	202	
41 87 4.44 0 0 000 0 0 000 0 0 000 0 0 0 0 0	29	13	0.23	0	0.00	29	0.11	88	0.14	0	0.00
HUMAN DRUGS	BIOLOGICS	192	10.41	0	0.84	0	0.00	0	0.00	0	
HUMAN DRUGS 273 19.46 0 14.63 112 0.71 109 0.32 0 0 0.00 0 0 0.00 46 2 0.01 0 0.00 46 20 1.17 0 0 0.00 2 0.01 0 0.00 0 0 0.00 0 0 0.00 48 46 20 1.17 0 0 0.00 2 0.01 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 52 2 0.01 0 0 0.00 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0 0.0	41	87	4.44	0	0.00	0	0.00	0	0.00	0	
HUMAN DRUGS 273 19.46 0 14.63 112 0.71 109 0.32 0 0 0.00 46 20 1.17 0 0.00 2 0.01 0 0.00 0 0 0.00 48 58 6.08 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 52 25 0.80 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 53 22 1.80 0 0.00 0 0 0.00 0 0 0.00 0 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 63 22 1.10 0 0.30 29 0.17 0 0.00 0 0.00 88 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 ANIMAL D&F 175 5.83 0 3.45 313 1.76 261 0.69 0 0 0.00 68 7 0.49 0 0.00 3 45 313 1.76 261 0.69 0 0 0.00 DEVICES & RAD H 390 19.16 0 430 19 0.12 224 0.59 157 0.50 81 15 0.29 0 0.00 3 15 0.10 222 0.58 0 0.00 82 233 13 36 0 2.32 15 010 222 0.58 0 0.00 83 0 5 402 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 84 0 0 0.00 85 1 0.36 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 86 36 36 1.13 0 1.21 1 0.00 22 0.58 0 0.00 87 10 0.00 0 0 0.00 0 0 0.00 0 0 0.00 88 0 0 0.00 0 0 0.00 0 0 0 0.00 0 0 0.00 89 0 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 80 0 0.00 0 0 0.00 0 0 0.00 0 0 0.00 81 0 0.00 0 0 0.00 0 0 0 0.00 0 0 0.00 82 0 0.00 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	42	98	5.25	0	0.84	0	0.00	0	0.00	0	
## 46	45	7	0.72	0	0.00	0	0.00	0	0.00	0	0.00
48	HUMAN DRUGS	273	19.46	0	14.63	112	0.71	109		0	
S2	46	20	1.17	0	0.00	2	0.01	0	0.00	0	
53 22 1.80 0 0.00 0 0 0.00 0 0 0.00 0 0 0 0.00 0 0 0.00 0 0 0 0 <th>48</th> <td>58</td> <td>6.08</td> <td>0</td> <td>0.00</td> <td>0</td> <td>0.00</td> <td>0</td> <td>0.00</td> <td>0</td> <td></td>	48	58	6.08	0	0.00	0	0.00	0	0.00	0	
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 0 0 0 0 0 0 0 0 0 0 0 0 0	52	25	0.80	0	0.02	4	0.03	23	0.07	0	
63	53	22	1.80	0	0.00	0	0.00	0		•	
88 0 0 0.00 0 000 0 0.00 0.00 0 0.00	56	126	8.52	0	14.30			86			
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 0.00 0 0 0.00 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00	63	22	1.10	0	0.30	29					
68 7 0.49 0 0.00 0.00 0	88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
68 7 0.49 0 0.00 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	ANIMAL D & F	175	5.83	0	3.45	313	1.76	261			
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 0 0.00 82 233 13.36 0 2.32 15 0.10 222 0.58 0 0.00 84 0 0.00 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 0 0.00 0 0.00 85 51 0.36 0 0.77 0 0.00 0 0.00 0 0.00 0 0.00 0 0.00 86 36 36 1.13 0 1.21 1 0.00 2 0.00 157 0.50 TOBACCO PROD 2 0.18 0 1.14 10 0.06 17 0.11 0 0.00 0.00 0.00	68	7	0.49	0	0.00						
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	71	168	5.34	. 0	3 45	313	1.76	261	0.69	0	0.00
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 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 <t< td=""><th>DEVICES & RAD H</th><td>390</td><td>19.16</td><td>0</td><td>4.30</td><td>19</td><td></td><td></td><td></td><td></td><td></td></t<>	DEVICES & RAD H	390	19.16	0	4.30	19					
83 55 4.02 0 0.00 0 0.00 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 0 0.00 85 51 0.36 0 0.77 0 0.00 0 0.00 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 0.00		15	0.29	0	0.00	3					
84 0 0.00 0 0.00 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 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	82	233	13.36	0	2.32	15		222			
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	83	55	4.02	0	0.00	0					
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	84	0		0							
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 0	85	51	0.36	0		0					
TOBACCO PROD 2 0.16 0 1.114 10 0.00		36	1.13	0	1.21	1	0.00	2			
\sim \sim \sim \sim \sim \sim \sim \sim \sim \sim	TOBACCO PROD	2	0.18	0	1.14	10				1=1	
		2	0.18	0	1.14	10	0.06	17	0.11	0	0.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Report Type: Complete

Region: NE REGN	6		7		8		9		10	
	IMPORT FIEL	D EXAMS	DOM SAMPL	ANALYSIS	IMP SAMPL A	NALYSIS	MISC		FOREIGN INSI	PECTIONS
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	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	9	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	d	0.00	0	0.00
41	0	0.00	0	0.00	0	0.00	\mathbf{o}_{i}	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 Workplan 0 - 2013

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Report Type: Complete

Region: NE REGN

8	Total			
	OPR FTE'S PERSNHRS			
	OTRITES	LKSMIKS		
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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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Report Type: Complete

Region: CE REGN	1		2		3		4		5	
	DOMESTIC IN	SPECTIONS	INVESTIG	ATIONS	DOM SAM	PL COLL	IMP SAME	L COLL	FIELD EXA	M/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
	1029	44.03	0	7.23	56	0.43	135	0.37	139	0.51
DEVICES & RAD H	5	0.10	0	0.02	0	0.00	0	0.00	0	0.00
81 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
	26	2.38	0	1.79	38	0.24	17	0.11	0	0.00
TOBACCO PROD	26 26	2.38	0	1.79	38	0.24	17	0.11	0	0.00
96	20	2.36	U	1.17	50					

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WORKPLAN SUMMARY / COMBINED OPERATIONS

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Report Type: Complete

Region: CE REGN	6		7		8		9		10	
	IMPORT FIEL	LD EXAMS	DOM SAMPL	ANALYSIS	IMP SAMPL A	ANALYSIS	MISC		FOREIGN INS	PECTIONS
	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 0.00
96	0	0.00	0	0.00	0	0.00	0	2.25	0	0.00

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Report Type: Complete

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		
	903.760.70	3.79563.53033.53		
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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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

Report: FWF118C Page 73 of 120

Region: SE REGN	1		2		3		4		5	
	DOMESTIC IN	ISPECTIONS	INVESTIG	ATIONS	DOM SAM	PL COLL	IMP SAMP	L COLL	FIELD EXA	M/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
	3	0.06	0	0.01	0	0.00	0	0.00	0	0.00
81 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
	38	3.48	0	1.70	62	0.39	13	0.08	0	0.00
TOBACCO PROD 96	38	3.48	0	1.70	62	0.39	13	0.08	0	0.00
90	38	J.46	U	1.70	02	0.07				

WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Region: SE REGN	6		7		8		9		10	
	IMPORT FIEL	D EXAMS	DOM SAMPL	ANALYSIS	IMP SAMPL A	NALYSIS	MISC	2	FOREIGN INS	PECTIONS
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	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	94()	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

WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Report Type: Complete

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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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Region: SW REGN	Ť		2		3		4		5	
	DOMESTIC IN	SPECTIONS	INVESTIG	ATIONS	DOM SAMI	PL COLL	IMP SAMP	L COLL	FIELD EXA	M/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	00.0	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 0.27
86	23	0.63	0	2.25	0	0.00	7	0.04	76	
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

WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Region: SW REGN	6		7		8		9		10	
	IMPORT FIEL	D EXAMS	DOM SAMPL	ANALYSIS	IMP SAMPL A	NALYSIS	MISC	3	FOREIGN INS	PECTIONS
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	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

WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Report Type: Complete

Region: SW REGN

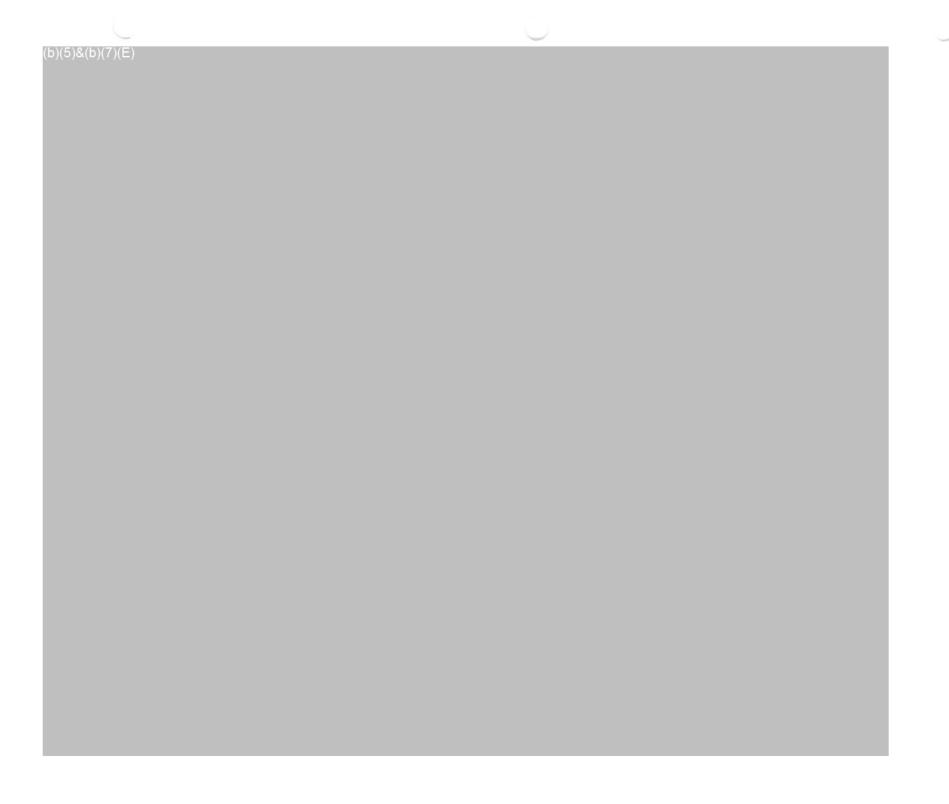
	Total				
	OPR FTE'S	PERSNHRS			
REGION TOTAL	465.22	494780.80			
FOOD SAFETY/COS	291.15	317199.60			
03	176.98	185849.80			
04	89.85	103753.30			
07	4.16	4691.00			
09	5.01	5613.70			
18	11.26	13469.00			
21	2.97	2825.70			
29	0.93	997.10			
BIOLOGICS	24.09	22884.10			
41	8.55	8125.00			
42	13.79	13096.50			
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			
70	2.00				



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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

Report Type: Complete

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Region: PA REGN	1	2	3	4	5

Region: PA REGN	1		2		3		4		5	
	DOMESTIC IN	ISPECTIONS	INVESTIG	ATIONS	DOM SAM	PL COLL	IMP SAME	L COLL	FIELD EXA	M/TESTS
	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
							122	0.70	0	0.00
HUMAN DRUGS	420	31.39	0	8.75	229	1.43	132	0.38 0.00	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 0.04	25	0.00	0	0.00
52	36	1.18	0	0.03	6	0.04	0	0.00	0	0.00
53	17	1.38	0 0	0.00 7.61	0 100	0.68	107	0.30	0	0.00
56	182	11.86	0	1.11	123	0.71	0	0.00	0	0.00
63	41	1.91	0	0.00	0	0.00	0	0.00	0	0.00
. 88	0	0.00	U						100	
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	14	0.09	0	0.55	2	0.01	7	0.05	0	0.00
	1	0.09	0	0.55	2	0.01	7	0.05	0	0.00
96	1	0.09	U	0.53	- 2	0.01	<i>∞</i> €	30.75		

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. WORKPLAN SUMMARY / COMBINED OPERATIONS

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Report Type: Complete

Region: PA REGN	6		7		8		9		10	
	IMPORT FIEL	D EXAMS	DOM SAMPL	ANALYSIS	IMP SAMPL A	NALYSIS	MISC	3	FOREIGN INS	PECTIONS
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	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
HUMAN DRUGS	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
	717	0.33	221	2.04	150	1.25	0	2.20	14	0.89
ANIMAL D & F 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
							0	2.24	45	2.89
DEVICES & RAD H	2200	0.98	0	0.00	429 0	2.14 0.00	0	0.00	0	0.00
81	0	0.00	0	0.00	429	2.14	0	0.00	32	2.37
82	2032	0.86	0	0.00 0.00	0	0 00	0	0.00	8	0.48
83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.83	5	0.03
85 86	0 168	0.00	0	0.00	Ö	0.00	0	1.40	0	0.00
					3.40		0	0.00	0	0.00
TOBACCO PROD	0	0.00	0	0.00	0	0.00 0.00	0	0.00	0	0.00
96	0	0.00	0	0.00	0	0.00	U	0.00	O .	3.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013

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Region: PA REGN

	Total				
	OPR FTE'S	PERSNHRS			
REGION TOTAL	487.99	501868.50			
FOOD SAFETY/COS					
03	324.57	341746.60			
04	256.79	265919,20			
07	42.42	47017.10			
09	3.72 2.47	4139.00			
		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			
70	U. /U	740.00			

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WORKPLAN SUMMARY / COMBINED OPERATIONS Workplan 0 - 2013 Pa

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		1		2		3		4		5	
	TOTAL FIELD	DOMESTIC IN	SPECTIONS	INVESTIG	ATIONS	DOM SAM	PL COLL	IMP SAMI	PL COLL	FIELD EXA	M/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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	6		7		8		9		10	
TOTAL FIELD	IMPORT FIEL	LD EXAMS	DOM SAMPL	ANALYSIS	IMP SAMPL	ANALYSIS	MIS	C	FOREIGN IN:	SPECTIONS
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	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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TOTAL FIELD

TOTAL FILLS	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