
FY 2009 ORA FIELD WORKPLAN



***MORE
RESOURCES!***

**DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION
PROGRAM PLANNING & WORKFORCE
MANAGEMENT BRANCH
ORA/ORM/DPEM**



**Memorandum**

Date September 22, 2008

From Deputy Director, Office of Resource Management

Subject Final FY 2009 ORA Field Workplan

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

The enclosed Final FY 2009 ORA Field Workplan incorporates several substantial changes. The first change you will notice is in the format of the Workplan. The Workplan is a much smaller document because items previously included with the Workplan, but not part of the Workplan, have been removed and are presented separately. This includes the narrative program descriptions, which are now contained in a separate document entitled "Program Descriptions", and the FTE/operations tables, which are contained in a separate document, entitled "FTE Reports". This change will not only make it easier for future FOI requestors to receive the Workplan, it will also make it easier to update the Workplan if the need arises.

Another change in the Workplan is the level of planned FTE. For the first time since the FY 2003 Workplan, total planned FTEs have increased. The FY 2009 Workplan is based on ORA's planning level of 1,872 Operational (3,400 Total) FTEs. This represents an overall increase of 125 Operational FTEs from the FY 2008 Workplan. This increase reflects the more optimistic budget outlook and the substantial hiring that occurred during the end of FY 2007 and throughout FY 2008. Even though the Workplan FTEs have increased, all Districts and Regional Laboratories will notice that their planned FTEs are below their numbers of investigators and analysts allocated in the [REDACTED]. This will allow for a training period for new hires to become functional in the activities planned in the Workplan.

Yet another change is in the Foods program, where there is a greater emphasis on a risk based approach to food Workplanning. Districts will now have specific lists of high risk firms to inspect, based on risk modeling by CFSAN. While it is difficult to plan for inspection of the high risk firms on a program by program basis, overall each District has sufficient planned inspectional resources and state contracts to cover all their high risk food firms. For a District, it means you may overburn in the Domestic Cheese Program, and underburn in the Domestic Food Safety Program, but overall the resources should balance out.

And the most significant change is the addition of a permanent Director for DPEM's Program Planning and Workforce Management Branch. Carrie Mampilly assumed leadership of the Branch on September 2. Carrie previously worked in the Branch as a planning analyst and most recently was at CDER/Office of Compliance as a Project Management Officer. Please feel free to contact Carrie on any Workplaning issues.

The "FY 2009 Workplan Changes" spreadsheets provide a listing of programs compared to the FY 2008 ORA Field Workplan, and will enable you to identify where specific resource shifts and programmatic cuts occurred.

The FY 2009 Servicing Laboratories Table continues to reflect the laboratory servicing changes consistent with ORA's Laboratory capabilities determined by the Division of Field Science. **Please review this table carefully before shipping any samples and note the latest changes.**

The FY 2009 Workplan has been published to a CD format. Your CD is non-writable and cannot be used to store or save data; however you may save any of the files to your PC system or to another media, i.e., zip drive, diskette, etc. You may make and distribute as many copies of this CD as needed. For further instructions, consult 'A User's Guide - **READ ME FIRST**' located on the CD. If you have any technical questions, please e-mail Anita McCurdy at amccurdy@ora.fda.gov.

Any questions about the attachments or programs in the Field Workplan should be addressed to the program/project's planning analyst identified on the workplanning sheets (Form FDA 2622). Policy concerns should be directed to Carrie Mampilly at (301) 827-2667.

Michael

Michael W. Roosevelt

FOODS AND COSMETICS

FY 2009 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2008	WORKPLAN FTEs FY 2009	FTE DIFFERENCE
03003,A	Import Acidified and Low Acid Canned Foods	14.8	18.0	3.2
03037,D	Domestic and Imported Cheese and Cheese Products	24.1	28.6	4.5
03803A	Domestic Acidified and Low Acid Canned Food	16.4	18.0	1.6
03803,B	Domestic Food Safety	96.3	139.7	43.4
03819A,B	Import Foods - General	267.1	247.1	-20.0
03842,B	Domestic Fish and Fishery Products	56.4	65.0	8.6
03844,B	Import Seafood Products	83.4	84.7	1.3
03847H	Juice HACCP Inspection Program	9.4	6.9	-2.5
03R233	Foreign Inspections/Assessments	5.7	7.3	1.6
03F098	Import/Domestic Micro Assignment	22.1	48.9	26.8
03R843	Contract Management	8.0	12.0	4.0
03R845	Food Defense	38.0	38.0	
03R816	Methods Validation/Development Program	11.0	10.0	-1.0
03	Foodborne Biological Hazards	652.7	724.2	71.5
04004A,D	Pesticides & Industrial Chemicals in Domestic & Import Food	59.7	59.7	
04018	Seafood Chemotherapeutics Sampling	32.7	32.6	-0.1
04019A,B,C	Toxic Elements in Foods & Foodware (Domestic & Import)	19.0	17.0	-2.0
04839	Total Diet Study	23.4	28.6	5.2
04F800	Field Assignments for Chemical Contaminants	7.8	6.4	-1.4
04R816	Methods Validation/Development Program	9.5	10.6	1.1
04R838	Forensic Evaluation and Sample Analysis	12.0	12.0	
04	Pesticides and Chemical Contaminants	164.1	166.9	2.8
07001	Mycotoxins in Domestic and Imported Foods	14.6	14.6	
07R816	Methods Validation/Development Program	4.5	4.5	
07	Molecular Biology and Natural Toxins	19.1	19.1	
09006A,B	Imported Foods-Food and Color Additives	13.6	13.6	
09	Food and Color Additives Petition Review	13.6	13.6	
18002	Retail Food Protection- State Program	23.0	24.0	1.0
18003	Milk Safety Program	20.3	20.4	0.1
18004	Molluscan Shellfish Evaluation Program	12.0	14.5	2.5
18029A-F	Interstate Travel Program Conveyances & Support Facilities	20.7	21.8	1.1
18	Technical Assistance: Food & Cosmetics	76.0	80.7	4.7
21002	Medical Foods - Domestic and Import	4.3	4.3	
21003	Domestic Food Labeling and Economics Program		3.1	3.1
21005	Domestic & Import NLEA	9.3	11.4	2.1
21006	Infant Formula Program	5.4	5.4	
21008	Dietary Supplements	16.9	20.3	3.4
21839	Selected Nutrients in Foods - Total Diet	3.4	3.4	
21R816	Methods Validation/Development Program	1.0	1.5	0.5
21	Food Composition, Standards, Labeling, & Econ	40.3	49.4	9.1
29001	Cosmetics Program - Imported and Domestic	8.4	8.1	-0.3
29	Colors and Cosmetics Technology	8.4	8.1	-0.3
	Total Mission Direct: Pre and Annual Planned FTEs	974.2	1062.0	87.8

BIOLOGICS

FY 2009 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2008	WORKPLAN FTEs FY 2009	FTE DIFFERENCE
41002	Tissue Establishments	19.5	22.5	3.0
41808	Good Laboratory Practices	*	*	
41809	Institutional Review Board	*	*	
41810	Sponsors, CROs, Monitors	*	*	
41811	Clinical Investigators	5.4	4.4	-1.0
41	Human Cellular, Tissue, & Gene Therapies	24.9	26.9	2.0
42001F,G	Blood Banks	53.0	53.0	
42002	Source Plasma Establishments	9.4	10.4	1.0
42007	Exam of Blood/Components - Import	2.5	3.0	0.5
42008,A	Licensed Viral Marker Test Kits	2.5	2.5	
42809	Institutional Review Board	*	*	
42810	Sponsors, CROs, Monitors	*	*	
42811	Clinical Investigators	3.5	4.0	0.5
42811	Foreign BIMO Inspection	**	**	
42845A,B,C	Medical Device Manufacturers (Biologics)	0.5	0.5	
42848A,F,G	Plasma Derivatives of Human Origin	3.0	3.0	
42	Blood & Blood Products	74.4	76.4	2.0
45809	Institutional Review Board	*	*	
45810	Sponsors, CROs, Monitors	*	*	
45811	Clinical Investigators	6.0	6.5	0.5
45848A,F,G	Licensed Allergenic Products	0.7	0.7	
45848B,C,D	Vaccine Products	4.0	4.5	0.5
45	Vaccines & Allergenic Products	10.7	11.7	1.0
	Total Mission Direct: Pre and Annual Planned FTEs	110.0	115.0	5.0

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

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

HUMAN DRUGS

FY 2009 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2008	WORKPLAN FTEs FY 2009	FTE DIFFERENCE
46832B,C	NDA Pre-Approval Inspections/Investigations (Domestic)	9.6	9.0	-0.6
46832B,C	NDA Pre-Approval Inspections/Investigations (Foreign)	14.0	14.0	
46	New Drug Evaluation	23.6	23.0	-0.6
48001/A	In Vivo Bioequivalence (Domestic)	6.0	5.5	-0.5
48001/A	Foreign Inspections (In Vivo, GLP, CI)	3.0	3.5	0.5
48808	Good Laboratory Practices	4.0	4.0	
48809	Institutional Review Boards	5.0	5.8	0.8
48810	Sponsors, Contract Research Orgs, Monitors	3.0	3.3	0.3
48811	Clinical Investigators (Domestic)	28.3	25.0	-3.3
48812	Clinical Investigators (Foreign)		15.0	15.0
48	Bioresearch Monitoring	49.3	62.1	12.8
52832	ANDA Pre-Approval Inspections/Investigations (Domestic)	13.1	5.0	-8.1
52832	ANDA Pre-Approval Inspections/Investigations (Foreign)	8.3	10.0	1.7
52	Generic Drug Evaluation	21.4	15.0	-6.4
53001A,B	Adverse Drug. Exp. Rpt. Regul (Domestic)	8.5	10.0	1.5
53001A,B	Adverse Drug. Exp. Rpt. Regul (Foreign)	1.0	1.0	
53	Postmarket Surv. & Epidemiology	9.5	11.0	1.5
56002A-F	Drug Process Inspections-Domestic	106.0	84.0	-22.0
56002E	Drug Process Inspections - Gas Manufacturers	4.0	5.0	1.0
56002A-F	Foreign Drug Inspections	12.5	34.0	21.5
56008A,C	Drug Product Surveillance (Domestic)	25.7	20.0	-5.7
56008H	Drug Product Surveillance (Import)	30.5	30.9	0.4
56021A,B	Drug Quality Reporting Systems-DQRS	4.0	4.5	0.5
56022	Enforcement of Rx Drug Marketing Act	2.0	2.0	
56843	Post-Approval Inspections/Investigations (Domestic)		2.0	2.0
56843	Post-Approval Inspections/Investigations (Foreign)		2.0	2.0
56D015	Pharmacy Compounding Assignments	4.0	5.0	1.0
56R838	Forensic Evaluation and Sample Analysis	10.0	10.0	
56	Drug Quality Assurance	198.7	199.4	0.7
63001	Internet, Health Fraud, & OTC Monographs	4.5	4.5	
63002	New Drugs (Prescription) Not Covered by Approved NDAs	4.0	5.0	1.0
63	Unapproved & Misbranded Drugs	8.5	9.5	1.0
88—	Shelf Life Extension Projects	12.0	12.0	
	United States Pharmacopeia (USP) Reference		7.0	7.0
88	Interagency Cooperative Activities	12.0	19.0	7.0
	Total Mission Direct: Pre and Annual Planned FTEs	323.0	339.0	16.0

ANIMAL DRUGS AND FEEDS

FY 2009 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2008	WORKPLAN FTEs FY 2009	FTE DIFFERENCE
68001	NADA Pre-Approval Inspections	2.3	2.9	0.6
68808	(Pre-Market) GLP and Spon/Mon/Com	2.0	2.0	
68810*	Sponsors Contract Research Orgs./Monitors	*	*	
68811	(Pre-Market) Clinical Investigators	2.5	2.4	-0.1
68	Pre-Approval Eval. of Animal Drugs & Food Additives	6.8	7.3	0.5
71001A,B**	Animal Drug Manufacturing Inspections	8.0	8.4	0.4
71003A-J	Feed Contaminants	14.2	18.3	4.1
71004A	Feed Manufacturing	5.3	4.2	-1.1
71006	Illegal Drug Residues in Meat and Poultry	12.0	16.9	4.9
71009, 71R844***	Ruminant Feed Ban Rule (BSE) Program	54.3	54.4	0.1
71R816	Methods Validation/Development Program	5.0	5.0	
71R831, 71R838	Forensic Evaluation and Sample Analysis	1.0	1.0	
71V800	Center Initiated Assignments	4.5	2.6	-1.9
71R852	Pandemic Preparedness (CANCELLED)			
71	Monitoring of Marketed Animal Drugs, Feed, & Devices	104.3	110.8	6.5
	Total Mission Direct: Pre and Annual Planned FTEs	111.1	118.1	7.0

* 68810 planned under 68808

** 71005 / A planned under 71001

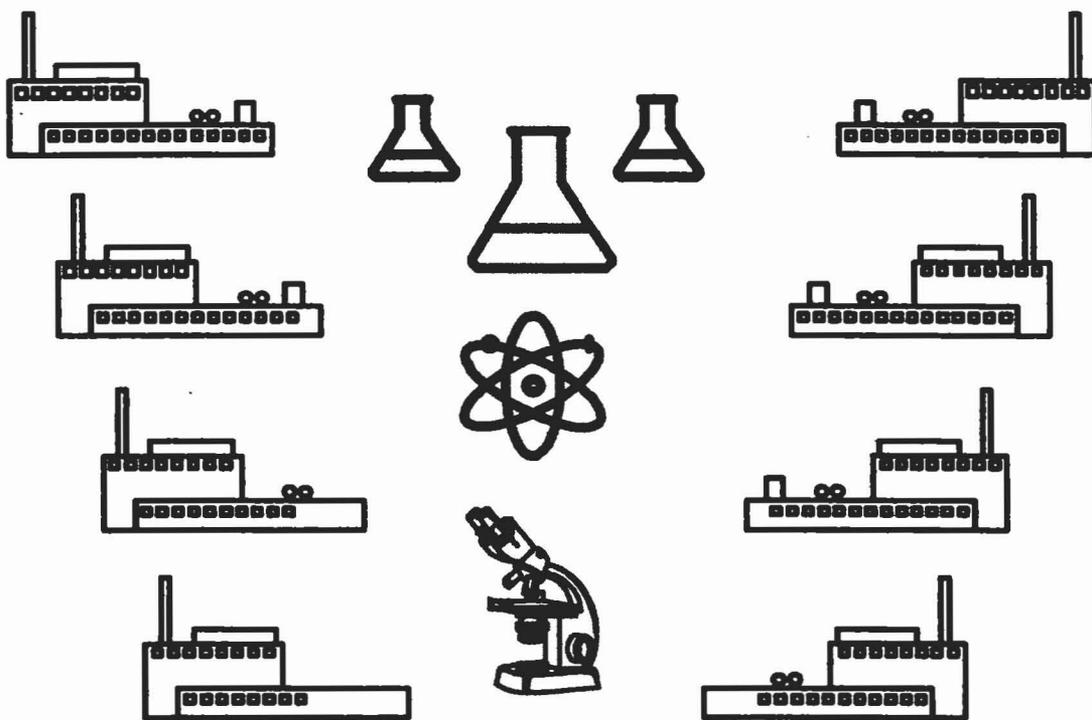
*** Includes 71R833, 99R833, and 71R824

MEDICAL DEVICES AND RADIOLOGICAL HEALTH

FY 2009 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2008	WORKPLAN FTEs FY 2009	FTE DIFFERENCE
81010	Med Dev Problem Reporting-MDR/DEN F/U	0.5	0.5	
81	Postmarket Assurance: Devices	0.5	0.5	
82008	Monitoring Device of Foreign Origin-Imports	28.1	29.1	1.0
82845A,B,C,G,S	Inspection of Medical Dev Mfgs: GMP Domestic	87.4	92.9	5.5
82845B	Inspection of Medical Dev Mfgs: GMP Foreign	13.7	17.2	3.5
82845P	Inspection of Accredited Persons: MDUFMA	1.0	0.5	-0.5
82845J	Audits of Accredited Persons	0.3	0.3	
82Z002	Condom Assignment	3.6	3.6	
82Z003	Mfgs & Importers of Surgical/Exam Gloves	6.5	6.5	
82Z005	BSE Assignment (CANCELLED)			
82Z800	Center Initiated Assignments	1.5	1.0	-0.5
82R816	Methods Validation/Development Program	2.0	2.0	
82R838	Forensic Evaluation and Sample Analysis	0.3	0.3	
82	Compliance: Devices	144.4	153.4	9.0
83001/A	Med Dev Premkt/Postmkt Insp Domestic	7.1	7.1	
83001/A	Med Dev Premkt/Postmkt Insp Foreign	2.6	2.6	
83808-11	Bioresearch Monitoring Domestic	24.5	24.5	
83810-11	Bioresearch Monitoring Foreign	0.8	0.8	
83	Project Evaluation: Devices	35.0	35.0	
84Z002	Test Method Development & Evaluation	3.7	3.7	
84R816	Methods Validation/Development Program	1.0	1.0	
84	Science: Devices	4.7	4.7	
85014	Mammography Facilities Insp Program Domestic	14.5	14.5	
85014	Mammography Facilities Insp Program Foreign	0.1	0.1	
85	Mammography Quality Standards Act (MQSA)	14.6	14.6	
86001	Inspection of Mfgs of Laser Products Domestic	4.2	4.2	
86001	Inspection of Mfgs of Laser Products Foreign	0.2	0.2	
86002	Field Implementation of Sunlamp Products	0.3	0.3	
86003	Field Compliance Testing of Diag X-Ray Equip Domestic	8.5	7.8	-0.7
86003	Field Compliance Testing of Diag X-Ray Equip Foreign		0.7	0.7
86004	Field Compliance Testing of Cab X-Ray Equip	0.5	0.5	
86006A,B,D,E	Compliance Testing of Elec Prod at WEAC Domestic	3.1	3.1	
86006	Compliance Testing of Elec Prod at WEAC Foreign	0.8	0.8	
86007	Imported Electronic Products	7.2	7.2	
86008	Med Dev & Rad Hlth Use Control & Policy Implementation	3.0	3.0	
86009	Emergency Planning & Response Activities	2.0	2.0	
86	Radiation Control & Health Safety Act (RCHSA)	29.8	29.8	
	Total Mission Direct: Pre and Annual Planned FTEs	229.0	238.0	9.0

FY 2009 SERVICING LABORATORIES



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

OCTOBER 2008

SERVICING LABORATORIES

FY 2009

MICROBIOLOGISTS

REGIONS >>>>>>>>>>>>	NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST				PACIFIC				
	NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA	
COLLECTING DISTRICT >>>>>														TX&NM CA&AZ								
ANIMAL DRUGS & FEED																						
71 POST APPR MON ANIMAL DRUGS FDS																						
DRUG PROCESS INSPECTION 71001	NRL	NRL	SRL	DEN	SRL	DEN	DEN	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN	
FEED CONTAMINANTS D/I 71003E	NRL	NRL	SRL	DEN	SRL	ARL	DEN	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	ARL	SAN	SAN	SAN	
MEDICATED FEEDS 71004	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
TYPE "A" MED ARTICLES 71005	-DEN-	-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-	-DEN-
METHOD VALIDATION 71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
MEDICAL DEV & RAD HLTH																						
81 POSTMKT ASSURANCE:DEVICES																						
PR MDR/DEN P/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																						
MON DEV FOREIGN-STERILE 82008	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-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-DISINFEC 82845C	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-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 DIAG 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-STER 822800	-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 822800	-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 842002	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-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.

**RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2009**

	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
	DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
TOTAL ALL PROGRAMS	1150.5	604.8	116.8	1872.1	2069.5	1118.3	212.2	3400.0
FOOD AND COSMETICS	549.8	504.9	7.3	1062.0	978.2	936.5	13.3	1928.0
BIOLOGICS	107.5	3.0	4.5	115.0	195.3	5.5	8.2	209.0
HUMAN DRUGS	228.6	30.9	79.5	339.0	415.5	56.1	144.4	616.0
ANIMAL DRUGS AND FEEDS	95.4	19.6	3.1	118.1	172.7	35.7	5.6	214.0
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	169.2	46.4	22.4	238.0	307.8	84.5	40.7	433.0

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2009**

October 1, 2008

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	549.8	504.9	7.3	1062.0	978.2	936.5	13.3	1928.0
3	FOODBORNE BIOLOGICAL HAZARDS	323.0	393.9	7.3	724.2	566.4	735.0	13.3	1314.7
4	PESTICIDES AND CHEMICAL CONTAMINANTS	92.7	74.2		166.9	168.4	134.6		303.0
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	13.8	5.3		19.1	25.1	9.6		34.7
9	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		13.6		13.6		24.7		24.7
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	80.7			80.7	146.5			146.5
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	36.6	12.8		49.4	66.3	23.4		89.7
29	COLOR AND COSMETICS TECHNOLOGY	3.0	5.1		8.1	5.5	9.2		14.7

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low Acid Canned Foods			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) 03003, 03003A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 18.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2	4	4	4	8	8
			IMPORT FIELD EXAMS (Hours) *	IMPORT SAMPLE COLLECTION	IMPORT SAMPLE COLL MICRO GUIDANCE	IMPORT SAMPLE COLL CHEM GUIDANCE	IMPORT SAMPLES TO BE ANALYZED MICRO **	IMPORT SAMPLES TO BE ANALYZED CHEM **
TOTAL FIELD			6400	1400	1300	100	1300	100
HEADQUARTERS			(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)	
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
REGIONAL LAB								
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
REGIONAL LAB								
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION				1.8			7.0	10.0
TOTAL HOURS			6400	2520			9100	1000
CONVERSION FACTOR			950	950			1180	1180
TOTAL OPERATIONAL FTEs			6.74	2.65			7.71	0.85
9. REMARKS								
<p>* Workload : Resource distribution for Field Exams and Import Sample Collections were determined by ORADSS line entry data as of June 6, 2008 for LACF, Acidified and aseptic foods. Field Exam hours are for field exams as required by the District to cover program priorities. Each field exam is estimated to take one hour.</p> <p>Import Field Exams, are to routinely include: verification that the imported product is the same as declared (reconciliation exam); an assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, report the CT exam under the CT PAC (03R845, 04R845 etc.). See IOM Section 5.4.1.4 for additional information on Food & Cosmetic activities.</p> <p>(b)(2)&(b)(7)(E)</p> <p>Surveillance activities under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program unless otherwise directed.</p> <p>** NOTE: SWID SAMPLES COLLECTED FROM TX & NM ARE SENT TO ARL. SWID SAMPLES COLLECTED FROM CA & AZ ARE SENT TO PRS.</p>								

2009 ORA WORKPLAN

OCTOBER 1, 2008 Page 1 of 2

1. PROGRAM/ASSIGNMENT TITLE Domestic and Imported Cheese and Cheese Products		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03									
3. PROGRAM/ASSIGNMENT CODE(S) 03037, 03037B, 03037D, 03R839		4. WORK ALLOCATION PLANNED BY ORA <input checked="" type="checkbox"/> CENTER <input checked="" type="checkbox"/>						5. OPERATIONAL FTE POSITIONS 28.6 (25.1) Page 1 (3.5) Page 2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	4	5	7	8	7	8
		INSPECTIONS (1)	INVESTIGATIONS (HOURS) (2)	DOMESTIC SAMPLES COLL (2)	DSC ENVIRON- MENTAL SAMPLE COLLECTION (3)	IMPORT SAMPLE COLL MICRO (3)	IMPORT SAMPLE COLLECTION (SURVEILLANCE CHEESE) (5)	DOMESTIC SAMPLES ANALYZED MICRO (4)	IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (5)	DSA MICRO ENVIRON- MENTAL ANALYSIS (6)	IMPORT SAMPLES TO BE ANALYZED MICRO (7)
TOTAL FIELD		270	950	270	270	630	75	270	75	270	630
HEADQUARTERS		(b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	NEW ENGLAND	(b)(2)&(b)(7)(E)									
	NEW YORK	(b)(2)&(b)(7)(E)									
	REGIONAL LAB WEAC	(b)(2)&(b)(7)(E)									
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	BALTIMORE	(b)(2)&(b)(7)(E)									
	CHICAGO	(b)(2)&(b)(7)(E)									
	CINCINNATI	(b)(2)&(b)(7)(E)									
	DETROIT	(b)(2)&(b)(7)(E)									
	MINNEAPOLIS	(b)(2)&(b)(7)(E)									
	NEW JERSEY	(b)(2)&(b)(7)(E)									
	PHILADELPHIA FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)									
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	ATLANTA	(b)(2)&(b)(7)(E)									
	FLORIDA	(b)(2)&(b)(7)(E)									
	NEW ORLEANS SAN JUAN	(b)(2)&(b)(7)(E)									
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	DALLAS	(b)(2)&(b)(7)(E)									
	DENVER	(b)(2)&(b)(7)(E)									
	KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2)&(b)(7)(E)									
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	LOS ANGELES	(b)(2)&(b)(7)(E)									
	SAN FRANCISCO	(b)(2)&(b)(7)(E)									
	SEATTLE	(b)(2)&(b)(7)(E)									
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)									
HOURS PER OPERATION		18.0		4.0	5.0	2.0		18.0	6.1	4.0	18.0
TOTAL HOURS		4860	950	1080	1350	1260		4860	458	1080	11340
CONVERSION FACTOR		950	950	950	950	950		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		5.12	1.00	1.14	1.42	1.33		4.12	0.39	0.92	9.61
9. REMARKS											
<p>(1) INSPECTIONS OF DOMESTIC FIRMS PRIORITIZES SOFT CHEESE (I.E. SOFT-FRESH, SEMI-SOFT, AND SOFT-RIPENED) MANUFACTURERS FIRST, HARD CHEESE MANUFACTURERS SECOND AND CHEESE PRODUCT MANUFACTURERS LAST. PRIORITIZE INSPECTIONS TO LOOK AT SMALL MANUFACTURERS I.E. ARTISANAL AND FARMSTEAD CHEESE MANUFACTURERS PRODUCING HIGH RISK CHEESE WHICH DISTRIBUTE CHEESE IN INTERSTATE COMMERCE. HIGH RISK FIRMS WHOSE LAST INSPECTION WAS NAI MAY BE PLACED ON A 3 YEAR INSPECTION FREQUENCY.</p> <p>(2) DOMESTIC SAMPLE COLLECTIONS: BASED ON INSPECTIONS. DISTRICTS MAY COLLECT BOTH COMPLIANCE AND SURVEILLANCE SAMPLES ACCORDING TO THE GUIDANCE IN THE COMPLIANCE PROGRAM TO FULFILL THEIR SAMPLING OBLIGATION. IF NO PROBLEMS ARE OBSERVED AT THE FIRM, THE DISTRICTS MAY ACCOMPLISH SAMPLING OBLIGATIONS BY COLLECTING SAMPLES DURING THE INSPECTION, OR BY COLLECTING SAMPLES AT THE WHOLESALE AND/OR RETAIL LEVEL.</p> <p>(3) INVESTIGATION HOURS BASED ON INSPECTIONS. TIME IS PROVIDED FOR ASSIGNMENTS TO COVER THE INVESTIGATION OF RAW MILK CHEESES.</p> <p>(4) DOMESTIC SAMPLE ANALYSIS: BASED ON DOMESTIC SAMPLE COLLECTIONS AND THE CURRENT SERVICING LABORATORIES CHART UNDER THE APPENDIX III OF THE ORA FIELD WORKPLAN.</p> <p>(5) PER CFSAN, IMPORT SAMPLE COLLECTIONS BASED ON THE PRIORITY COUNTRIES OF (b)(2)&(b)(7)(E)</p> <p>NOTE: SWID SAMPLES COLLECTED FROM TX & NM ARE SENT TO NRL. SWID SAMPLES COLLECTED FROM CA & AZ SENT TO NRL.</p> <p>(6) FILTH ANALYSIS SHOULD BE DONE AS NEEDED ON SPLIT IMPORT SAMPLES COLLECTED FOR MORE THEN ONE ATTRIBUTE.</p> <p>(7) IMPORT SAMPLE ANALYSIS CHEM/MICRO: BASED ON IMPORT SAMPLE COLLECTIONS AND THE CURRENT SERVICING LABORATORIES CHART UNDER APPENDIX III OF THE ORA FIELD WORKPLAN.</p> <p>(8) INVESTIGATOR/ANALYST WILL CONSULT ON ENVIRONMENTAL SAMPLING QUESTIONS.</p> <p>(9) 10 % OF INSPECTIONAL AND ANALYTICAL RESOURCES ARE SET ASIDE AS HOURS FOR OUTBREAK AND EMERGENCY OPERATIONS TO BE REPORTED UNDER 03R839.</p>											

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low Acid Canned Food					2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03803A, 03R839, (2)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 18.0			
R E G I O N	5. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1) (3)	3 FIELD EXAMS (1) (6) HOURS*	4 DOMESTIC SAMPLE COLLECTION (1) (5)	4 DOMESTIC SAMPLE COLLECTION MICRO GUIDANCE	4 DOMESTIC SAMPLE COLLECTION CHEM GUIDANCE	3 OUTBREAK AND EMERGENCY CSO (1) HOURS	7 MICRO- BIOLOGIST OUTBREAK AND EMERGENCY ANALYST HOURS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	8 BETTER PROCESS- ING SCHOOL (Training Hours) (4)
	TOTAL FIELD		360	1900	180	160	20	1200	280	20	160
HEADQUARTERS (b)(2)&(b)(7)(E)											
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
SEATTLE											
PACIFIC REGIONAL LABORATORY-SW											
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION		27.0		6.0					14.0	14.0	
TOTAL HOURS		9720	1900	1080			1200	280	280	2240	950
CONVERSION FACTOR		950	950	950			950	1180	1180	1180	950
TOTAL OPERATIONAL FTEs		10.23	2.00	1.14			1.26	0.24	0.24	1.90	1.00
9. REMARKS											
<p>(1) Source of workload: Inspections, Field Exam Hours, Outbreak & Emergency CSO hours and DSC's resource distribution based on CFSAN's LACF database.</p> <p>(2) Report all resources expended for NLEA under PAC 21005.</p> <p>(3) Inspect NAI firms on 3-year inspection cycle. State inspections may be conducted in addition to the number of inspections assigned per district.</p> <p>(4) Attendance at Better Processing Schools (BPS).</p> <p>(5) Planned collections are for projected "for cause" sampling.</p> <p>(6) Field Exams to include pH and canned seam evaluation.</p> <p>Surveillance activities under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.</p>											

FY 2009 ORA WORKPLANNING SHEET

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03										
3. PROGRAM/ASSIGNMENT CODE(S) 03803, B, C, D, E; 04803; 09803E,F; 03R839 (2) (5) (8)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 139.7 (99.3) Page 1 (40.4) Page 2					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS INCLUDING HIGH RISK (1) (3) (8)	2 NON- CLINICAL GLP INSPECTIONS (4)	4 INVESTI- GATIONS (HOURS) INCLUDES NATL EXPERT (1)	3 DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL MICRO GUIDANCE	DOMESTIC SAMPLE COLL CHEM GUIDANCE	DSAs MICRO SALMONELLA SEROTYPING (HOURS) (6)	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	FOOD SAFETY METHOD VALIDATION MICRO (HRS) (7)	FOOD SAFETY METHOD VALIDATION CHEM (HRS) (7)
	TOTAL FIELD	3600	10	20500	360	216	144	1180	216	144	1500	1500
(b)(2)&(b)(7)(E)												
	HEADQUARTERS											
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
	REGIONAL LAB											
SW	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
PA	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW											
PACIFIC REGIONAL LAB - NW												
HOURS PER OPERATION	18.0			6.0				12.0	12.0			
TOTAL HOURS	64800		20500	2160			1180	2592	1728	1500	1500	
CONVERSION FACTOR	950		950	950			1180	1180	1180	1180	1180	
OPERATIONAL FTEs	68.21		21.58	2.27			1.00	2.20	1.46	1.27	1.27	
7. REMARKS												
<p>(1) FY 2009 100% INSP, DSC, and Investigations based on: OEI of firms flagged as High Risk in FACTS less firms with only industry code 12, 16, or 51 as of January 18, 2008. Includes time for National Experts (3 FTEs). Resources have been allocated for 3600 total inspections. High Risk and GLP firms are included in this total number. Some of the inspectional & analytical resources planned may be directed for Allergen Work, once an Allergen Program or Assignment is issued by CFSAN.</p> <p>(2) Resources for 04803 and 09803E,F are included. Resources for audits are under State Contracts Program, 03R843.</p> <p>(3) Allergen Inspections may be assigned upon the issuance of an Allergen Program. * Do Not Initiate Surveillance (Allergen) Inspections until a New Allergen Program is issued. * Report Allergen inspections under PAC 03803E. "For Cause" Allergen Inspections are to be conducted as needed.</p> <p>(4) Non-Clinical Good Laboratory Practice Inspections: CFSAN will contact affected Districts to arrange inspections during the course of the year.</p> <p>(5) Assignments for sprout producers and egg farms, if needed in FY 09, will be taken from this Program.</p> <p>(6) Salmonella Serotyping: Samples generated from SRL & ARL go to ARL; Samples generated from other labs go to Denver.</p> <p>(7) Food Safety Method Validation for CHEM and MICRO: Resources are Pro-Rated based on the CHEM and MICRO Labs in the ORA Field Workplan Lab Servicing Table.</p> <p>(8) Non Seafood Inspections for EU and Chilean Certification will be handled by CFSAN Assignment and counted against the inspectional obligations of this program.</p> <p>(9) 10% of inspection and analytical resources are set aside for outbreak and emergency operations [page 2 of 2].</p> <p>(10) Investigator/analyst will consult on environmental sampling questions [page 2 of 2].</p>												

FY 2009 ORA WORKPLANNING SHEET

October 1, 2008

Page 2 of 2

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety (Continued from page 03-6)		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) 03803, B, C, D, E; 04803; 09803E,F; 03R839 (2) (5) (8)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 40.4				
R E G I O N	5. DISTRICT/ SPECIALIZED LABORATORY	OUTBREAK & EMERGENCY CSO HOURS (8)	MICRO- BIOLOGIST OUTBREAK & EMERGENCY ANALYST HOURS (9)	DOMESTIC ENVIRON- MENTAL SAMPLE COLLECTION DSC	MICRO ENVIRON- MENTAL SAMPLE ANALYSIS	MICRO- BIOLOGIST INVESTIGATOR ANALYST HOURS (10)			
	TOTAL FIELD	7440	480	3600	3600	950			
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
			5.00	4.00					
		7440	480	18000	14400	950			
		950	1180	950	1180	950			
		7.83	0.41	18.95	12.20	1.00			
7. REMARKS									
(9) 10% of inspection and analytical resources are set aside for outbreak and emergency operations.									
(10) Investigator/analyst will consult on environmental sampling questions.									

1. PROGRAM ASSIGNMENT TITLE Import Foods General			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03										
3. PROGRAM ASSIGNMENT CODE(S) 03819A,B,C (03R833/99R/833/03R824)(1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 247.1						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HRS OPR 14 03R833 (2)	2 PRIOR NOTICE REVIEW HOURS OPR 14 03R833 (5)	2 INVESTI- GATION HOURS (3)		4 IMPORT SAMPLE COLL PHYSICAL		4 IMPORT SAMPLE COLL MICRO GUIDANCE	4 IMPORT SAMPLE COLL CHEM GUIDANCE	8 IMPORT SAMPLES TO BE ANALYZED MICRO		8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED SALM RESIST (Hours) (4)
	TOTAL FIELD	98004	30000	67925		7500		4850	2650	4850		2650	1180
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)		
	REGIONAL STAFF					(b)(7)(E)							
	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB WEAC												
CE	REGIONAL STAFF												
	BALTIMORE												
	CHICAGO												
	CINCINNATI												
	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA FORENSIC CHEM. CTR												
SE	REGIONAL STAFF												
	ATLANTA												
	FLORIDA												
	NEW ORLEANS												
	SAN JUAN REGIONAL LAB												
SW	REGIONAL STAFF												
	DALLAS												
	DENVER												
	KANSAS CITY												
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB												
PA	REGIONAL STAFF												
	LOS ANGELES												
	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW												
HOURS PER OPERATION						2.2			8.2			7.5	
TOTAL HOURS		98004	30000	67925		16500			39770			19875	1180
CONVERSION FACTOR		1200	1200	950		950			1180			1180	1180
OPERATIONAL FTEs		81.67	25.00	71.50		17.37			33.70			16.84	1.00

7. REMARKS

(1) Resources in this program can be used to report Import Food activities under the following PAC codes: 03R833- Import/Entry Review hours; 99R833 - Evaluation hours; R824 - Follow-up-to-Refusal.

(2) Import Entry Review Hours: resources for these activities cover all Import Food programs.

(3) Investigation hours: resources are for Import Field Exams, Import Filer Evaluations, Follow-up to refusals (marking and tracking the disposition of detained lots) and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Note: Additional time for Import Field Exams under investigation hours is planned in the Import LACF, Import Seafood and Toxic Elements Program.

ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:

- (a) VERIFICATION THAT THE IMPORTED PRODUCT IS THE SAME AS THAT WHICH WAS DECLARED (RECONCILIATION EXAM);
- (b) AN ASSESSMENT OF SECURITY CONCERNS RELATED TO LABELING AND SOURCE COUNTRY (INCLUDING CONTAINER INTEGRITY, SIGNS OF INTENTIONAL ADULTERATION, ETC.);
- (c) TRADITIONAL SAFETY CONCERNS.

THESE ACTIVITIES ARE TO BE REPORTED AS A SINGLE IMPORT FIELD EXAM UNDER THIS COMPLIANCE PROGRAM AND PAC. ONLY ONE EXAM SHOULD BE REPORTED PER LINE ENTRY. ONLY IN THE EVENT OF A PRE-DETERMINED "FOR CAUSE" CT EXAM, OR IN THE EVENT CT SUSPICIONS ARE RAISED CONDUCTING ROUTINE FOLLOW-UP, SHOULD AN ADDITIONAL EXAM AND TIME BE REPORTED UNDER THE CT PAC (03R845, 04R845 ETC.). SEE IOM SECTION 5.4.1.4 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES.

(4) Denver Laboratory: Salmonella Resistance

(5) Resources in headquarters for review of prior notices at the Prior Notice Center.

NOTE: Please review CFSAN's Import Risk Based Priorities List available at CFSAN OC Intranet site.

2009 ORA WORKPLAN

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03												
3. PROGRAM/ASSIGNMENT CODE(S) 03842, B, C, D, H, 03R839 (1)			4. WORK ALLOCATION PLANNED BY ORA <input checked="" type="checkbox"/> CENTER <input checked="" type="checkbox"/>					5. OPERATIONAL FTE POSITIONS 65.0 (38.4) Page 1 (6.6) Page 2						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	3	3	7	7	7	7			
		INSPECTIONS INCLUDING HIGH RISK (4) (5)	OUTBREAK & EMERGENCY CSO (HOURS) (6)	DOMESTIC SAMPLES COLL. (3) (5)	DOMESTIC SAMPLES COLL. MICRO GUIDANCE 210	DOMESTIC SAMPLES COLL. CHEM GUIDANCE 70	ENVIRONMENTAL SAMPLE COLLECTION (7)	500	DSAs ORGANO EXAMS (Hours) (2)	400	DOMESTIC SAMPLES TO BE ANALYZED CHEM (8)	70	DOMESTIC SAMPLES TO BE ANALYZED MICRO (9)	182
TOTAL FIELD		1710	4890	280	210	70	500	400	70	182	475			
HEADQUARTERS		(b)(2)&(b)(7)(E)												
REGIONAL STAFF														
NEW ENGLAND														
NEW YORK														
REGIONAL LAB														
WEAC														
REGIONAL STAFF														
BALTIMORE														
CHICAGO														
CINCINNATI														
DETROIT														
MINNEAPOLIS														
NEW JERSEY														
PHILADELPHIA														
FORENSIC CHEM. CTR														
REGIONAL STAFF														
ATLANTA														
FLORIDA														
NEW ORLEANS														
SAN JUAN														
REGIONAL LAB														
REGIONAL STAFF														
DALLAS														
DENVER														
KANSAS CITY														
SOUTHWEST IMPORT DISTRICT														
REGIONAL LAB														
REGIONAL STAFF														
LOS ANGELES														
SAN FRANCISCO														
SEATTLE														
PACIFIC REGIONAL LABORATORY-SW														
PACIFIC REGIONAL LABORATORY-NW														
HOURS PER OPERATION		25.0		5.0			5.0		13.0	17.0				
TOTAL HOURS		42750	4890	1400			2500	400	910	3094	475			
CONVERSION FACTOR		950	950	950			950	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs		45.00	5.15	1.47			2.63	0.34	0.77	2.62	0.40			

9. REMARKS

- (1) ADDITIONAL PACs: 04842A, H; 07842, H; 09842E, F, H; 21005; 21842; 21R811; 21R829, 03R839.
- (2) ORGANOLEPTIC NATIONAL EXPERT
- (3) SEAFOOD COLLECTIONS ARE PLANNED "FOR CAUSE ONLY." THE NUMBER OF SAMPLES PLANNED PER DISTRICT ARE NOT TO BE CONSIDERED A GOAL OR TARGET. ONLY COLLECT "FOR CAUSE" SAMPLES FOLLOWING THE GUIDANCE IN PART III, PAGE 5, SECTION E, 1 OF THE COMPLIANCE PROGRAM. VERIFICATION SAMPLES ARE NOT TO BE COLLECTED.
- (4) IN FY 09 HIGH RISK POTENTIAL PRODUCTS (HRPP) PROCESSORS WHOSE LAST TWO INSPECTIONS WERE NAI, CAN BE CONSIDERED FOR A 2-YEAR INSPECTION CYCLE UNLESS THE FIRM HAS ADDED A NEW HIGH RISK SEAFOOD PRODUCT TO THEIR LINE.
- SOURCE OF SEAFOOD WORKLOAD:**
- (5) CFSAN PROVIDED THE RESOURCE DISTRIBUTION FOR INSPECTIONS.
DSCs BASED ON INSPECTIONS.
- (6) E.U. CERTIFICATION PROCESSING HOURS DISTRIBUTED BY CFSAN. USE REPORTING OPERATION 92.
- (7) ENVIRONMENTAL SAMPLES ARE ONLY TO BE COLLECTED AT FIRMS WHICH PROCESS RTE PRODUCT.
- (8) LEVEL II AUDITORS CERTIFICATION: THESE HOURS ARE TO PROVIDE AUDITORS THE TIME TO EVALUATE/TRAIN OTHER INVESTIGATORS TRYING TO OBTAIN LEVEL II CERTIFICATION.
- (9) 10% OF INSPECTIONAL AND ANALYTICAL RESOURCES ARE SET ASIDE FOR OUTBREAK AND EMERGENCY OPERATIONS USING PAC: 03R839.
- (10) FOR A MICROBIOLOGIST TO ASSIST IN THE COLLECTION OF ENVIRONMENTAL SAMPLES.

2009 ORA WORKPLAN

OCTOBER 1, 2008 Page 2 of 2

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (Continued from page 03-9)		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03									
3. PROGRAM/ASSIGNMENT CODE(S) 03842, B, C, D, H, 03R839 (1)		4. WORK ALLOCATION PLANNED BY ORA <input checked="" type="checkbox"/> CENTER <input checked="" type="checkbox"/>			5. OPERATIONAL FTE POSITIONS (6.6)						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 MICROBIOLOGIST ON ENVIRONMENTAL SAMPLE COLLECTION (HOURS) 10	7 DSA MICRO ANALYSIS ON ENVIRONMENTAL SAMPLES COLLECTED	9 EU CERTIFICATION (HOURS) (8)	8 LEVEL 9 AUDITORS CERTIFICATION (HOURS) (8)						
	TOTAL FIELD	950	500	1860	1840						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	NEW ENGLAND	(b)(2)&(b)(7)(E)									
	NEW YORK	(b)(2)&(b)(7)(E)									
	REGIONAL LAB	(b)(2)&(b)(7)(E)									
CE	WEAC	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	BALTIMORE	(b)(2)&(b)(7)(E)									
	CHICAGO	(b)(2)&(b)(7)(E)									
	CINCINNATI	(b)(2)&(b)(7)(E)									
	DETROIT	(b)(2)&(b)(7)(E)									
	MINNEAPOLIS	(b)(2)&(b)(7)(E)									
	NEW JERSEY	(b)(2)&(b)(7)(E)									
	PHILADELPHIA	(b)(2)&(b)(7)(E)									
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)									
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	ATLANTA	(b)(2)&(b)(7)(E)									
	FLORIDA	(b)(2)&(b)(7)(E)									
	NEW ORLEANS	(b)(2)&(b)(7)(E)									
	SAN JUAN	(b)(2)&(b)(7)(E)									
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	DALLAS	(b)(2)&(b)(7)(E)									
	DENVER	(b)(2)&(b)(7)(E)									
	KANSAS CITY	(b)(2)&(b)(7)(E)									
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)									
	REGIONAL LAB	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF	(b)(2)&(b)(7)(E)									
	LOS ANGELES	(b)(2)&(b)(7)(E)									
	SAN FRANCISCO	(b)(2)&(b)(7)(E)									
SEATTLE		(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LABORATORY-SW		(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LABORATORY-NW		(b)(2)&(b)(7)(E)									
HOURS PER OPERATION		4.0									
TOTAL HOURS		950	2000	1860	1840						
CONVERSION FACTOR		950	1180	950	950						
TOTAL OPERATIONAL FTEs		1.00	1.69	1.96	1.94						
9. REMARKS											

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Products						2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03			
3. PROGRAM/ASSIGNMENT CODE(S) 03844,B, C, D, H; 07844: 09844E,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 84.7			
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	1	4	4	4	6	8	8	8
		IMPORTER RSP - 63844H (1)	IMPORT SAMPLE COLL PHYSICAL (2) / (5)	IMPORT SAMPLE COLL MICRO GUIDANCE	IMPORT SAMPLE COLL CHEM GUIDANCE	INVESTIGATION HOURS (3)	HEA ORGANO ANALYSES (4) (6)	IMPORT SAMPLES TO BE ANALYZED CHEM (4) / (5)	IMPORT SAMPLES TO BE ANALYZED MICRO (4) / (5)
TOTAL FIELD		500	6400	4480	3050	3200	1180	3050	4480
HEADQUARTERS (b)(2)&(b)(7)(E) REGIONAL STAFF NE NEW ENGLAND NEW YORK REGIONAL LAB WEAC REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI CE DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR REGIONAL STAFF SE ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB REGIONAL STAFF SW DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB REGIONAL STAFF PA LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		14.0	2.8					5.3	11.0
TOTAL HOURS		7000	18640			3200	1180	16185	49280
CONVERSION FACTOR		950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs		7.37	17.52			3.37	1.00	13.70	41.76
B. REMARKS (1) FY 2009 : IMPORTER INSPECTIONS: BASED ON OASIS CONSIGNEE DATA. PER CFSAN, INSPECTIONS OF IMPORTERS ARE TO ASCERTAIN THAT THE IMPORTER HAS COMPLIED WITH SEAFOOD HACCP REGULATIONS (NOT TO PERFORM FILER INSPECTIONS). (2) IMPORT SAMPLE COLLECTION: PER CFSAN BASED ON A TOTAL NUMBER OF LINE ENTRIES WITH SPECIAL EMPHASIS TOWARDS THE OFFICE OF FOOD SAFETY, DIVISION OF SEAFOOD SAFETY TOP THREE PRIORITY PRODUCTS: READY TO EAT (RTE); MODIFIED ATMOSPHERE PACKAGING (MAP) AND HISTAMINE FORMING. CONSEQUENTLY, SEVERAL DISTRICTS WILL NOTE AN INCREASE IN THE SAMPLE COLLECTION TARGETS BECAUSE THEY HAVE A HIGH PERCENTAGE OF RTE, MAP AND HISTAMINE LINE ENTRIES. ALL DISTRICTS SHOULD CONCENTRATE ON COLLECTIONS AS PER THE PRIORITIES SET IN THE IMPORT SEAFOOD COMPLIANCE PROGRAM. WHEN PHYSICAL SAMPLES ARE COLLECTED FOR ANALYSIS, THE GUIDANCE IN THE COMPLIANCE PROGRAM SHOULD BE FOLLOWED IN DETERMINING WHAT THE PRODUCT SHOULD BE ANALYZED FOR. SPECIFICALLY, RAW SCROMBROTIC FISH SHOULD BE ANALYZED FOR HISTAMINE NOT FOR MICRO; RAW SHRIMP SHOULD BE ANALYZED FOR UNDECLARED SULFITE (AND/OR CHEMOTHERAPEUTICS UNDER PAC 04018 FOLLOWING THE GUIDANCE IN THE COMPLIANCE PROGRAM COLLECTION SCHEDULE) NOT FOR MICRO. (3) IMPORT INVESTIGATION HOURS WERE DISTRIBUTED BY CFSAN. RESOURCES ARE FOR FIELD EXAMS, 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. ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING: (a) VERIFICATION THAT THE IMPORTED PRODUCT IS THE SAME AS THAT WHICH WAS DECLARED (RECONCILIATION EXAM); (b) AN ASSESSMENT OF SECURITY CONCERNS RELATED TO LABELING AND SOURCE COUNTRY (INCLUDING CONTAINER INTEGRITY, SIGNS OF INTENTIONAL ADULTERATION, ETC.); AND (c) TRADITIONAL SAFETY CONCERNS. THESE ACTIVITIES ARE TO BE REPORTED AS A SINGLE IMPORT FIELD EXAM UNDER THIS COMPLIANCE PROGRAM AND PAC. ONLY ONE EXAM SHOULD BE REPORTED PER LINE ENTRY. ONLY IN THE EVENT OF A PRE-DETERMINED "FOR CAUSE" CT EXAM, OR IN THE EVENT CT SUSPICIONS ARE RAISED CONDUCTING ROUTINE FOLLOW-UP, SHOULD AN ADDITIONAL EXAM AND TIME BE REPORTED UNDER THE CT PAC (03R845, 04R845 ETC). SEE IOM SECTION 5.4.1.4 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES. (4) MULTIPLE ANALYSES (I.E., CHEM AND MICRO) WILL BE RUN ON NUMEROUS SAMPLES, THEREFORE, ANALYSES OUTNUMBER COLLECTIONS. (5) ORGANOLEPTIC NATIONAL EXPERT (6) WEAC MICRO & CHEM: PER DFS AN INTERNAL AGREEMENT BETWEEN THE WEAC LAB DIRECTOR AND THE NEW ENGLAND IB DIRECTOR TO HAVE 119 CHEM AND 76 MICRO SAMPLES SENT TO WEAC. NOTE: SWID SAMPLES COLLECTED FOR TX & NM ARE SENT TO ARL. SWID SAMPLES COLLECTED FOR CA & AZ ARE SENT TO PRS.									

2009 ORA WORKPLAN

OCTOBER 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03F098 (Import) 03F100 (Domestic)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 48.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLLECTION	IMPORT SAMPLE COLLECTION	DOMESTIC SAMPLE ANALYSIS MICRO	IMPORT SAMPLE ANALYSIS MICRO				9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	1100	700	1000	1000	1000				
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION		3.0	3.0	25.0	25.0				
	TOTAL HOURS	1100	2100	3000	25000	25000				
	CONVERSION FACTOR	950	950	950	1180	1180				
	TOTAL OPERATIONAL FTEs	1.16	2.21	3.16	21.19	21.19				

9. REMARKS

CFSAN will work with ORA to determine how resources will be allocated in FY 2009.

Note: SWID samples collected from TX & NM are sent to ARL. SWID samples collected from CA & AZ are sent to DEN.
Resource distribution per CFSAN.

* In FY 2009 an additional 300 domestic samples will be collected under state contracts.
Domestic and Import Sample Analysis based on Domestic and Import Sample collection(s) and Laboratory Servicing Table.

2009 ORA WORKPLAN

OCTOBER 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM/ASSIGNMENT CODE(S) 03R233	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.3

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN.	2 INVESTIG- ATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS)*					9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	200		950					
NE	HEADQUARTERS	(b)(2)&(b)		(b)(2)&(b)					
	REGIONAL STAFF	(7)(E)		(7)(E)					
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL LAB								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	30.0							
	TOTAL HOURS	6000		950					
	CONVERSION FACTOR	950		950					
	TOTAL OPERATIONAL FTEs	6.32		1.00					

9. REMARKS

Foreign activities per DFI inspection distribution. * Technical Assistance can include but is not limited to training, presentations, speeches, site visits, outreach, workshops, seminars or meetings with partnership groups trade associations etc. Per CFSAN, report accomplishments under PAC 03R233.

NOTE: CFSAN may request additional foreign inspections as warranted by foodborne outbreaks and other "for cause" reasons.

FY 2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) 03R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 10.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		METHODS VAL/DEV MICRO (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)					
	TOTAL FIELD		7220	4720					
NE	HEADQUARTERS		(b)(2)&(b)(7)(E)						
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS			7220	4720					
CONVERSION FACTOR			1205	1180					
TOTAL OPERATIONAL FTEs			6.00	4.00					
9. REMARKS									
<p>Workload Source: Determined by Division of Field Science, ORO.</p>									

2009 ORA WORKPLAN

OCTOBER 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Contract Management	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM/ASSIGNMENT CODE(S) 03R843	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 12.0	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 CONTRACT MANAGE- MENT HOURS								
	TOTAL FIELD	(1) 11400								
	HEADQUARTERS	(b)(2)& (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	11400								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	12.00								

9. REMARKS

(1) Time planned for contract management includes resources to conduct audits. Allocation of planned hours for contract activities is based on time reported in FACTS by operational employees under PAC 03R843 during the period March 19, 2007 - March 20, 2008.

2009 ORA WORKPLAN

OCTOBER 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Food Defense				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 38.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	8	8	DOMESTIC	DOMESTIC	CHEM	MICRO	BIOTERRORISM
		CSO DOMESTIC HOURS	CSO IMPORT HOURS	IMPORT CHEM HOURS	IMPORT MICRO HOURS	CHEM HOURS	MICRO HOURS	FD METHOD VALIDATION	FD METHOD VALIDATION	(BT) FIRMS OEI MAINTENANCE
	TOTAL FIELD	11400	3800	3540	1770	6490	4720	900	800	1900
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN REGIONAL LAB	(b)(2)&(b)(7)(E)								
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2)&(b)(7)(E)								
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)								
HOURS PER OPERATION										4.00
TOTAL HOURS		11400	3800	3540	1770	6490	4720			7600
CONVERSION FACTOR		950	950	1180	1180	1180	1180			950
TOTAL OPERATIONAL FTEs		12.00	4.00	3.00	1.50	5.50	4.00			8.00
9. REMARKS										
<p>Reporting: Food Defense activities are reported under 03R845, expanded time should be reported under 04R845, 07R845, 09R845, 21R845.</p> <p>Planned resources are for all special food defense related activities, over and above resources for food defense activities that are incorporated into routine safety monitoring activities (i.e., food defense coverage during routine food safety inspection and import and domestic food defense reconciliation exams). Resources for food defense coverage during routine operations are included in the parent programs.</p> <p>Domestic & import resources have been separated for planning purposes. Based on circumstances, resources may be shifted between Import and Domestic.</p> <p>Resources are to be used for CFSAN food defense assignments for inspections, sample collections and analyses, including those to support the FERN.</p> <p>Total lab time may be used for maintaining general food defense capabilities.</p> <p>* Resources for food defense method validation are a subset of the total Chemist and Microbiologist resources planned by DFS (Information Only).</p> <p>** Resources provided for district determination of workload obligation of new firms based on Bioterrorism (BT) Legislation.</p> <p>Note: SWID samples collected from TX & NM are sent to ARL. SWID samples collected from CA & AZ are sent to PRS.</p> <p>WORKLOAD: CSO DOMESTIC HOURS BASED ON TOTAL FOODS M/R OEI INCLUDING IND CODE 02-51 DATED 2/25/2008. CSO IMPORT HOURS BASED ON TOTAL FOODS ACS FDA REVIEW LINES FROM MAY 15, 2007 - MAY 15, 2008. LAB RESOURCES PRE-PLANNED BY DFS.</p>										

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04					
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3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 59.7 (32.3)		
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs CHEM		DSCs DIOXINS	DSAs DIOXINS	DSAs DIOXINS	DSCs SEAFOOD	DSAs SEAFOOD
	HEADQUARTERS	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)				
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW									
HOURS PER OPERATION -			3.0	6.5		4.0	20.0	11.6	3.0	6.5
TOTAL HOURS		1100	4200	9100		3000	15000	2691	300	650
CONVERSION FACTOR		950	950	1180		950	1180	1180	950	1180
TOTAL OPERATIONAL FTEs		1.16	4.42	7.71		3.16	12.71	2.28	0.32	0.55

7. REMARKS

CFSAN will issue biannual Dioxin Schedule.
 DSC Seafoods: See compliance program for collection details.
 *Includes analysis of 232 Total Diet Study Sample homogenates. ARL will analyze 518 of the 750 dioxin DSCs.

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (27.4)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY					ISCs	ISAs CHEM			ISCs SEAFOOD	ISAs SEAFOOD CHEM	
	HEADQUARTERS											
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
FORENSIC CHEM. CTR												
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY- SW											
	PACIFIC REGIONAL LABORATORY- NW											
	HOURS PER OPERATION					1.6	7.8			1.6	7.8	
	TOTAL HOURS					4800	23400			480	2340	
	CONVERSION FACTOR					950	1180			950	1180	
	TOTAL OPERATIONAL FTEs					5.05	19.83			0.51	1.98	

(b)(2)&(b)(7)(E)

9. REMARKS
 ISC Seafoods: See compliance program for collection details.
 ISAs: Planned numbers based on SWID sending 40% of ISAs to ARL and 60% of ISAs to PRL-SW.

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04019A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 17.0 (12.5)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSC NON- SEAFOOD	ISC NON- SEAFOOD	DSA NON- SEAFOOD CHEM	ISA NON- SEAFOOD CHEM	DSCs SEAFOOD	DSAs SEAFOOD CHEM			
		TOTAL FIELD	25	625	25	625	310	310		
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN	(b)(2)&(b)(7)(E)								
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY - SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY - NW	(b)(2)&(b)(7)(E)								
	HOURS PER OPERATION	3.5	1.8	12.0	12.0	4.5	12.0			
	TOTAL HOURS	88	1125	300	7500	1395	3720			
	CONVERSION FACTOR	950	950	1180	1180	950	1180			
	TOTAL OPERATIONAL FTEs	0.09	1.18	0.25	6.36	1.47	3.15			

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

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foodware (Domestic and Import)			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04														
3. PROGRAM/ASSIGNMENT CODE(S) 04019B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (3.7)										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		DSCs (Houseware)	ISCs (Houseware)	DOMESTIC FIELD EXAMS	IMPORT INV HOURS	DSAs CHEM	ISAs CHEM									
	TOTAL FIELD		10	200	25	1400	10	200									
NE	HEADQUARTERS		(b)(2)&(b)(7)(E)														
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
SE	PHILADELPHIA																
	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
SW	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
PA	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY - SW																
	PACIFIC REGIONAL LABORATORY - NW																
HOURS PER OPERATION										3.5	1.8	0.7		10.0	10.0		
TOTAL HOURS										35	360	18	1400	100	2000		
CONVERSION FACTOR										950	950	950	950	1180	1180		
TOTAL OPERATIONAL FTEs										0.04	0.38	0.02	1.47	0.08	1.69		
7. REMARKS *IMPORT INV Hours are for field exams and any other import operations as required by the District to cover import priorities. District should report time under the appropriate operation and PAC for the activities performed. Import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) For districts that are not provided domestic field exam and sample collection resources, district should still collect samples, if necessary.																	

1. PROGRAM/ASSIGNMENT TITLE Radionuclides in Foods (Domestic and Import)				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04			
3. PROGRAM/ASSIGNMENT CODE(S) 04019C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (0.8)	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		DSC	ISC		DSA _a CHEM	ISA _a CHEM
	TOTAL FIELD		16	84		16	84
NE	HEADQUARTERS		(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LABORATORY - SW						
	PACIFIC REGIONAL LABORATORY - NW						
HOURS PER OPERATION			2.5	1.7		15.0	8.0
TOTAL HOURS			40	143		240	504
CONVERSION FACTOR			950	950		1180	1180
TOTAL OPERATIONAL FTEs			0.04	0.15		0.20	0.43

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04					
3. PROGRAM/ASSIGNMENT CODE(S) 04839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 28.6		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSCs (TOTAL) (DIET)	DOMESTIC SAMPLE TO BE ANALYZED CHEM	TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) CHEM	TOTAL DIET SAMPLES ANALYSIS (PERCHLORATES) CHEM				
		(1)	(2)	(3)	(4)				
	TOTAL FIELD	60	1136	2	1136				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	NEW ENGLAND	(b)(2)&(b)(7)(E)							
	NEW YORK	(b)(2)&(b)(7)(E)							
	REGIONAL LAB	(b)(2)&(b)(7)(E)							
CE	WEAC	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	BALTIMORE	(b)(2)&(b)(7)(E)							
	CHICAGO	(b)(2)&(b)(7)(E)							
	CINCINNATI	(b)(2)&(b)(7)(E)							
	DETROIT	(b)(2)&(b)(7)(E)							
	MINNEAPOLIS	(b)(2)&(b)(7)(E)							
	NEW JERSEY	(b)(2)&(b)(7)(E)							
	PHILADELPHIA	(b)(2)&(b)(7)(E)							
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)							
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	ATLANTA	(b)(2)&(b)(7)(E)							
	FLORIDA	(b)(2)&(b)(7)(E)							
	NEW ORLEANS	(b)(2)&(b)(7)(E)							
	SAN JUAN	(b)(2)&(b)(7)(E)							
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	DALLAS	(b)(2)&(b)(7)(E)							
	DENVER	(b)(2)&(b)(7)(E)							
	KANSAS CITY	(b)(2)&(b)(7)(E)							
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)							
	REGIONAL LAB	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	LOS ANGELES	(b)(2)&(b)(7)(E)							
	SAN FRANCISCO	(b)(2)&(b)(7)(E)							
	SEATTLE	(b)(2)&(b)(7)(E)							
	PACIFIC REGIONAL LABORATORY - SW	(b)(2)&(b)(7)(E)							
	PACIFIC REGIONAL LABORATORY - NW	(b)(2)&(b)(7)(E)							
	HOURS PER OPERATION	26.0	20.1	2800.0	3.0				
	TOTAL HOURS	1560	22834	5600	3408				
	CONVERSION FACTOR	950	1180	1180	1180				
	TOTAL OPERATIONAL FTEs	1.64	19.35	4.75	2.89				

7. REMARKS

- (1) Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over five week period and involves 3 separate districts. Four market baskets are planned annually.
- (2) Represents the total number of food items analyzed for various attributes. VOC analyses will no longer be conducted on TDS foods.
- (3) All TDS food items from two market basket analyzed by WEAC for selected radionuclides.
- (4) All TDS foods from each market basket are analyzed for perchlorates.

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04						
3. PROGRAM/ASSIGNMENT CODE(S) 04F800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.4			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY			DSC FURAN IN FOODS	DSA FURAN IN FOODS	ISC CONTAMINANTS IN HONEY	ISA CONTAMINANTS IN HONEY	ISC/DISC PES & TE DIETARY SUPPL.	ISA/DISA PES DIETARY SUPPL. Sub 1	ISA/DISA TE DIETARY SUPPL. Sub 2
	TOTAL FIELD			100	100	100	100	250	250	231
	HEADQUARTERS			(b)(2)&(b)(7)(E)						
NE	REGIONAL STAFF			(b)(2)&(b)(7)(E)						
	NEW ENGLAND			(b)(2)&(b)(7)(E)						
	NEW YORK			(b)(2)&(b)(7)(E)						
	REGIONAL LAB			(b)(2)&(b)(7)(E)						
	WEAC			(b)(2)&(b)(7)(E)						
CE	REGIONAL STAFF			(b)(2)&(b)(7)(E)						
	BALTIMORE			(b)(2)&(b)(7)(E)						
	CHICAGO			(b)(2)&(b)(7)(E)						
	CINCINNATI			(b)(2)&(b)(7)(E)						
	DETROIT			(b)(2)&(b)(7)(E)						
	MINNEAPOLIS			(b)(2)&(b)(7)(E)						
	NEW JERSEY			(b)(2)&(b)(7)(E)						
	PHILADELPHIA			(b)(2)&(b)(7)(E)						
SE	FORENSIC CHEM. CTR			(b)(2)&(b)(7)(E)						
	REGIONAL STAFF			(b)(2)&(b)(7)(E)						
	ATLANTA			(b)(2)&(b)(7)(E)						
	FLORIDA			(b)(2)&(b)(7)(E)						
	NEW ORLEANS			(b)(2)&(b)(7)(E)						
SW	SAN JUAN			(b)(2)&(b)(7)(E)						
	REGIONAL LAB			(b)(2)&(b)(7)(E)						
	REGIONAL STAFF			(b)(2)&(b)(7)(E)						
	DALLAS			(b)(2)&(b)(7)(E)						
	DENVER			(b)(2)&(b)(7)(E)						
PA	KANSAS CITY			(b)(2)&(b)(7)(E)						
	SOUTHWEST IMPORT DISTRICT			(b)(2)&(b)(7)(E)						
	REGIONAL LAB			(b)(2)&(b)(7)(E)						
	REGIONAL STAFF			(b)(2)&(b)(7)(E)						
	LOS ANGELES			(b)(2)&(b)(7)(E)						
PA	SAN FRANCISCO			(b)(2)&(b)(7)(E)						
	SEATTLE			(b)(2)&(b)(7)(E)						
	PACIFIC REGIONAL LABORATORY - SW			(b)(2)&(b)(7)(E)						
	PACIFIC REGIONAL LABORATORY - NW			(b)(2)&(b)(7)(E)						
	HOURS PER OPERATION			3.0	3.0	3.0	6.5	3.0	6.5	14.5
	TOTAL HOURS			300	300	300	850	750	1825	3350
	CONVERSION FACTOR			950	1180	950	1180	950	1180	1180
	TOTAL OPERATIONAL FTEs			0.32	0.25	0.32	0.55	0.79	1.38	2.84
7. REMARKS										
Collections for Dietary Supplements will be directed by CFSAN field assignments. Contaminants in honey include chloroamphenicol (See Import Bulletin).										

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC SAMPLE ANALYSIS (CHEM)	FORENSIC EVALUATION							
	TOTAL FIELD	1205	13255							
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1205	13255							
	CONVERSION FACTOR	1205	1205							
	TOTAL OPERATIONAL FTEs	1.00	11.00							

7. REMARKS
 The hours planned above are estimates. Report Forensic activities under the appropriate PAC 04R838; PODS operation code 03, Petition Evaluation, Methods Development, or Forensic Evaluation (Forensic Evaluation added in FY 1999); PODS operation code 41 or 43, domestic or import sample analysis, PAC 04R838 or OCI PAC 04R831. Contact Division of Field Science (HFC-140), ORA, for additional reporting instructions.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DOMESTIC)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (Total 14.6) 9.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	3	3	3	7	7	7	7
		DSCs AFLA- TOXIN	DSCs FUMON- ISON	DSCs DON	DSCs OCHRA TOXIN	DSCs PATULIN	ALL DOMESTIC SAMPLE ANALYSES	DSAs AFLA- TOXIN	DSAs FUMON- ISON	DSAs DON
	TOTAL FIELD	465	190	145	60	140	1000	465	190	145

	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										

HOURS PER OPERATION	4.0	4.0	4.0	4.0	4.0	6.0				
TOTAL HOURS	1860	760	580	240	560	6000				
CONVERSION FACTOR	950	950	950	950	950	1180				
TOTAL OPERATION FTEs	1.96	0.80	0.61	0.25	0.59	5.08				

7. REMARKS

Report all Domestic and Import Operations under PAC 07001.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 2	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DSA, ISCs)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7	7	4	4	4	4	4	4	4									
		DSAs OCHRA TOXIN	DSAs PATULIN	ISCs AFLA TOXIN	ISCs PEANUT BUTTER	ISCs FUMON- ISON	ISCs DON	ISCs OCHRA TOXIN	ISCs PATUIN	ISCs SPECIAL SURVEY									
	TOTAL FIELD	60	140	284	(105)	90	90	40	140	20									
	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
SE	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
	REGIONAL LAB																		
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
PA	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LAB - SW																		
	PACIFIC REGIONAL LAB - NW																		
	HOURS PER OPERATION												2.0		2.0	2.0	2.0	2.0	2.0
	TOTAL HOURS												588		180	180	80	280	40
	CONVERSION FACTOR												950		950	950	950	950	950
	TOTAL OPERATION FTEs												0.60		0.18	0.18	0.08	0.29	0.04

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 3	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001 (ISAs)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8	8	8	8	8	8	8	8	8
		ALL IMPORT SAMPLE ANALYSES	ISAs AFLA TOXIN	ISAs FUMON- ISON	ISAs DON	ISAs OCHRA TOXIN	ISAs PATULIN	ISAs SPECIAL SURVEY	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERAT- IONS (HOURS)
	TOTAL FIELD	664	284	90	90	40	140	20		
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION	7.0								
	TOTAL HOURS	4848								
	CONVERSION FACTOR	1180								
	TOTAL OPERATION FTEs	3.94								

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives	2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09
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3. PROGRAM/ASSIGNMENT CODE(S) 09006A (Foods), 09006B (Colors)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 ISCs FOOD ADDITIVES	8 ISAs FOOD ADDITIVES	4 ISCs COLOR ADDITIVES	8 ISAs COLOR ADDITIVES	9 IMPORT INVESTI- GATIONS (HOURS)	OTHER OPERATIONS (Hours)
	TOTAL FIELD	310	310	865	865	1087	
	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)	
NE	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		1.4	13.0	1.4	10.0		
TOTAL HOURS		434	4030	1211	8650	1087	
CONVERSION FACTOR		950	1180	950	1180	950	
OPERATIONAL FTEs		0.48	3.42	1.27	7.33	1.14	

7. REMARKS

Note: Resources for Entry Review and Filer Evaluation are planned under the Import Foods - General Program (PAC 03819). Import Field Exams are to routinely include: verification that the imported products are the same as that which were declared (Reconciliation Exams), an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.), and traditional safety concerns. These activities are to be reported as a single Import Field Exam under this compliance program and PAC. Only one exam should be reported per line entry.

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

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

FY 2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18								
3. PROGRAM/ASSIGNMENT CODE(S) 18002		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 24.0 (22.2)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL/FOOD PROGRAM STANDARDS BASELINE SUPPORT (1)	STANDARD- IZATION (ITP CDC IHS, STATE AND LOCAL) (2)	RE-STANDARD- IZATION (ITP, STATE AND LOCAL) (3)	FDA FOOD- BORNE ILLNESS RISK FACTOR STUDY (4)	TEAM LEADERS SC/NATIONAL (5)	NATL TEAM WORK GROUP (6)	REGIONAL SEMINARS (7)	TRAINING WORKSHOPS PRE-STANDARD- IZATION TRAINING (8)	TECHNICAL ASSISTANCE (9)
	TOTAL FIELD	7200	1872	2304	2880	1200	3600	1200	2400	4032
HEADQUARTERS		(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
SW	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
PA	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
PA	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)								
HOURS PER OPERATION										
TOTAL HOURS		7200	1872	2304	2880	1200	3600	1200	2400	4032
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		6.00	1.56	1.92	2.40	1.00	3.00	1.00	2.00	3.36

7. REMARKS:

Report Counter Terrorism work performed only under 18R845.

- (1) Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards. Contact with jurisdictions to assist them with completing their self assessments, strategic plans, and verification audits performed directly by the FDA Food Specialists.
- (2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting risk-based inspections. Continued support of the ITP Program. FDA Food Specialists will be standardizing a few ITP Associate Standards.
- (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. Also included is the re-standardization of FDA Food Specialists by their respective Regional Associate Standard. The joint inspections required in the re-standardization process may be completed in one fiscal year or spread out over a three year period.
- (4) Allocation of time to work with the 2008 Risk Factor Study Design Work Group for the FDA Foodborne Illness Risk Factor Study and to collect data, data entry, quality assurance, and data analysis.
- (5) Time allocated for team leaders of the National Retail Food Team Steering Committee for retail food program planning, development, coordination.
- (6) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards, and initiatives of national importance. Includes attendance and active participation in team conference calls and face -to-face meetings/planning sessions.
- (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 workshops not limited to Food Code courses, pre-standardization workshops, HACCP workshops, and other identified training topics. Also includes time for the Specialists' to prepare candidates for standardization, as well as, the presentation and training sessions given to stakeholders groups via conference calls, seminars, conferences, web meetings, or other means.
- (9) Includes technical assistance and consultation to enrolled state and local jurisdictions performing self-assessments and developing strategic plans using the Program Standards as the foundation for enhancing the effectiveness of their retail food programs. Also includes interpretations and consultations on the Food Code and other food safety issues. Also includes planning and field activities related to food safety and security events working in conjunction with other federal agencies.

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18								
3. PROGRAM/ASSIGNMENT CODE(S) 18002		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS (1.8)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CONFERENCE FOR FOOD PRO- TECTION ACTIVITIES (10)	FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (11)							
	TOTAL FIELD	960	1152							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION										
TOTAL HOURS			960	1152						
CONVERSION FACTOR			1200	1200						
TOTAL OPERATIONAL FTEs			0.80	0.96						
7. REMARKS:										
<p>(10) Includes all committee work for the Conference for Food Protection and preliminary work on issues/position paper development for 2008 CFP.</p> <p>(11) Time allocated for the presentation and distribution of FDA materials related to food defense, such as guidance document, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures ", to state and local regulatory agencies and industry. Includes counter-terrorism presentations at seminars, meetings, conferences, etc. Also includes Specialists' activities related to CFSAN priority assignments in response to national food safety needs.</p>										

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18003	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 20.4 (17.8)
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B R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANT ¹	CHECK RATINGS TRANSFER AND RECEIVING ¹	CHECK RATING BTU ¹	SINGLE SERVICE AUDITS ¹	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICA- TION ²	TECHNICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION ³	STATE MILK SAMPLING SURVEILLANCE OFFICER INITIAL CONT ²	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER ⁴
	TOTAL FIELD	149	40	269	65	43	51	17	51	32
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	24.0	12.0	20.0	8.0	40.0	100.0	120.0	24.0	40.0
	TOTAL HOURS	3576	480	5380	520	1720	5100	2040	1224	1280
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	2.98	0.40	4.48	0.43	1.43	4.25	1.70	1.02	1.07

7. REMARKS:

1/ Check Ratings of Plants and RS/TS Every 3 Years, BTUs Every 4 Years and Audits Every 5 Years

2/ Activities Include the Initial (Including HACCP) and Continuous Certifications of State Rating Officers and Sampling Surveillance Officers.

3/ State Program Evaluations Conducted of 1/3 of the States (Including Puerto Rico) Every 3 Years.

4/ Activities Include the National Steering Team Meetings and conference calls and time for team leader activities (2 RMSs with an additional 240 hours each identified).

FY 2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18003	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (2.6)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	RMS †	Food	TRAINING	NCIMS				
		STANDARDI- ZATION	Defense † COORDINATION	GIVEN †					
	TOTAL FIELD	7	20	20	20				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)							
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)								
PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	40.0	20.0	40.0	80.0				
	TOTAL HOURS	280	400	800	1600				
	CONVERSION FACTOR	1200	1200	1200	1200				
	TOTAL OPERATIONAL FTEs	0.23	0.33	0.67	1.33				

7. REMARKS:

5/ Activities include the Re-standardization (Group Field Exercise) of the RMS

6/ Includes time for presentation and distribution of the food defense preventive measures guidance document for dairy products to the state regulatory agencies during check ratings routine field work and state program assessments. Presentations may be made at regional seminars or local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of food defense activities and field activities related to food defense. Report time against PAC 18R845.

7/ Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops.

FY 2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18									
3. PROGRAM/ASSIGNMENT CODE(S) 18004		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 14.5 (12.6)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION (1)	PATROL EVALUATION (2)	VIBRIO SPECIES MANAGE- MENT (HOURS) (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	TRAINING WORKSHOPS (7)	PLANT EVALUATION (8)	STANDARD- IZATION & RE-STAND- IZATION (9)	
	TOTAL FIELD	190	22	1900	4040	4	2	14	125	14	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	NEW ENGLAND	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	NEW YORK	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	REGIONAL LAB	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
CE	WEAC	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	BALTIMORE	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	CHICAGO	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	CINCINNATI	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	DETROIT	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
SE	NEW JERSEY	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	PHILADELPHIA	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	ATLANTA	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
SW	FLORIDA	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	NEW ORLEANS	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	SAN JUAN	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	REGIONAL LAB	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	DALLAS	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	DENVER	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	KANSAS CITY	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
REGIONAL LAB		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
REGIONAL STAFF		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
LOS ANGELES		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
SAN FRANCISCO		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
SEATTLE		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
PACIFIC REGIONAL LAB - SW		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
PACIFIC REGIONAL LAB - NW		(b)(2)&(b)(7)(E)								(b)(2)&(b)(7)(E)	
HOURS PER OPERATION		20.0	90.0			200.0	180.0	30.0	10.0	40.0	
TOTAL HOURS		3800	1980	1900	4040	800	360	420	1250	560	
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200	
TOTAL OPERATIONAL FTEs		3.17	1.65	1.58	3.37	0.67	0.30	0.35	1.04	0.47	

7. REMARKS:

- (1) Time is allocated for planning, field evaluations, file reviews (Comprehensive Growing Area Sanitary Surveys, Triennial Evaluations and Annual Updates), growing area data reviews and report writing to determine state program conformity to the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The overwhelming majority of shellfish related illnesses have been attributed to shellfish contamination due to conditions in the shellfish growing areas.
- (2) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity to the requirements of the NSSP MO. Illnesses and outbreaks have been attributed to the illegal harvest of shellfish from closed waters.
- (3) Activities include technical assistance, education, and evaluation of state shellfish programs *Vibrio vulnificus* and *vibrio parahaemolyticus* and management programs.
- (4) Includes interpretations and consultation on NSSP MO requirements related to program administration, risk management, laboratory, shellfish growing areas, shell stock relaying, shellfish aquaculture, shellfish wet storage and depuration, patrol, shellfish harvest and transportation, HACCP, and general sanitation in processing plants.
- (5) Activities include planning, field evaluations, file reviews, and report writing for countries with MOUs with the FDA. Current MOU countries include Canada, Chile, South Korea Mexico, and New Zealand.
- (6) Includes time for shellfish program planning, development and coordination responsibilities assigned to two specialists selected as team representatives of the Regional Shellfish Specialists' team.
- (7) Includes training workshops coordinated and delivered by the specialists, including but not limited to basic shellfish plant and program courses applied concepts for shellfish growing areas courses and HACCP workshops.
- (8) Includes time for planning, field evaluations of processing plants, file reviews, and final report writing to determine state conformity with the NSSP MO. Plant evaluations include a full evaluation of HACCP, including plan implementation and adherence to the sanitation requirements of the NSSP MO.
- (9) Standardization conducted every 5 years for all FDA and state standardization officers. Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs.

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18										
3. PROGRAM/ASSIGNMENT CODE(S) 18004		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER							5. OPERATIONAL FTE POSITIONS (1.9)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM WORKSHOP (10)	CENTER INITI- ATIVES/LAB (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE COORDINATION (13)	ISSC COMMITTEE (14)						
	TOTAL FIELD	11	7	12	11	11						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)										
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
CE	WEAC	(b)(2)&(b)(7)(E)										
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
NEW JERSEY												
SE	PHILADELPHIA	(b)(2)&(b)(7)(E)										
	FORENSIC CHEM. CTR											
	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
SW	NEW ORLEANS	(b)(2)&(b)(7)(E)										
	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
PA	DENVER	(b)(2)&(b)(7)(E)										
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES	(b)(2)&(b)(7)(E)										
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)										
	PACIFIC REGIONAL LAB - NW											
	HOURS PER OPERATION	40.0	40.0	30.0	20.0	90.0						
	TOTAL HOURS	440	280	360	220	990						
	CONVERSION FACTOR	1200	1200	1200	1200	1200						
	TOTAL OPERATIONAL FTE	0.37	0.23	0.30	0.18	0.83						

7. REMARKS:

- (10) Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, and initiatives of national importance. Includes discussions of FDA issues for the ISSC agency program priorities, etc.
- (11) Time allocated for CFSAN priority assignments in response to national shellfish safety. Time is also allocated for the specialists to assist the FDA Laboratory Evaluation Officer (LEO) in the planning and evaluation activities of state shellfish program labs.
- (12) Includes time for the Regional Shellfish Specialists to attend regional shellfish Conferences, Pacific Rim Shellfish Conference, Gulf and South Atlantic States Shellfish Conference, Interstate Seafood Seminar and the Northeast Shellfish Sanitation Conference.
- (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. Presentations may be made at regional seminars or local meetings and presentations may also be included in training sessions for all segments of the regulatory and industry community.
- (14) Time allocated for the specialists to attend the biennial Interstate Shellfish Sanitation Conference to address program related issues and new ISSC proposals. Represent FDA on ISSC committees, task forces and work groups. Prior to the conference FDA receives the submitted issue that will be considered at the meeting. There is a serious burden upon FDA to consider the issues as submitted and to formulate agency-approved scientific and policy positions that will be communicated at the meeting.

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18						
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 21.8			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	INSP CTIONS	CONVEY UNDER CONSTRUCTION HOURS (*)	WATERING POINTS INSP (A) (***)	CATERING POINTS INSP (B) (**)	CONVEYANCE INSP (C)	AIRLINE WATERING POINTS INSP (D)	DSCs	DSA MICRO	INV (HOURS)
	TOTAL FIELD	1555	1360	(282)	(493)	(259)	(319)	200	200	900
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
CE	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
SE	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN	(b)(2)&(b)(7)(E)								
PA	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
REGIONAL LAB	(b)(2)&(b)(7)(E)									
REGIONAL STAFF	(b)(2)&(b)(7)(E)									
LOS ANGELES	(b)(2)&(b)(7)(E)									
SAN FRANCISCO	(b)(2)&(b)(7)(E)									
SEATTLE	(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)									
HOURS PER OPERATION		10.5						4.0	8.0	
TOTAL HOURS		16328	1360					800	1600	900
CONVERSION FACTOR		950	950					950	1180	950
TOTAL OPERATIONAL FTEs		17.19	1.43					0.84	1.36	0.95

7. REMARKS:

Inspections in Columns A-D are included in Column I. The additional inspections can be used on other establishments under the program. Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B. DSCs should be randomly collected from on-board conveyances water systems outlets ex. faucets, as close to the water holding tank as possible. (*)Time for Conveyance under Construction- time to be used for plan review, meetings, and final inspections. It includes galleys in DAL, LOS and Aircraft/Vessels in SAN & SEA. (**)Catering Point Insp. (B) is High Risk Priority and some potential Food Allergen firms identified by the District. Districts should increase inspections of airline watering points because of pending new EPA regulations. (***) all other watering points

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
3. PROGRAM/ASSIGNMENT CODE(S) 21002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 4.3	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8
		INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	IMPORT SAMPLE COLL *	DSAs MICRO	DSAs CHEM	ISAs CHEM **	
	TOTAL FIELD	22	44	25	19	8	19	25	8	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
PACIFIC REGIONAL LABORATORY - NW										
	HOURS PER OPERATION	30.0	5.2			5.0	30.0	100.0	100.0	
	TOTAL HOURS	660	229			40	570	2500	800	
	CONVERSION FACTOR	950	950			950	1180	1180	.1180	
	TOTAL OPERATIONAL FTEs	0.69	0.24			0.04	0.48	2.12	0.68	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Labeling and Economics Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8
		INV HOURS	DSC			DSA				
	TOTAL FIELD	950	100			100				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)				
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION		4.2			19.0				
	TOTAL HOURS	950	420			1900				
	CONVERSION FACTOR	950	950			1180				
	TOTAL OPERATIONAL FTEs	1.00	0.44			1.61				

7. REMARKS
To be issued as CFSAN Field Assignments

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21005, 03R833, 99R833 21R824, 21R829(Health Fraud)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 11.4				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DSC	2 DSCs (DOCUMENTARY)	3 DSCs (PHYSICAL)	4 DSAs	5 DOMESTIC FIELD EXAMS **	3 ISCs (PHYSICAL) OASIS #51 (SEE REMARKS) ****	ISAs	7 IMPORT INV HOURS (SEE REMARKS) ---	ISCs (PAPER) OASIS #41 (SEE REMARKS) -----
	TOTAL FIELD	340	240	100	100	2000	125	125	5000	785
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY PHILADELPHIA FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION		4.2			19.0	0.4	1.2	10.0		1.2
TOTAL HOURS		1428			1900	800	150	1250	5000	942
CONVERSION FACTOR		0.50			1180	950	950	1180	950	950
TOTAL OPERATIONAL FTEs		1.50			1.61	0.84	0.16	1.06	5.26	0.99
7. REMARKS										
<p>*DSCs (Physical) includes both compliance (for cause) sampling and surveillance sampling. The field should attempt to collect sufficient surveillance sample as well as needed compliance samples to meet their workplan obligations. See compliance program for details.</p> <p>**Domestic operations to be conducted during inspections conducted under CP 7303.803,7303.803A,7303.037, 7303.842 and 7303.847. Districts should report time spent reviewing labels that does not result in a collection.</p> <p>***IMPORT INV Hours are for field exams and any other import operations as required by the district to cover import priorities. Districts should report time under the appropriate operation and PAC for the activities performed. For Import Field Exams, report time spent reviewing import labels that does not result in Import Sample Collection.</p> <p>****ISCs (Physical) includes time to collect and forward samples to the lab for analysis to support violations.</p> <p>*****ISCs (Paper) includes time spent collecting labels, records or other documentation for submission to Compliance and does not include time spent reviewing the import labels. Time spent reviewing the label will be included as OASIS #27 and reported along with compliance review time as OASIS #43.</p> <p>All import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc); and safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under CT PAC (03R845, 04R845, etc.) See IOM Section 5.4.1.4 for additional information on Food and Cosmetic Security Activities.</p> <p>Prior to collecting product labels for trans fat and/or allergen contact CFSAN.</p>										

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21															
3. PROGRAM/ASSIGNMENT CODE(S) 21006			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.4												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	4 IMPORT SAMPLES COLL *	8 IMPORT SAMPLES TO BE ANALYZED CHEM **									
	TOTAL FIELD	22	200	30	20	10	20	10	15	15									
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB																			
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY-SW																		
PACIFIC REGIONAL LABORATORY-NW																			
HOURS PER OPERATION											42.0		5.3			100.0	120.0	5.0	100.0
TOTAL HOURS											924	200	159			2000	1200	75	1500
CONVERSION FACTOR											950	950	950			1180	1180	950	1180
TOTAL OPERATIONAL FTEs											0.97	0.21	0.17			1.69	1.02	0.08	1.27
7. REMARKS CFSAN spreads inspections and DSCs, CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. ORA spreads import operations * Includes samples resulting from import entry review as well as samples collected during foreign inspections. Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819) ** May also be used for microbiological analysis.																			

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21008, 21R829 (Health Fraud)	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 20.3 (17.1)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	DOMESTIC FIELD EXAMS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED	HQ INIT DOMESTIC SAMPLE COLL	HQ INIT DOMESTIC SAMPLE ANALYZED CHEM				INV HOURS										
												TOTAL FIELD	250	400	200	100	50	50			2000
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																			
	REGIONAL STAFF																				
	NEW ENGLAND																				
	NEW YORK																				
	REGIONAL LAB																				
	WEAC																				
CE	REGIONAL STAFF																				
	BALTIMORE																				
	CHICAGO																				
	CINCINNATI																				
	DETROIT																				
	MINNEAPOLIS																				
	NEW JERSEY																				
	PHILADELPHIA																				
	FORENSIC CHEM. CTR																				
SE	REGIONAL STAFF																				
	ATLANTA																				
	FLORIDA																				
	NEW ORLEANS																				
	SAN JUAN																				
SW	REGIONAL LAB																				
	REGIONAL STAFF																				
	DALLAS																				
	DENVER																				
	KANSAS CITY																				
PA	SOUTHWEST IMPORT DISTRICT																				
	REGIONAL LAB																				
	REGIONAL STAFF																				
	LOS ANGELES																				
	SAN FRANCISCO																				
	SEATTLE																				
	PACIFIC REGIONAL LABORATORY-SW																				
	PACIFIC REGIONAL LABORATORY-NW																				
HOURS PER OPERATION												40.0	0.5	4.2	25.0	4.2	25.0				
TOTAL HOURS												10000	200	840	2500	210	1250				2000
CONVERSION FACTOR												950	950	950	1180	950	1180				950
TOTAL OPERATIONAL FTEs												10.53	0.21	0.88	2.12	0.22	1.06				2.11

7. REMARKS

Field Exams and sample collections may be conducted at packers/repackers, distributors, or warehouses if the levels planned cannot be performed during the inspections.

Investigational hours are planned primarily for CFSAN directed assignments.

Import resources planned in page 2.

*Half of the planned samples are physical and other half are documentary samples.

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21008, 21R829 (Health Fraud)	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (3.2)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISC PAPER OASIS #41	ISC PHYSICAL ***	IMPORT INV HOURS	ISA PHYSICAL CHEM				
	TOTAL FIELD	360	70	900	70				
	HEADQUARTERS								
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	1.6	1.6		25.0				
	TOTAL HOURS	576	112	900	1750				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	0.61	0.12	0.95	1.48				

7. REMARKS

* IMPORT INV Hours are for field exams and any other import operations as required by the District to cover import priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams are time spent reviewing import labels that does not result in a sample collection.

**Time spent collecting labels, records, or other documentation for submission to Compliance. Does not include time spent reviewing the import labels. Field Exams Time spent reviewing the label will be included as OASIS # 27 and reported along with compliance review time as OASIS #43.

***Physical samples collected and forwarded to the laboratory for analyses to support violations.

All import field exams are to routinely include verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event suspicious are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) See IOM for additional information on Food and Cosmetic Defense activities.

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrient in Foods Survey - Total Diet				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) 21839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 WHARF EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM*	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD							1040	
NE	HEADQUARTERS							(b)(2)&	
	REGIONAL STAFF							(b)(7)(E)	
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
SE	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
SW	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
HOURS PER OPERATION								3.8	
TOTAL HOURS								3952	
CONVERSION FACTOR								1180	
TOTAL OPERATIONAL FTEs								3.35	

7. REMARKS

* Represents total number of TDS foods for all four market baskets to be analyzed for selected nutrients by KAN-DO labs.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)							
	TOTAL FIELD	600	1180							
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	600	1180							
	CONVERSION FACTOR	1205	1180							
	TOTAL OPERATIONAL FTEs	0.50	1.00							

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports				2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29						
3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 8.1			
R E G I O N	6.	1	2	3	7		4	8	8	
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPECT- IONS	DOMESTIC INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT INVESTI- GATIONS (HOURS)	IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	IMPORT SAMPLE ANALYSIS (CHEM)	IMPORT SAMPLE ANALYSIS (MICRO)	
	TOTAL FIELD	100		60	60	1500	230	115	115	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)			
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SW	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		17.0		4.4	18.0		1.5	16.0	16.0	
TOTAL HOURS		1700		284	1080	1500	345	1840	1840	
CONVERSION FACTOR		950		950	1180	950	950	1180	1180	
OPERATIONAL FTEs		1.79		0.28	0.92	1.58	0.36	1.56	1.56	

7. REMARKS

* Import Investigation Hour Resources cover: Entry Review Hours, Import Investigation, and time for 700 Import Label Reviews.

All Import Field Exams are to routinely include: verification that the imported product is the same as that which was declared (Reconciliation Exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety or label concerns. These activities are to be reported as 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 that 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 Security Activities.

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

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2009**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	107.5	3.0	4.5	115.0	195.3	5.5	8.2	209.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	26.9			26.9	48.9			48.9
42	BLOOD AND BLOOD PRODUCTS	71.2	3.0	2.2	76.4	129.3	5.5	4.0	138.8
45	VACCINES AND ALLERGENIC PRODUCTS	9.4		2.3	11.7	17.1		4.2	21.3

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY		2. PPS PROJECT NAME/NUMBER						
Biologics		Human Cellular, Tissue and Gene Therapeutics - 41						
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		26.9			26.9	48.9	
1	Inspection of Human Cells, Tissues, and Tissue-Based Products (HCT/Ps)	41002B,C,D	22.5			22.5	40.9	41-2
2	Bioresearch Monitoring Programs *		4.4			4.4	8.0	41-3
	Good Laboratory Practices (Nonclinical Labs)	41808	*			*		
	Institutional Review Board	41809	*			*		
	Sponsors, Contract Research Organizations, and Monitors	41810	*			*		
	Clinical Investigators *	41811	(4.4)			(4.4)	(8.0)	
	* All resources planned under PAC 41811.							

CENTER PROJECT MANAGER/TELEPHONE
Anita Richardson, 301 827-6220

ORA PLANNER/TELEPHONE
Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE Inspection of Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps) Inspection of Tissue Establishments					2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41					
3. PROGRAM/ASSIGNMENT CODE(S) 41002B, C, D			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 22.5			
REGION	DISTRICT/SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 CBER PRIORITY ESTAB	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	494	(27)							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		43.3								
TOTAL HOURS		21390								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		22.52								

9. REMARKS

* Refer to CBER's 6-13-08 Memo for inspectional priorities.

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

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

PAC 41002B for Product Codes: 57K Reproductive Tissue

PAC 41002C for Product Codes: 57M Hematopoietic Stem Cells

PAC 41002D for Product Codes: 57J Musculoskeletal Tissue; 57 L Ocular Tissue;
57 O Other Tissue (human skin, pericardium, dura mater, heart valves)

For Inspection Risk Based Approach, Refer to CBER's June 13, 2008 Memo,

Subject: HCT/P, Blood Bank, and Source Plasma Inspection Priorities for FY09.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue & Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41808-GLP, 41809-IRB, 41810-Spon/ Mon/CROs, 41811 Clinical Investigator*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	59								
NE	HEADQUARTERS	(b)(2)&								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	70.9								
	TOTAL HOURS	4183								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	4.40								

9. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign) *			2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42							
3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G 42R825			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 53.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSPEC- TIONS	1	2 DOMESTIC INVESTI- GATIONS (Hours) **	1 FOREIGN BLOOD BANK INSPEC- TIONS ***	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDIN- ATION (Hours)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		1093		2469	12			2375	
NE	HEADQUARTERS	(b)(2)&(b)		(b)(2)&(b)(7)(E)				(b)(2)&(b)		
	REGIONAL STAFF	(7)(E)						(7)(E)		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEWORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		41.2			43.0					
TOTAL HOURS		45032		2469	516			2375		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		47.40		2.60	0.54			2.50		

7. REMARKS

* All listed resources are planned under PAC 42001F. Resources cover all facilities listed in current compliance program. Pre-License Inspections for PPS 41, 42, 45 and Field Investigation Hours are not planned separately. Use above resources for these as needed, at district discretion.
For Inspection Risk Based Approach, Refer to CBER's June 13, 2008 Memo,
Subject: HCT/P, Blood Bank, and Source Plasma Inspection Priorities for FY09.

Domestic Inspectional Module Includes Time for AIDS.
 Blood Bank PAC's: 42001F, Level 1 Inspection and 42001G, Level 2 Inspection.
 BLT-DO, Report Technical Assistance Time under Operation Code 92.

** Domestic Investigative Time is for National Expert Domestic Investigations and Follow-Up Inspections.

*** Foreign Blood Bank Inspections spread by DFI.

Personnel Types Required: Investigator, National Experts

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42002F,G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours)
	TOTAL FIELD	205	1330							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	41.8								
	TOTAL HOURS	8569	1330							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATION FTEs	9.02	1.40							

7. REMARKS

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

For Inspection Risk Based Approach, Refer to CBER's June 13, 2008 Memo, Subject: HCT/P, Blood Bank, and Source Plasma Inspection Priorities for FY09.

Personnel Types Required: Investigator, Team Biologics

1. PROGRAM/ASSIGNMENT TITLE Imported CBER-Regulated Products	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42007, 42R833, 42R824, 99R833 41R824, 45R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 IMPORT INVESTI- GATION HOURS	3 DOMESTIC INVESTI- GATIONS (HOURS)	4 IMPORT INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		2850							
NE	HEADQUARTERS		(b)(2)&(b)							
	REGIONAL STAFF		(7)(E)							
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION										
TOTAL HOURS			2850							
CONVERSION FACTOR			950							
TOTAL OPERATION FTES			3.00							

9. REMARKS

ALL Resources are planned under PAC 42007, as Import Investigation Hours.
 Report Accomplishments under Appropriate PAC and Operation.
 Planned Resources are to Cover ALL Import Operations: 42R833 Entry Review; 41R824, 42R824, 45R824 Follow-Up to Refusals; 99R833 Filer Evaluation, Import Investigation Hours, and any inspections needed for PAC 42007.

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Viral Marker Test Kits	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42008, A Domestic & Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Post-Licensed DOMESTIC INSP CTIONS	1 Post-Licensed FOREIGN INSP CTIONS	3 DOMESTIC INV (Hours)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	10	2	475						
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	150.0	200.0							
	TOTAL HOURS	1500	400	475						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	1.58	0.42	0.50						

7. REMARKS

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

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

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/Contract Research Organizations, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42809-IRB, 42810-Spon/Monitor/CROs, 42811 Clinical Investigator *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	54								
NE	HEADQUARTERS	(b)(2)&								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	70.4								
	TOTAL HOURS	3802								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	4.00								

9. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE STI G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	10								
NE	HEADQUARTERS	(b)(2)&								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
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SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		47.5								
TOTAL HOURS		475								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.50								

7. REMARKS

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

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

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Plasma Derivatives of Human Origin	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42848A, F, G; 41848A, F, G Domestic & Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPECT- IONS	1 FOREIGN LICENSED INSPECT- IONS	3 DOMESTIC SAMPLE COLL	2 DOMESTIC INVESTI- GATIONS (Hours)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	9	7							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		180.6	175.2							
TOTAL HOURS		1825	1226							
CONVERSION FACTOR		950	950							
OPERATIONAL FTEs		1.71	1.29							

7. REMARKS

* Core Team Compliance Program new in FY05 - Inspection of Biological Drug Products (CBER), (Previously covered by PAC 42006):
 All Inspections will be performed by Core Team Biologics.
 42848A Pre-Licensed Inspection - Plasma Derivatives, 42848F Level 1 CGMP Inspection - Plasma Derivative,
 42848G Level 2 CGMP Inspection - Plasma Derivatives; 41848A Pre-Licensed Inspection-Therapeutic Drugs,
 41848F Level 1 CGMP Inspection - Therapeutic Drugs, 41848G Level 2 CGMP Inspection - Therapeutic Drugs

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

Report Foreign Inspections under Operation Code 11.
 Personnel Types Required: Core Team Biologics, Investigator

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA)			2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45							
3. PROGRAM/ASSIGNMENT CODE(S) 45809 IRBs, 45810 Spon/Mon/CROs, 45811 Clinical Investigators			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	SPECIALIZED									
	TOTAL FIELD	76								
NE	HEADQUARTERS	(b)(2)&(b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		81.3								
TOTAL HOURS		6179								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		6.50								

7. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products (Post-Market & Pre-License)					2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45					
3. PROGRAM/ASSIGNMENT CODE(S) 45848A,F,G Domestic/Foreign *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC- TIONS	1 FOREIGN INSPEC- TIONS	2 DOMESTIC INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		5	1						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		108.0	125.0							
TOTAL HOURS		540	125							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.57	0.13							

7. REMARKS

* New in FY05 Core Team Compliance Program - Inspection of Biological Drug Products (CBER)
 (Previously covered by PAC 45001):
 PAC 45848A Pre-License Inspection - Allergenic
 PAC 45848F Level 1 CGMP Inspection - Allergenic
 PAC 45848G Level 2 CGMP Inspection - Allergenic
 All Inspections will be conducted by Core Team Biologics.
 Resources are planned under PAC 45848F. Use Resources As Needed and Report Under Appropriate PAC.

Personnel Types Required: Investigator, Core Team Biologics
 Report Foreign Inspections under Operation Code 11.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)				2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45						
3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic/Foreign *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC- TIONS	1 FOREIGN INSPEC- TIONS	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		8	8	570					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		203.0	260.0							
TOTAL HOURS		1624	2080	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.71	2.19	0.60						

7. REMARKS

* New Core Team Compliance Program in FY05 - Inspection of Biological Drug Products (CBER):
 (Previously covered by PAC 45002)
 45848B Pre-License Inspection - Vaccines;
 45848C Level 1 CGMP Inspection - Vaccines;
 45848D Level 2 CGMP Inspection - Vaccines.
 All inspections will be performed by Core Team Biologics.
 Resources are planned under 45848C. Use Resources' As Needed and Report Under Appropriate PAC.
 Field Investigation Hours may be used to assist any Core Team Program.

Personnel Types Required: Investigator, Core Team Biologics
 Report Foreign Inspections under Operation Code 11.

**CENTER FOR DRUG EVALUATION AND RESEARCH
 RESOURCE SUMMARY
 FY 2009 ORA WORKPLAN
 October 1, 2008**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES	PROGRAM FTES			TOTAL PROGRAM FTES
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	228.6	30.9	79.5	339.0	415.5	56.1	144.4	616.0
46	NEW DRUG EVALUATION	9.0		14.0	23.0	16.4		25.4	41.8
48	BIORESEARCH MONITORING HUMAN DRUGS	43.6		18.5	62.1	79.2		33.6	112.8
52	GENERIC DRUG EVALUATION	5.0		10.0	15.0	9.1		18.2	27.3
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	10.0		1.0	11.0	18.2		1.8	20.0
56	DRUG QUALITY ASSURANCE	132.5	30.9	36.0	199.4	240.8	56.1	65.4	362.3
63	UNAPPROVED AND MISBRANDED DRUGS	9.5			9.5	17.3			17.3
88	INTERAGENCY COOPERATIVE ACTIVITIES	19.0			19.0	34.5			34.5

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations -Domestic (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46				
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46832M <input checked="" type="checkbox"/>			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDAs TO INSPECT	1 CHEMIST INSPECT (HOURS)		3 DOMESTIC SAMPLE COLL	7 DSAs PROFILE (Hours)	
	TOTAL FIELD	120	2272		17	17	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)		
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
SE	PHILADELPHIA						
	FORENSIC CHEM. CTR.						
	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
SW	NEW ORLEANS						
	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
PA	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		46.0			5.0	50.0	
TOTAL HOURS		5520	2272		85	850	
CONVERSION FACTOR		950	950		950	1180	
TOTAL OPERATIONAL FTES		5.81	2.39		0.09	0.72	
7. REMARKS * Includes Microbiologists on Inspections. <input checked="" type="checkbox"/> 46832M Therapeutic Biologics Products PAC- Resources under 56002M.							

FY2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46					
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46832D			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 14.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS ++	1 CHEMIST INSPS (Hours) ..				9 OTHER OPERATIONS (Hours)	
	TOTAL FIELD	192	3325					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)						
	REGIONAL STAFF	(b)(2)&(b)(7)(E)						
	NEW ENGLAND	(b)(2)&(b)(7)(E)						
	NEW YORK	(b)(2)&(b)(7)(E)						
	REGIONAL LAB WEAC	(b)(2)&(b)(7)(E)						
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)						
	BALTIMORE	(b)(2)&(b)(7)(E)						
	CHICAGO	(b)(2)&(b)(7)(E)						
	CINCINNATI	(b)(2)&(b)(7)(E)						
	DETROIT	(b)(2)&(b)(7)(E)						
	MINNEAPOLIS	(b)(2)&(b)(7)(E)						
	NEW JERSEY	(b)(2)&(b)(7)(E)						
	PHILADELPHIA FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)						
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)						
	ATLANTA	(b)(2)&(b)(7)(E)						
	FLORIDA	(b)(2)&(b)(7)(E)						
	NEW ORLEANS	(b)(2)&(b)(7)(E)						
	SAN JUAN REGIONAL LAB	(b)(2)&(b)(7)(E)						
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)						
	DALLAS	(b)(2)&(b)(7)(E)						
	DENVER	(b)(2)&(b)(7)(E)						
	KANSAS CITY	(b)(2)&(b)(7)(E)						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2)&(b)(7)(E)						
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)						
	LOS ANGELES	(b)(2)&(b)(7)(E)						
	SAN FRANCISCO	(b)(2)&(b)(7)(E)						
	SEATTLE	(b)(2)&(b)(7)(E)						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)						
HOURS PER OPERATION		52.0						
TOTAL HOURS		9984	3325					
CONVERSION FACTOR		950	950					
TOTAL OPERATIONAL FTEs		10.50	3.50					
7. REMARKS * Report as follows: Insp./Chem on Insp. under foreign operation code 11, Pac Code 46832; M. Valid.-46832; Profile ISCs & ISAs - 46832B; Biotest ISCs & ISAs (not planned) if collected -46832C. ** Includes microbiologists on inspections. ++ Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).								

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY		2. PPS PROJECT NAME/NUMBER						
Human Drugs		Bioresearch Monitoring: Human Drugs - 48						
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		43.6		18.5	62.1	112.8	
1	In Vivo Bioequivalence - ANDAs & NDAs PDUFA (NDAs)	48001,A	5.5			5.5	10.0	2
	Foreign Inspections (In Vivo Bioequivalence, GLPs)*	48001,A; 48808			3.5	3.5	6.4	3
	* Foreign Inspections PEPFAR (AIDS Relief) (planned under 48001A and 48001) National Experts (NDAs & ANDAs 0.1)	48001D,E;						
2	Bioresearch Monitoring							4
	Good Laboratory Practices (Non-Clinical Lab) National Experts	48808	4.0			4.0	7.3	
	** Institutional Review Board	48809, 48809A	5.8			5.8	10.5	
	Sponsors, Contract Research Organizations, and Monitors	48810	3.3			3.3	6.0	
3	Clinical Investigators	48811, D	25.0		15.0	40.0	72.6	5
	National Experts		(0.24)					
* PEPFAR work is not planned separately, NDA PEPFAR resources are planned under 48001A and ANDA PEPFAR resources are planned under 48001.								
** Resources in the Radioactive Drug Research Committee (48809A) have been collapsed into Institutional Review Board (48809).								

CENTER PROJECT MANAGER/TELEPHONE
Joanne L. Rhoads, (301) 594-0020

ORA PLANNER/TELEPHONE
Anita McCurdy, (301) 827-1632

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (Pre-Approval)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48							
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.5					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSP ECTI ONS DOME STIC	1 48001A NDA INSP ECTI ONS (PDUFA) DOME STIC							
TOTAL FIELD		31	36							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LAB - (SW)									
	PACIFIC REGIONAL LAB - (NW)									
HOURS PER OPERATION		70.0	85.0							
TOTAL HOURS		2170	3060							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.28	3.22							
7. REMARKS Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification. An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 48%, PDUFA 48001A (NDA) 52%. Personnel Types Required: Investigator										

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48001D,E NDA &, ANDA *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.5			
R E G I O N	6.	1	1	4	5	7	8	9	
	DISTRICT/ SPECIALIZED LABORATORY	FOREIGN 48001A NDA INSP CTIONS (PDUFA)	FOREIGN 48001 ANDA INSP CTIONS (PRE-APPR)	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED		
	TOTAL FIELD	23	18						
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB (SW)								
	PACIFIC REGIONAL LAB (NW)								
HOURS PER OPERATION		78.0	85.0						
TOTAL HOURS		1794	1530						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		1.89	1.61						

7. REMARKS

* Planned inspections include: 48001,A In Vivo Bioequivalence, 48808 GLPs (PDUFA), PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence.

Report Inspections under Appropriate PAC, Foreign Inspections under Operation Code 11.

HIGH PRIORITY for NDA inspections.

48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence.

NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001.

We are not planning separate PEPFAR work.

Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs.

Data audit under PEPFAR will be verified by on site inspections.

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors; Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48				
3. PROGRAM/ASSIGNMENT CODE(S) 48808, 48809, 48809A, 48810			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 13.2			
R E G I O N	6.	1	2	1	1				
	DISTRICT/ SPECIALIZED LABORATORY	GLP INSP CTIONS 48808	NAT'L EXPERT INVESTI- GATIONS (Hours) 48808 - GLP	IRB INSP CTIONS 48808, 48809A §	SPONSOR, CRO, MONITORS INSP CTIONS 48810 **				
TOTAL FIELD		39	380	99	35				
N E	HEADQUARTERS		(b)(2)&(b)(7)(E)						
	REGIONAL STAFF								
NEW ENGLAND									
NEW YORK									
REGIONAL LAB									
WEAC									
C E	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
S E	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
S W	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
P A	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - (SW)								
PACIFIC REGIONAL LAB - (NW)									
HOURS PER OPERATION		87.8		56.0	90.0				
TOTAL HOURS		3424	380	5544	3150				
CONVERSION FACTOR		950	950	950	950				
TOTAL OPERATIONAL FTEs		3.60	0.40	5.84	3.32				
9. REMARKS 48808: Resources planned for Inspections may also be used for DSCs. Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER. CDER assignments, i.e. Directed Inspections, cover studies associated with IND's and NDA's. Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-3). * Institutional Review Board ** Sponsors, Contract Research Organizations, and Monitors §48809A: Resources for the Radioactive Drug Research Committee (RDRC, PAC 48809A) are not planned, please use above resources as needed. Personnel Types Required: Investigator, National Expert									

FY 2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48			
3. PROGRAM/ASSIGNMENT CODE(S) 48811		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 40.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	2 Nat'l Experts INVESTI- GATIONS (Hours)		1 INSPEC- TIONS FOREIGN	
	TOTAL FIELD	250	228		169	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)	
	REGIONAL STAFF					
	NEW ENGLAND					
	NEW YORK					
	REGIONAL LAB WEAC					
CE	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
	PHILADELPHIA FORENSIC CHEM. CTR					
SE	REGIONAL STAFF					
	ATLANTA					
	FLORIDA					
	NEW ORLEANS					
	SAN JUAN REGIONAL LAB					
SW	REGIONAL STAFF					
	DALLAS					
	DENVER					
	KANSAS CITY					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB					
PA	REGIONAL STAFF					
	LOS ANGELES					
	SAN FRANCISCO					
	SEATTLE					
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)					
HOURS PER OPERATION		94.1			84.5	
TOTAL HOURS		23525	228		14281	
CONVERSION FACTOR		950	950		950	
TOTAL OPERATIONAL FTEs		24.76	0.24		15.03	

7. REMARKS

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Inv. - Domestic				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52					
3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAs TO INSPECT		3 DOMESTIC SAMPLE COLL		7 DOMESTIC SAMPLE ANALYSES PROFILE (Hours)	7 BIOTEST (Chem)		
	TOTAL FIELD	51		62		31	31		
NE	HEADQUARTERS	(b)(2)&(b)		(b)(2)&(b)		(b)(2)&(b)(7)(E)			
	REGIONAL STAFF	(7)(E)		(7)(E)					
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		48.0		5.0		50.0	30.0		
TOTAL HOURS		2448		310		1550	930		
CONVERSION FACTOR		950		950		1180	1180		
TOTAL OPERATIONAL FTEs		2.58		0.33		1.31	0.79		
7. REMARKS									

1. ANDA Pre - Approval Inspections/Investigations - Foreign				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52			
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B, 52832C, 52832E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 10.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS = (Foreign) ++	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS	5 IMPORT SAMPLE COLL ***	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****
	TOTAL FIELD	69	2200	950	140	70	70
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)		
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
SE	PHILADELPHIA						
	FORENSIC CHEM. CTR						
	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
SW	NEW ORLEANS						
	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
PA	DENVER						
	KANSAS CITY						
	Southwest Import District						
	REGIONAL LAB						
	REGIONAL STAFF						
PA	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		50.0			3.0	30.0	15.0
TOTAL HOURS		3450	2200	950	420	2100	1050
CONVERSION FACTOR		950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		3.63	2.30	1.00	0.44	1.78	0.89
7. REMARKS							
<p>* Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;</p> <p>++ PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).</p> <p>Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C.</p> <p>** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers.</p> <p>**** NRL analyzes all Profile/Biotest ISCs and methods development ISAs.</p>							

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B *	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.0
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	4	5	6	7	8	9
		INSP E C T I O N S DOMESTIC	INSP E C T I O N S FOREIGN	INVEST I G A T I O N	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	M I S C. H O U R S
	TOTAL FIELD	144	16							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - NW									
PACIFIC REGIONAL LAB - SW										
HOURS PER OPERATION		66.0	60.0							
TOTAL HOURS		9504	960							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		10.00	1.01							

7. REMARKS
 *Report both Domestic and Foreign inspections under 53001A for Center-Initiated and 53001B for District-Initiated. Domestic inspections are spread by CDER HFD-332 based upon where inspections are likely to occur. Numbers for domestic inspections may change slightly pending CDER assignment. Foreign inspections are spread by ORA/DFI.

FY 2009 ORA Workplan

October 1, 2008

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832, 56R359, 56002M*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 84.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	3	3	3	7	7	
		INSPECTIONS	INVESTIGATIONS (Hours) *	CHEMIST ON INSPECTIONS (Hours)	MICRO ON INSPEC- TIONS (Hours)	DOMESTIC SAMPLE COLL **	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	
	TOTAL FIELD	1085	1900	6650	1900	350	229	40	229	40	
	HEADQUARTERS	(b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION	55.0				5.0			38.0	28.0	
	TOTAL HOURS	59675	1900	6650	1900	1750			8702	1120	
	CONVERSION FACTOR	950	950	950	950	950			1180	1180	
	TOTAL OPERATIONAL FTEs	62.82	2.00	7.00	2.00	1.84			7.37	0.95	

7. REMARKS

* Hours for certification audits or general investigations as needed by the District.
(b)(2)&(b)(7)(E)

Gas firms are under a separate worksheet 56-5 . ** DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.

Domestic Sample Collections (Chem and Micro) : These areas break out the sample collections and are only guidelines for Districts.

FY2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE DRUG Process Inspections- Domestic (Gas Manufacturer)					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56				
3. PROGRAM/ASSIGNMENT CODE(S) 56002E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS MEDICAL GAS	2 INVESTI- GATION Hours	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLE ANALYSES	8 IMPORT SAMPLES ANALYSES	9 MISC. HOURS
	TOTAL FIELD		159						
NE	HEADQUARTERS	(b)(2)&(b)(7) (E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
SE	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
SW	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
PA	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
HOURS PER OPERATION		30.0							
TOTAL HOURS		4770							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		5.02							
9. REMARKS * Total number of planned gas inspections in the Program for FY 2009									

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002,A,B,C,D,E,F 56832	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 34.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S F O R E I G N	1 C H E M I S T I N S P E C T I O N S (Hours) F O R E I G N **								
	TOTAL FIELD	487	7950								
	HEADQUARTERS	(b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION	50.0									
	TOTAL HOURS	24350	7950								
	CONVERSION FACTOR	950	950								
	TOTAL OPERATIONAL FTEs	25.63	8.37								

7. REMARKS
 * Foreign inspections (DPI) are planned under 56002 and should be reported under operation 11 PACs 56002A, B, C, D, E, F, 56832. ** Time planned in this column may be used by chemists or microbiologists.

FY 2009 ORA Workplan

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56008A, C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 20.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTIONS	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	7 DOMESTIC SAMPLES ANALYZED (CHEM)	7 DOMESTIC SAMPLES ANALYZED (MICRO)	7 METHODS DEVELOPMENT HOURS (Chem)	
	TOTAL FIELD	836	470	376	94	376	94	3615	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL STAFF	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	NEW ENGLAND	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	NEW YORK	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL LAB	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
CE	WEAC	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL STAFF	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	BALTIMORE	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	CHICAGO	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	CINCINNATI	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	DETROIT	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	MINNEAPOLIS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
SE	NEW JERSEY	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	PHILADELPHIA	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL STAFF	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	ATLANTA	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
SW	FLORIDA	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	NEW ORLEANS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	SAN JUAN	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL LAB	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL STAFF	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
PA	DALLAS	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	DENVER	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	KANSAS CITY	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	REGIONAL LAB	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	LOS ANGELES	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	SAN FRANCISCO	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	SEATTLE	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
	PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)				
PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)					
HOURS PER OPERATION			5.5			36.3	22.0		
TOTAL HOURS		836	2585			13649	2068	3615	
CONVERSION FACTOR		950	950			1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.88	2.72			11.57	1.75	3.06	
9. REMARKS									
Domestic Sample Collections (Chem and Micro) : These areas break out the sample collections and are only guidelines for Districts.									

FY 2009 ORA Workplan

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56					
3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 30.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGATIONS HOURS **		MAIL/ COURIERS REVIEWS INV HOURS	4 IMPORT SAMPLE COLLECT- IONS	8 IMPORT SAMPLES ANALYZED APIs CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	10992	6654		10640	118	60	60
	HEADQUARTERS				(b)(2)&(b)(7)(E)			
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
SEATTLE								
PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION						2.7	38.0	25.0
TOTAL HOURS		10992	6654		10640	319	2280	1500
CONVERSION FACTOR		1200	950		950	950	1180	1180
TOTAL OPERATIONAL FTEs		9.16	7.00		11.20	0.34	1.93	1.27

7. REMARKS

* Reporting Guidance:

- Import Entry Reviews (electronic and manual-- operation code 14) PAC 56R833;
- Filer Evaluations (operation code 95) PAC 99R833;
- Follow-Up to Refusals 56R824, 63R824

- Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001, 63002;
- Report finished dosage form drugs and APIs collected at the site of entry under 56008H.

** Import investigation hours are for field exams, 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.

FY 2009 ORA Workplan

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL			7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)		
	TOTAL FIELD	120		40			40		
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			(b)(2)&(b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		25.0		4.0			35.0		
TOTAL HOURS		3000		160			1400		
CONVERSION FACTOR		950		950			1180		
TOTAL OPERATIONAL FTEs		3.15		0.17			1.19		
7. REMARKS									

FY 2009 ORA Workplan

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56			
3. PROGRAM/ASSIGNMENT CODE(S) 56022, 56022A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL		7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	
	TOTAL FIELD	21	945	34		34	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN REGIONAL LAB						
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		30.0		2.0		11.0	
TOTAL HOURS		630	945	68		374	
CONVERSION FACTOR		950	950	950		1180	
TOTAL OPERATIONAL FTEs		0.66	0.99	0.07		0.32	
7. REMARKS							

FY2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Domestic		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56843		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					
5. OPERATIONAL FTE POSITIONS 2.0							
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS	2 INVESTIGATION Hours				9 MISC. HOURS
	TOTAL FIELD	48					
	HEADQUARTERS	(b)(2)&(b)(7) (E)					
NE	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
PA	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
PA	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL-SW						
	PACIFIC REGIONAL-NW						
	HOURS PER OPERATION	40.0					
	TOTAL HOURS	1920					
	CONVERSION FACTOR	950					
	TOTAL OPERATIONAL FTEs	2.02					
9. REMARKS							

FY2009 ORA WORKPLAN

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Foreign				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56				
3. PROGRAM/ASSIGNMENT CODE(S) 56843		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS	2 INVESTI- GATION Hours				9 MISC. HOURS	
	TOTAL FIELD	48						
NE	HEADQUARTERS	(b)(2)&(b)(7) (E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
WEAC								
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
REGIONAL LAB								
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
REGIONAL LAB								
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL-SW							
PACIFIC REGIONAL-NW								
HOURS PER OPERATION		40.0						
TOTAL HOURS		1920						
CONVERSION FACTOR		950						
TOTAL OPERATIONAL FTEs		2.02						
9. REMARKS								

FY 2009 ORA Workplan

October 1, 2008

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56D015	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS							9 Misc. (Hours)
	TOTAL FIELD	70							
	HEADQUARTERS	(b)(2)&							
NE	REGIONAL STAFF	(b)(7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
	HOURS PER OPERATION	67.4							
	TOTAL HOURS	4718							
	CONVERSION FACTOR	950							
	TOTAL OPERATIONAL FTEs	4.97							

7. REMARKS

Resources for collection and analysis of any samples under this program should be taken from Drug Product Surveillance - Domestic Drugs (56008A,C).

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

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs				2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63			
3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.5	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL *		7 DOMESTIC SAMPLES TO BE ANALYZED Chem	8 Misc. (Hours)
	TOTAL FIELD	48	1900	118		59	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
SE	PHILADELPHIA						
	FORENSIC CHEM. CTR						
	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
SW	NEW ORLEANS						
	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF						
PA	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		20.0		4.0		20.0	
TOTAL HOURS		960	1900	472		1180	
CONVERSION FACTOR		950	950	950		1180	
TOTAL OPERATIONAL FTEs		1.01	2.00	0.50		1.00	

7. REMARKS

*Not all samples collected will require analysis; some will be collected for documentary and label review.

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

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Without Approved NDAs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVEST- GATIONS (Hours)							
	TOTAL FIELD	69	1986							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		40.0								
TOTAL HOURS		2760	1986							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.91	2.09							

7. REMARKS

* Samples collected will not require analysis; These samples will be collected for documentary and label review.

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

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects				2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88							
3. PROGRAM/ASSIGNMENT CODE(S) All Appropriate PACs			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.0				
R E G I O N	6.	1	2	3	4	5	6	7	8	9	
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC SAMPLE COLL	IMP O R T S A M P L E C O L L	FIELD EXAMS/ TESTS	IMP O R T F I E L D E X A M S	DOMESTIC SAMPLES TO BE ANALYZED (Chem) Hours	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours)	
	TOTAL FIELD							14160			
NE	HEADQUARTERS							(b)(2)&(b) (7)(E)			
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS										
		SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
		PACIFIC REGIONAL LAB-SW									
	PACIFIC REGIONAL LAB-NW										
	HOURS PER OPERATION										
	TOTAL HOURS							14160			
	CONVERSION FACTOR							1180			
	TOTAL OPERATIONAL FTEs							12.00			

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

1. PROGRAM/ASSIGNMENT TITLE USP Reference Standards	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
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3. PROGRAM/ASSIGNMENT CODE(S) 88R451	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC CHEM HOURS	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD							8260		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB-SW									
	PACIFIC REGIONAL LAB-NW									
HOURS PER OPERATION										
TOTAL HOURS								8260		
CONVERSION FACTOR								1180		
TOTAL OPERATIONAL FTEs								7.00		

7. REMARKS
Seven FTEs are assigned to this Program using dollars reimbursed by United States Pharmacopeia.

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2009**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	95.4	19.6	3.1	118.1	172.7	35.7	5.6	214.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	4.9		2.4	7.3	8.9		4.4	13.3
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	90.5	19.6	0.7	110.8	163.8	35.7	1.2	200.7

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68						
3. PROGRAM/ASSIGNMENT CODE(S) 68001			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.9				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	1 CHEMIST ON INSP --	1 INSPEC- TIONS (Foreign) ---	3	7	9			
	TOTAL FIELD	6	285	25						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		36.0		90.0						
TOTAL HOURS		180	285	2250						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		0.19	0.30	2.37						
7. REMARKS										
<p>** Analyst will participate on inspections as necessary.</p> <p>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.</p> <p>*** Foreign inspections spread by DFI. Use Operation Code 11 to report foreign inspections.</p> <p>Workload Source: FACTS database (registered firms in IND 56, 67, and 68; Workload Obligation is "Yes" and Status is "Operational".)</p>										

1. PROGRAM/ASSIGNMENT TITLE GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)			2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68							
3. PROGRAM/ASSIGNMENT CODE(S) 68808, 68810, 68811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 4.4					
R E G I O N	6.	1 68808 INSPEC- TIONS (GLPs) (SPON/MON)	1 68811 INSPEC- TIONS (CLINICAL INVEST)							
	TOTAL FIELD		30	44						
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		63.3	52.0							
TOTAL HOURS		1899	2288							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.00	2.41							
7. REMARKS * Resources for 68808 and 68810 are planned under 68808. Report inspections under the appropriate PAC. Inspections are to be conducted only when assignments are received from CVM. Workload Source: FACTS database (BIMO firms in IND 67, 68, and 69 with Status of "Operational").										

1. PROGRAM/ASSIGNMENT TITLE Animal Drug Manufacturing Inspections / Type A Medicated Articles	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71001 /A /B, 71005 /A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	1 CHEM ON INSP (Hours)	1 INSPEC- TIONS (Foreign)	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)
	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)
NE	REGIONAL STAFF	(b)(7)(E)						
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION	40.0		63.5		6.0		18.4
	TOTAL HOURS	6040		475		635		250
	CONVERSION FACTOR	950		950		950		950
	TOTAL OPERATIONAL FTEs	6.36		0.50		0.67		0.26
						0.32		0.31

9. REMARKS

Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples. Investigational or official samples should be collected as appropriate. Resources for Type A Medicated Articles Program (71005/A) are now under 71001.

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

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

Foreign Inspections spread by Division of Field Investigations, DFI.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants - DOMESTIC		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71											
3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-J		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS TOTAL 18.3 DOMESTIC 14.8 IMPORT 3.5					
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1	3	4	5	6	7	7	7	7	7	7	
		INSPEC- TIONS (Dioxin)	DOMESTIC SAMPLE COLL.	DOMESTIC SAMPLE COLL. Metals	DOMESTIC SAMPLE COLL. Myc.	DOMESTIC SAMPLE COLL. Micro	DOMESTIC SAMPLE COLL. Chem	DOMESTIC SAMPLE COLL. Dioxin	DOMESTIC SAMPLE ANALYSIS Metals	DOMESTIC SAMPLE ANALYSIS Myc	DOMESTIC SAMPLE ANALYSIS Micro ***	DOMESTIC SAMPLE ANALYSIS Chem	DOMESTIC SAMPLE ANALYSIS Dioxin
		"	** ***	71003B	71003C	71003E	71003A	71003G	71003B	71003C	71003E	71003A	71003G
TOTAL FIELD		20	1300	20	290	300	330	60	20	290	300	290	60
HEADQUARTERS		(b)(2)&(b)(7)(E)											
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)											
	NEW ENGLAND	(b)(2)&(b)(7)(E)											
	NEW YORK	(b)(2)&(b)(7)(E)											
	REGIONAL LAB	(b)(2)&(b)(7)(E)											
	WEAC	(b)(2)&(b)(7)(E)											
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)											
	BALTIMORE	(b)(2)&(b)(7)(E)											
	CHICAGO	(b)(2)&(b)(7)(E)											
	CINCINNATI	(b)(2)&(b)(7)(E)											
	DETROIT	(b)(2)&(b)(7)(E)											
	MINNEAPOLIS	(b)(2)&(b)(7)(E)											
	NEW JERSEY	(b)(2)&(b)(7)(E)											
	PHILADELPHIA	(b)(2)&(b)(7)(E)											
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)											
	REGIONAL STAFF	(b)(2)&(b)(7)(E)											
SE	ATLANTA	(b)(2)&(b)(7)(E)											
	FLORIDA	(b)(2)&(b)(7)(E)											
	NEW ORLEANS	(b)(2)&(b)(7)(E)											
	SAN JUAN	(b)(2)&(b)(7)(E)											
	REGIONAL LAB	(b)(2)&(b)(7)(E)											
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)											
	DALLAS	(b)(2)&(b)(7)(E)											
	DENVER	(b)(2)&(b)(7)(E)											
	KANSAS CITY	(b)(2)&(b)(7)(E)											
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)											
PA	REGIONAL LAB	(b)(2)&(b)(7)(E)											
	REGIONAL STAFF	(b)(2)&(b)(7)(E)											
	LOS ANGELES	(b)(2)&(b)(7)(E)											
	SAN FRANCISCO	(b)(2)&(b)(7)(E)											
	SEATTLE	(b)(2)&(b)(7)(E)											
PACIFIC REGIONAL LABORATORY-SW		(b)(2)&(b)(7)(E)											
PACIFIC REGIONAL LABORATORY-NW		(b)(2)&(b)(7)(E)											
HOURS PER OPERATION		20.0	4.2						22.0	8.0	16.0	6.6	11.7
TOTAL HOURS		400	5460						440	2320	4800	1914	702
CONVERSION FACTOR		950	950						1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.42	5.75						0.37	1.97	4.07	1.62	0.59

9. REMARKS

* Inspections performed as F/U to violative dioxin samples

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

**Domestic Sample Collections: 300 micro samples are to be collected and shipped to CVM's Office of Research for additional analysis. They will not be analyzed by ORA laboratories (71003E). Another 300 micro samples will be collected by the field and analyzed by ORA labs.

***Domestic Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods as well as other animal feed/ingredients.

EXPECT THREE CENTER ASSIGNMENTS:

- Continuation of the assignment for collecting Direct Human Contact Feeds and analyzing for S almonella (n=300). [71003E]
- Melamine in pet food/feed/feed ingredients, domestic samples (n=50, import samples (n=50). [71003A]
- Antibiotics in distilled grains (DDG), domestic samples (n=40), import samples (n=20) - the Field will collect and ship samples to CVM/OR. [71003A]

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

NOTE: Continued on Page 71-4

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-3		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices -71			
3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-J		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 3.5	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4. IMPORT SAMPLE COLL	6. IMPORT SAMPLE COLL Chem	4. IMPORT SAMPLE COLL Micro	4. IMPORT SAMPLE ANALYSIS Chem	8. IMPORT SAMPLE ANALYSIS Micro													
	TOTAL FIELD	340	160	160	160	160													
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB																			
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
SOUTHWEST IMPORT DISTRICT																			
REGIONAL LAB																			
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY-SW																		
PACIFIC REGIONAL LABORATORY-NW																			
	HOURS PER OPERATION										2.5			7.0	12.0				
	TOTAL HOURS										850			1120	1820				
	CONVERSION FACTOR										850			1180	1180				
	TOTAL OPERATIONAL FTEs										0.89			0.95	1.63				

9. REMARKS

Dioxin Samples, 71003G, will be analyzed by ARL and chem samples, 71003 A/B, will follow the distribution of this workplan and Servicing Laboratory Table.

Mycotoxin samples, 71003C, will be analyzed by PRN. Mycotoxin and dioxin samples should be collected as necessary.

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.

*Import Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods as well as other animal feed/ingredients.

Workload Source: FACTS and OASIS databases.

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71004 / A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	7	DOMESTIC SAMPLES COLL (GUIDE)			
		INSPECTIONS FEED ESTABS	INSPECTIONS (FOREIGN)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES ANALYZED (CHEM)				
	TOTAL FIELD	141	5	60	15	15			
	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	22.0	22.0	6.5	35.0				
	TOTAL HOURS	3102	110	390	525				
	CONVERSION FACTOR	950	850	950	1180				
	TOTAL OPERATIONAL FTEs	3.27	0.12	0.41	0.44				

9. REMARKS

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

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

There are 354 State Contract inspections. Charge inspectional time for these contracts under 71S004.

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

In FY 2009 Voluntary Self Inspection Program (VSIP) resources are cancelled.

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

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

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71006			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 16.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)	9 METHODS VALID (Hours) *			
	TOTAL FIELD	320	950	225	850	250	360			
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	39.0		6.6						
	TOTAL HOURS	12480	950	1485	850	250	360			
	CONVERSION FACTOR	950	950	950	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	13.14	1.00	1.56	0.72	0.21	0.31			
9. REMARKS * Planned analytical time may be converted to methods development (including bridging methods) per CVM's concurrence. Methods development work will be assigned by CVM. Additional time for method validation and methods development studies. Sample collections represent CR's of FSIS violative samples and should not be analyzed further unless approved by CVM. Feed and Animal Drug samples are analyzed by Denver Laboratory. 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. <u>Workload Source:</u> Resource distribution is based on the CVM risk model for ranking residue violations in this program.										

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71009, 71R844, 71R843 (99R833, 71R833, 71R824)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 54.4 Domestic 38.3 Import 16.1			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSPEC- TIONS	BSE PARTNERSHIP INSPEC- TIONS	DOMESTIC INVESTI- GATION HOURS	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INVESTI- GATIONS (Hours) ***	3 DOMESTIC SAMPLE COLLECTI- ONS	4 IMPORT SAMPLE COLLECTI- ONS ****	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES ANALYZED	9 TECHNICAL SUPPORT (HOURS) **
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
SE	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
SW	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
PA	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		7.5	3.0				4.0	2.5	6.0	4.3	
TOTAL HOURS		19455	1575	2670	11700	3610	3420	1000	5130	1720	5131
CONVERSION FACTOR		950	950	950	1200	950	950	950	1180	1180	950
TOTAL OPERATION FTEs		20.48	1.66	2.81	9.75	3.80	3.60	1.05	4.35	1.46	5.40
7. REMARKS											
<p>* 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.</p> <p><u>Workload Distribution: Resource distribution based on the CVM risk model for ranking firms in this program.</u></p> <p>** Technical support hours include supporting state activities under the Ruminant Feed Ban Regulation and supporting state activities under the Feed Manufacturing Program, 71004, and the Illegal Residues in Meat/Poultry program, 71006. These hours also include resources for audits of state contract inspections.</p> <p>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)</p> <p>*** Import Investigation Hours are for field exams, 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.</p> <p>**** 200 BSE samples are to be collected [redacted] product and the remaining 200 samples are to be collected from products originating from countries identified as at risk (b)(2)&(b)(7)(E)</p> <p>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).</p>											

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

Inspection Priorities.

The first inspectional priority under this program is to inspect those firms that have a violative history that have been classified by the FDA as "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 pertains to a variety of firms and animal production operations that involve the manufacture, distribution, transportation, and feeding of animal feeds. Although the intent of the rule is to ensure that specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with the regulations be encountered. In planning and prioritizing inspections, the following firm/industry types should be considered, in order of descending priority:

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

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

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71R838		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 1.0					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)							
	TOTAL FIELD	1205							
NE	HEADQUARTERS	(b)(2)&							
	REGIONAL STAFF	(b)(7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		1205							
CONVERSION FACTOR		1205							
TOTAL OPERATIONAL FTEs		1.00							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71V800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	INVESTI- GATIONS 71V800 (Hours)	DOMESTIC CHEM HOURS 71V800						
	TOTAL FIELD	1520	1180							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		1520	1180							
CONVERSION FACTOR		950	1180							
TOTAL OPERATIONAL FTEs		1.60	1.00							
9. REMARKS These resources include time for investigating pet turtle establishments, and to inspect pharmacies compounding animal animal products. 71V800: Workload Source: Based on a pro-rated inventory in Feed Manufacturing, Feed Contaminants and Pre-Approval programs.										

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2009**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	169.2	46.4	22.4	238.0	307.8	84.5	40.7	433.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	97.0	39.2	17.2	153.4	176.7	71.4	31.3	279.4
83	PRODUCT EVALUATION: DEVICES	31.6		3.4	35.0	57.6		6.2	63.8
84	SCIENCE: DEVICES	4.7			4.7	8.6			8.6
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.5		0.1	14.6	25.9		0.2	26.1
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	20.9	7.2	1.7	29.8	38.1	13.1	3.0	54.2

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM/ASSIGNMENT CODE(S) 81010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	3	7	7	7	
		INSPEC- TIONS (1)	INVESTI- GATIONS (Hours) (2)	DOMESTIC SAMPLE COLL ENG	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL STER	DOMESTIC SAMPLES TO BE ANALYZED ENG (3)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (4)	DOMESTIC SAMPLES TO BE ANALYZED STER (5)	
	TOTAL FIELD	21	16	1	1	1	1	1	1	1
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	15.6		10.3	10.3	10.3	37.0	36.0	20.0	
	TOTAL HOURS	328	16	10	10	10	37	36	20	
	CONVERSION FACTOR	950	950	950	950	950	1180	1180	1180	
	TOTAL OPERATIONAL FTEs	0.35	0.02	0.01	0.01	0.01	0.03	0.03	0.02	

9. REMARKS

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

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

(3) MDR samples to confirm reported defects.

(4) Performance testing of chemical and serological test kits.

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

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 29.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2		4		8	
		ENTRY REVIEW (Hours)	IMPORT INV HOURS	IMPORT SAMPLE COLL (Physical) ENG	IMPORT SAMPLE COLL (Physical) MICRO **	IMPORT SAMPLES TO BE ANALYZED ENG	IMPORT SAMPLES TO BE ANALYZED MICRO ***
	TOTAL FIELD	26521	3910	60	60	60	60
	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	NEW ENGLAND	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	NEW YORK	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	REGIONAL LAB	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	WEAC	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	BALTIMORE	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	CHICAGO	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	CINCINNATI	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	DETROIT	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	MINNEAPOLIS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	NEW JERSEY	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	PHILADELPHIA FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	ATLANTA	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	FLORIDA	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	NEW ORLEANS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	SAN JUAN REGIONAL LAB	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	DALLAS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	DENVER	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	KANSAS CITY	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	LOS ANGELES	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	SAN FRANCISCO	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	SEATTLE	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	HOURS PER OPERATION			2.2	2.2	25.5	25.5
	TOTAL HOURS	26521	3910	132	132	1530	1530
	CONVERSION FACTOR	1200	950	950	950	1180	1180
	TOTAL OPERATIONAL FTEs	22.10	4.12	0.14	0.14	1.30	1.30

9. REMARKS

* Import investigation hours are for field exams, 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.

** Audit samples for problems other than failure to register or list (eg. special assignment, import alert). Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

*** Sterile devices to be tested by USP XX method. Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 110.9 [108.0]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	2	2
		INSPEC- TIONS LEVEL I DOMESTIC 82845A	INSPEC- TIONS LEVEL II DOMESTIC 82845B	INSPEC- TIONS LEVEL III COMPLIANCE DOMESTIC 82845C	INSPEC- TIONS FOREIGN 82845B	INSPEC- TIONS FOR CAUSE DOMESTIC 82845G	INSPEC- TIONS FOR CAUSE HIGH RISK DOMESTIC 82845G	INSPEC- TIONS ACCRED PERSONS DOMESTIC 82845P	INVESTI- GATIONS (Hours) 82845B	INVESTI- GATIONS (Hours) A.P. AUDITS MDUFMA 82845J
TOTAL FIELD		724	486	109	251	75	75	7	3309	255
HEADQUARTERS		(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
SW	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
PACIFIC REGIONAL LABORATORY-SW		(b)(2)&(b)(7)(E)								
PACIFIC REGIONAL LABORATORY-NW		(b)(2)&(b)(7)(E)								
HOURS PER OPERATION		40.0	62.5	100.0	65.0	71.0	90.0	63.0		
TOTAL HOURS		28960	30375	10900	16315	5325	6750	441	3309	255
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		30.48	31.97	11.47	17.17	5.61	7.11	0.46	3.48	0.27
9. REMARKS										
<p>For FY 2009, the hours/operation module for Level I inspections has been planned at 40 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) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause " inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Reprogram any unused resources into Level 1 and 2 inspections. Inspectional modules include time for 82845S (sterilization), MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections. Investigational Hours resources have also been planned for National Experts (HQ line) and State Contract Monitoring (DAL-DO line). Foreign inspections include resources for Level I, II, III, and For Cause-related inspections. For planning purposes Foreign inspections will be planned under the Level II inspection PAC (82845B); use the appropriate reporting PAC to record accomplishments associated with these Foreign inspections. Accredited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program. Accredited Person Audits are conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO.</p>										

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 110.9 [2.5]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3		3		7		7		
		DOMESTIC SAMPLE COLL 82845C	DOMESTIC SAMPLE COLL ENG 82845C	DOMESTIC SAMPLE COLL MICRO 82845C	DOMESTIC SAMPLE COLL CHEM 82845C	DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C		
	TOTAL FIELD	42	10	26	6	10	26	6		
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
SW	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
PA	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)								
HOURS PER OPERATION		6.0				80.0	62.0	38.0		
TOTAL HOURS		252				800	1812	228		
CONVERSION FACTOR		950				1180	1180	1180		
TOTAL OPERATIONAL FTEs		0.27				0.68	1.37	0.19		
9. REMARKS										
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.										
MICRO Sample Analyses: Antisera and Products Media Testing to support GMP observations at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.										
CHEM Sample Analyses: Test Kit or Reagent Testing to support GMP observations at WEAC.										

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 110.9 [0.4]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	3	7	7											
		DOMESTIC SAMPLE COLL 82845S	DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR 82846S	DOMESTIC SAMPLE COLL STERILITY 82846S	DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82846S	DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82846S											
	TOTAL FIELD	15	10	5	10	5											
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
SW	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
PA	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
SEATTLE																	
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
	HOURS PER OPERATION									4.7			25.0	29.5			
	TOTAL HOURS									71			250	148			
	CONVERSION FACTOR									950			1180	1180			
	TOTAL OPERATIONAL FTEs									0.07			0.21	0.13			

9. REMARKS

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.

Note: Domestic Sample Collections for Bioburden, Bioindicator are to be collected "for cause".

Domestic Sample Collections for Contract Sterilizers are to be collected "for cause".

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82			
3. PROGRAM/ASSIGNMENT CODE(S) 82Z002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.6	
R E G I O N	6.	1	4	8			
	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	IMPORT SAMPLE COLL CHEM (PHYSICAL)	IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)			
TOTAL FIELD		3	264	264			
NE	HEADQUARTERS	(b)(2)&(b)			(b)(2)&(b)		
	REGIONAL STAFF	(7)(E)			(7)(E)		
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
PACIFIC REGIONAL LABORATORY-SW							
PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION		24.0		2.3			
TOTAL HOURS		72		607			
CONVERSION FACTOR		950		950			
TOTAL OPERATIONAL FTEs		0.08		0.64			

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82			
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.5	
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY			4	4	8	8
	TOTAL FIELD			IMPORT SAMPLE COLL ENG (PHYSICAL)	IMPORT SAMPLE COLL CHEM (PHYSICAL)	IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
				194	563	194	563
	HEADQUARTERS			(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)	
NE	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LABORATORY-SW						
	PACIFIC REGIONAL LABORATORY-NW						
	HOURS PER OPERATION			2.1	2.1	7.5	7.5
	TOTAL HOURS			407	1182	1455	4223
	CONVERSION FACTOR			950	950	1180	1180
	TOTAL OPERATIONAL FTEs			0.43	1.24	1.23	3.58

9. REMARKS

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

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

(b)(2)&(b)(7)(E)

1. PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER								
Center Initiated Assignments		Compliance: Devices - 82								
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY				5. OPERATIONAL FTE POSITIONS			
82Z005, 82Z800			<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				1.0			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY		1		3	7	7	7		9
			INSP CTIONS CENTER- INITIATED 82Z800		DOMESTIC SAMPLE COLL (1) 82Z800	DOMESTIC SAMPLES TO BE ANALYZED CHEM (2) 82Z800	DOMESTIC SAMPLES TO BE ANALYZED STERILITY(3) 82Z800	DOMESTIC SAMPLES TO BE ANALYZED MICRO (4) 82Z800		OTHER OPERATIONS (Hours) METH DEV ENG (5) 82Z800
	TOTAL FIELD		8		13	1	2	2		400
	HEADQUARTERS		(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)					(b)(2)&(b)(7)(E)
NE	REGIONAL STAFF		(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)					(b)(2)&(b)(7)(E)
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION			42.0		10.0	15.0	50.0	50.0		
TOTAL HOURS			336		130	15	100	100		400
CONVERSION FACTOR			950		950	1180	1180	1180		1180
TOTAL OPERATIONAL FTEs			0.35		0.14	0.01	0.08	0.08		0.34

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
--	--

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

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.3
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN							
	TOTAL FIELD	300	10							
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	77.5	77.5							
	TOTAL HOURS	23250	775							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	24.47	0.82							

9. REMARKS
 Device Bioresearch Monitoring inspections should be prioritized according to the following scheme:
 1) For Cause with 30-day due dates;
 2) Directed data audit for expedited PMA;
 3) Directed data audit for non-expedited PMA;
 4) For Cause with 60-90 day due dates;
 5) OAI Follow-up (6 months);
 6) Early Intervention (Probability Sampling, Vulnerable Population, and IDE-based)
 7) Routine Surveillance.

Please contact Bridget Foltz at (240) 276-0262 with any questions.

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.6 [8.4]
--	--	--

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	2	
		INSP CTIONS 85014 (1)	INSP CTIONS FOREIGN 85014 (2)	INSP CTIONS 85014 (3)	INSP CTIONS 85014 (4)	INSP CTIONS 85014F (5)	INSP CTIONS 85014F (6)	INVESTI GATIONS (Hours) 85014A (7)	OTHER OPERATIONS (Hours) 85014C (8)	
	TOTAL FIELD	192	14	124	30	9	9	2376	4312	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	8.0	8.0	8.0	8.0	11.0	11.0			
	TOTAL HOURS	1536	112	992	240	99	99	2376	4312	
	CONVERSION FACTOR	1160	1160	1160	1160	1160	1160	1160	1160	
	TOTAL OPERATIONAL FTEs	1.32	0.10	0.86	0.21	0.09	0.09	2.05	3.72	

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

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program					2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85				
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 14.6 [6.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY						9	9	9
	TOTAL FIELD						OTHER OPERATIONS (Hours) 85014C (9)	OTHER OPERATIONS (Hours) 85014C (10)	OTHER OPERATIONS (Hours) 85014C (11)
	HEADQUARTERS						(b)(2)&(b)(7)(E)		
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS						1200	5941	52	
CONVERSION FACTOR						1200	1180	1180	
TOTAL OPERATIONAL FTEs						1.00	5.12	0.04	
9. REMARKS RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS									
9) Technical Assistance and Coordination Activities: RRHRs.									
10) Technical Assistance and Coordination Activities: non-RRHRs.									
11) Compliance Activities: Warning Letters.									

PROJECT SUMMARY SHEET

FY 2009

1. PROGRAM CATEGORY		2. PPS PROJECT NAME/NUMBER						
Medical Devices and Radiological Health		Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		20.9	7.2	1.7	29.8	54.2	
1	Inspection and Field Testing of Radiation-Emitting Electronic Products:		5.0		0.2	5.2	9.5	86-23-4
	Inspection of Manufacturers of Laser Products	86001	(4.2)		(0.2)	(4.4)	(8.1)	
	Field Implementation of the Sunlamp & Sunlamp Products Performance Standard as Amended	86002	(0.3)			(0.3)	(0.5)	
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	(0.5)			(0.5)	(0.9)	
2	Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-Ray Equipment	86003	7.8		0.7	8.5	15.4	86-25-30
3	Compliance Testing of Electronic Products at WEAC	86006, A, B, D, E	3.1		0.8	3.9	7.1	86-31
4	Imported Electronic Products	86007 *		7.2		7.2	13.1	86-32
5	Radiological Health Control Activities:		5.0			5.0	9.1	86-33-4
	Medical Device and Radiological Health Use Control and Policy Implementation	86008	(3.0)			(3.0)	(5.5)	
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	(3.6)	
	* In addition to PAC 86007, includes reporting PACs 86R824, 86R833, and 99R833.							
CENTER PROJECT MANAGER/TELEPHONE						ORA PLANNER/TELEPHONE		
Lynne L. Rice 240-276-3209						John Aydinian 301-827-1634		

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 5.2	

REG I O N	6. DISTRICT/SPECIALIZED LABORATORY	1	1	1	1	2	2	3	5	5
		INSP E C T I O N S 86001 (1)	INSP E C T I O N S FOREIGN 86001 (2)	INSP E C T I O N S 86002 (3)	INSP E C T I O N S 86004 (4)	INVEST I G A T I O N S (Hours) 86001 (5)	INVEST I G A T I O N S (Hours) 86004	DOMESTIC SAMPLE COLL 86001	FIELD EXAMS/ TESTS 86001 (6)	FIELD EXAMS/ TESTS 86002 (7)
TOTAL FIELD		100	5	3	22	658	31	5	75	30
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN	(b)(2)&(b)(7)(E)								
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
SEATTLE	(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LABORATORY-SW	(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)									
HOURS PER OPERATION		17.2	52.4	36.0	20.0			3.0	5.0	4.4
TOTAL HOURS		1720	262	108	440	658	31	15	375	132
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		1.81	0.22	0.11	0.46	0.69	0.03	0.02	0.39	0.14

9. Remarks

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86				
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY						9 OTHER OPERATIONS (Hours) 86001 (8)	9 OTHER OPERATIONS (Hours) 86002	
	TOTAL FIELD						1197	75	
NE	HEADQUARTERS						(b)(2)&(b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS						1197	75		
CONVERSION FACTOR						950	950		
TOTAL OPERATIONAL FTEs						1.26	0.08		

9. Remarks

Laser products (86001)

B) To include all other activities such as technical assistance, coordination, and training.

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

1. PROGRAM/ASSIGNMENT TITLE Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	1	2	5	5B	9
		INSP CTIONS DOMESTIC (1)	INSP CTIONS FOREIGN (2)	INSP CTIONS DIRECTED (3)	INVEST GATIONS (Hours) (4)	INSP CTIONS (5)	INVEST GATIONS (Hours) (6)	FIELD EXAMS/ TESTS (7)	AUDITS (7)	OTHER OPERATIONS (Hours) (8)
	TOTAL FIELD	50	15	5	884	18	1051	345	30	965
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
CE	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
SE	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
PA	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)								
	HOURS PER OPERATION	50.0	65.0	50.0		16.0		3.0	4.0	
	TOTAL HOURS	2500	975	250	884	288	1051	1035	120	965
	CONVERSION FACTOR	950	950	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	2.63	1.03	0.26	0.93	0.30	1.11	1.09	0.13	1.02

9. REMARKS

- 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.
- Foreign inspections should be joint QSIT and electronic product radiation control inspections if possible.
- Directed Inspections based on the OEI of diagnostic x-ray equipment manufacturers.
- Investigation hours for review and planning of activities under columns 1 (Domestic), 2 (Foreign), and 3 (Directed) Inspections. (b)(2)&(b)(7)(E)
- Investigation hours for review of 2579 forms (reports of assembly) in preparation for performing field tests and field test follow up activities.
- 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.
- Coordination/technical assistance hours for field test activities.

**ATTACHMENT A - 2009 WORKPLAN
INSPECTIONS OF MANUFACTURERS (FOREIGN AND
DOMESTIC) AND FIELD COMPLIANCE TESTING
OF DIAGNOSTIC X-RAY EQUIPMENT**

NEW ENGLAND DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
CT	(b)(2)&(b)(7)(E)			
ME				
MA				
NH				
RI				
VT				
Total				

NEW YORK DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
NY	(b)(2)&(b)(7)(E)			

BALTIMORE DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
DC	(b)(2)&(b)(7)(E)			
MD				
VA				
WV				
Total				

CHICAGO DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
IL	(b)(2)&(b)(7)(E)			

CINCINNATI DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
KY	(b)(2)&(b)(7)(E)			
OH				
Total				

DETROIT DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
IN	(b)(2)&(b)(7)(E)			
MI				
Total				

MINNEAPOLIS DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
MN	(b)(2)&(b)(7)(E)			
ND				
SD				
WI				
Total				

NEW JERSEY DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
NJ	(b)(2)&(b)(7)(E)			

PHILADELPHIA DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
DE	(b)(2)&(b)(7)(E)			
PA				
Total				

ATLANTA DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
GA	(b)(2)&(b)(7)(E)			
NC				
SC				
Total				

FLORIDA DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
FL	(b)(2)&(b)(7)(E)			

NEW ORLEANS DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AL	(b)(2)&(b)(7)(E)			
LA				
MS				
TN				
Total				

SAN JUAN DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
PR	(b)(2)&(b)(7)(E)			

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AR				
OK				
TX				
Total				

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
CO				
NM				
UT				
WY				
Total				

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

State	Number	FDA	FDA	Audits
	Systems Installed			
IA	(b)(2)&(b)(7)(E)			
KS				
NE				
MO				
Total				

LOS ANGELES DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
AZ	(b)(2)&(b)(7)(E)			
CA				
Total				

SAN FRANCISCO DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
CA				
HI				
NV				
Total				

SEATTLE DISTRICT

State	Number	FDA	FDA	Audits
	Systems Installed			
AK				
ID				
MT				
OR				
WA				
Total				

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	7	7	7	7	7												
		FOREIGN INSPECTIONS (PL 90-602 STANDARD)	DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	DOMESTIC SAMPLES TO BE ANALYZED NON-MEDICAL LASERS	DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS												
	TOTAL FIELD	13	100	3	5	18	10												
	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
PA	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY-SW																		
	PACIFIC REGIONAL LABORATORY-NW																		
	HOURS PER OPERATION										70.0	18.0	39.0	252.0	15.0	25.0			
	TOTAL HOURS										910	1800	117	1260	270	250			
	CONVERSION FACTOR										1180	1180	1180	1180	1180	1180			
	TOTAL OPERATIONAL FTEs										0.77	1.53	0.10	1.07	0.23	0.21			

9. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.2				
R E G I O N	6.	DISTRICT/ SPECIALIZED LABORATORY	2	2						
			ENTRY REVIEW (Hours)	IMPORT INV HOURS						
		TOTAL FIELD	6875	1400						
		HEADQUARTERS								
NE		REGIONAL STAFF								
		NEW ENGLAND								
		NEW YORK								
		REGIONAL LAB								
		WEAC								
CE		REGIONAL STAFF								
		BALTIMORE								
		CHICAGO								
		CINCINNATI								
		DETROIT								
		MINNEAPOLIS								
		NEW JERSEY								
		PHILADELPHIA								
SE		REGIONAL STAFF								
		ATLANTA								
		FLORIDA								
		NEW ORLEANS								
		SAN JUAN								
SW		REGIONAL LAB								
		REGIONAL STAFF								
		DALLAS								
		DENVER								
		KANSAS CITY								
PA		SOUTHWEST IMPORT DISTRICT								
		REGIONAL LAB								
		REGIONAL STAFF								
		LOS ANGELES								
		SAN FRANCISCO								
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
		HOURS PER OPERATION								
		TOTAL HOURS	6875	1400						
		CONVERSION FACTOR	1200	950						
		TOTAL OPERATIONAL FTEs	5.73	1.47						
9. REMARKS * Import investigation hours are for field exams, 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.										
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).										

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

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



**DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION
PROGRAM PLANNING & WORKFORCE
MANAGEMENT BRANCH
ORA/ORM/DPEM**



Total Field
 INVESTIGATION SUMMARY TABLE
 FY 2009

Page: 1
 Date: 17-SEPT-2008

	DOMESTIC INVESTIGATION FTE	IMPORT INVESTIGATION FTE	TOTAL INVESTIGATION FTE
FIELD TOTAL	954.66	352.16	1306.82
HQ	23.22	25.00	48.22
NE REGN	121.30	75.74	197.04
NE RO	10.49	0.00	10.49
NWE	57.42	17.54	74.96
NYK	53.39	58.20	111.59
NRL	0.00	0.00	0.00
WEAC	0.00	0.00	0.00
CE REGN	295.02	50.63	345.65
CE RO	17.48	0.00	17.48
BLT	38.98	9.63	48.61
CIN	37.97	4.74	42.71
DET	33.00	14.67	47.67
CHI	32.80	7.13	39.93
MIN	56.96	7.32	64.28
NWJ	39.28	1.00	40.28
PHI	38.55	6.14	44.69
FCC	0.00	0.00	0.00
SE REGN	164.07	40.90	204.97
SE RO	12.42	0.00	12.42
ATL	46.98	6.62	53.60
FLA	46.63	19.36	65.99
NOL	40.72	11.13	51.85
SJV	17.32	3.79	21.11
SRL	0.00	0.00	0.00
SW REGN	141.87	67.92	209.79
SW RO	14.97	0.00	14.97
DAL	54.16	0.16	54.32
DEN	28.49	0.18	28.67
KAN	43.80	0.20	44.00
SWID	0.45	67.38	67.83
ARL	0.00	0.00	0.00
PA REGN	209.18	91.97	301.15
PA RO	13.38	0.00	13.38
LOS	84.20	46.08	130.28
SAN	57.11	19.90	77.01
SEA	54.49	25.99	80.48
PRL-SW	0.00	0.00	0.00
PRL-NW	0.00	0.00	0.00



POSITION CLASS

COMBINED ANALYTICAL & DISTRICT RESOURCES



(b)(2)&(b)(7)(E)





Workplan Summary / Position Class (Combined Anal & District Resources)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects OPR FTES (Complete)

Date: 09/17/2008 02:21 PM
 Report: FWF109

REGION: NE REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	197.05	59.68	50.95	10.75	0.00	1.00	319.43	340561.10
FOOD SAFETY/COS	111.44	40.86	44.29	0.00	0.00	0.00	196.59	212986.20
03	87.70	11.15	43.17	0.00	0.00	0.00	142.02	151646.40
04	4.38	23.51	0.00	0.00	0.00	0.00	27.89	31931.00
07	0.67	1.59	0.00	0.00	0.00	0.00	2.26	2521.00
09	0.88	3.70	0.00	0.00	0.00	0.00	4.58	5189.80
18	12.31	0.00	0.20	0.00	0.00	0.00	12.51	14314.00
21	4.47	0.00	0.00	0.00	0.00	0.00	4.47	4251.70
29	1.03	0.91	0.92	0.00	0.00	0.00	2.86	3138.30
BIOLOGICS	10.11	0.00	0.00	0.00	0.00	0.00	10.11	9601.60
41	3.12	0.00	0.00	0.00	0.00	0.00	3.12	2960.60
42	6.24	0.00	0.00	0.00	0.00	0.00	6.24	5930.60
45	0.75	0.00	0.00	0.00	0.00	0.00	0.75	710.40
HUMAN DRUGS	32.75	12.30	1.19	0.00	0.00	0.00	46.24	46513.70
46	1.78	1.18	0.00	0.00	0.00	0.00	2.96	2804.00
48	6.95	0.00	0.00	0.00	0.00	0.00	6.95	6601.90
52	0.96	3.20	0.00	0.00	0.00	0.00	4.16	4564.00
53	2.14	0.00	0.00	0.00	0.00	0.00	2.14	2028.00
56	19.88	6.39	1.19	0.00	0.00	0.00	27.46	27714.80
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.04	0.03	0.00	0.00	0.00	0.00	1.07	1031.00
88	0.00	1.50	0.00	0.00	0.00	0.00	1.50	1770.00
ANIMAL D & F	12.14	1.81	1.13	0.00	0.00	0.00	15.08	16203.10
68	0.63	0.03	0.00	0.00	0.00	0.00	0.66	615.60
71	11.51	1.78	1.13	0.00	0.00	0.00	14.42	15587.50
DEVICES & RAD H	30.61	4.71	4.34	10.75	0.00	1.00	51.41	55256.50
81	0.11	0.03	0.02	0.03	0.00	0.00	0.19	201.90
82	19.44	4.68	3.64	3.55	0.00	0.00	31.31	33256.30
83	4.87	0.00	0.00	0.00	0.00	0.00	4.87	4628.30
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	2.46	0.00	0.00	0.00	0.00	0.00	2.46	2846.00
86	3.73	0.00	0.00	4.13	0.00	0.00	7.86	8754.00







Workplan Summary / Postion Class (Combined Anal & District Resources)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:21 PM
 Report: FWF109

REGION: CE REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	345.66	54.05	0.00	0.00	0.00	0.00	399.71	401533.50
FOOD SAFETY/COS	143.14	14.65	0.00	0.00	0.00	0.00	157.79	160212.60
03	107.35	0.99	0.00	0.00	0.00	0.00	108.34	105903.00
04	4.46	12.50	0.00	0.00	0.00	0.00	16.96	19291.70
07	1.58	0.00	0.00	0.00	0.00	0.00	1.58	1516.00
09	0.50	1.04	0.00	0.00	0.00	0.00	1.54	1711.40
18	19.83	0.00	0.00	0.00	0.00	0.00	19.83	22699.50
21	8.48	0.00	0.00	0.00	0.00	0.00	8.48	8056.00
29	0.94	0.12	0.00	0.00	0.00	0.00	1.06	1035.00
BIOLOGICS	33.90	0.00	0.00	0.00	0.00	0.00	33.90	32198.40
41	8.48	0.00	0.00	0.00	0.00	0.00	8.48	8051.00
42	23.49	0.00	0.00	0.00	0.00	0.00	23.49	22311.40
45	1.93	0.00	0.00	0.00	0.00	0.00	1.93	1836.00
HUMAN DRUGS	78.66	38.10	0.00	0.00	0.00	0.00	116.76	119331.10
46	5.37	2.35	0.00	0.00	0.00	0.00	7.72	7510.00
48	18.31	0.00	0.00	0.00	0.00	0.00	18.31	17391.60
52	3.32	2.63	0.00	0.00	0.00	0.00	5.95	6132.00
53	5.06	0.00	0.00	0.00	0.00	0.00	5.06	4800.00
56	44.23	22.40	0.00	0.00	0.00	0.00	66.63	68582.50
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.37	0.22	0.00	0.00	0.00	0.00	2.59	2528.00
88	0.00	10.50	0.00	0.00	0.00	0.00	10.50	12390.00
ANIMAL D & F	32.09	1.00	0.00	0.00	0.00	0.00	33.09	32325.40
68	2.81	0.00	0.00	0.00	0.00	0.00	2.81	2664.90
71	29.28	1.00	0.00	0.00	0.00	0.00	30.28	29660.50
DEVICES & RAD H	57.87	0.30	0.00	0.00	0.00	0.00	58.17	57466.00
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	62.40
82	34.44	0.30	0.00	0.00	0.00	0.00	34.74	33609.90
83	12.23	0.00	0.00	0.00	0.00	0.00	12.23	11624.90
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.36	0.00	0.00	0.00	0.00	0.00	4.36	5079.00
86	6.76	0.00	0.00	0.00	0.00	0.00	6.76	7089.80









Workplan Summary / Position Class (Combined Anal & District Resources)

Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:21 PM

Report: FWF109

REGION: SE REGN

	1	2	3	4	5	6	TOTAL	TOTAL
	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	204.98	58.02	46.33	0.00	0.00	3.00	312.33	327321.50
FOOD SAFETY/COS	89.87	40.74	42.49	0.00	0.00	3.00	176.10	192333.20
03	66.11	8.10	39.95	0.00	0.00	0.00	114.16	121967.80
04	4.29	13.05	0.00	0.00	0.00	0.00	17.34	19491.60
07	0.80	3.62	0.00	0.00	0.00	3.00	7.42	8571.00
09	0.17	0.63	0.00	0.00	0.00	0.00	0.80	906.60
18	14.80	0.00	0.47	0.00	0.00	0.00	15.27	17337.00
21	3.04	15.20	1.50	0.00	0.00	0.00	19.74	22604.80
29	0.66	0.14	0.57	0.00	0.00	0.00	1.37	1454.40
BIOLOGICS	21.07	0.00	0.00	0.00	0.00	0.00	21.07	20030.30
41	4.82	0.00	0.00	0.00	0.00	0.00	4.82	4582.20
42	14.76	0.00	0.00	0.00	0.00	0.00	14.76	14027.30
45	1.49	0.00	0.00	0.00	0.00	0.00	1.49	1420.80
HUMAN DRUGS	51.72	14.47	2.04	0.00	0.00	0.00	68.23	67982.60
46	3.68	0.80	0.00	0.00	0.00	0.00	4.48	4253.00
48	11.86	0.00	0.00	0.00	0.00	0.00	11.86	11260.60
52	1.28	0.16	0.00	0.00	0.00	0.00	1.44	1371.00
53	1.17	0.00	0.00	0.00	0.00	0.00	1.17	1104.00
56	31.30	8.25	2.04	0.00	0.00	0.00	41.59	41493.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.43	0.26	0.00	0.00	0.00	0.00	2.69	2601.00
88	0.00	5.00	0.00	0.00	0.00	0.00	5.00	5900.00
ANIMAL D & F	8.81	2.81	1.80	0.00	0.00	0.00	13.42	13788.40
68	1.11	0.05	0.00	0.00	0.00	0.00	1.16	1100.90
71	7.70	2.76	1.80	0.00	0.00	0.00	12.26	12687.50
DEVICES & RAD H	33.51	0.00	0.00	0.00	0.00	0.00	33.51	33187.00
81	0.06	0.00	0.00	0.00	0.00	0.00	0.06	46.80
82	21.24	0.00	0.00	0.00	0.00	0.00	21.24	20559.90
83	5.35	0.00	0.00	0.00	0.00	0.00	5.35	5082.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.06	0.00	0.00	0.00	0.00	0.00	3.06	3557.00
86	3.80	0.00	0.00	0.00	0.00	0.00	3.80	3940.80

(b)(2)&(b)(7)(E)







Workplan Summary / Postion Class (Combined Anal & District Resources)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:21 PM
 Report: FWF109

REGION: SW REGN

	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	5 DISTRICT METHODS VAL/DEV	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRS
FIELD TOTAL	209.79	95.11	40.44	0.00	0.00	8.50	353.84	379575.80
FOOD SAFETY/COS	92.17	78.39	37.46	0.00	0.00	5.00	213.02	236683.30
03	64.96	7.53	36.69	0.00	0.00	0.00	109.18	117686.00
04	6.46	61.14	0.00	0.00	0.00	5.00	72.60	84224.90
07	1.25	2.75	0.00	0.00	0.00	0.00	4.00	4434.00
09	0.83	3.51	0.00	0.00	0.00	0.00	4.34	4929.60
18	12.70	0.00	0.26	0.00	0.00	0.00	12.96	15049.00
21	5.46	3.35	0.00	0.00	0.00	0.00	8.81	9150.20
29	0.51	0.11	0.51	0.00	0.00	0.00	1.13	1209.60
BIOLOGICS	19.14	0.00	0.00	0.00	0.00	0.00	19.14	18179.70
41	4.81	0.00	0.00	0.00	0.00	0.00	4.81	4566.50
42	12.35	0.00	0.00	0.00	0.00	0.00	12.35	11734.60
45	1.98	0.00	0.00	0.00	0.00	0.00	1.98	1878.60
HUMAN DRUGS	38.26	8.10	0.52	0.00	0.00	0.00	46.88	45723.20
46	2.30	0.99	0.00	0.00	0.00	0.00	3.29	3121.00
48	12.62	0.00	0.00	0.00	0.00	0.00	12.62	11986.80
52	1.12	0.37	0.00	0.00	0.00	0.00	1.49	1418.00
53	0.53	0.00	0.00	0.00	0.00	0.00	0.53	504.00
56	20.76	6.66	0.52	0.00	0.00	0.00	27.94	27710.40
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.93	0.08	0.00	0.00	0.00	0.00	1.01	983.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	20.51	8.62	1.93	0.00	0.00	3.50	34.56	35985.60
68	1.56	0.19	0.00	0.00	0.00	0.00	1.75	1669.40
71	18.95	8.43	1.93	0.00	0.00	3.50	32.81	34316.20
DEVICES & RAD H	39.71	0.00	0.53	0.00	0.00	0.00	40.24	43004.00
81	0.11	0.00	0.00	0.00	0.00	0.00	0.11	94.00
82	27.47	0.00	0.53	0.00	0.00	0.00	28.00	30181.90
83	4.70	0.00	0.00	0.00	0.00	0.00	4.70	4466.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.13	0.00	0.00	0.00	0.00	0.00	2.13	2480.00
86	5.30	0.00	0.00	0.00	0.00	0.00	5.30	5781.60







Workplan Summary / Position Class (Combined Anal & District Resources)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:21 PM
 Report: FWF109

REGION: PA REGN

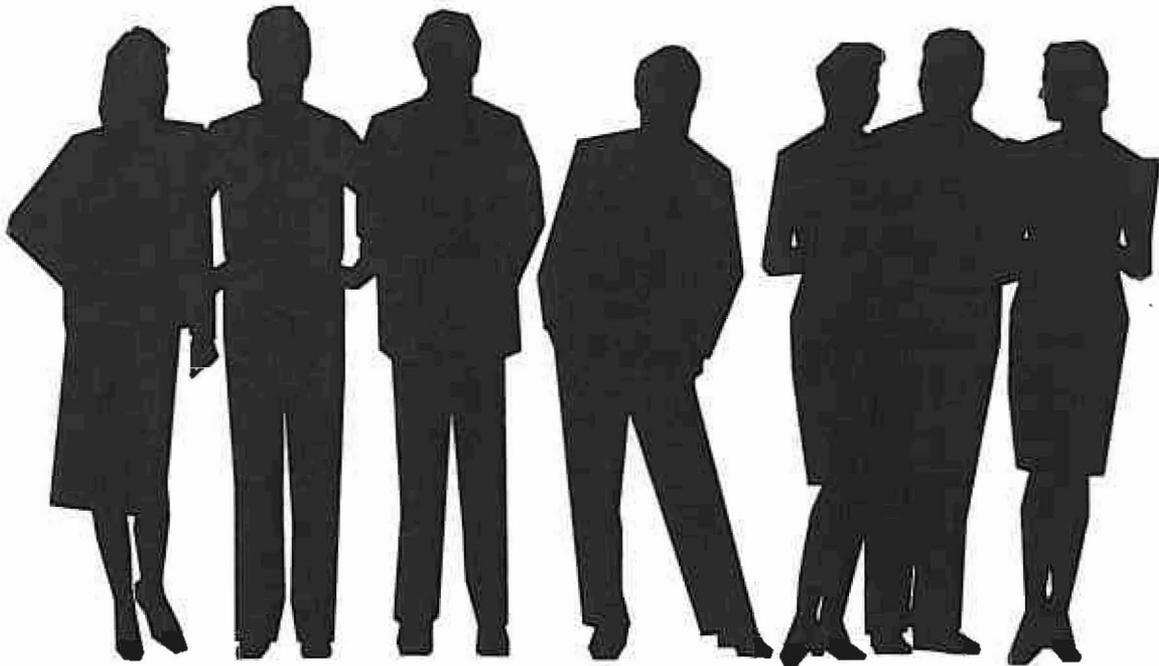
	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	5 DISTRICT METHODS VAL/DEV	6 APPLIED TECH CENTER	TOTAL OPR FTE'S	TOTAL PERSNHRS
FIELD TOTAL	301.16	66.00	64.93	0.00	0.00	6.50	438.67	459154.20
FOOD SAFETY/COS	173.49	47.64	62.94	0.00	0.00	6.00	290.07	312162.60
03	138.40	17.77	62.04	0.00	0.00	4.00	222.21	237005.30
04	6.09	26.17	0.00	0.00	0.00	0.00	32.26	36704.90
07	1.30	1.56	0.00	0.00	0.00	1.00	3.86	4254.00
09	0.51	1.86	0.00	0.00	0.00	0.00	2.37	2674.60
18	19.57	0.00	0.42	0.00	0.00	0.00	19.99	22188.00
21	6.76	0.00	0.00	0.00	0.00	1.00	7.76	7604.10
29	0.86	0.28	0.48	0.00	0.00	0.00	1.62	1731.70
BIOLOGICS	18.24	0.00	0.00	0.00	0.00	0.00	18.24	17324.70
41	5.70	0.00	0.00	0.00	0.00	0.00	5.70	5413.00
42	11.59	0.00	0.00	0.00	0.00	0.00	11.59	11008.70
45	0.95	0.00	0.00	0.00	0.00	0.00	0.95	903.00
HUMAN DRUGS	43.66	12.83	0.95	0.00	0.00	0.00	97.44	56655.50
46	2.62	1.30	0.00	0.00	0.00	0.00	3.92	3719.00
48	11.13	0.00	0.00	0.00	0.00	0.00	11.13	10573.80
52	1.13	0.74	0.00	0.00	0.00	0.00	1.87	1773.00
53	2.13	0.00	0.00	0.00	0.00	0.00	2.13	2028.00
56	24.93	8.38	0.95	0.00	0.00	0.00	34.26	34083.70
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.72	0.41	0.00	0.00	0.00	0.00	2.13	2118.00
88	0.00	2.00	0.00	0.00	0.00	0.00	2.00	2360.00
ANIMAL D & F	17.75	2.63	1.04	0.00	0.00	0.50	21.94	22336.50
68	0.87	0.03	0.00	0.00	0.00	0.00	0.90	851.20
71	16.88	2.62	1.04	0.00	0.00	0.50	21.04	21485.30
DEVICES & RAD H	48.02	2.96	0.00	0.00	0.00	0.00	50.98	50674.90
81	0.06	0.00	0.00	0.00	0.00	0.00	0.06	62.40
82	31.41	2.96	0.00	0.00	0.00	0.00	34.37	33763.60
83	7.85	0.00	0.00	0.00	0.00	0.00	7.85	7455.10
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.58	0.00	0.00	0.00	0.00	0.00	2.58	2997.00
86	6.12	0.00	0.00	0.00	0.00	0.00	6.12	6396.80

Workplan Summary / Position Class (Combined Anal & District Resources)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTES (Complete)

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 Report: FWF109

TOTAL FIELD	1 INVEST	2 METH VAL & ANALYTICAL CHEM	3 METH VAL & ANALYTICAL MICRO	4 METH VAL & ANALYTICAL ENG/PHY	5 DISTRICT METHODS VAL/DEV	6 APPLIED TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	1306.86	332.94	202.65	10.75	0.00	19.00	1872.20	1960200.50
FOOD SAFETY/COS	638.22	222.28	187.18	0.00	0.00	14.00	1,061.68	1147331.90
03	492.63	45.54	181.85	0.00	0.00	4.00	724.02	767156.50
04	25.68	136.37	0.00	0.00	0.00	5.00	167.05	191644.10
07	5.60	9.52	0.00	0.00	0.00	4.00	19.12	21296.00
09	2.89	10.74	0.00	0.00	0.00	0.00	13.63	15412.00
18	79.21	0.00	1.35	0.00	0.00	0.00	80.56	91587.50
21	28.21	18.55	1.50	0.00	0.00	1.00	49.26	51666.80
29	4.00	1.56	2.48	0.00	0.00	0.00	8.04	8569.00
BIOLOGICS	115.09	0.00	0.00	0.00	0.00	0.00	115.09	109335.10
41	26.93	0.00	0.00	0.00	0.00	0.00	26.93	25573.30
42	76.46	0.00	0.00	0.00	0.00	0.00	76.46	72644.00
45	11.70	0.00	0.00	0.00	0.00	0.00	11.70	11117.80
HUMAN DRUGS	248.79	85.80	4.70	0.00	0.00	0.00	339.29	339756.10
46	16.41	6.62	0.00	0.00	0.00	0.00	23.03	22031.00
48	62.21	0.00	0.00	0.00	0.00	0.00	62.21	59085.70
52	7.97	7.10	0.00	0.00	0.00	0.00	15.07	15408.00
53	11.03	0.00	0.00	0.00	0.00	0.00	11.03	10464.00
56	142.68	52.08	4.70	0.00	0.00	0.00	199.46	201089.40
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	8.49	1.00	0.00	0.00	0.00	0.00	9.49	9258.00
88	0.00	19.00	0.00	0.00	0.00	0.00	19.00	22420.00
ANIMAL D & F	91.30	16.89	5.90	0.00	0.00	4.00	118.09	120639.00
68	6.98	0.30	0.00	0.00	0.00	0.00	7.28	6902.00
71	84.32	16.59	5.90	0.00	0.00	4.00	110.81	113737.00
DEVICES & RAD H	213.46	7.97	4.87	10.75	0.00	1.00	238.05	243138.40
81	0.42	0.03	0.02	0.03	0.00	0.00	0.50	467.50
82	137.74	7.94	4.17	3.55	0.00	0.00	153.40	154921.60
83	35.00	0.00	0.00	0.00	0.00	0.00	35.00	33257.30
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	14.59	0.00	0.00	0.00	0.00	0.00	14.59	16959.00
86	25.71	0.00	0.00	4.13	0.00	0.00	29.84	31963.00



POSITION CLASS

SEPARATE LAB RESOURCES

(b)(2)&(b)(7)(E)





WORKPLAN SUMMARY / POSITION CLASS (SEPERATE LAB RESOURCES)

Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:08 PM

Report: FWF106

REGION: NE REGN

	1	2	3	4	5	6			
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS	
FIELD TOTAL	197.04	57.19	47.96	10.75	5.49	1.00	319.42	340561.10	
FOOD SAFETY/COS	111.45	39.67	42.29	0.00	3.20	0.00	196.60	212986.20	
03	87.70	11.15	41.17	0.00	2.00	0.00	142.02	151640.40	
04	4.38	22.51	0.00	0.00	1.00	0.00	27.89	31931.00	
07	0.67	1.40	0.00	0.00	0.20	0.00	2.26	2521.00	
09	0.87	3.70	0.00	0.00	0.00	0.00	4.57	5189.80	
18	12.32	0.00	0.20	0.00	0.00	0.00	12.52	14314.00	
21	4.48	0.00	0.00	0.00	0.00	0.00	4.48	4251.70	
29	1.03	0.91	0.92	0.00	0.00	0.00	2.86	3138.30	
BIOLOGICS	10.11	0.00	0.00	0.00	0.00	0.00	10.11	9601.60	
41	3.12	0.00	0.00	0.00	0.00	0.00	3.12	2960.60	
42	6.24	0.00	0.00	0.00	0.00	0.00	6.24	5930.60	
45	0.75	0.00	0.00	0.00	0.00	0.00	0.75	710.40	
HUMAN DRUGS	32.75	12.30	1.19	0.00	0.00	0.00	46.23	46513.70	
46	1.78	1.18	0.00	0.00	0.00	0.00	2.95	2804.00	
48	6.95	0.00	0.00	0.00	0.00	0.00	6.95	6601.90	
52	0.96	3.20	0.00	0.00	0.00	0.00	4.16	4564.00	
53	2.14	0.00	0.00	0.00	0.00	0.00	2.14	2028.00	
56	19.88	6.39	1.19	0.00	0.00	0.00	27.46	27714.80	
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
63	1.04	0.03	0.00	0.00	0.00	0.00	1.08	1031.00	
88	0.00	1.50	0.00	0.00	0.00	0.00	1.50	1770.00	
ANIMAL D & F	12.14	1.51	1.13	0.00	0.29	0.00	15.07	16203.10	
68	0.62	0.03	0.00	0.00	0.00	0.00	0.65	615.60	
71	11.51	1.49	1.13	0.00	0.29	0.00	14.42	15587.50	
DEVICES & RAD H	30.61	3.72	3.34	10.75	2.00	1.00	51.41	55256.50	
81	0.12	0.03	0.02	0.03	0.00	0.00	0.19	201.90	
82	19.45	3.69	2.64	3.55	2.00	0.00	31.32	33256.30	
83	4.87	0.00	0.00	0.00	0.00	0.00	4.87	4628.30	
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00	
85	2.45	0.00	0.00	0.00	0.00	0.00	2.45	2846.00	
86	3.73	0.00	0.00	4.13	0.00	0.00	7.85	8754.00	





WORKPLAN SUMMARY / POSITION CLASS (SEPERATE LAB RESOURCES)

Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02 08 PM

Report: FWF106

REGION: CE REGN

	1	2	3	4	5	6		
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	345.65	53.55	0.00	0.00	0.50	0.00	399.70	401533.50
FOOD SAFETY/COS	143.14	14.16	0.00	0.00	0.50	0.00	157.79	160212.60
03	107.34	0.99	0.00	0.00	0.00	0.00	108.34	105903.00
04	4.46	12.00	0.00	0.00	0.50	0.00	16.95	19291.70
07	1.60	0.00	0.00	0.00	0.00	0.00	1.60	1516.00
09	0.51	1.04	0.00	0.00	0.00	0.00	1.55	1711.40
18	19.82	0.00	0.00	0.00	0.00	0.00	19.82	22699.50
21	8.48	0.00	0.00	0.00	0.00	0.00	8.48	8056.00
29	0.94	0.12	0.00	0.00	0.00	0.00	1.06	1035.00
BIOLOGICS	33.89	0.00	0.00	0.00	0.00	0.00	33.89	32198.40
41	8.47	0.00	0.00	0.00	0.00	0.00	8.47	8051.00
42	23.49	0.00	0.00	0.00	0.00	0.00	23.49	22311.40
45	1.93	0.00	0.00	0.00	0.00	0.00	1.93	1836.00
HUMAN DRUGS	78.68	38.10	0.00	0.00	0.00	0.00	116.78	119331.10
46	5.38	2.35	0.00	0.00	0.00	0.00	7.73	7510.00
48	18.31	0.00	0.00	0.00	0.00	0.00	18.31	17391.60
52	3.32	2.63	0.00	0.00	0.00	0.00	5.95	6132.00
53	5.05	0.00	0.00	0.00	0.00	0.00	5.05	4800.00
56	44.23	22.40	0.00	0.00	0.00	0.00	66.63	68582.50
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.39	0.22	0.00	0.00	0.00	0.00	2.61	2525.00
88	0.00	10.50	0.00	0.00	0.00	0.00	10.50	12390.00
ANIMAL D & F	32.08	1.00	0.00	0.00	0.00	0.00	33.08	32325.40
68	2.81	0.00	0.00	0.00	0.00	0.00	2.81	2664.90
71	29.28	1.00	0.00	0.00	0.00	0.00	30.28	29660.50
DEVICES & RAD H	57.86	0.30	0.00	0.00	0.00	0.00	58.16	57466.00
81	0.06	0.00	0.00	0.00	0.00	0.00	0.06	62.40
82	34.44	0.30	0.00	0.00	0.00	0.00	34.74	33609.90
83	12.24	0.00	0.00	0.00	0.00	0.00	12.24	11624.90
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.37	0.00	0.00	0.00	0.00	0.00	4.37	5079.00
86	6.76	0.00	0.00	0.00	0.00	0.00	6.76	7089.80





WORKPLAN SUMMARY / POSITION CLASS (SEPERATE LAB RESOURCES)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

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 Report: FWF106

REGION: SE REGN

	1	2	3	4	5	6			
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS	
FIELD TOTAL	204.97	56.34	45.83	0.00	2.17	3.00	312.31	327321.50	
FOOD SAFETY/COS	89.88	39.35	41.99	0.00	1.88	3.00	176.10	192333.20	
03	66.11	8.10	39.46	0.00	0.50	0.00	114.16	121967.80	
04	4.29	12.37	0.00	0.00	0.68	0.00	17.34	19491.60	
07	0.80	3.42	0.00	0.00	0.20	3.00	7.42	8571.00	
09	0.17	0.63	0.00	0.00	0.00	0.00	0.80	906.60	
18	14.82	0.00	0.47	0.00	0.00	0.00	15.29	17337.00	
21	3.04	14.70	1.50	0.00	0.50	0.00	19.74	22604.80	
29	0.66	0.14	0.57	0.00	0.00	0.00	1.36	1454.40	
BIOLOGICS	21.08	0.00	0.00	0.00	0.00	0.00	21.08	20030.30	
41	4.82	0.00	0.00	0.00	0.00	0.00	4.82	4582.20	
42	14.77	0.00	0.00	0.00	0.00	0.00	14.77	14027.30	
45	1.50	0.00	0.00	0.00	0.00	0.00	1.50	1420.80	
HUMAN DRUGS	51.70	14.46	2.04	0.00	0.00	0.00	68.20	67982.60	
46	3.68	0.80	0.00	0.00	0.00	0.00	4.48	4253.00	
48	11.85	0.00	0.00	0.00	0.00	0.00	11.85	11260.60	
52	1.29	0.16	0.00	0.00	0.00	0.00	1.44	1371.00	
53	1.16	0.00	0.00	0.00	0.00	0.00	1.16	1104.00	
56	31.30	8.25	2.04	0.00	0.00	0.00	41.59	41493.00	
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
63	2.42	0.26	0.00	0.00	0.00	0.00	2.68	2601.00	
88	0.00	5.00	0.00	0.00	0.00	0.00	5.00	5900.00	
ANIMAL D & F	8.81	2.52	1.80	0.00	0.29	0.00	13.43	13788.40	
68	1.11	0.05	0.00	0.00	0.00	0.00	1.16	1100.90	
71	7.70	2.47	1.80	0.00	0.29	0.00	12.27	12687.50	
DEVICES & RAD H	33.50	0.00	0.00	0.00	0.00	0.00	33.50	33187.00	
81	0.05	0.00	0.00	0.00	0.00	0.00	0.05	46.80	
82	21.24	0.00	0.00	0.00	0.00	0.00	21.24	20559.90	
83	5.35	0.00	0.00	0.00	0.00	0.00	5.35	5082.50	
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
85	3.06	0.00	0.00	0.00	0.00	0.00	3.06	3557.00	
86	3.80	0.00	0.00	0.00	0.00	0.00	3.80	3940.80	



WORKPLAN SUMMARY / POSITION CLASS (SEPERATE LAB RESOURCES)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

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 Date: 09/17/2008 02.09 PM
 Report: FWF106

REGION: SW REGN

	1	2	3	4	5	6		
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	209.79	92.99	39.43	0.00	3.12	8.50	353.83	379575.80
FOOD SAFETY/COS	92.18	76.52	36.46	0.00	2.87	5.00	213.02	236683.30
03	64.95	7.53	35.69	0.00	1.00	0.00	109.17	117686.00
04	6.46	59.37	0.00	0.00	1.78	5.00	72.60	84224.90
07	1.25	2.65	0.00	0.00	0.10	0.00	4.00	4434.00
09	0.83	3.51	0.00	0.00	0.00	0.00	4.34	4929.60
16	12.71	0.00	0.26	0.00	0.00	0.00	12.98	15049.00
21	5.47	3.35	0.00	0.00	0.00	0.00	8.82	9150.20
29	0.51	0.11	0.51	0.00	0.00	0.00	1.12	1209.60
BIOLOGICS	19.14	0.00	0.00	0.00	0.00	0.00	19.14	18179.70
41	4.81	0.00	0.00	0.00	0.00	0.00	4.81	4566.50
42	12.35	0.00	0.00	0.00	0.00	0.00	12.35	11734.60
45	1.98	0.00	0.00	0.00	0.00	0.00	1.98	1878.60
HUMAN DRUGS	38.26	8.10	0.52	0.00	0.00	0.00	46.88	45723.20
46	2.30	0.99	0.00	0.00	0.00	0.00	3.29	3121.00
48	12.62	0.00	0.00	0.00	0.00	0.00	12.62	11986.80
52	1.13	0.37	0.00	0.00	0.00	0.00	1.49	1418.00
53	0.53	0.00	0.00	0.00	0.00	0.00	0.53	504.00
56	20.76	6.66	0.52	0.00	0.00	0.00	27.93	27710.40
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.93	0.09	0.00	0.00	0.00	0.00	1.01	983.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	20.51	8.37	1.93	0.00	0.25	3.50	34.56	35985.60
68	1.56	0.19	0.00	0.00	0.00	0.00	1.76	1669.40
71	18.95	8.18	1.93	0.00	0.25	3.50	32.81	34316.20
DEVICES & RAD H	39.70	0.00	0.53	0.00	0.00	0.00	40.23	43004.00
81	0.10	0.00	0.00	0.00	0.00	0.00	0.10	94.00
82	27.48	0.00	0.53	0.00	0.00	0.00	28.01	30181.90
83	4.70	0.00	0.00	0.00	0.00	0.00	4.70	4466.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.13	0.00	0.00	0.00	0.00	0.00	2.13	2480.00
86	5.29	0.00	0.00	0.00	0.00	0.00	5.29	5781.60



(b)(2)&(b)(7)(E)







WORKPLAN SUMMARY / POSITION CLASS (SEPERATE LAB RESOURCES)
 Workplan 0 - 2009 (2009 Workplan)

Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:09 PM
 Report: FWF106

REGION: PA REGN

	1	2	3	4	5	6		
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	301.15	64.24	62.44	0.00	4.34	6.50	438.68	459154.20
FOOD SAFETY/COS	173.50	45.98	60.45	0.00	4.17	6.00	290.09	312162.60
03	138.40	17.78	59.54	0.00	2.50	4.00	222.22	237005.30
04	6.09	24.49	0.00	0.00	1.68	0.00	32.26	36704.90
07	1.30	1.56	0.00	0.00	0.00	1.00	3.86	4254.00
09	0.50	1.86	0.00	0.00	0.00	0.00	2.36	2674.60
18	19.58	0.00	0.42	0.00	0.00	0.00	20.00	22188.00
21	6.76	0.00	0.00	0.00	0.00	1.00	7.76	7604.10
29	0.87	0.29	0.48	0.00	0.00	0.00	1.64	1731.70
BIOLOGICS	18.24	0.00	0.00	0.00	0.00	0.00	18.24	17324.70
41	5.70	0.00	0.00	0.00	0.00	0.00	5.70	5413.00
42	11.59	0.00	0.00	0.00	0.00	0.00	11.59	11008.70
45	0.95	0.00	0.00	0.00	0.00	0.00	0.95	903.00
HUMAN DRUGS	43.67	12.82	0.95	0.00	0.00	0.00	57.43	56655.50
46	2.62	1.29	0.00	0.00	0.00	0.00	3.92	3719.00
48	11.13	0.00	0.00	0.00	0.00	0.00	11.13	10573.80
52	1.13	0.74	0.00	0.00	0.00	0.00	1.87	1773.00
53	2.14	0.00	0.00	0.00	0.00	0.00	2.14	2028.00
56	24.93	8.38	0.95	0.00	0.00	0.00	34.25	34083.70
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.72	0.41	0.00	0.00	0.00	0.00	2.13	2118.00
88	0.00	2.00	0.00	0.00	0.00	0.00	2.00	2360.00
ANIMAL D & F	17.74	2.48	1.04	0.00	0.17	0.50	21.93	22336.50
68	0.86	0.03	0.00	0.00	0.00	0.00	0.90	851.20
71	16.87	2.45	1.04	0.00	0.17	0.50	21.04	21485.30
DEVICES & RAD H	48.02	2.96	0.00	0.00	0.00	0.00	50.99	50674.90
81	0.07	0.00	0.00	0.00	0.00	0.00	0.07	62.40
82	31.40	2.96	0.00	0.00	0.00	0.00	34.37	33763.60
83	7.85	0.00	0.00	0.00	0.00	0.00	7.85	7455.10
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.58	0.00	0.00	0.00	0.00	0.00	2.58	2997.00
86	6.13	0.00	0.00	0.00	0.00	0.00	6.13	6396.80

WORKPLAN SUMMARY / POSITION CLASS (SEPERATE LAB RESOURCES)

Workplan 0 - 2009 (2009 Workplan)

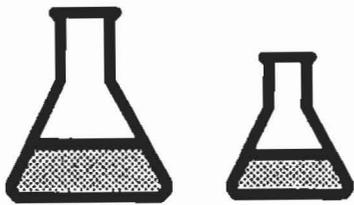
Output Reflects: OPR FTE'S (Complete)

Date: 09/17/2008 02:09 PM

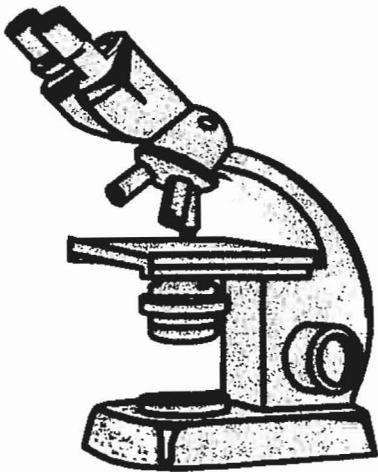
Report: FWF106

TOTAL FIELD

	1	2	3	4	5	6		
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	OPR FTE'S	PERSNHRS
FIELD TOTAL	1306.82	324.32	195.65	10.75	15.61	19.00	1872.15	1960200.50
FOOD SAFETY/COS	638.26	215.67	181.18	0.00	12.61	14.00	1,061.72	1147331.90
03	492.62	45.55	175.85	0.00	5.99	4.00	724.01	767156.50
04	25.68	130.74	0.00	0.00	5.63	5.00	167.04	191644.10
07	5.61	9.02	0.00	0.00	0.50	4.00	19.13	21296.00
09	2.88	10.75	0.00	0.00	0.00	0.00	13.62	15412.00
18	79.24	0.00	1.36	0.00	0.00	0.00	80.60	91587.50
21	28.23	18.05	1.50	0.00	0.50	1.00	49.28	51666.80
29	4.01	1.56	2.47	0.00	0.00	0.00	8.04	8569.00
BIOLOGICS	115.09	0.00	0.00	0.00	0.00	0.00	115.09	109335.10
41	26.92	0.00	0.00	0.00	0.00	0.00	26.92	25573.30
42	76.47	0.00	0.00	0.00	0.00	0.00	76.47	72644.00
45	11.70	0.00	0.00	0.00	0.00	0.00	11.70	11117.80
HUMAN DRUGS	248.78	85.78	4.70	0.00	0.00	0.00	339.26	339756.10
46	16.40	6.61	0.00	0.00	0.00	0.00	23.02	22031.00
48	62.20	0.00	0.00	0.00	0.00	0.00	62.20	59085.70
52	7.98	7.09	0.00	0.00	0.00	0.00	15.07	15408.00
53	11.02	0.00	0.00	0.00	0.00	0.00	11.02	10464.00
56	142.68	52.08	4.70	0.00	0.00	0.00	199.46	201089.40
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	8.50	1.00	0.00	0.00	0.00	0.00	9.50	9258.00
88	0.00	19.00	0.00	0.00	0.00	0.00	19.00	22420.00
ANIMAL D & F	91.28	15.89	5.91	0.00	1.00	4.00	118.07	120639.00
68	6.97	0.30	0.00	0.00	0.00	0.00	7.27	6902.00
71	84.31	15.59	5.91	0.00	1.00	4.00	110.81	113737.00
DEVICES & RAD H	213.43	6.98	3.86	10.75	2.00	1.00	238.01	243138.40
81	0.39	0.03	0.02	0.03	0.00	0.00	0.47	467.50
82	137.74	6.95	3.17	3.55	2.00	0.00	153.41	154921.60
83	35.01	0.00	0.00	0.00	0.00	0.00	35.01	33257.30
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	14.59	0.00	0.00	0.00	0.00	0.00	14.59	16959.00
86	25.70	0.00	0.00	4.13	0.00	0.00	29.82	31963.00



OPERATIONS

















WORKPLAN SUMMARY / COMBINED OPERATIONS
Workplan 0 - 2009 (2009 Workplan)

Report Type: Complete

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Report: FWF118

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Region: NE REQN

	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	2340	73.76	143	69.19	1744	8.74	6398	14.79	323	0.55
FOOD SAFETY/COS	1291	26.08	143	47.80	1471	7.35	5846	13.38	178	0.38
03	1016	21.98	143	43.92	916	4.86	4156	10.19	0	0.25
04	0	0.00	0	0.76	342	1.57	997	2.05	10	0.01
07	0	0.00	0	0.00	85	0.36	147	0.31	0	0.00
09	0	0.00	0	0.35	0	0.00	357	0.53	0	0.00
18	230	2.54	0	0.16	30	0.13	0	0.00	0	0.00
21	32	1.33	0	2.06	91	0.41	60	0.10	268	0.12
29	13	0.23	0	0.56	7	0.03	129	0.20	0	0.00
BIOLOGICS	200	9.55	0	0.56	0	0.00	0	0.00	0	0.00
41	62	3.12	0	0.00	0	0.00	0	0.00	0	0.00
42	130	3.75	0	0.30	0	0.00	0	0.00	0	0.00
45	8	0.69	0	0.06	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	281	16.58	0	7.95	120	0.63	42	0.12	0	0.00
46	16	0.78	0	0.00	3	0.02	0	0.00	0	0.00
48	53	4.39	0	0.00	0	0.00	0	0.00	0	0.00
52	9	0.46	0	0.09	12	0.06	12	0.04	0	0.00
53	28	1.95	0	0.00	0	0.00	0	0.00	0	0.00
56	161	8.49	0	7.38	97	0.51	30	0.09	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	14	0.53	0	0.48	8	0.03	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	150	2.64	0	7.07	136	0.64	332	0.87	0	0.00
68	4	0.24	0	0.00	0	0.00	0	0.00	0	0.00
71	146	2.39	0	7.07	136	0.64	332	0.87	0	0.00
DEVICES & RAD H	418	18.91	0	5.81	17	0.12	178	0.41	45	0.17
81	5	0.08	0	0.00	3	0.03	0	0.00	0	0.00
82	226	12.84	0	3.66	13	0.09	178	0.41	0	0.00
83	61	4.32	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	92	0.65	0	0.92	0	0.00	0	0.00	0	0.00
86	34	1.03	0	1.23	1	0.00	0	0.00	45	0.17

WORKPLAN SUMMARY / COMBINED OPERATIONS
 Workplan 0 - 2009 (2009 Workplan)

Date: 09/17/2008 02:30 PM

Report Type: Complete

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 Report: FWF118

Region: NE REGN

	6		7		8		9		10	
	OPRNS	OPR FTE'S								
FIELD TOTAL	0	1.86	1984	36.25	7642	73.25	726	27.69	232	13.35
FOOD SAFETY/COS	0	1.86	1570	20.44	6508	61.20	726	16.94	37	1.17
03	0	1.86	1137	11.62	4641	40.38	190	5.80	37	1.17
04	0	0.00	272	7.88	1207	14.64	0	1.00	0	0.00
07	0	0.00	124	0.63	129	0.77	0	0.20	0	0.00
09	0	0.00	0	0.00	404	3.70	0	0.00	0	0.00
18	0	0.00	30	0.20	0	0.00	206	9.49	0	0.00
21	0	0.00	0	0.00	0	0.00	330	0.46	0	0.00
29	0	0.00	7	0.11	127	1.72	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	0	0.00	104	9.28	156	3.18	0	1.02	122	7.46
46	0	0.00	0	1.18	0	0.00	0	0.00	18	0.99
48	0	0.00	0	0.00	0	0.00	0	0.00	29	2.56
52	0	0.00	0	0.53	140	2.67	0	0.00	6	0.32
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.19
56	0	0.00	102	6.05	16	0.52	0	1.02	66	3.41
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	2	0.03	0	0.00	0	0.00	0	0.00
88	0	0.00	0	1.50	0	0.00	0	0.00	0	0.00
ANIMAL D & F	0	0.00	119	1.09	258	1.56	0	0.69	6	0.51
68	0	0.00	0	0.03	0	0.00	0	0.00	4	0.38
71	0	0.00	119	1.06	258	1.56	0	0.69	2	0.13
DEVICES & RAD H	0	0.00	191	5.44	720	7.31	0	9.04	67	4.21
81	0	0.00	3	0.08	0	0.00	0	0.00	0	0.00
82	0	0.00	52	2.23	720	7.31	0	2.34	36	2.46
83	0	0.00	0	0.00	0	0.00	0	0.00	10	0.55
84	0	0.00	0	0.00	0	0.00	0	4.72	0	0.00
85	0	0.00	0	0.00	0	0.00	0	0.89	0	0.00
86	0	0.00	136	3.13	0	0.00	0	1.09	21	1.20

WORKPLAN SUMMARY / COMBINED OPERATIONS
 Workplan 0 - 2009 (2009 Workplan)

Date: 09/17/2008 02:30 PM

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 Report: FWF118

Region: NE REGN

	Total	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	319.42	340561.10
FOOD SAFETY/COS	196.60	212986.20
03	142.02	151640.40
04	27.89	31931.00
07	2.26	2321.00
09	4.57	5189.80
18	12.52	14314.00
21	4.48	4251.70
29	2.86	3138.30
BIOLOGICS	10.11	9601.60
41	3.12	2960.60
42	6.24	5930.60
45	0.75	710.40
HUMAN DRUGS	46.23	46513.70
46	2.95	2804.00
48	6.95	6601.90
52	4.16	4564.00
53	2.13	2028.00
56	27.46	27714.80
61	0.00	0.00
63	1.08	1031.00
88	1.50	1770.00
ANIMAL D & F	15.07	16203.10
68	0.65	615.60
71	14.42	15587.50
DEVICES & RAD H	51.41	55256.50
81	0.19	201.90
82	31.32	33256.30
83	4.87	4628.30
84	4.72	5570.00
85	2.45	2846.00
86	7.85	8754.00





(b)(2)&(b)(7)(E)



















(b)(2)&(b)(7)(E)









WORKPLAN SUMMARY / COMBINED OPERATIONS
Workplan 0 - 2009 (2009 Workplan)

Report Type Complete

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Report: FWF118

Date: 09/17/2008 02.30 PM

Region: CE REGN

	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	6092	185.61	144	66.47	4613	22.07	3249	7.46	900	1.48
FOOD SAFETY/COS	2377	49.16	144	42.44	3321	15.79	2771	6.25	750	0.94
03	1892	40.38	144	38.91	1975	10.05	1880	4.55	0	0.61
04	0	0.00	0	0.51	695	2.90	517	1.05	0	0.00
07	0	0.00	0	0.00	335	1.41	88	0.19	0	0.00
09	0	0.00	0	0.20	0	0.00	206	0.30	0	0.00
18	347	3.84	0	0.32	45	0.19	0	0.00	0	0.00
21	106	4.37	0	2.28	251	1.16	46	0.11	750	0.33
29	32	0.57	0	0.22	20	0.09	34	0.05	0	0.00
BIOLOGICS	630	29.94	0	1.46	0	0.00	0	0.00	0	0.00
41	170	8.47	0	0.00	0	0.00	0	0.00	0	0.00
42	440	19.75	0	1.23	0	0.00	0	0.00	0	0.00
45	20	1.71	0	0.22	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	806	48.09	0	10.19	366	1.94	83	0.25	0	0.00
46	46	2.23	0	0.00	7	0.03	0	0.00	0	0.00
48	153	13.28	0	0.00	0	0.00	0	0.00	0	0.00
52	27	1.37	0	0.36	32	0.17	50	0.16	0	0.00
53	70	4.86	0	0.00	0	0.00	0	0.00	0	0.00
56	476	25.11	0	8.76	310	1.67	33	0.09	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	34	1.24	0	1.07	17	0.07	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	1564	18.87	0	5.69	905	4.18	214	0.56	0	0.00
68	30	1.76	0	0.00	0	0.00	0	0.00	0	0.00
71	1534	17.10	0	5.69	905	4.18	214	0.56	0	0.00
DEVICES & RAD H	715	39.56	0	6.70	21	0.15	177	0.40	150	0.54
81	4	0.06	0	0.00	0	0.00	0	0.00	0	0.00
82	449	26.39	0	2.79	20	0.15	177	0.40	0	0.00
83	151	11.14	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	56	0.40	0	1.82	0	0.00	0	0.00	0	0.00
86	55	1.57	0	2.09	1	0.00	0	0.00	150	0.54

WORKPLAN SUMMARY / COMBINED OPERATIONS
Workplan 0 - 2009 (2009 Workplan)

Date 09/17/2008 02.30 PM

Report Type: Complete

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Report: FWF118

Region: CE REGN

	6		7		8		9		10	
	IMPORT FIELD EXAMS OPRNS	OPR FTE'S	DOM SAMPL ANALYSIS OPRNS	OPR FTE'S	IMP SAMPL ANALYSIS OPRNS	OPR FTE'S	MISC OPRNS	OPR FTE'S	FOREIGN INSPECTIONS OPRNS	OPR FTE'S
FIELD TOTAL	0	1.07	329	49.34	140	2.01	1253	36.98	473	27.18
FOOD SAFETY/COS	0	1.07	0	11.55	123	1.46	1253	27.37	56	1.77
03	0	1.07	0	0.55	0	0.30	665	10.15	56	1.77
04	0	0.00	0	11.00	0	0.00	0	1.50	0	0.00
07	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
09	0	0.00	0	0.00	114	1.04	0	0.00	0	0.00
18	0	0.00	0	0.00	0	0.00	413	15.48	0	0.00
21	0	0.00	0	0.00	0	0.00	175	0.24	0	0.00
29	0	0.00	0	0.00	9	0.12	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	2.50	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	2.50	0	0.00
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	0	0.00	329	36.50	17	0.55	0	1.06	307	18.19
46	0	0.00	17	2.35	0	0.00	0	0.00	57	3.12
48	0	0.00	0	0.00	0	0.00	0	0.00	57	5.02
52	0	0.00	62	2.63	0	0.00	0	0.00	24	1.26
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.19
56	0	0.00	237	20.80	17	0.55	0	1.06	166	8.59
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	13	0.22	0	0.00	0	0.00	0	0.00
88	0	0.00	0	10.50	0	0.00	0	0.00	0	0.00
ANIMAL D & F	0	0.00	0	1.00	0	0.00	0	1.61	13	1.17
68	0	0.00	0	0.00	0	0.00	0	0.00	11	1.04
71	0	0.00	0	1.00	0	0.00	0	1.61	2	0.13
DEVICES & RAD H	0	0.00	0	0.30	0	0.00	0	4.45	97	6.06
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	0	0.00	0	0.30	0	0.00	0	0.00	69	4.72
83	0	0.00	0	0.00	0	0.00	0	0.00	20	1.10
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	2.11	5	0.03
86	0	0.00	0	0.00	0	0.00	0	2.34	3	0.21

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	Total	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	399.69	401533.50
FOOD SAFETY/COS	157.79	160212.60
03	108.33	105903.00
04	16.95	19291.70
07	1.60	1516.00
09	1.53	1711.40
18	19.82	22699.50
21	8.48	8056.00
29	1.06	1035.00
BIOLOGICS	33.89	32198.40
41	8.47	8051.00
42	23.49	22311.40
49	1.94	1836.00
HUMAN DRUGS	116.76	119331.10
46	7.73	7510.00
48	18.30	17391.60
52	5.95	6132.00
53	5.05	4800.00
56	66.63	68582.50
61	0.00	0.00
63	2.60	2525.00
88	10.50	12390.00
ANIMAL D & F	33.08	32325.40
68	2.80	2664.90
71	30.27	29660.50
DEVICES & RAD H	58.16	57466.00
81	0.06	62.40
82	34.74	33609.90
83	12.24	11624.90
84	0.00	0.00
85	4.37	5079.00
86	6.79	7089.80

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WORKPLAN SUMMARY / COMBINED OPERATIONS
Workplan 0 - 2009 (2009 Workplan)

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	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	3013	102.57	85	44.31	2502	11.69	3686	9.06	457	0.73
FOOD SAFETY/COS	1328	26.28	85	30.45	1896	8.78	3350	8.24	356	0.38
03	947	20.95	85	28.78	957	4.76	2559	6.57	0	0.22
04	0	0.00	0	0.26	607	2.59	655	1.44	0	0.00
07	0	0.00	0	0.00	171	0.72	37	0.08	0	0.00
09	0	0.00	0	0.07	0	0.00	69	0.10	0	0.00
18	330	3.65	0	0.16	42	0.18	0	0.00	0	0.00
21	33	1.36	0	0.93	108	0.48	12	0.02	356	0.16
29	18	0.32	0	0.26	11	0.05	18	0.03	0	0.00
BIOLOGICS	428	19.95	0	1.00	0	0.00	0	0.00	0	0.00
41	102	4.82	0	0.00	0	0.00	0	0.00	0	0.00
42	310	13.76	0	0.87	0	0.00	0	0.00	0	0.00
45	16	1.37	0	0.13	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	522	30.21	0	7.58	236	1.22	54	0.16	0	0.00
46	28	1.36	0	0.00	4	0.02	0	0.00	0	0.00
48	94	8.40	0	0.00	0	0.00	0	0.00	0	0.00
52	3	0.15	0	0.23	3	0.02	32	0.10	0	0.00
53	14	0.97	0	0.00	0	0.00	0	0.00	0	0.00
56	349	18.19	0	6.19	198	1.05	22	0.06	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	34	1.14	0	1.16	31	0.13	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	337	4.56	0	0.68	398	1.62	18	0.05	0	0.00
68	13	0.73	0	0.00	0	0.00	0	0.00	0	0.00
71	324	3.83	0	0.68	398	1.62	18	0.05	0	0.00
DEVICES & RAD H	398	21.58	0	4.61	12	0.07	264	0.61	101	0.35
81	3	0.05	0	0.00	0	0.00	0	0.00	0	0.00
82	259	15.64	0	2.04	11	0.07	264	0.61	0	0.00
83	65	4.81	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	45	0.33	0	1.34	0	0.00	0	0.00	0	0.00
86	26	0.75	0	1.23	1	0.00	0	0.00	101	0.35

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	6		7		8		9		10	
	OPRNS	OPR FTE'S								
FIELD TOTAL	0	0.70	4217	54.71	4989	46.67	641	24.01	311	17.85
FOOD SAFETY/COS	0	0.70	3530	34.98	4931	46.04	641	19.25	32	1.01
03	0	0.70	1884	15.82	3745	31.41	380	3.95	32	1.01
04	0	0.00	593	3.91	757	8.45	0	0.68	0	0.00
07	0	0.00	538	2.74	115	0.68	0	3.20	0	0.00
09	0	0.00	0	0.00	69	0.63	0	0.00	0	0.00
18	0	0.00	69	0.47	0	0.00	193	10.84	0	0.00
21	0	0.00	424	11.71	218	4.49	68	0.59	0	0.00
29	0	0.00	22	0.34	27	0.37	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	3	0.14
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	0.14
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	0	0.00	227	15.65	12	0.39	0	0.47	212	12.53
46	0	0.00	0	0.80	0	0.00	0	0.00	42	2.30
48	0	0.00	0	0.00	0	0.00	0	0.00	39	3.45
52	0	0.00	0	0.16	0	0.00	0	0.00	15	0.79
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.19
56	0	0.00	212	9.43	12	0.39	0	0.47	113	5.80
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	15	0.26	0	0.00	0	0.00	0	0.00
88	0	0.00	0	5.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	0	0.00	460	4.08	46	0.25	0	1.64	8	0.56
68	0	0.00	0	0.05	0	0.00	0	0.00	4	0.38
71	0	0.00	460	4.03	46	0.25	0	1.64	4	0.18
DEVICES & RAD H	0	0.00	0	0.00	0	0.00	0	2.65	56	3.62
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	0	0.00	0	0.00	0	0.00	0	0.00	42	2.87
83	0	0.00	0	0.00	0	0.00	0	0.00	11	0.54
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	1.40	0	0.00
86	0	0.00	0	0.00	0	0.00	0	1.25	3	0.21

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	Total	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	312.31	327321.50
FOOD SAFETY/COS	176.10	192333.20
03	114.16	121967.80
04	17.34	19491.60
07	7.42	8571.00
09	0.80	906.60
18	15.29	17337.00
21	19.74	22604.80
29	1.36	1454.40
BIOLOGICS	21.09	20030.30
41	4.82	4582.20
42	14.77	14027.30
45	1.50	1420.80
HUMAN DRUGS	68.20	67982.60
46	4.48	4253.00
48	11.85	11260.60
52	1.44	1371.00
53	1.16	1104.00
56	41.59	41493.00
61	0.00	0.00
63	2.68	2601.00
88	5.00	5900.00
ANIMAL D & F	13.42	13788.40
68	1.16	1100.90
71	12.26	12687.50
DEVICES & RAD H	33.49	33187.00
81	0.05	46.80
82	21.24	20559.90
83	5.35	5082.30
84	0.00	0.00
85	3.06	3557.00
86	3.79	3940.80









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WORKPLAN SUMMARY / COMBINED OPERATIONS
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	1		2		3		4		5	
	DOMESTIC INSPECTIONS		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	3197	86.25	40	64.88	2243	10.71	5848	12.31	467	0.91
FOOD SAFETY/COS	837	17.48	40	39.82	1369	6.58	5614	11.73	370	0.57
03	609	13.00	40	36.87	584	3.08	2660	6.52	0	0.41
04	0	0.00	0	0.28	416	1.90	2397	4.28	7	0.01
07	0	0.00	0	0.00	210	0.88	173	0.36	0	0.00
09	0	0.00	0	0.33	0	0.00	339	0.50	0	0.00
18	160	1.98	0	0.00	21	0.09	0	0.00	0	0.00
21	54	2.25	0	2.15	129	0.58	35	0.05	363	0.16
29	14	0.25	0	0.20	9	0.04	10	0.02	0	0.00
BIOLOGICS	382	18.22	0	0.78	0	0.00	0	0.00	0	0.00
41	101	4.81	0	0.00	0	0.00	0	0.00	0	0.00
42	259	11.53	0	0.69	0	0.00	0	0.00	0	0.00
45	22	1.88	0	0.10	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	372	22.38	0	3.15	162	0.86	39	0.12	0	0.00
46	10	0.48	0	0.00	1	0.01	0	0.00	0	0.00
48	92	8.20	0	0.00	0	0.00	0	0.00	0	0.00
52	4	0.20	0	0.18	5	0.03	26	0.08	0	0.00
53	4	0.28	0	0.00	0	0.00	0	0.00	0	0.00
56	249	12.77	0	2.54	143	0.77	13	0.04	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	13	0.44	0	0.43	13	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	1247	13.35	0	1.70	704	3.22	40	0.11	0	0.00
68	24	1.38	0	0.00	0	0.00	0	0.00	0	0.00
71	1223	11.97	0	1.70	704	3.22	40	0.11	0	0.00
DEVICES & RAD H	359	14.83	0	19.43	8	0.05	155	0.36	97	0.34
81	5	0.08	0	0.02	0	0.00	0	0.00	0	0.00
82	149	9.05	0	15.98	7	0.05	155	0.36	0	0.00
83	56	4.20	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	125	0.87	0	0.54	0	0.00	0	0.00	0	0.00
86	24	0.63	0	2.88	1	0.00	0	0.00	97	0.34

WORKPLAN SUMMARY / COMBINED OPERATIONS
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	6		7		8		9		10	
	OPRNS	OPR FTE'S								
FIELD TOTAL	0	1.51	7867	80.40	5155	50.72	790	30.36	266	15.77
FOOD SAFETY/COS	0	1.51	6759	62.79	4937	49.39	790	22.58	18	0.57
03	0	1.51	1556	16.18	2515	26.25	380	4.78	18	0.57
04	0	0.00	3839	41.37	1795	18.00	0	6.78	0	0.00
07	0	0.00	267	1.36	218	1.29	0	0.10	0	0.00
09	0	0.00	0	0.00	384	3.51	0	0.00	0	0.00
18	0	0.00	39	0.26	0	0.00	193	10.64	0	0.00
21	0	0.00	1040	3.35	0	0.00	217	0.28	0	0.00
29	0	0.00	18	0.27	25	0.34	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	3	0.14
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	0.14
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	0	0.00	135	8.22	6	0.19	0	0.20	189	11.75
46	0	0.00	0	0.99	0	0.00	0	0.00	33	1.81
48	0	0.00	0	0.00	0	0.00	0	0.00	50	4.42
52	0	0.00	0	0.37	0	0.00	0	0.00	12	0.63
53	0	0.00	0	0.00	0	0.00	0	0.00	4	0.25
56	0	0.00	130	6.78	6	0.19	0	0.20	90	4.64
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	5	0.09	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	0	0.00	963	8.87	212	1.13	0	5.66	9	0.53
68	0	0.00	0	0.19	0	0.00	0	0.00	2	0.19
71	0	0.00	963	8.67	212	1.13	0	5.66	7	0.34
DEVICES & RAD H	0	0.00	10	0.53	0	0.00	0	1.92	47	2.79
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	0	0.00	10	0.53	0	0.00	0	0.00	30	2.05
83	0	0.00	0	0.00	0	0.00	0	0.00	9	0.50
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	0.69	5	0.03
86	0	0.00	0	0.00	0	0.00	0	1.23	3	0.21

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	Total	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	353.82	379575.80
FOOD SAFETY/COS	213.02	236683.30
03	109.16	117686.00
04	72.60	84224.90
07	4.00	4434.00
09	4.34	4929.60
18	12.98	15049.00
21	8.82	9150.20
29	1.12	1209.60
BIOLOGICS	19.14	18179.70
41	4.81	4566.50
42	12.35	11734.60
45	1.98	1878.60
HUMAN DRUGS	46.88	45723.20
46	3.29	3121.00
48	12.62	11986.80
52	1.49	1418.00
53	0.53	504.00
56	27.93	27710.40
61	0.00	0.00
63	1.01	983.00
88	0.00	0.00
ANIMAL D & F	34.56	35985.60
68	1.76	1669.40
71	32.81	34316.20
DEVICES & RAD H	40.23	43004.00
81	0.10	94.00
82	28.01	30181.90
83	4.70	4466.50
84	0.00	0.00
85	2.13	2480.00
86	5.29	5781.60

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	1		2		3		4		5	
	DOMESTIC INSPECTIONS		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	4192	132.65	188	91.23	3687	17.10	7738	18.61	758	1.15
FOOD SAFETY/COS	2256	46.37	188	72.58	3073	13.93	7195	17.31	671	0.80
03	1676	36.46	188	68.79	1803	8.89	5675	14.19	0	0.51
04	0	0.00	0	0.84	811	3.06	993	2.18	8	0.01
07	0	0.00	0	0.00	199	0.84	219	0.46	0	0.00
09	0	0.00	0	0.20	0	0.00	204	0.30	0	0.00
18	488	6.61	0	0.32	62	0.26	0	0.00	0	0.00
21	69	2.89	0	2.11	185	0.83	65	0.12	663	0.29
29	23	0.41	0	0.34	13	0.06	39	0.06	0	0.00
BIOLOGICS	347	16.40	0	1.71	0	0.00	0	0.00	0	0.00
41	118	5.70	0	0.00	0	0.00	0	0.00	0	0.00
42	219	9.84	0	1.61	0	0.00	0	0.00	0	0.00
45	10	0.86	0	0.10	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	444	26.71	0	6.66	207	1.06	40	0.12	0	0.00
46	20	0.97	0	0.00	2	0.01	0	0.00	0	0.00
48	98	8.75	0	0.00	0	0.00	0	0.00	0	0.00
52	8	0.41	0	0.14	10	0.05	20	0.06	0	0.00
53	28	1.95	0	0.00	0	0.00	0	0.00	0	0.00
56	268	14.08	0	5.58	146	0.79	20	0.06	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	22	0.57	0	0.95	49	0.21	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	532	10.51	0	4.09	387	1.97	136	0.36	0	0.00
68	8	0.49	0	0.00	0	0.00	0	0.00	0	0.00
71	524	10.02	0	4.09	387	1.97	136	0.36	0	0.00
DEVICES & RAD H	613	32.66	0	6.19	20	0.13	367	0.82	87	0.34
81	4	0.07	0	0.00	0	0.00	0	0.00	0	0.00
82	404	23.63	0	2.52	19	0.13	367	0.82	0	0.00
83	100	7.04	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	46	0.32	0	1.15	0	0.00	0	0.00	0	0.00
86	39	1.61	0	2.52	1	0.00	0	0.00	87	0.34

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	6		7		8		9		10	
	OPRNS	OPR FTE'S								
FIELD TOTAL	0	1.59	3183	41.58	10657	83.82	842	34.27	300	16.68
FOOD SAFETY/COS	0	1.59	2719	27.25	9963	78.20	842	30.33	54	1.71
03	0	1.59	1930	22.44	7234	53.91	285	13.74	54	1.71
04	0	0.00	643	3.83	2281	20.66	0	1.68	0	0.00
07	0	0.00	71	0.36	202	1.20	0	1.00	0	0.00
09	0	0.00	0	0.00	204	1.86	0	0.00	0	0.00
18	0	0.00	62	0.42	0	0.00	202	12.38	0	0.00
21	0	0.00	0	0.00	0	0.00	355	1.53	0	0.00
29	0	0.00	13	0.20	42	0.57	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	0.00	3	0.14
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	0.14
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	0	0.00	156	11.90	69	1.56	0	0.31	154	9.11
46	0	0.00	0	1.29	0	0.00	0	0.00	30	1.64
48	0	0.00	0	0.00	0	0.00	0	0.00	27	2.38
52	0	0.00	0	0.74	0	0.00	0	0.00	9	0.47
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.19
56	0	0.00	132	7.46	69	1.56	0	0.31	85	4.42
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	24	0.41	0	0.00	0	0.00	0	0.00
88	0	0.00	0	2.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	0	0.00	308	2.43	204	1.10	0	1.10	4	0.38
68	0	0.00	0	0.03	0	0.00	0	0.00	4	0.38
71	0	0.00	308	2.40	204	1.10	0	1.10	0	0.00
DEVICES & RAD H	0	0.00	0	0.00	421	2.96	0	2.53	85	5.35
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	0	0.00	0	0.00	421	2.96	0	0.00	63	4.31
83	0	0.00	0	0.00	0	0.00	0	0.00	15	0.80
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	1.08	4	0.03
86	0	0.00	0	0.00	0	0.00	0	1.45	3	0.21

WORKPLAN SUMMARY / COMBINED OPERATIONS
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	Total	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	438.68	459154.20
FOOD SAFETY/COS	290.09	312162.60
03	222.22	237005.30
04	32.26	36704.90
07	3.86	4254.00
09	2.36	2674.60
18	19.99	22188.00
21	7.76	7604.10
29	1.64	1731.70
BIOLOGICS	18.24	17324.70
41	5.70	5413.00
42	11.59	11008.70
45	0.95	903.00
HUMAN DRUGS	57.43	56655.50
46	3.92	3719.00
48	11.13	10573.80
52	1.87	1773.00
53	2.14	2028.00
56	34.26	34083.70
61	0.00	0.00
63	2.13	2118.00
88	2.00	2360.00
ANIMAL D & F	21.93	22336.50
68	0.90	851.20
71	21.04	21485.30
DEVICES & RAD H	50.99	50674.90
81	0.07	62.40
82	34.37	33763.60
83	7.85	7455.10
84	0.00	0.00
85	2.58	2997.00
86	6.13	6396.80

WORKPLAN SUMMARY / COMBINED OPERATIONS
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TOTAL FIELD	1 DOMESTIC INSPECTIONS		2 INVESTIGATIONS		3 DOM SAMPL COLL		4 IMP SAMPL COLL		5 FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	18870	587.36	600	370.45	14789	70.30	26915	62.23	2905	4.82
FOOD SAFETY/COS	8089	165.37	600	261.08	11130	52.43	24776	56.92	1425	3.07
03	6140	132.77	600	245.25	6235	31.63	16930	42.02	0	2.00
04	0	0.00	0	2.63	2871	12.02	5559	11.01	25	0.02
07	0	0.00	0	0.00	1000	4.21	664	1.40	0	0.00
09	0	0.00	0	1.14	0	0.00	1175	1.73	0	0.00
18	1555	18.62	0	0.95	200	0.84	0	0.00	0	0.00
21	294	12.20	0	9.53	764	3.46	218	0.40	2400	1.05
29	100	1.79	0	1.58	60	0.28	230	0.36	0	0.00
BIOLOGICS	2023	99.92	0	8.11	0	0.00	0	0.00	0	0.00
41	553	26.92	0	0.00	0	0.00	0	0.00	0	0.00
42	1381	64.21	0	7.50	0	0.00	0	0.00	0	0.00
45	89	8.78	0	0.61	0	0.00	0	0.00	0	0.00
HUMAN DRUGS	2425	144.62	0	36.32	1091	5.71	258	0.78	0	0.00
46	120	5.81	0	0.00	17	0.09	0	0.00	0	0.00
48	490	43.66	0	0.00	0	0.00	0	0.00	0	0.00
52	51	2.58	0	1.00	62	0.32	140	0.44	0	0.00
53	144	10.01	0	0.00	0	0.00	0	0.00	0	0.00
56	1503	78.64	0	31.24	894	4.80	118	0.34	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	117	3.91	0	4.09	118	0.50	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	3830	49.91	0	19.22	2490	11.64	740	1.94	0	0.00
68	79	4.60	0	0.00	0	0.00	0	0.00	0	0.00
71	3751	45.32	0	19.22	2490	11.64	740	1.94	0	0.00
DEVICES & RAD H	2503	127.54	0	45.72	78	0.52	1141	2.59	480	1.75
81	21	0.34	0	0.02	3	0.03	0	0.00	0	0.00
82	1487	87.53	0	29.97	70	0.48	1141	2.59	0	0.00
83	433	31.52	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	364	2.56	0	5.77	0	0.00	0	0.00	0	0.00
86	198	5.58	0	9.96	5	0.02	0	0.00	480	1.75

WORKPLAN SUMMARY / COMBINED OPERATIONS
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TOTAL FIELD	6		7		8		9		10	
	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
FIELD TOTAL	0	6.74	17580	262.29	28583	256.47	4252	153.33	1655	98.15
FOOD SAFETY/COS	0	6.74	14578	157.01	26462	236.30	4252	116.48	200	6.31
03	0	6.74	6507	66.61	18135	152.25	1900	38.43	200	6.31
04	0	0.00	5347	67.99	6040	61.75	0	11.62	0	0.00
07	0	0.00	1000	5.09	664	3.94	0	4.50	0	0.00
09	0	0.00	0	0.00	1175	10.75	0	0.00	0	0.00
18	0	0.00	200	1.36	0	0.00	1207	58.83	0	0.00
21	0	0.00	1464	15.06	218	4.49	1145	3.09	0	0.00
29	0	0.00	60	0.92	230	3.12	0	0.00	0	0.00
BIOLOGICS	0	0.00	0	0.00	0	0.00	0	2.50	30	4.58
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	2.50	21	2.26
45	0	0.00	0	0.00	0	0.00	0	0.00	9	2.32
HUMAN DRUGS	0	0.00	951	81.59	260	5.87	0	3.06	1022	61.34
46	0	0.00	17	6.61	0	0.00	0	0.00	192	10.51
48	0	0.00	0	0.00	0	0.00	0	0.00	210	18.53
52	0	0.00	62	4.42	140	2.67	0	0.00	69	3.63
53	0	0.00	0	0.00	0	0.00	0	0.00	16	1.01
56	0	0.00	813	50.52	120	3.20	0	3.06	535	27.65
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	59	1.00	0	0.00	0	0.00	0	0.00
88	0	0.00	0	19.00	0	0.00	0	0.00	0	0.00
ANIMAL D & F	0	0.00	1850	17.46	720	4.03	0	10.70	40	3.15
68	0	0.00	0	0.30	0	0.00	0	0.00	25	2.36
71	0	0.00	1850	17.16	720	4.03	0	10.70	15	0.79
DEVICES & RAD H	0	0.00	201	6.27	1141	10.27	0	20.58	363	22.78
81	0	0.00	3	0.08	0	0.00	0	0.00	0	0.00
82	0	0.00	62	3.06	1141	10.27	0	2.34	251	17.18
83	0	0.00	0	0.00	0	0.00	0	0.00	65	3.49
84	0	0.00	0	0.00	0	0.00	0	4.72	0	0.00
85	0	0.00	0	0.00	0	0.00	0	6.17	14	0.10
86	0	0.00	136	3.13	0	0.00	0	7.36	33	2.02

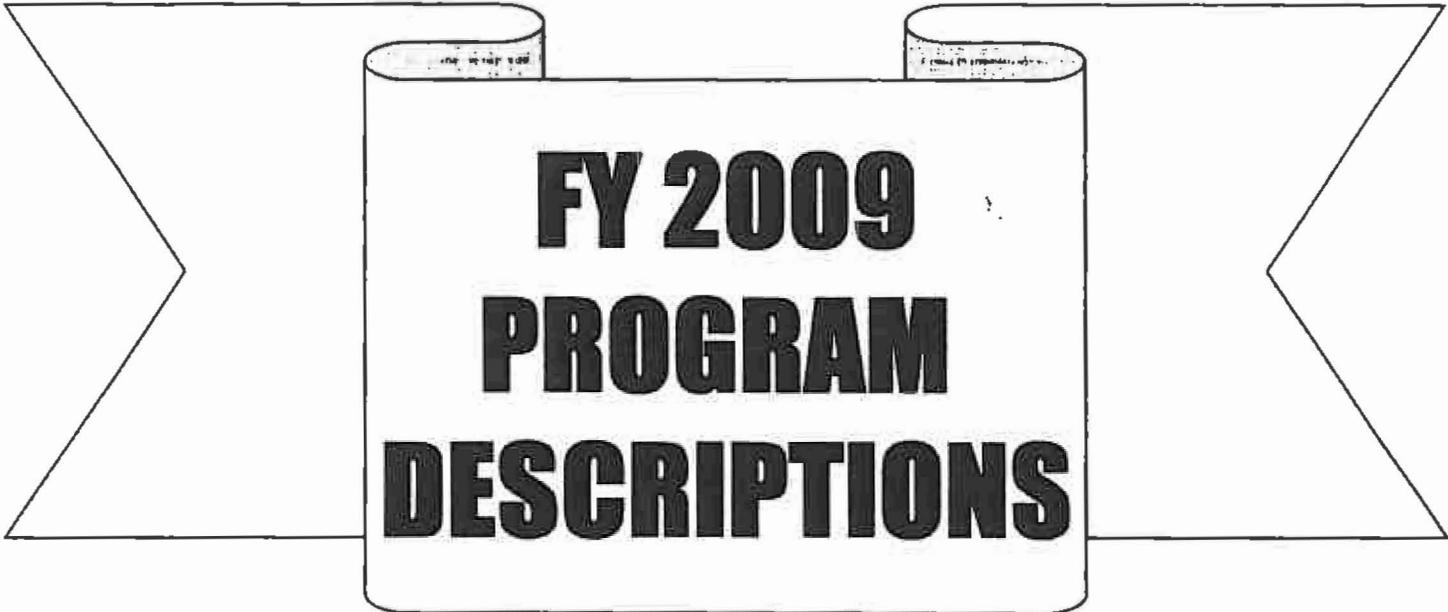
WORKPLAN SUMMARY / COMBINED OPERATIONS
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	OPR FTE'S	PERSNHR
FIELD TOTAL	1872.14	1960200.50
FOOD SAFETY/COS	1061.72	1147331.90
03	724.00	767156.50
04	167.04	191644.10
07	19.13	21296.00
09	13.62	15412.00
18	80.60	91587.50
21	49.28	51666.80
29	8.05	8569.00
BIOLOGICS	115.10	109338.10
41	26.92	25573.30
42	76.47	72644.00
45	11.71	11117.80
HUMAN DRUGS	339.25	339756.10
46	23.02	22031.00
48	62.19	59085.70
52	15.06	15408.00
53	11.02	10464.00
56	199.46	201089.40
61	0.00	0.00
63	9.50	9258.00
88	19.00	22420.00
ANIMAL D & F	118.07	120639.00
69	7.26	6902.00
71	110.81	113737.00
DEVICES & RAD H	238.01	243138.40
81	0.47	467.50
82	153.41	154921.60
83	35.01	33257.30
84	4.72	5570.00
85	14.59	16959.00
86	29.82	31963.00



**FY 2009
PROGRAM
DESCRIPTIONS**



**DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION
PROGRAM PLANNING & WORKFORCE
MANAGEMENT BRANCH
ORA/ORM/DPEM**

Center for Food Safety & Applied Nutrition
PROGRAM DESCRIPTIONS
FY2009

PAC CODE	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PAGE NO.
03003,A	Import Acidified and Low-Acid Canned Foods	FC-1
03037,B,D	Domestic and Imported Cheese and Cheese Products	FC-2
03803A	Domestic Acidified and Low-Acid Canned Foods	FC-3
03803	Domestic Food Safety	FC-4
03819A	Import Foods - General	FC-5
03842	Domestic Fish and Fishery Products Inspection Program	FC-6
03844	Import Seafood Program	FC-7
03847H	Juice HACCP Inspection Program	FC-8
03F098, 03F100	Import and Domestic Produce Assignments	FC-9
03R816	Methods Validation/Development Program	FC-10
03R233	Foreign Inspections/Assesments	FC-11
03R843	Contract Management	FC-12
03R845	Food Defense	FC-13
04004A,D	Pesticides & Industrial Chemicals in Domestic & Imported Foods	FC-14
04018	Chemotherapeutics in Seafood	FC-15
04019A,B,C	Toxic Elements in Food, Foodware, and Radionuclides in Foods	FC-16
04839	Total Diet Study	FC-17
04F800	Field Assignments for Chemical Contaminants	FC-18
04R816	Methods Validation/Development Program	FC-19
04R838	Forensic Evaluation and Sample Analysis	FC-20
07001	Mycotoxins in Domestic and Import Foods	FC-21
07R816	Methods Validation/Development Program	FC-22
09006A,B	Imported Foods - Food and Color Additives	FC-23
18002	Retail Food Protection - State Program	FC-24
18003	(NCIMS) Milk Safety Program	FC-25
18004	Molluscan Shellfish Evaluation Program	FC-26
18029A-F	Interstate Travel Program - Conveyances and Support Facilities	FC-27
21002	Medical Foods - Domestic and Import	FC-28
21003	Field Assignments for Economic Fraud	FC-29
21005	Domestic & Import NLEA Nutrient Sample/Analysis & General Food Labeling Program	FC-30
21006	Infant Formula - Domestic and Import	FC-31
21008	Dietary Supplements - Domestic and Import	FC-32
21839	Selected Nutrients in Food Survey - Total Diet	FC-33
21R816	Methods Validation/Development Program	FC-34
29001	Cosmetics: Domestic and Import	FC-35

Center for Biologics Evaluation & Research
PROGRAM DESCRIPTIONS
FY2009

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

Center for Drug Evaluation & Research

PROGRAM DESCRIPTIONS

FY2009

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

Center for Veterinary Medicine
PROGRAM DESCRIPTIONS
FY2009

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

Center for Devices & Radiological Health
PROGRAM DESCRIPTIONS
FY2009

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

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low-Acid Canned Foods, CP 7303.003	2. FPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

To detain Acidified and Low-Acid Canned Foods which are packed in food canning establishments not in compliance with 21 CFR 108, 113 and 114.

(b)(2)&(b)(7)(E)

5. PROGRAM JUSTIFICATION

Acidified and Low-Acid Canned Foods continue to be the source of sporadic problems from improper processing (e.g., under-processing, inadequate pH or Aw control, leakage). Inspections of foreign firms have shown many firms (and their products) to be out of compliance with 21 CFR Parts 108, 113 and 114.

The number of foreign AF/LACF firms submitting registrations has been increasing significantly each year. In FY 2009 the hours planned for investigations increased to 6400. Additional time will be used for increased field exams such as pH determination and can examinations.

6. FIELD OBLIGATIONS

The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements.

All import field exams are to routinely include: pH determination, can examination and verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised 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 for additional information on Food and Cosmetic Defense Activities.

Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.

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

b. INSPECTION TYPE NA COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT (S) Refer to Compliance Program (7303.003)	d. INDUSTRY/PRODUCT CODE (S) 03-04, 09, 12-18, 20-25, 27, 29, 30-31, 33-41
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (Specify)

f. CHECK THE FOLLOWING ATTRIBUTES

pH, water activity, salinity, soluble solids.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Domestic and Imported Cheese and Cheese Products 03037, 03R839		2. PMS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To conduct inspections of domestic soft cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered. Inspection and analytical resources have been planned separately for out break and emergency operations (PAC 03R839).			
5. PROGRAM JUSTIFICATION Cheese and cheese products have been demonstrated to contain pathogenic microorganisms and to cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.			
6. FIELD OBLIGATIONS The field is requested to conduct inspections of domestic cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings. The field is also requested to conduct sample collections and analyses of imported cheese focusing on soft cheese as high priority. Refer to the guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections. Collection and analysis of environmental samples will be conducted in appropriate firms. CFSAN will issue separate instructions for this type of sampling. As in FY 08: High Risk firms whose last inspection was NAI may be placed on a 3-year inspection frequency. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. NOTE: (For specialized micro testing below, see compliance program or contact DFS for additional details) DEN will perform Salmonella serotyping for isolates originating from the following labs: DEN, SAN, PRL-SW, PRL-NW. ARL will perform Salmonella serotyping for isolates originating from all labs: ARL, SRL, NRL.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER
		<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED
		<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Hard and Soft Cheeses		d. INDUSTRY/PRODUCT CODE(S) 12	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES <u>Salmonella</u> , <u>Listeria</u> , <u>E. coli</u> , <u>Enterotoxigenic E. Coli (ETEC)</u> , <u>Enterohemorrhagic E. Coli EHEC 0157:H7</u> - <u>S. Aureus</u> , And Phosphatase and Filth			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low-Acid Canned Foods, CP 7303.803A,	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine if the firms comply with 21 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act. To perform annual inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods. A continued priority will remain with out- of- compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Firms who have been in compliance are on a 3-year inspection cycle. Please refer to the compliance program for guidance.	
5. PROGRAM JUSTIFICATION <u>Low-Acid Canned Foods:</u> Inspections conducted in prior year's programs have demonstrated that the degree of compliance with low-acid canned food regulations relate directly to the degree of freedom from hazard to consumers found in the food produced. High risk industry segments, identified under previous programs, as well as re-inspection of the remaining portions of the industry are needed to establish and maintain compliance with the low-acid canned food regulations. <u>Acidified Foods:</u> The program is needed to ensure that the acidified food industry's degree of freedom from public health hazard continues and to monitor industry's compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas which need emphasis in future programs.	
6. FIELD OBLIGATIONS Firms in compliance and that have not registered new products nor significantly changed a current process, may be inspected on a 3-year frequency. Special situation firms are to be inspected according to the guidance in the compliance program (see program). It is estimated that 360 FDA inspections are needed to fulfill program obligations in FY 09. State contract inspections are to be used to increase firm coverage under this program. State inspections may be conducted in addition to the number of inspections assigned per district. Resources include coverage of food security issues (see IOM) at domestic processors. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT (S) See Compliance Program	d. INDUSTRY/PRODUCT CODE(S) 16, 20-22, 24-25, 27, 35, 37, 38, 40-41
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)	
f. CHECK THE FOLLOWING ATTRIBUTES Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety 03803, 03R839		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -- 03	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE	<input type="checkbox"/> PROGRAM <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. The top program priority for FY 2009 remains to inspect all high-risk firms annually. Ample resources have been provided to cover the full high-risk inventory covered by this program as well as to accomplish other program objectives (see compliance program). Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate district, will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. Resources from this program may be directed to monitor chicken eggs for <i>Salmonella</i> Enteritidis and for follow-up Assignments. Also, resources needed for inspections of domestic firms for FDA E.U. certification will be taken from this program. Food security issues are to be covered during all inspections (See IOM). Inspection and analytical resources have been planned separately for outbreak and emergency operations (PAC 03R839).			
5. PROGRAM JUSTIFICATION Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibilities of assuring that manufacturers produce these products under current Good Manufacturing Practices.			
6. FIELD OBLIGATIONS To conduct domestic inspections, focusing on high-risk firms and allergen firms with additional program resources to provide coverage with the priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk, allergen, and other firms. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations. Collection and analysis of environmental samples will be conducted in appropriate firms. CFSAN will issue separate instructions for this type of sampling. Currently, allergen surveillance inspections are on hold pending finalization of the Agency's allergen enforcement strategy. The field may do "for cause" allergen inspections as needed, but only proceed with surveillance inspections when new allergen guidance is issued by CFSAN. NOTE: Confirmation tests for <i>Clostridium botulinum</i> , <i>Yersinia enterocolitica</i> will be split between SRL & Pacific Regional Laboratory-NW. SRL will be the confirmation servicing laboratory for NE, CE, & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions. Surveillance activities planned under this program may be pro-rated by enforcement initiatives agreed upon by ORA & CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) All Food Products (Except 12 & 16)		d. INDUSTRY/PRODUCT CODE (S) 02-11, 13-15, 17-41, 45-46, 50	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING	<input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Filth, Decomposition and Microbiological Contamination (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

1. PROGRAM/ASSIGNMENT TITLE Import Foods – General 03819		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.			
6. FIELD OBLIGATIONS To conduct activities directed by CFSAN, identified through program guidance, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth disease vector, or decomposition. Districts should emphasize priority products from CFSAN's Import Risk-Based Priorities List. Districts should deemphasize coverage of products that are not consistent with priorities noted in the list. (b)(2)&(b)(7)(E) (b)(2)&(b)(7)(E) (b)(2)&(b)(7)(E) See full program for additional details. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. NOTE TO LABS: (see compliance program or contact DFS for additional details) DEN will perform Salmonella antibiotic resistance testing. Salmonella Isolates from NRL, SRL and ARL will be serotyped in ARL. Salmonella Isolates from SAN, PRL-NW, PRL-SW and DEN will be serotyped in DEN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		NA <input type="checkbox"/>	BY DISTRICT OFFICE <input type="checkbox"/>
		<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		NA <input type="checkbox"/>	COMPREHENSIVE <input type="checkbox"/>
		<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
c. PRODUCT(S) All Food Products (except industry code 12, 16, 40, 41)		d. INDUSTRY/PRODUCT CODE(S) 02-09, 13-15, 17-39, 45-54	
e. EXAM TYPE		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Microbiological Contamination, Filth, and Decomposition (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (03842, 03R839)		2. PFS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the Act. Inspections and analytical resources have been planned separately for out break and emergency operations (03R839).			
5. PROGRAM JUSTIFICATION FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices, the Seafood HACCP Regulation, and the FD&C Act.			
6. FIELD OBLIGATIONS As in FY08, High Risk Potential Products (HRPP) processors whose last inspection was NAI, can be considered for a 2-year inspection cycle. An exception would be if the firm added a new high risk seafood product to their line since the last inspection. HACCP verification samples are not to be routinely collected. Collection of environmental samples will be conducted at Ready-to-eat (RTE) firms. CFSAN will issue separate instructions for collecting environmental samples. Sample collections and analyses are to be made only for cause or as part of a CFSAN issued assignment. It is important that products be analyzed for the health hazard as identified in the HACCP guide – i.e., raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw Seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw. There are obligations to provide the states with standards and instructions for sampling/analyzing for PSP/ASP in seafood. Note: Animal confirmation tests for PSP, NSP, ciguatera toxin and botulinum toxins will be done at ARL for all regions. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE		<input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Domestic Fish and Fishery Products		d. INDUSTRY/PRODUCT CODE(S) 16	
e. EXAM TYPE		<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) (PSP, ASP, Standards, Economic Deception, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fisheries Products Hazards & Controls guidance manual (most recent edition) for hazards associated with each specific seafood product.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program 03844		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP Regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and regulations promulgated under the Act.			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP Regulation.			
6. FIELD OBLIGATIONS The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. It is equally important that products be analyzed for the health hazard as identified in the HACCP Guide. Raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw. HACCP trained investigators, will review importers' written verification procedures, product specifications and affirmative step documents, which demonstrate that the foreign processors' product was produced under HACCP, Food Safety Hazards Prevention Program. Inspectional priorities should be based on those listed in the current compliance program. Surveillance activities planned under this program may be pre-empted by enforcement initiatives or other special assignments agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. NOTE: Animal confirmation tests for PSP, NSP, ciguatera toxin and botulinum toxins will be done at ARL for all regions.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER
		<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products		d. INDUSTRY/PRODUCT CODE(S) 16	
e. EXAM TYPE		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input checked="" type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input checked="" type="checkbox"/> OTHERS (Specify) (PSP, ASP, Standards, Labeling)
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fisheries Products Hazards & Controls Guidance Manual (most recent edition) for hazards associated with each specific seafood product.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program 03847, 03847H		2. FPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To ensure that domestic and import juice processing establishments are in compliance with the Juice HACCP Regulations as well as the FD&C Act and other regulations promulgated under the Act.			
5. PROGRAM JUSTIFICATION The Juice HACCP regulation was adopted to ensure safe and sanitary processing of fruit and vegetable juices after reports of many outbreaks of foodborne illnesses, some of which directly affected children. FDA is responsible for assuring that juice processing firms establish and implement the principles of HACCP. HACCP plans must include a minimum five-log pathogen reduction process control (or performance standard) for juices that are not thermally processed concentrates or that are not shelf-stable according to the regulation. The collection of verification samples will be conducted to help validate the firm's HACCP plans.			
6. FIELD OBLIGATIONS Inspectional priority should be the following: Firms associated with recent outbreaks, unpasteurized juice firms whose previous inspections were OAI, followed by firms that have not been inspected and followed by firms whose last previous HACCP inspection was VAI or NAI. HACCP-trained investigators will also review importers' product specifications and will review the affirmative steps the importer has documented to assure that they demonstrate that the foreign processor's product was produced according to U.S. HACCP requirements. Resources have been provided for "for cause" samples. State inspections may be conducted in addition to the number of inspections assigned per district. Resources have also been added to cover food security issues (see IOM) at domestic processors. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) Juice Products		d. INDUSTRY/PRODUCT CODE (S) 20-22, 24, 25	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify) Importer Verification of HACCP			
f. CHECK THE FOLLOWING ATTRIBUTES Refer to compliance program.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to Compliance Program.			

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Produce Assignments 03F098 (Domestic), 03F100 (Import)	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected types of soft produce of domestic and foreign origin for pathogenic microorganisms as needed and directed by CFSAN assignments.	
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens have reached an unacceptably high level in the U.S. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. Produce continues to be one of the major contributors to outbreaks.	
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the FY 09 produce assignments issued by CFSAN.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED NA <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE NA <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh fruits and vegetables as specified in the assignment.	d. INDUSTRY/PRODUCT CODE(S) 20-22, 24-25
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments 03R233		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE:		<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
		<input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, to take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety.			
5. PROGRAM JUSTIFICATION As part of the Agency's strategy of focusing on risk based firms under the Food Protection Plan, FDA plans to work with foreign governments and Federal partners to ensure that foods produced in foreign facilities meet the U.S. safety requirements.			
6. FIELD OBLIGATIONS ORA/DFI shall assist CFSAN by reviewing imported food entry and compliance data to assist in determining the countries and firms whose inspections would be of greatest value to the Agency. ORA/DFI shall plan inspections of foreign firms recommended by CFSAN in so far as contacting the firms and foreign governments and working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN review and classification. The Investigator shall prepare and, after obtaining any CFSAN team member concurrence, submit the entire original EIR to the Manufacturing and Storage Adulteration Branch no later than 30 days following the trip. Submit individual EIRs as they are completed. Don't delay until all EIRs from a particular trip are completed; rather submit each EIR individually as they are completed due to workflow issues. Prioritize submission of EIRs based on classification (i.e., OAI and VAI before NAI). In FY 09, 200 foreign inspections of food firms are planned. On a "for cause" basis as needed, additional inspections may be requested by CFSAN, such as those needed to follow-up on food borne outbreaks. PAC REPORTING INSTRUCTIONS: All CFSAN foreign inspection time is planned under PAC 03R233. Report accomplishments against PAC 03R233, using the Foreign Inspection Operation Code 11.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED
		<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection outbreaks, infant formulas, medical foods, seafood & cheese.		d. INDUSTRY/PRODUCT CODE(S) 02-50, 54	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input checked="" type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Check appropriate domestic compliance program for details.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Resources for samples collected as part of infant formula or medical food foreign inspections are planned under those programs.			

1. PROGRAM/ASSIGNMENT TITLE Contract Management 03R843	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT By DFSR	
4. OBJECTIVES To conduct an effective state contract inspection program, augmenting regulatory inspections conducted by Agency investigators. To perform audits of inspections by states that are under contract to FDA to conduct food inspections.	
5. PROGRAM JUSTIFICATION Over 10,000 food inspections are anticipated to be contracted out in FY 09 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.	
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the district. Inspections should be planned by the field. Report under Operation Code 13 (Domestic Investigation). Audits are not considered inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED Audits	
c. PRODUCT(S) All Food Products	d. INDUSTRY/PRODUCT CODE(S) 02-41, 45-46, 50
a. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Audits of State Contract Food Inspections.	
f. CHECK THE FOLLOWING ATTRIBUTES Follow DFSR guidance.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods (04004)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To sample and analyze domestic and imported foods for pesticide residues and industrial chemicals. There is an ongoing emphasis to obtain comprehensive data on background levels of dioxin in a variety of foods. This information will help the agency to determine how to reduce dietary exposure to dioxin.	
5. PROGRAM JUSTIFICATION The food supply requires monitoring for both pesticides and industrial chemicals to protect the public health. The residue data are also used to estimate dietary exposure for risk assessments performed by the agency and EPA, as well as, by other national and international organizations.	
6. FIELD OBLIGATIONS Emphasis on pesticide/commodity combinations with high exposure potentials in planning sampling for pesticides. Emphasis should also be given on foods eaten by infants and children. Designation of each district's portion of total resources may be devoted to special assignments (e.g., Center-directed surveys and District-initiated surveys). The field is to collect and analyze general pesticide samples, seafood samples, and dioxin samples as directed in the compliance program. Dioxin collections will be handled by bi-annual collection schedules issued by CFSAN. Dioxin investigation assignments and follow-up sampling may be issued by CFSAN under this program when typically high dioxin levels are found. Surveillance activities will be reported under and credited to the Program PAC, unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All human foods.	d. INDUSTRY/PRODUCT CODE(S) All human food codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)	
f. CHECK THE FOLLOWING ATTRIBUTES Pesticides and industrial chemicals as directed by compliance program.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program, PAM, IOM, etc.	

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood (04018)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To sample and analyze selected import and domestic aquaculture seafood products. To determine the presence of unapproved chemical compounds such as drugs or antifungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.	
5. PROGRAM JUSTIFICATION Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.	
6. FIELD OBLIGATIONS Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 09 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or as additional validated methods are ready to implement. As a budget relief, two agent analyses may be run per sample for all products except crab, provided the second agent is one of interest for that product. Please refer to the FY 09 Collection Schedule (when issued) for species to collect, and agents of interest. Individual subsample analyses will only be required for crab and shrimp samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining samples will be a composite of 12 sub-samples. Please refer to the FY 09 Collection Schedule for additional collection instructions when issued. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved drugs per the Compliance Program and the Collection Schedule.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic) (04019A, B, C)		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine the incidence and levels of lead, cadmium, mercury and other toxic elements of significance and radionuclides in domestic and imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in foodware and to take regulatory action against any food or foodware found to contain levels of toxic elements or radionuclides of regulatory significance.			
5. PROGRAM JUSTIFICATION Historical evidence mandates the continued monitoring of domestic and imported food (including seafood) and foodware for the presence of toxic elements (i.e. lead, cadmium, and mercury). The continuing monitoring of radionuclides in foods is necessary to guard against any dangerous level of radiochemical contamination of domestic and imported foods. Also, this monitoring will provide continuing background data to identify any upward trend in tritium, gamma-ray emitters and Sr levels.			
6. FIELD OBLIGATIONS Foods that may be significant sources of lead in children are Mexican candy, chocolate/cocoa, and seafood. These products are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" program and assignments (to be issued). Planned assignments include mercury in specific seafood species. CFSAN will issue collection schedules and direct other FY 09 food work. Import field exams should be focused upon (b)(2)&(b)(7)(E) Sample collections & analyses of domestic and imported foodware will continue as directed by the "Toxic Element" program. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides. The program should be maintained to keep expertise and proficiency in this area. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) 02-41, 52A	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify)			
f. CHECK THE FOLLOWING ATTRIBUTES Lead, cadmium, mercury and other toxic elements as directed. Domestic - tritium, 90 Sr & gamma ray emitters; IMPORTS; 134 Cs, 137 Cs, 90 Sr			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Radiochemical analysis capability. (Available only at WEAC). Graphite furnace atomic absorption with Zeeman background correction.			

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study (04839)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex groups through analyses of table-ready foods. In addition, to observe differences or trends in the intake of these chemicals and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.	
5. PROGRAM JUSTIFICATION The continuing study has provided valuable information on dietary intakes of residues and nutrients and has often been used to gauge intakes in ready-to-eat foods. EPA relies on the data for hazard assessment in special review and other proceedings. Portions of the Total Diet samples are used for other analysis (e.g., radionuclides, selected nutrients, pesticides, industrial chemicals, and toxic elements). Additionally, selected Total Diet Study foods are analyzed for dioxins under the pesticide program.	
6. FIELD OBLIGATIONS The collection and analysis of four market baskets each consisting of three separate samplings of approximately 284 food items are to be collected from three locales in the region over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, toxic elements, and selected nutrients. WEAC will analyze all foods from two market baskets for radionuclides.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Various Human Foods	d. INDUSTRY/PRODUCT CODE(S) All Human Food Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Radiochemical Analysis	
f. CHECK THE FOLLOWING ATTRIBUTES 	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING 	

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods PAC 07001		2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To collect and analyze domestic and import samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin. To remove from interstate commerce, or to detain upon entry, those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established. Data from current monitoring will be used to establish enforcement levels.			
5. PROGRAM JUSTIFICATION <p>Mycotoxins are metabolic products of specific molds commonly found on foods, some (the aflatoxins) are hepatocarcinogens in a number of animal species, and until proven otherwise must be assumed to be carcinogenic to man. The FDA, in conjunction with other agencies and the food industries, has devised and will continue to improve on practical programs for ensuring minimum exposure of the population to mycotoxins without jeopardizing the food supply. Aflatoxins may occur in food as a result of mold growth in a number of susceptible commodities, including peanuts and corn. The current action level for aflatoxins in human food is 20 ppb.</p> <p>Fumonisin B₁ and B₂ are naturally occurring toxic metabolites produced mainly by the fungus, <i>Fusarium verticilloides</i>, which are found ubiquitously on corn from around the world. Because of their potential carcinogenicity and frequent occurrence in corn-based feeds and foods, their presence should be monitored, especially for incidence data.</p> <p>Deoxynivalenol (DON) is a trichothecene mycotoxin produced by several strains of <i>Fusarium</i>, which under certain climate conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated gastrointestinal illnesses in China and India. FDA has issued an advisory level of 1ppm for DON in finished wheat products. There is a need for continuous monitoring of this toxin.</p> <p>Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera <i>Aspergillus</i> and <i>Penicillium</i>. It is mainly a contaminant in cereal grains and is carcinogenic in mice and rats. There is a need for current information on the incidence and levels of this toxin in the U.S. food supply.</p> <p>Patulin is a mold metabolite produced by several species of mold fungi including <i>Penicillium expansum</i>, the casual organism of apple rot. Apple juice prepared from rotten apples is a possible source of patulin in the human diet. Patulin is regulated in at least 10 countries so far. There is a need for more exposure data to further review the international standards for patulin. The current action level for patulin in apple juice and apple juice components is 50 ppb.</p>			
6. FIELD OBLIGATIONS <p>The Field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic and imported products as directly by the Compliance Program.</p> <p>Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited, to the Program PAC unless otherwise directed.</p>			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) See Attachment "A" C.P. 7307.001 for list of Products.		d. INDUSTRY/PRODUCT CODE(S) See Attachment "A" C.P. 7307.001 for Product Codes.	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)			
f. CHECK THE FOLLOWING ATTRIBUTES Aflatoxins, Fumonisin B ₁ and B ₂ , Deoxynivalenol (DON), Ochratoxin A, and Patulin.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program (C.P.) 7307.001			

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 07R816	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <div style="display: flex; justify-content: space-around; width: 100%;"> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH </div>	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives PAC 09006A,B		2. PPS PROJECT NAME/NUMBER Food and Color Additives - 09	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To direct examination of imported food products to determine their compliance with the Federal Food, Drug, and Cosmetic Act (the ACT) and regulations with respect to food and color additives, and to detain those entries found to be in violation of the Act.			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the Act and implementing regulations for food and color additives. The compliance program directs sample collections and label review of imported foods for unapproved or undeclared food additives, and for non-permitted or undeclared color additives.			
6. FIELD OBLIGATIONS Districts should conduct label reviews, collect and analyze imported foods for potential food and color additive violations and take appropriate regulatory actions when violations are found. Import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 5.4.1.4.1 for additional information on Food and Cosmetic Security Activities. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human foods		d. INDUSTRY/PRODUCT CODE(S) All food codes	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Reviews			
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved or undeclared food additives, and non-permitted or undeclared color additives.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

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

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

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation PAC 18004	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Evaluate the shellfish sanitation program of ISSC participating states and the 5 nations with whom the Agency has MOU in place with regard to the sanitary control of shellfish intended for interstate and overseas commerce under the cooperative arrangements for the federal-state National Shellfish Sanitation Program (NSSP). Provide standardization, technical assistance, training and evaluation of state and international shellfish control programs.	
5. PROGRAM JUSTIFICATION Shellfish, by virtue of their habitat, physiological characteristics, and the manner in which they are consumed, require specialized comprehensive sanitary control measures to ensure the safety of human consumption. The management of the program requires a cooperative federal-state effort as defined in the National Shellfish Sanitation Program (NSSP). Consumption of raw or partially cooked shellfish presents a high risk factor to a portion of the population, and requires specialized health control measures to oversee. The 1991 National Academy of Sciences report entitled "Seafood Safety" estimated that up to 85 percent of seafood-related illnesses originate with the consumption of molluscan shellfish. FDA is committed to improving the safety of molluscan shellfish through the NSSP, a program of newly developed safety controls. These initiatives are the direct result of Congressional and public comments directed toward the establishment of a "level playing field" for both domestic and international producers of molluscan shellfish. These program improvements are intended to provide improved shellfish safety through improved program criteria, procedures, and technical support under the NSSP. FDA is committed to improving the safety of shellfish through program enhancement activities. FDA has committed support to the NSSP both administratively and technically through an MOU with ISSC.	
6. FIELD OBLIGATIONS Provide technical assistance and training to states and foreign programs in the prevention of shellfish-borne illness and enforcement of appropriate public health controls. Oversee national standardization program for inspecting shellfish processing plants and evaluation of state and foreign shellfish growing areas. Participate in the evaluation of national shellfish control programs in countries applying to import molluscan shellfish into the U.S. Program time has been allocated for each Regional Shellfish Specialist to hold one regional workshop. Regional workshops provide the opportunity for the specialists to exchange information and provide technical assistance and guidance to their state counterparts. Time has been allocated to educate and evaluate state <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> management programs and to assist in the EU audit of the NSSP.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh and fresh frozen molluscan shellfish	d. INDUSTRY/PRODUCT CODE(S) 16, 52 B, Y
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import PAC 21002		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods. To collect and analyze domestic and imported medical foods and to assure that they are properly formulated and labeled and free from microbial contaminants.			
5. PROGRAM JUSTIFICATION Medical foods are formulated to be consumed or administered internally under the supervision of a physician and are intended for specific dietary management of specific disease or condition for which distinctive nutritional requirements, based on recognized scientific principles established by medical evaluation. The products are often used for life support and are subject to compositional errors and microbiological errors. In addition to four infant deaths in 1986, there have been a number of medical food recalls associated with compositional deviations and under processing. Medical foods are identified as "high-risk" foods under the Center's Food Safety Initiatives. Firms producing Oral Rehydration Solutions (ORS) will continue to be inspected annually. All other medical food firms will be inspected every two years unless the last inspection was classified as VAI or OAI or unless other factors warrant annual inspection. Foreign inspections of medical foods are planned under PAC 03R833. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food security issues are to be covered during all inspections. CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: N/A <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Medical Foods		d. INDUSTRY/PRODUCT CODE(S) 41G[] [] Use appropriate product identification number	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify) Label Review			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations, Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , and Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

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

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis and General Food Labeling Program PAC 21005		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine the compliance of domestic and imported food product labels with regulations promulgated under the Federal Food, Drug and Cosmetic Act; including the Nutrition Labeling and Education Act (NLEA) and the Food Allergen Labeling and Consumer Protection Act (FALCPA). This objective is to be accomplished by reviewing labels of domestic and imported food products and by collecting compliance and surveillance samples for label review and analyses to assure: (1) that the nutrition label is in compliance with the regulations in Title 21 Code of Federal Regulations 101.9; (2) that labeled nutrient content and health claims are made in a manner that complies with applicable regulations; (3) that the label complies with FALCPA; and (4) that all labels include all required label elements.			
5. PROGRAM JUSTIFICATION Two new labeling requirements related to public health and safety went into effect on January 1, 2006. All domestic and imported foods labeled on or after January 1, 2006 must disclose the presence of any ingredient that is or contains protein derived from one of the 8 major food allergens so that individuals with allergies will be able to easily identify the presence of substances that they must avoid. In addition, most food products entering interstate commerce on or after January 1, 2006 must list trans fat in the nutrition label. The FD&C Act also mandates other required label information and valid nutrient content and health claims provide useful information that assists consumers in selecting foods that promote good health and weight management. Continuous monitoring of food labels is necessary to ensure that consumers are provided with truthful information that they need to select foods that are appropriate for their specific dietary needs and health maintenance.			
6. FIELD OBLIGATIONS Districts will review import and domestic product labels for compliance with FALCPA, NLEA, and other mandatory label requirements by conducting field exams. Districts will collect labels that do not appear to comply with FDA's food labeling laws and regulations for review by the district's compliance branch. Physical samples will be collected for lab analyses as follows: (1) compliance samples that do not appear to qualify for labeled health or nutrient content claims (see C.P. Area of Emphasis #2); and (2) surveillance samples collected for general nutrient analyses (see C.P. Area of Emphasis #6). Prior to collecting labels for trans fat and allergens, contact CFSAN. Domestic Field Exams and sample collections to be conducted during inspections under the following compliance programs: 7303.803, 7303.803A, 7303.037, 7303.842, and 7303.847. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. For all import field exams, see note under "Remarks" section on the 2621a for this program.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All food products (except vitamins/minerals)		d. INDUSTRY/PRODUCT CODE(S) 02-41	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify) Label Reviews			
f. CHECK THE FOLLOWING ATTRIBUTES Label review and nutrient analyses as appropriate, focus should be given to allergen and trans fat labeling.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Samples for nutrient analyses to be sent to SRL/ACNA. See compliance program for details.			

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import PAC 21006		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To ensure compliance with the Infant Formula Act and regulations promulgated there under by inspection of domestic and foreign manufacturers of infant formula and collection and analysis of infant formula samples.			
5. PROGRAM JUSTIFICATION Serious infant health problems arising from inadequate nutrient content of infant formula prompted Congress to pass the Infant Formula Act of 1980. This inspection and analysis program assures adherence to the provisions of the Act. Violations and recalls over the past several years (and the continuing keen interest by Congress, as evidenced in part by the 1986 amendments to the Act) indicate the need for continued compliance monitoring. The large number of applications for approval of the formulas exempt from the Act requires expansion of oversight activities into this area. Infant formulas are identified as "high-risk" foods under the Center's Food Safety Initiatives. Additional resources have been budgeted to allow annual inspections and sample collections from infant formula firms. Inspections of foreign infant formula firms are planned under PAC 03R233. Investigational time to determine admissibility of import lots of infant formula from foreign manufacturers are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples. Atlanta Center for Nutrient Analysis (ACNA) will perform nutrient analyses and label reviews. Southeast Regional Laboratory, Microbiology Branch will perform microbiological analyses. CFSAN/OC/FPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed. Food security issues (see IOM) are to be covered during all inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Infant Formula		d. INDUSTRY/PRODUCT CODE(S) 40C	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify) Label Review			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrients as required by the Act. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

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

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrients in Food Survey -Total Diet PAC 21839	2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To monitor the mineral nutrients in foods from typical American diets. To identify mineral and vitamin nutrient intake trends. To provide baseline data on mineral nutrient and vitamin intake for intervention studies and other nutrition studies. To function as an important component in the National Nutrition Monitoring System.	
5. PROGRAM JUSTIFICATION Congress has given the Secretaries of DHHS and USDA a mandate to set up a National Nutrition Monitoring System (NNMS). The current Selected Nutrients in Food Survey is an important segment of the NNMS that provides the only continuous analysis of nutrient minerals in the American food supply. This permits identification of trends in nutrient intake over time as well as information on the general nutritional status of the population at any point in time.	
6. FIELD OBLIGATIONS KAN-DO will analyze Total Diet Study foods from all market baskets for 12 nutrients identified below in 7F , and all TDS foods from one market basket annually for moisture.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Various foods as required by the Total Diet Studies Program	d. INDUSTRY/PRODUCT CODE(S) 37, 40
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Calcium, phosphorus, iron, selenium, zinc, copper, magnesium, manganese, nickel, potassium, sodium, iodine and water.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 21R816	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Import PACs 29001, 29R833, 29R824, 99R833	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine by inspection, sample collection, and label exam if domestic cosmetic manufacturing or repacking establishments, and cosmetics offered for importation, comply with regulations enforced by the Food and Drug Administration. To initiate corrective action when violations of the FD & C Act are identified.	
5. PROGRAM JUSTIFICATION Both domestically manufactured and imported cosmetic products must be: 1) safe under intended conditions of use, 2) properly labeled, and 3) not otherwise adulterated or misbranded under the provisions of the Act. Major safety concerns associated with cosmetics involve microbial contamination of eye-area products and the use of non-approved color additives. Many cosmetic violations also involve products which fail to comply with the labeling regulations of 21 CFR 701.	
6. FIELD OBLIGATIONS Districts will conduct inspections, perform import field exams, collect and analyze samples for non-permitted ingredients, conduct microbiological analyses and perform evaluations for labeling compliance. Cosmetic security issues (see IOM 5.4.1.4.1) are to be covered during all inspections. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Cosmetic Products	d. INDUSTRY/PRODUCT CODE(S) 53
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Reviews	
f. CHECK THE FOLLOWING ATTRIBUTES Non-permitted ingredients (including color additives), microbiological/contaminants, labeling statements.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program	

1. PROGRAM/ASSIGNMENT TITLE GLPs (Nonclin. Lab), IRBs, Spon/Mon/CROs, Clinical (PDUFA) PACs 41808, 41809, 41810, 41811 Investigators		2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES GLP: To assure compliance with GLP regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans. IRB: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50). Spon/Mon/CROs: To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies. Clin. Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).			
5. PROGRAM JUSTIFICATION GLP: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans. IRB: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected. Spon/Mon/CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies. Clin. Investigators: The Kefauver Harris amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.			
6. FIELD OBLIGATIONS GLP: Conduct inspections and forward report(s) to the assigning office in CBER. IRB: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office. Spon/Mon/CROs: Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office. Clin. Investigators: Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Biologics		d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products n.e.c.	
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks PACs 42001F,G		2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations: (a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products: (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products: (b) Licensed Blood Donor Centers which collect blood and ship to the Licensed Blood Banks of which they are a part; (c) Laboratories that perform testing on blood products and donors, e.g. donor screening for communicable disease agents (HIV 1 and 2, Hepatitis B and C, HTLV I and II, syphilis) and supplemental testing on reactive tests (HIV Western Blot, HCV RIBA). (d) Laboratories that perform quality control testing for licensed blood establishments, e.g., platelet q.c. GMP evaluation to determine the level of competency and adherence to contractual agreements with the licensed establishments.			
5. PROGRAM JUSTIFICATION Blood and Blood Products are vitally important products in medical treatment. Monitoring the collection of whole blood and the processing, manufacturing, and preparation of products derived from human blood assures consumer protection from defective products which may endanger public health.			
6. FIELD OBLIGATIONS ORA will perform the inspections, prepare and submit the certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed. Training of field personnel will be coordinated with CBER.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Blood and Blood Products		d. INDUSTRY/PRODUCT CODE(S) 55, 57	
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments PACs 42002F,G	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine through inspections if Source Plasma establishments are operating in compliance with applicable regulations to assure donor protection and to assure that Source Plasma is safe, effective, and adequately labeled.	
5. PROGRAM JUSTIFICATION The collection of Source Plasma as source material for further manufacturing into products used in the prevention and treatment of disease is of immeasurable value to the consumer. Through this program the Agency can accomplish its objectives of donor protection and product safety, purity, and potency.	
6. FIELD OBLIGATIONS ORA will perform inspections, prepare and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Source Plasma	d. INDUSTRY/PRODUCT CODE(S) 55, 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE PACs 42008,A Inspections of Licensed Viral Marker Test Kits (Inspections of In Vitro Diagnostic Product Manufacturers)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the manufacturing process for licensed <i>in vitro</i> diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including the Quality System regulations (21 CFR 820), <i>In Vitro</i> Diagnostic Products regulations (21 CFR 809), Biologics regulations (21CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.	
5. PROGRAM JUSTIFICATION <i>In Vitro</i> Diagnostic Kits are important tools in medical treatment and blood and plasma donor screening. This program enables the Agency to continue to protect the public health by assuring safety, purity, potency, and efficacy of these products.	
6. FIELD OBLIGATIONS Conduct comprehensive inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a Biennial Basis . Inspections will be conducted by a Team Biologics Core Team member and may include a district representative and / or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) <i>In Vitro</i> Diagnostic Products accordance with the stated objective.	d. INDUSTRY/PRODUCT CODE(S) 55, 57, 65 & 81 (Device Categories)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Device Specific	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics) PACs 42845A,B,C	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the manufacturing processes for those medical devices and <i>in vitro</i> diagnostic products regulated by the Center for Biologics Evaluation and Research (CBER) through the use of the Medical Device Authorities (e.g. PMA, 510K) and other generic devices outlined in the October 31, 1991 intercenter agreement between CBER and the Center for Devices and Radiological Health (CDRH).	
5. PROGRAM JUSTIFICATION As described in the October 31, 1991 intercenter agreement, CBER is the focal point for the review and evaluation of several categories of medical devices. Our strategy for inspecting those firms not regulated under the licensing provisions of Section 351 of the Public Health Service Act are for biennial inspection. The product categories are primarily in the area of devices used in blood banking.	
6. FIELD OBLIGATIONS Conduct inspections pursuant to the instructions in the OMD Program - Inspection of Medical Device Manufacturers, CP 7382.845. Report findings/observations to the Center for Biologics Evaluation and Research (CBER). Recommend/initiate regulatory follow-up consistent with the compliance program guidance and Agency policy.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All devices in the product categories transferred to CBER	d. INDUSTRY/PRODUCT CODE(S) 65 & 81 (Device Categories)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Device Specific	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspections of Plasma Derivatives of Human Origin PACs 42848A,F,G	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which plasma derivatives are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.	
5. PROGRAM JUSTIFICATION Plasma derivatives are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.	
6. FIELD OBLIGATIONS ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a Biennial Basis. Inspections will be conducted by a Team biologics Core Team member, and may include a district representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fractionation Products	d. INDUSTRY/PRODUCT CODE(S) 55, 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

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

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

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

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

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE ANDA - Pre-Approval Inspections/Investigations PAC 52832	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM TYPE	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before ANDA approval.

6. FIELD OBLIGATIONS

Conduct pre-approval inspections of establishments as requested by the Center for Drug Evaluation and Research.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

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

<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED
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c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
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e. EXAM TYPE:

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations PAC 53001A,B		2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To provide assignments, guidance and instructions to field offices for inspecting drug firms to determine compliance with the ADE reporting requirements of 21 CFR 310.305,314.80 and 318.98. Regulatory and/or administrative follow-up will be coordinated between the field and headquarters in cases where significant violations of reporting regulations or deficiencies in following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by responsible parties, including applicants, manufacturers, packers and distributors.			
5. PROGRAM JUSTIFICATION The postmarketing adverse drug experience (ADE) regulations (21CFR 310.305,314.80 and 314.98) became effective on August 22, 1985, September 2, 1986 and June 29, 1992 and cover prescription drugs. The regulations also apply to OTC drugs that have approved applications, including those initially marketed as prescription drugs under approved applications (i.e., Rx to OTC switched drugs). The purpose of postmarketing ADE surveillance is to obtain information on rare, latent or long term drug effects not identified during pre-market testing. Accurate, complete, and timely reporting of ADE information is essential to the safety evaluation of marketed drug products. It enables FDA to act when information concerning the use and safety of marketed drug products suggests that new labeling, market withdrawal or other action is required.			
6. FIELD OBLIGATIONS Conduct inspections and forward reports directly to the Division of Compliance Risk Management and Surveillance (DCRMS)/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up. Issue regulatory letters as approved by DCRMS. Notify DCRMS of findings from other inspectional program activities which are relevant to ADE reporting.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, 60-66	
e. EXAM TYPE		<input type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> PHYSICAL
		<input type="checkbox"/> OTHERS (Specify)	<input type="checkbox"/> ENGINEERING
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments PAC 56D015		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES Monitor, investigate and take regulatory action, (including working jointly with state regulatory officials), on complaints involving pharmacy compounded drug products and pharmacy compounding operations that are in violation of applicable sections of the Federal Food, Drug, and Cosmetic Act (the Act).			
5. PROGRAM JUSTIFICATION While the pharmacy compounding law section 503A of the Act was recently struck down by the courts, the agency is still engaged in determining whether or not a pharmacy compounder and its compounded drug products comply with all other applicable sections of the Act. FDA continues to ensure the availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. The agency needs to investigate pharmacy-compounding reports of illnesses associated with compounded drug products. In cases where it is determined that exercising the agency's enforcement discretion in regard to pharmacy compounding is not warranted, the agency will consider regulatory action, where necessary, to address applicable violations of the Act.			
6. FIELD OBLIGATIONS Districts will conduct inspections and investigations, collect evidence, samples and develop cases in accordance with Assignments from HFD-330.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56 and 60-66	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES			

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

1. PROGRAM/ASSIGNMENT TITLE New Drug (Prescription) Without Approved NDAs PAC 63002		2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To establish uniform procedures for removal from the market of all prescription drug products described by FDA to be new drugs not covered by approved New Drug Applications; complete Category VII of Compliance Policy Guide (CPG) 7132c.02 which are not in the earlier categories of this CPG; and any drug products in prior categories remaining for regulatory action.			
5. PROGRAM JUSTIFICATION The Drug Amendments of 1962 to the FD&C Act require that all marketed drug products be safe and effective. Judge June L. Green of the U.S. District Court for the District of Columbia ruled (July 29, 1975) that an approved new drug application for prescription drugs which the FDA has previously declared to be a new drug within the meaning of 21 USA 321(p) is required in order for the drug product to be introduced into interstate commerce. Therefore, those without approved applications must be withdrawn from the market. This compliance program is responsive to this mandate.			
6. FIELD OBLIGATIONS -Assign District Coordinator, whose name shall be supplied to HFD-310. -Identify all drug products which require regulatory letters and prepare such letters to be signed by the District Director. -Maintain records of all activities under this program, including a list of drug products voluntarily removed from the market in compliance with the warning letters, products removed by recall, etc. -Initiate regulatory actions, where appropriate, to assure compliance with program. Submit monthly report to HFD-310.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) Human Prescription Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, and 60-66	
e. EXAM TYPE:		<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects PAC 88--	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
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3. PROGRAM TYPE	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input checked="" type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

To develop an effective program for extending the shelf Life of about-to expire drugs and medical devices.

5. PROGRAM JUSTIFICATION

Congress has placed a high priority on maintaining the military in a state of readiness. This includes purchasing and storing for contingency use sufficient quantities of medical products needed to sustain our military forces under wartime conditions. This project is established to assist DOD in reducing the cost of replacement stocks as the stockpiled materials expire.

6. FIELD OBLIGATIONS

Selected laboratories, on assignment from MPQAS.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

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

<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED
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c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56, and 60-66
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e. EXAM TYPE

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Environmental chambers used to stress drug products.

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections PAC 68001	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities to fulfill their NADA commitments to manufacture, process, and pack new animal drugs that are safe and effective for their intended use. Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION Domestic and foreign plant inspections are necessary to determine whether the establishment can produce the new animal drug in accordance with current good manufacturing practice regulations and comply with the commitments in the NADA. Inspections will be issued by assignment. Priority will be specified by CVM. Outcome: Reduce new animal drug development and review time.	
6. FIELD OBLIGATIONS The Field will conduct NADA Pre-Approval Inspections at domestic and foreign plants in accordance with the assignment. Establishment inspection reports will be submitted to the New Animal Drug Evaluation (NADE) Program Manager (HFV-142) according to the procedures outlined for field reporting requirements in the compliance program. Field laboratories on an assignment basis will validate methodology submitted with NADAs.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs, Type A Medicated Feed Articles	d. INDUSTRY/PRODUCT CODE(S) 56, 67, 68
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)	
f. CHECK THE FOLLOWING ATTRIBUTES Petition validation work	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE BSE/Ruminant Feed Ban Inspections 71009	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To enhance the FDA's uniformity in inspection and compliance of firms subject to the regulation prohibiting the utilization of specified animal proteins in ruminant feeds. 21 CFR 589.2000. To ensure that specified animal proteins do not enter the U.S. from BSE-at-risk countries. On April 27, 2009, a new rule, 21 CFR 589.2001, becomes effective and will be incorporated into the BSE inspection program. That rule is additive to the existing rule and prohibits the use of specified material in all animal feed.	
5. PROGRAM JUSTIFICATION Bovine Spongiform Encephalopathy (BSE) is the bovine form of a group of uniformly fatal neurological diseases known as Transmissible Spongiform Encephalopathies (TSEs). BSE appears to be spread through the feeding of infected material to cattle. BSE is a public health issue for the U.S. This disease has been linked to the human TSE known as variant Creutzfeldt-Jakob Disease (vCJD), presumably through people consuming ruminant tissues infected with the BSE agent. In addition, BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected. Outcome: To prevent the establishment and amplification of BSE through feed in the United States.	
6. FIELD OBLIGATIONS To conduct inspections, investigations, and sample collections/analyses to implement this program. All firms that handle animal feed and feed ingredients containing ruminant-based material are the subject of this program. To provide guidance concerning the importation of animal feeds and feed ingredients from BSE at-risk countries, in accordance with Import Alert #99-25. Field activities will cover the assessment of all aspects of animal feed and feed ingredient manufacture and distribution, as described by the ruminant feed ban regulation, 21 CFR 589.2000.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal feeds and feed ingredients	d. INDUSTRY/PRODUCT CODE(S) 67-72
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A	

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

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

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

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

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 82R838	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related Acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize, and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. The specific addition of Forensic Evaluation to the Operation Code was new in FY 1999. Please consult the Division of Field Science and/or the Division of Planning, Evaluation, and Management for additional reporting guidance.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/A <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) N/A
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

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

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

1 PROGRAM/ASSIGNMENT TITLE
Methods Validation/Development Program
PAC 84R816

2 PPS PROJECT NAME/NUMBER
Science: Devices - 84

3. PROGRAM TYPE: N/A COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC PAC 86006		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of laboratory tests conducted under this program are:			
<ol style="list-style-type: none"> 1. To ensure that the regulated products conform to EPRC regulations; 2. To identify products which fail to comply with the applicable performance standard requirements; 3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and 4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA. 			
5. PROGRAM JUSTIFICATION Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Electronic product manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Products also subject to performance standards must comply with the specific standards found in 21 CFR 1020 - 1050. EPRC laboratory tests verify that electronic products comply with performance standards at the point of manufacture, and that the manufacturer's quality control testing program ensures product compliance and radiation safety.			
6. FIELD OBLIGATIONS WEAC will test all products in accordance with the appropriate Compliance Program and/or test methods. Products to be tested to available performance standards include: Microwave ovens (21 CFR 1030.10); dental, portable and mobile x-ray equipment (21 CFR 1020.30); ultrasonic therapy devices (21 CFR 1050.10); and television receivers (21 CFR 1020.10); sunlamp and mercury vapor lamps (21 CFR 1040.20, 1040.30) and laser products (21 CFR 1040.10). Products will be identified for testing by both WEAC and CDRH for either routine or for cause testing. WEAC will request samples for direct shipment from manufacturer or distributor of product. Upon completion of analysis, all lab results will be submitted to CDRH. WEAC will retain products tested until all compliance actions have been completed or upon notification from CDRH. WEAC will also conduct all foreign inspections for electronic product manufacturers, other than diagnostic x-ray manufacturers, in accordance with Compliance Program 7386.001. Firms and product areas to be inspected will be determined with input from CDRH. Joint EPRC/medical device (QSIT) inspections may be conducted under both Compliance Programs 7386.003a and 7382.845. CDRH is responsible for the final review of inspections and lab tests conducted under this program and for the issuance of letters resulting from inspections and tests performed by WEAC staff.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) Lasers and laser products, sunlamp and sunlamp products, mercury vapor lamps, diagnostic x-ray systems, cabinet x-ray products, ultrasound therapy products, televisions and microwave ovens		d. INDUSTRY/PRODUCT CODE(S) 96MS, 94VS, 94DS, 95US, 97US	
e. EXAM TYPE:		<input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING	<input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

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