FY 2007
ORA
FIELD WORKPLAN

DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE MANAGEMENT BRANCH

ORA/ORM/DPEM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Memorandum

Date September 12, 2006

From Director, Program Planning & Workforce Management Branch

Subject Final FY 2007 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 2007 ORA Field Workplan is based on the Center's compliance program forecasts and incorporates input of the Centers and the Field Committees during their review of the draft Workplanning Sheets. The Workplan is based on the FY 2007 FDA Appropriation Request submitted to Congress in February 2006. The ORA Field Workplan includes Part I - Planning Guidance and the Servicing Laboratories Table, Part II - the Workplan Summary of Operations and Positions Reports, and Part III - FY 2007 Program Forecasts. **New this year: the first page of Part II is a breakdown of each District's investigational FTE into domestic and import totals.**

The FY 2007 ORA Field Workplan is based on ORA's planning level of 1,848 Operational (3,200 Total) FTEs. This represents an overall reduction of 85 Operational FTEs from the FY 2006 Workplan. Only the Biologics program received an FTE increase for FY 2007. This increase is a result of specific Congressional mandates for increased funding for human tissues and pandemic flu.

ORA's budget resources have continued to erode due to increasing payroll, rent, and shared services taps that are not adequately funded in the base budget. The result over time is a reduction in the level of FTEs that ORA can support. With a few exceptions, the current freeze on outside hiring will likely continue for the foreseeable future.

Foods and Cosmetics

There are 1013 Operational FTEs for FY 2007. This is a reduction of 42 Operational FTEs from FY 2006. Significant changes include:

Domestic and Imported Cheese and Cheese Products (03037): Domestic inspections decreased from 400 to 300; domestic sample collections and analyses decreased from 400 to 300.

Domestic Food Safety (03803): Inspections increased from 3,400 to 4,000; investigations hours increased from 7,207 to 13,860; sample collections/analyses reduced from 600 to 400.

Import Foods (03819): Investigations hours reduced from 86,500 to 82,380; sample collections/analyses reduced from 8,300 to 7,750.

Domestic Fish and Fishery Products (03842): Inspections decreased from 2,480 to 2,330; new assignment for vibrio sample collection/analysis.

Import Seafood Products (03844): Sample collections reduced from 7,500 to 6,400 with a corresponding reduction in analyses.

Juice HACCP Program (03847H): Domestic inspections reduced from 375 to 300; sample collections/analyses reduced from 225 to 150; importer inspections reduced from 200 to 100.

Import/Domestic Micro Assignment: Both import and domestic sample collections/analyses reduced from 500 to 450.

Foreign Inspections (03R233): Inspections reduced from 200 to 100.

Contract Management (03R843): Planned time reduced by 2 FTEs.

Chemotherapeutics in Seafood (04018): Domestic sample collections and analyses reduced from 200 to 150; import sample collections/analyses increased from 750 to 1,150.

Field Assignments for Chemical Contaminants (04F800): Sample collections/analyses reduced.

Biologics

There are 121 Operational FTEs for FY 2007. This is an increase of 4 Operational FTEs from FY 2006. Significant changes include:

Tissue Inspections (41002): Inspections increased from 385 to 484.

Blood Banks (42001): Foreign inspections decreased from 24 to 12.

Source Plasma Establishments (42002): Inspections increased from 164 to 174; investigations hours reduced from 2,271 to 1,331.

Examination of Biological Products Offered for Import (42007/42R833): Entry review hours reduced from 4,200 to 3,600.

Inspection of Medical Device Manufacturers (Biologics) (42845A,B,C): Inspections reduced from 35 to 16.

Vaccines and Allergenic Products – BIMO (45809/45810/45811): Inspections increased from 33 to 66.

Human Drugs

There are 354 Operational FTEs for FY 2007. This is a reduction of 36 Operational FTEs from FY 2006. Significant changes include:

NDA Inspections – Domestic (46832): Inspections reduced from 129 to 112.

Foreign BIMO Inspections: NDA inspections reduced from 41 to 25; ANDA inspections reduced from 30 to 19.

Good Laboratory Practices (48808): Inspections increased from 38 to 50.

Institutional Review Board (48809): Inspections increased from 107 to 123.

Clinical Investigators (48811): Inspections increased from 264 to 282.

ANDA Inspections/Methods Validation – Domestic (52832): Inspections reduced from 137 to 110; methods validation time reduced by 1.7 FTE.

ANDA Inspections – Foreign (52832): Inspections decreased from 62 to 42.

Drug Process Inspections – Domestic (56002): Inspections reduced from 1,504 to 1,377; headquarters time for therapeutic biologics not separately planned.

Drug Process Inspections – Foreign (56002): Inspections reduced from 195 to 174.

Drug Product Surveillance – Domestic (56008A,C): Total sample collections/analyses reduced from 1,175 to 1,050; methods validation time reprogrammed from PAC 56R816.

Drug Product Surveillance – Imports (56008H): Import entry review hours reduced from 18,295 to 14,700; import investigations hours reduced from 9,899 to 7,510; sample collections/analyses reduced from 150 to 120.

Internet, Health Fraud, and OTC Monographs (63001A/63D012): Inspections reduced from 47 to 32; investigations hours reduced from 4,775 to 3,325.

New Drugs Rx without Approved NDAs (63002): Inspections reduced from 79 to 47.

Animal Drugs and Feeds

There are 123 Operational FTEs for FY 2007. This is a reduction of 4 Operational FTEs from FY 2006. Significant changes include:

Feed Manufacturing (71004): Inspections reduced from 243 to 220.

Ruminant Feed Ban/BSE Program (71009): Inspections reduced from 3,760 to 2594; resources are planned for FDA review of 895 state partnership inspections; Import entry review reduced from 12,900 hours to 11,700 hours; technical support hours for state activities were consolidated from the Feed Manufacturing Program and increased from 1,500 hours to 4,921 hours; import investigations hours were reduced from 7,900 hours to 3,800 hours; domestic investigation hours

are planned for OEI improvement activities; domestic sample collections/analyses reduced from 900 to 855; import sample collections/analyses also reduced from 900 to 855.

Pandemic Preparedness (71R852): 4 FTEs planned for assignments/activities related to avian flu.

Devices and Radiological Health

There are 237 Operational FTEs for FY 2007. This is a decrease of 7 Operational FTEs from FY 2006. Significant changes include:

Inspection of Medical Device Manufacturers: GMP program (82845): Total FTEs for Domestic Inspections increased from 87.3 FTE to 88.4 FTE; Accredited Persons Inspections decreased from 95 to 24; Foreign Inspections decreased from 207 to 200.

BSE Assignment (82Z005): Inspections reduced from 23 to 10.

Medical Device Premarket Approval and Postmarket Inspections (83001): Pre-Approval Domestic Inspections reduced from 33 to 20.

Imported Electronic Products (86007): Import entry review decreased from 10,195 hours to 7,790 hours.

Workplan Changes between FY 2006 and FY 2007

There have been some changes in the FY 2007 Workplan. Significant changes include:

- The program "ORA/Center Directed Research Projects" has been renamed "Methods Validation/Development Program" to more accurately reflect the activities conducted under this program. Resources previously planned as "District Research" will now be planned as "Methods Validation/Development". Resources previously planned as "Research Center" will now be planned as "Applied Technology Center". Laboratories should coordinate with ORO's Division of Field Science (DFS) regarding the utilization and reporting of this time.

- Total import investigational FTEs are planned to closely match the on-board operational FTEs reported by the Districts to DPEM. Unlike in the FY 2006 Workplan, domestic investigational and laboratory resources have not been adjusted to account for the on-board operational staff within a District or Regional Laboratory. The planned distribution of these resources is the result of the Workplanning process and represents the risk-based prioritization of program activities by the Centers, Field Committees, and ORA Headquarters. Analysis of the on-board staffing information from FACTS indicates that some Districts may not have enough domestic investigators on-board to conduct all the planned domestic investigational activities. The shortage of domestic investigators in some locations is the consequence of the extended hiring freeze and inconsistent rates of attrition across the country. The staffing levels for each office will be determined by the Table of Organization (T.O.) which will be based on the FY 2007 Workplan. The final T.O. for some offices will be different from the projected T.O. circulated earlier this year.

- The investigator FTE conversion factor for Animal Drugs and Feeds has been changed to 950 hours. All programs now have the same investigator FTE conversion factor. **The**

total number of operational hours expected from an investigator remains at 1,160. The 950 hours represents the portion of the 1,160 hours that is specifically planned in the Workplan for the operations of inspections, investigations, field exams, and sample collections. The remaining 210 operational hours (1,160-950) are for any other operational activities, such as recalls, emergency response, or unplanned inspections and investigations.

The "Reasons for Change" spreadsheets provide a listing of programs compared to the FY 2006 ORA Field Workplan, and will enable you to identify where specific resource shifts and programmatic cuts occurred.

The FY 2007 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 2007 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 Michael W. Roosevelt at (301) 827-1638.

Michael W. Roosevelt

Michael W. Roosevelt

Attachments- See "Reasons for Change" files

FOODS AND COSMETICS

FY 2007 Workplan
REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2006	WORKPLAN FTEs FY 2007	FTE DIFFERENCE	REASON FOR CHANGE
03003	Import Acidified and Low Acid Canned Foods	14.8	14.8		
03037	Domestic and Imported Cheese and Cheese Products	26.3	22.7	-3.6	Budget reduction
03803A	Domestic Acidified and Low Acid Canned Food	14.7	14.7		
03803, B	Domestic Food Safety	88.6	96.1	7.5	Program increase
03819	Import Foods	282.2	277.1	-5.1	Budget reduction
03842	Domestic Fish and Fishery Products	57.3	69.7	12.4	Program increase
03844	Import Seafood Products	99.7	80.3	-19.4	Budget reduction
03847H	Juice HACCP Inspection Program	14.2	10.0	-4.2	Budget reduction
03F098	Import/Domestic Micro Assignment	24.3	21.9	-2.4	Budget reduction
03R233	Foreign Inspections/Assessments	7.3	4.2	-3.1	Budget reduction
03R816	Methods Validation/Development Program	12.5	12.5		
03R839	Emergency Response to Foodborne Outbreaks	7.0	0.0	-7.0	Program eliminated
03R843	Contract Management	16.0	14.0	-2.0	Budget reduction
03R845	Food Defense	38.0	38.0		
03	**Foodborne Biological Hazards**	**702.9**	**676.0**	**-26.9**	
04004A,D	Pesticides & Industrial Chemicals in Domestic & Imported Foods	77.1	77.1		
04018	Chemotherapeutics in Seafood	17.3	25.2	7.9	Program increase
04019A,B,C	Toxic Elements in Foods & Foodware (Domestic & Import)	21.8	17.7	-4.1	Budget reduction
04839	Total Diet Study	23.4	23.4		
04F800	Field Assignments for Chemical Contaminants	12.8	6.7	-6.1	Budget reduction
04R816	Methods Validation/Development Program	10.8	10.0	-0.8	Budget reduction
04R838	Forensic Evaluation and Sample Analysis	10.8	12.0	1.2	Program increase
04	**Pesticides and Chemical Contaminants**	**174.0**	**172.1**	**-1.9**	
07001	Mycotoxins in Domestic & Imported Foods	25.3	25.3		
07R816	Methods Validation/Development Program	4.6	4.5	-0.1	Budget reduction
07	**Molecular Biology and Natural Toxins**	**29.9**	**29.8**	**-0.1**	
09006A,B	Imported Foods-Food and Color Additives	11.6	11.6		
09	**Food and Color Additives Petition Review**	**11.6**	**11.6**		
18002	Retail Food Protection- State Program	26.0	23.0	-3.0	Budget reduction
18003	Milk Safety Program	26.0	19.1	-6.9	Budget reduction
18004	Molluscan Shellfish Evaluation Program	14.0	13.0	-1.0	Budget reduction
18029A-E	Interstate Travel Program Conveyances & Support Facilities	23.3	22.7	-0.6	Budget reduction
18	**Technical Assistance: Food & Cosmetics**	**89.3**	**77.8**	**-11.5**	
21002	Medical Foods	3.7	4.3	0.6	Program increase
21005	Domestic & Import NLEA	9.3	9.3		
21006	Infant Formula Program	5.6	4.3	-1.3	Budget reduction
21008	Dietary Supplements	15.9	15.9		
21839	Selected Nutrients in Foods - Total Diet	4.2	3.4	-0.8	Budget reduction
21R816	Methods Validation/Development Program	1.3	1.0	-0.3	Budget reduction
21	**Food Composition, Standards, Labeling, & Econ**	**40.0**	**38.2**	**-1.8**	
29001	Cosmetics: Domestic and Imports	7.2	7.6	0.4	Program increase
29	**Colors and Cosmetics Technology**	**7.2**	**7.6**	**0.4**	
	Total Mission Direct: Pre and Annual Planned FTEs	**1054.9**	**1013.1**	**-41.8**	

BIOLOGICS

FY 2007 WORKPLAN
REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2006	WORKPLAN FTEs FY 2007	FTE DIFFERENCE	REASON FOR CHANGE
41002	Human Cells, Tissues & Cellular & Tissue Products	15.5	19.5	4.0	Targeted increase
41808	Good Laboratory Practices	*			
41809	Institutional Review Board	*			
41810	Sponsors, CROs, Monitors	*			
41811	Clinical Investigators	7.4	7.4		
41	**Human Cellular, Tissue, & Gene Therapies**	**22.9**	**26.9**	**4.0**	
42001F,G	Blood Banks	60.5	59.5	-1.0	Budget reduction
42002	Source Plasma Establishments	10.4	9.9	-0.5	Budget reduction
42007	Exam of Blood/Components - Import	3.5	3.0	-0.5	Budget reduction
42008,A	Licensed Viral Marker Test Kits	3.0	3.0		
42809	Institutional Review Board	*			
42810	Sponsors, CROs, Monitors	*			
42811	Clinical Investigators	3.5	3.5		
42811	Foreign BIMO Inspection	**			
42845A,B,C	Medical Device Manufacturers (Biologics)	2.0	1.0	-1.0	Budget reduction
42848	Plasma Derivatives of Human Origin	3.0	3.0		
42	**Blood & Blood Products**	**85.9**	**82.9**	**-3.0**	
45809	Institutional Review Board	*			
45810	Sponsors, CROs, Monitors	*			
45811	Clinical Investigators	3.0	6.0	3.0	Targeted increase
45848A,F,G	Licensed Allergenic Products	1.2	1.2		
45848B,C,D	Vaccine Products	4.0	4.0		
45	**Vaccines & Allergenic Products**	**8.2**	**11.2**	**3.0**	
	Total Mission Direct: Pre and Annual Planned FTEs	**117.0**	**121.0**	**4.0**	

* 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 2007 WORKPLAN
REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2006	WORKPLAN FTEs FY 2007	FTE DIFFERENCE	REASON FOR CHANGE
46832	NDA Pre-Approval/Meth. Valid. (Domestic)	14.0	12.3	-1.7	Budget reduction
46832	NDA Pre-Approval/Meth. Valid. (Foreign)	15.0	15.0		
46	**New Drug Evaluation**	**29.0**	**27.3**	**-1.7**	
48001/A	In Vivo Bioequivalence (Domestic)	5.4	5.0	-0.4	Program decrease
48001/A	Foreign Inspections (In Vivo, GLP, CI)	4.6	3.0	-1.6	Program decrease
48808	Good Laboratory Practices	4.2	5.0	0.8	Program increase
48809	Institutional Review Boards	6.9	8.0	1.1	Program increase
48810	Sponsors, Contract Research Orgs, Monitors	2.7	2.7		
48811	Clinical Investigators	26.5	28.3	1.8	Program increase
48	**Bioresearch Monitoring**	**50.3**	**52.0**	**1.7**	
52832	ANDA Pre-Approval/Meth Valid (Domestic)	18.7	15.0	-3.7	Budget reduction
52832	ANDA Pre-Approval/Meth Valid (Foreign)	11.1	9.0	-2.1	Budget reduction
52	**Generic Drug Evaluation**	**29.8**	**24.0**	**-5.8**	
53001A,B	Adverse Drug. Exp. Rpt. Regul (Domestic)	8.3	8.0	-0.3	Budget reduction
53001A,B	Adverse Drug. Exp. Rpt. Regul (Foreign)	1.7	1.0	-0.7	Budget reduction
53	**Postmarket Surv. & Epidemiology**	**10.0**	**9.0**	**-1.0**	
56002A-F	Drug Process Inspections-Domestic	134.1	120.5	-13.6	Budget reduction
56002E	Drug Process Inspections - Gas Manufacturers	5.0	5.0		
56002	Foreign Drug Inspections	18.0	15.0	-3.0	Budget reduction
56008A,C	Drug Product Surveillance (Domestic)	25.7	25.7		
56008H	Drug Product Surveillance (Import)	41.1	34.5	-6.6	Budget reduction
56021A,B	Drug Quality Reporting Systems-DQRS	4.0	4.0		
56022	Enforcement of Rx Drug Marketing Act	2.0	2.0		
56D015	Pharmacy Compounding Assignments	4.0	4.0		
56R816	Methods Validation/Development Program	3.6	0.0	-3.6	Planned under 56008A,C
56R838	Forensic Evaluation and Sample Analysis	9.0	10.0	1.0	Program increase
56	**Drug Quality Assurance**	**246.5**	**220.7**	**-25.8**	
63001	Internet, Health Fraud, & OTC Monographs	8.0	6.0	-2.0	Budget reduction
63002	New Drugs (Prescription) Without Approved NDAs	4.0	3.0	-1.0	Budget reduction
63	**Unapproved & Misbranded Drugs**	**12.0**	**9.0**	**-3.0**	
88---	Shelf Life Extension Projects	12.0	12.0		
88	**Interagency Cooperative Activities**	**12.0**	**12.0**		
	Total Mission Direct: Pre and Annual Planned FTEs	**389.6**	**354.0**	**-35.6**	

ANIMAL DRUGS AND FEEDS

FY 2007 WORKPLAN
REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2006	WORKPLAN FTEs FY 2007	FTE DIFFERENCE	REASON FOR CHANGE
68001	NADA Pre-Approval Inspections	5.7	5.7		
68808	(Pre-Market) GLP and Spon/Mon/Com	2.9	2.9		
68810	Sponsors Contract Research Orgs./Monitors	*	*		
68811	(Pre-Market) Clinical Investigators	2.1	2.1		
68	**Pre-Approval Eval. of Animal Drugs & Food**	**10.7**	**10.7**		
71001	Drug Process & New Animal Drug Inspections	9.6	9.6		
71003	Feed Contaminants	14.1	14.2	0.1	**Program increase**
71004	Feed Manufacturing	6.1	6.1		
71006	Illegal Drug Residues in Meat and Poultry	12.0	12.0		
71009	Ruminant Feed Ban Rule (BSE) Program	66.8	59.5	-7.3	**Budget reduction**
71R816	Methods Validation/Development Program	5.8	5.0	-0.8	**Budget reduction**
71R838	Forensic Evaluation and Sample Analysis	0.7	1.0	0.3	**Program increase**
71V800 & 71R852	Center Initiated Assignments, Pandemic Preparedness	1.0	5.0	4.0	**Targeted increase**
71	**Monitoring of Marketed Animal Drugs, Feed, & Devices**	**116.1**	**112.4**	**-3.7**	
	Total Mission Direct: Pre and Annual Planned FTEs	**126.8**	**123.1**	**-3.7**	

* 68810 planned under 68808

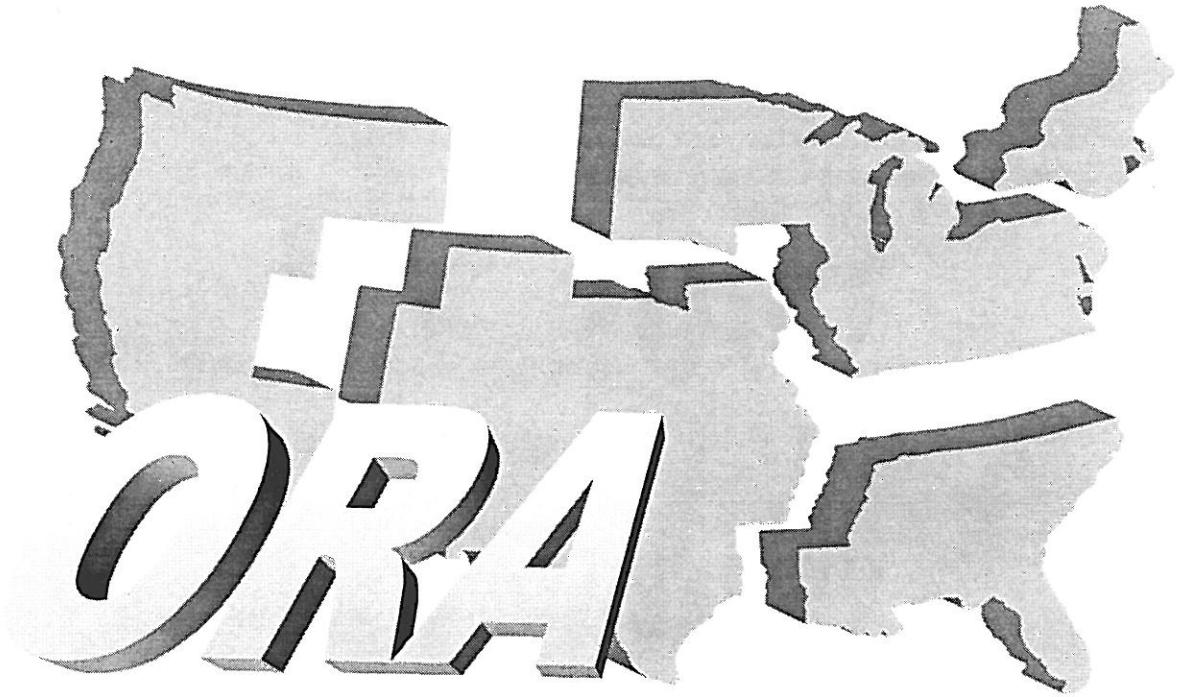
MEDICAL DEVICES AND RADIOLOGICAL HEALTH

FY 2007
REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2006	WORKPLAN FTEs FY 2007	FTE DIFFERENCE	REASON FOR CHANGE
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	28.1		
82845A,B,C,G,S	Inspection of Medical Dev Mfgrs: GMP Domestic	87.3	88.4	1.1	Targeted increase
82845B	Inspection of Medical Dev Mfgrs: GMP Foreign	14.2	13.7	-0.5	Budget reduction
82845P	Inspection of Accredited Persons: MDUFMA	5.0	2.0	-3.0	Budget reduction
82845J	Audits of Accredited Persons	0.3	0.3		
82Z002	Condom Assignment	4.3	4.1	-0.2	Budget reduction
82Z003	Mfgrs & Importers of Surgical/Exam Gloves	8.1	7.6	-0.5	Budget reduction
82Z005	BSE Assignment	0.5	0.2	-0.3	Budget reduction
82Z800	Center Initiated Assignments	1.5	1.5		
82R816	Methods Validation/Development Program	2.0	2.0		
82R838	Forensic Evaluation and Sample Analysis	0.3	0.3		
82	**Compliance: Devices**	**151.6**	**148.2**	**-3.4**	
83001/A	Med Dev Premkt/Postmkt Insp Domestic	8.8	8.1	-0.7	Budget reduction
83001/A	Med Dev Premkt/Postmkt Insp Foreign	3.2	3.1	-0.1	Budget reduction
83808-11	Bioresearch Monitoring Domestic	24.5	24.5		
83810-11	Bioresearch Monitoring Foreign	0.8	0.8		
83	**Project Evaluation: Devices**	**37.3**	**36.5**	**-0.8**	
84Z002	Test Method Development & Evaluation	3.7	3.7		
84R816	Methods Validation/Development Program	1.4	1.0	-0.4	Budget reduction
84	**Science: Devices**	**5.1**	**4.7**	**-0.4**	
85014	Mammography Facilities Insp Program Domestic	14.8	14.8		
85014	Mammography Facilities Insp Program Foreign	0.1	0.1		
85	**Mammography Quality Standards Act (MQSA)**	**14.9**	**14.9**		
86001	Inspection of Mfgrs of Laser Products Domestic	4.2	4.2		
86001	Inspection of Mfgrs 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	9.0	9.0		
86004	Field Compliance Testing of Cab X-Ray Equip	1.0	1.0		
86006A-F	Compliance Testing of Elec Prod at WEAC	3.4	3.1	-0.3	Budget reduction
86006	Compliance Testing of Elec Prod at WEAC Foreign	0.8	0.8		
86007	Imported Electronic Products	10.2	8.2	-2.0	Budget reduction
86008	Med Dev & Rad Hlth Use Control & Policy Implementation	3.6	3.4	-0.2	Budget reduction
86009	Emergency Planning & Response Activities	2.0	2.0		
86	**Radiation Control & Health Safety Act (RCHSA)**	**34.7**	**32.2**	**-2.5**	
	Total Mission Direct: Pre and Annual Planned FTEs	**244.1**	**237.0**	**-7.1**	

FY 2007

PART I - PLANNING GUIDANCE



DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE MANAGEMENT BRANCH

ORA/ORM/DPEM

PART I - PLANNING GUIDANCE

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GENERAL PLANNING GUIDANCE

A. PLAN OVERVIEW

1. OBJECTIVE

The purpose of this workplan is to provide field managers with resources and output projections deemed necessary to carry out FDA's mission in the field during the period, October 1, 2006 to September 30, 2007.

The workplan is designed to be an effective management tool which can be revised to accommodate emergency situations and unforeseen changes in program priorities. The goals provided in the workplan should be interpreted as statements of intent rather than as rigid requirements. Ideally, field offices should accomplish all planned operations and use all planned resources. If it is determined during the early months of the fiscal year that the planned operations will not require the use of the resources planned for a project or program category, alternative plans should be developed for the accomplishment of additional work in the same project or program activity.

Whenever it is determined that a region is unable to complete a significant portion of the workplan obligations because of emergencies or other unforeseen circumstances, the RFDD should inform the Director, Office of Resource Management, in writing, identifying the problem(s) and the recommended course of action. ORA management will work with the appropriate center director(s) to resolve the situation.

2. AN OVERVIEW OF FDA's PROGRAM AND PROJECT STRUCTURE (PPS)

The Field Workplan is developed within the framework of FDA's Program and Project Structure (PPS) formerly Program Management System (PMS). This system utilizes a structure of programs and projects to provide a common language for planning and strategic decision-making in FDA.

More specifically, the PPS is used as the common denominator for tactical and strategic operations including:

- Long-range planning
- Budgeting
- Operational planning
- FDA accounting system
- Developing financial operating plans
- Satisfying HHS reporting requirements
- Implementing evaluation programs
- Center and ORA project reporting of obligations

2. AN OVERVIEW OF FDA's PROGRAM AND PROJECT STRUCTURE (PPS) (Continued)

The PPS assures that appropriate types and levels of resources can be allocated, reported, and managed by means of a system of organized priorities and objectives.

All budgeted field operational resources are accounted for in the projected compliance programs and assignments.

A significant portion of the allocated resources is covered by general guidance programs that provide the flexibility necessary for the Regional Food and Drug Directors to respond properly to emergencies and problems indigenous to their regions and districts.

3. TERMS AND DEFINITIONS

During FY 2007, the Program and Project Structure (PPS) will function under the following framework:

TERM	DEFINITION	EXAMPLE
Budget Activity	The broadest of classifications, this is the basic break-down of FDA's areas of activity used in developing and implementing the FDA budget and ancillary justifications.	Foods
Program Activity	A general mission-oriented activity comprised of one or more projects.	Food and Cosmetics
Projects	A group of compliance programs/assignments which together form a work effort towards a common objective. Each project is identified by a two-digit code.	03 Foodborne Biological Hazards
Compliance Programs	Informative and instructive documents concerning field operations (prepared by centers and ORA).	
	a. **General Guidance Programs:** contain instructions as to general approach and requirements in carrying out certain operations. These programs do not include assignments relating to specific establishments or products. Instead, they provide resource and output projections by district, thus giving field managers latitude to meet particular problems unique to their region or district.	Import Foods - General Program
	b. **Specific Action Programs, Assignments and/or Special Surveys:**	
	(1) **Industry and Product Regulatory Survey and Action Programs** - provide guidance and direction in approaching certain problems and an operational schedule with specific assignments to the field.	Import and Domestic Micro Assignment

3. TERMS AND DEFINITIONS (Continued)

TERM	DEFINITION	EXAMPLE
	(2) **Surveys** – provide guidance and direction to enable the field to perform surveys according to a specific operational schedule.	Drug Product Surveillance--Center Initiated Surveys
	In general, the compliance programs and assignments serve the following purposes: a. Recognize and deal with problem areas. b. Determine the degree of noncompliance with respect to recognized problems. c. Gather data for the promulgation of regulations or establishing administrative guidelines. d. Direct numbers/hours, and kinds of operations to be performed by field offices.	
Operations	The quantifiable activities to be done by field personnel.	Inspections, Sample Collections, Samples to be Analyzed, etc.

Appendix I lists all FY 2007 PPS Projects.

4. WORK ASSIGNMENT TO FIELD LABORATORIES

The basic policy followed by the ORA planning staff is to plan analytical work to the designated servicing laboratory for a specific collecting district or, if appropriate, national coverage. The designation of a servicing laboratory may in part be predicated on specialized equipment or expertise in that particular laboratory or the designation of that laboratory as a national servicing lab in a smaller program.

The FY 2007 ORA Workplan reflects assignment of work in regional laboratories (Arkansas, Northeast, Pacific Northwest, Pacific Southwest, and Southeast); specialty laboratories (Forensic Chemistry Center (FCC), Philadelphia, San Juan, and Winchester Engineering and Analytical Center (WEAC)); or district laboratories (Denver, Detroit, Kansas City, San Francisco).

Appendix III represents the current capabilities of ORA's laboratories. Changes should be noted in relation to the FY 2006 ORA Field Workplan.

5. RELATION TO OTHER PLANS

The FY 2007 ORA Field Workplan is the product of a series of planning and budget operations. It represents the conversion of objectives and directions effected by Congress, OMB, HHS, PHS, OC, Associate Commissioners, the Centers, and the ORA organization into projected program outputs and resource allocations.

a. **Annual FDA Program Planning Process:** The objective of this planning activity is to provide the basis for the development of future budget requests for FDA. Projections are provided for

accomplishment objectives at various levels of funding. The results of this planning process are used to provide support for the development of FDA priorities, budget requests to DHHS, and FDA planning.

The planning process proposes and develops initiatives or strategies for Agency use in the budget process. The strategies reflect the Commissioner's intentions for the future of FDA.

b. **Annual FDA Congressional Budget Request:** The primary basis for this Workplan is the FY 2007 FDA budget. This budget outlines the planned Agency direction and objectives in relation to each of the major budget categories. Resource levels expressed in the budget provide the basis for the development of compliance programs and assignments. Work assignments projected for each district and region in these compliance programs provide the matrix against which staffing guidelines are developed. The request to Congress is not the level at which FDA is funded. The final appropriation amount, usually not known until just before the new fiscal year, historically is lower than the requested level except for special areas.

B. FY 2007 GUIDANCE

This section provides guidance in relation to programmatic objectives and operational requirements related to the FY 2007 Workplan.

1. COMPLIANCE POLICY AND PHILOSOPHY

Formal methods of issuing FDA compliance policy/philosophy are:

- Federal Register Announcements and the Code of Federal Regulations
- Compliance Policy Guides Manual
- Regulatory Procedures Manual

Less formal methods of issuing FDA compliance policy/philosophy include:

- Regulatory action recommendation memoranda from centers to the field
- Letters and speeches to industry and other outside associations or individuals by the centers or other FDA units
- Memoranda issued by centers or other headquarters units on specific current activities
- ORA Conference calls

All of the above sources should be monitored and referred to for FDA compliance policy/philosophy and all are used in the development of the ORA Field Workplan.

2. ORA CONTACTS FOR WORKPLAN-RELATED PROBLEMS

General inquiries or problems experienced by field managers concerning programs in the workplan should be addressed to the planning analyst identified in the Workplan (Form FDA 2622) as responsible for the program/project. Policy concerns should be directed to Michael W. Roosevelt (HFC-41), 301-827-1638.

ORA management will work with the appropriate center to resolve any planning problems identified by the field.

3. FY 2007 RESOURCE ACTIVITIES

The FY 2007 ORA Field Workplan is based on a FTE level of 3,200 FTEs which is a decrease of 128 FTEs from the FY 2006 ORA Field Workplan level of 3,328 FTEs. The FY 2007 FTE level is the result of the budget reductions faced by ORA.

4. PRODUCT CODE

Whenever possible, the Industry Code portion of the Product Code (the first two code characters) is included on the Form FDA 2621 for guidance and assistance in planning.

5. NATIONAL EXPERTS

The Field Workplan includes program operations to be performed by personnel designated as "National Experts". National experts are investigative personnel who perform foreign and domestic inspections that require specialized knowledge and experience.

6. TEAM BIOLOGICS

Team Biologics is a partnership between the Office of Regulatory Affairs (ORA) and the Center for Biologic Evaluation and Research (CBER). This partnership uses the diverse skills and knowledge of both ORA and CBER staffs to focus resources on inspectional and compliance issues in the biologics area. The goal of Team Biologics is to ensure the quality and safety of biologic products and quickly resolve inconsistencies and bring products into compliance.

ORA has established a cadre of specially trained investigators whose principle focus will be biological products inspections. The ORA Field Workplan includes program operations to be performed by members of this cadre.

7. EMERGENCIES

a. ***Impact on Plan: Time is made available for handling some emergencies through the workplanning process. However, no workplan can include full provision for unforeseen emergencies or critical situations requiring significant amounts of personnel in varying programs/locations. Should these problems arise, the Field Workplan provides a tool for the establishment of priorities and the organized revision of programs and workloads to meet the field's most urgent obligations.***

b. **Efficient Use of Field Resources:** In some emergency situations, field offices must stop or curtail activities in certain lower priority program areas to redirect resources to meet the emergency situation in the most efficient manner. Investigational and analytical staff may be called on to assist or perform activities (interchangeably) to maximize the efficient utilization of available resources. Personnel may be deployed from district to district, region to region, and if necessary, laboratory workloads may be reassigned to assure work accomplishment.

C. REPORTING REQUIREMENTS

1. REPORTING OF OPERATIONS

Projections in the FY 2007 ORA Field Workplan are expressed in terms of either operations and

hours or only hours per compliance program within each Program and Project Structure project. Please note that many compliance programs may involve multiple projects, and should be reported as such.

2. PROJECTS WITH NO PLANNED FIELD RESOURCES

Appendix I details those projects for which no resources have been planned for FY 2007. No activities should be planned for these projects unless specifically directed by an assignment from the responsible center.

3. DATA REPORTING

The Agency relies on the data in the Field Accomplishments and Compliance Tracking System (FACTS), and Operational and Administrative System for Import Support (OASIS) to provide information regarding resource expenditures and operational accomplishments to the Department of Health and Human Services, Office of Management and Budget, Congress, consumer organizations, state agencies, and other federal agencies. Monthly and quarterly reports prepared from this data are also used by ORA and other headquarters units for planning, preparing budget resource requests, and evaluating field accomplishments in relation to planned work. In addition, ORA planning personnel use the FACTS and OASIS data for the development of the Field Work-plan. Therefore, it is important for data reporting to be both accurate and complete.

4. HARD COPY REPORTING

During FY 2007, ORA will continue, through the development of compliance programs, with the cooperation of the centers to limit hard copy report requests to only those cases of absolute need. At the request of ORA, the centers will identify, on all compliance programs and assignments requiring hard copy reports, a central place to which all reports bearing on that center should be routed. Please assure that all reports are submitted in accordance with the instructions in the compliance programs and field management directives (e.g., FMD 71 and 92).

D. REVISIONS TO THE FY 2007 FIELD WORKPLAN - PLANNING BULLETINS

Planning bulletins are issued to notify the field of workplan changes. Such bulletins may be issued as a result of requests for changes concerning workload, availability of products, etc., addressed during the field's critique of the workload analyses and the final Field Workplan. Planning bulletins are also issued for inter/intra center midyear resources reprogramming needed to adjust significant resource overburn in program(s) resulting from emergency situations or changing priorities.

The Planning bulletins are used to convey and explain workplan changes to the field and will include the following:

1. Part III.
   a. Operational changes
   b. New compliance programs or assignments
   c. Canceled compliance programs or assignments
   d. Changes in resources or issuance dates, etc.

2. New Part II to reflect new district office resources resulting from changes in work assignments.

3. New Part I as necessary.

E. OFFICIAL ESTABLISHMENT INVENTORY (OEI) DEVELOPMENT AND MAINTENANCE

1. One of FDA's basic responsibilities is to have complete and accurate information on the establishments for which we have regulatory responsibility. This allows us to effectively and efficiently:

   a. Assess and then communicate to the Executive Branch and Congress our responsibilities and resources needs; in terms of money and FTEs in order to enforce the laws under FDA jurisdiction.

   b. Allocate resources to district offices in direct proportion to their share of the establishment workload; for the various compliance programs and assignments identified in the annual ORA Field Workplan.

   c. Provide other governmental organizations and the public under the Freedom of Information Act data about the types and numbers of firms FDA regulates.

2. Field Management Directive FMD-130, OEI Development and Maintenance Procedures, provides guidance to field and headquarters units on all facets of OEI development and maintenance.

APPENDIX I

PPS
PROGRAM AND PROJECT STRUCTURE
FY 2007 PROJECT LIST

FOOD AND COSMETICS

MICROBIOLOGICAL SAFETY OF FOODS

03 Foodborne Biological Hazards
18 Technical Assistance: Food and Cosmetics

CHEMICAL SAFETY OF FOODS

04 Pesticides and Chemical Contaminants
07 Molecular Biology and Natural Toxins
09 Food and Color Additive Petition Review and Policy Development

NUTRIENT QUALITY AND FOOD LABELING

21 Food Composition, Standards, Labeling, and Economics

COSMETICS SAFETY AND LABELING

29 Colors and Cosmetics Technology

BIOLOGICS

41 Human Cellular, Tissue and Gene Therapies
42 Blood and Blood Products
45 Vaccines and Allergenic Products

HUMAN DRUGS

46 New Drug Evaluation
48 Bioresearch Monitoring: Human Drugs
52 Generic Drug Evaluation
53 Postmarketing Surveillance and Epidemiology: Human Drugs
56 Drug Quality Assurance
61 Over-The-Counter Drug Evaluation
63 Unapproved and Misbranded Drugs

ANIMAL DRUGS AND FEEDS

68 Pre-Approval Evaluation of Animal Drugs and Food Additives
71 Monitoring of Marketed Animal Drugs, Feeds, and Devices

MEDICAL DEVICES & RADIOLOGICAL HEALTH

81 Post-Market Assurance: Devices
82 Compliance: Devices
83 Product Evaluation: Devices
84 Science: Devices
85 Mammography Quality Standards Act (MQSA) Authority
86 Radiation Control and Health Safety Act (RCHSA) Authority

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

*34 Integrated Research For Health Protection: NCTR
*35 Methods Development For Regulatory Needs: NCTR

ORA PROJECTS FOR FIELD REPORTING PURPOSES ONLY

88 ICA (Interagency Cooperative Activities)
*99 General

*No Resources Planned in FY 2007

OCTOBER 1, 2006

SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2007			FY 2006	
NO.	NAME		NO.	NAME
FOOD AND COSMETICS				
Microbiological Safety of Foods				
03	Foodborne Biological Hazards			
18	Technical Assistance: Food and Cosmetics			
Chemical Safety of Foods				
04	Pesticides and Chemical Contaminants			
07	Molecular Biology and Natural Toxins			
09	Food and Color Additive Petition Review and Policy Development	<	No Change	
Nutrient Quality & Food Labeling				
21	Food Composition, Standards, Labeling and Economics			
Cosmetics Safety & Labeling				
29	Colors and Cosmetics Technology			

APPENDIX II

SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2007			FY 2006	
NO.	NAME		NO.	NAME
BIOLOGICS				
41	Human Cellular, Tissue and Gene Therapies			
42	Blood and Blood Products	<	No Change	
45	Vaccines and Allergenic Products			
HUMAN DRUGS				
46	New Drug Evaluation			
48	Bioresearch Monitoring: Human Drugs			
52	Generic Drug Evaluation			
53	Postmarketing Surveillance and Epidemiology: Human Drugs	<	No Change	
56	Drug Quality Assurance			
61	Over-the-Counter Drug Evaluation			
63	Unapproved and Misbranded Drugs			

SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2007			FY 2006	
NO.	NAME		NO.	NAME
ANIMAL DRUGS AND FEEDS				
68	Pre-Approval Evaluation of Animal Drugs and Food Additives	<	No Change	
71	Monitoring of Marketed Animal Drugs, Feeds and Devices			
MEDICAL DEVICES & RADIOLOGICAL HEALTH				
81	Postmarket Assurance	<	No Change	
82	Compliance: Devices			
83	Product Evaluation: Devices			
84	Science: Devices			
85	Mammography Quality Standards Act (MQSA) Authority			
86	Radiation Control and Health Safety Act (RCHSA) Authority			

APPENDIX II

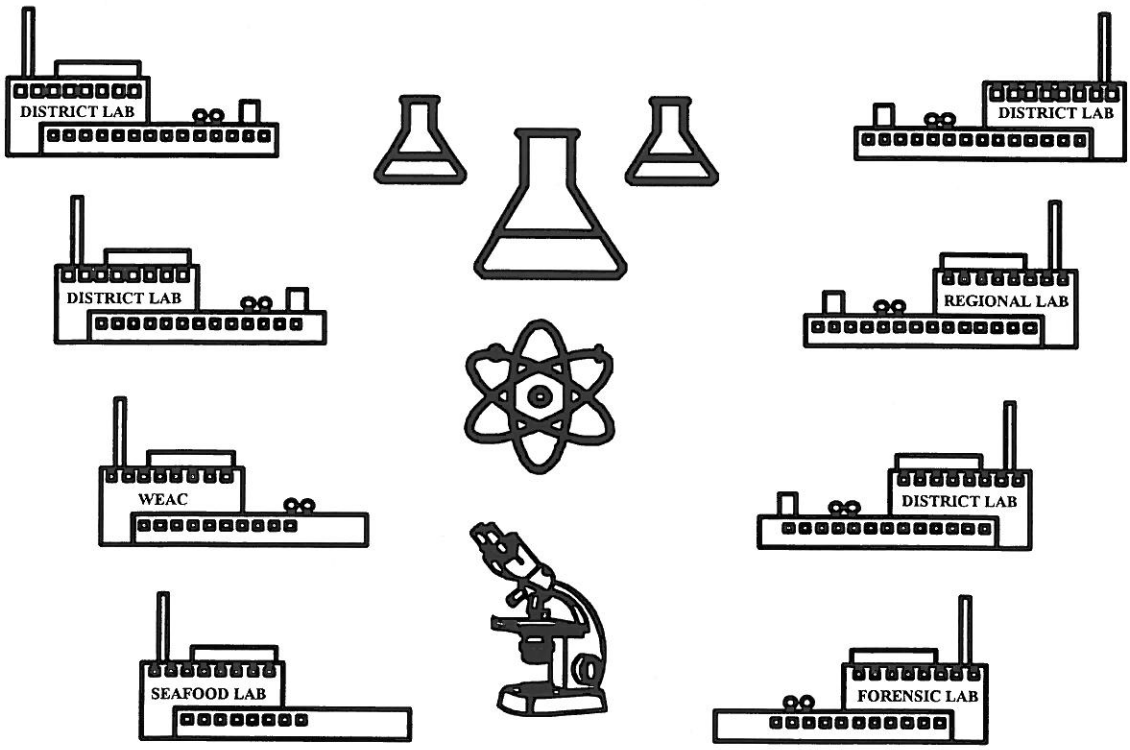
SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2007			FY 2006	
NO.	NAME		NO.	NAME
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH				
*34	Integrated Research for Health Protection: NCTR	<	No Change	
*35	Methods Development for Regulatory Needs: NCTR			
ORA				
88	ICA (Interagency Cooperative Activities	<	No Change	
*99	General	<	No Change	

*** No Resources Planned in FY 2007**

Appendix III

FY 2007 SERVICING LABORATORIES



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

OCTOBER 2006

SERVICING LABORATORIES
FY 2007

CHEMISTS / ENTOMOLOGISTS/BIOLOGISTS

REGIONS>>>>>>>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT>>>>>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
FOOD & COSMETICS																		TX&NM	CA&AZ			
03 FOODBORNE BIOLOG HAZARDS																						
IMPORT A/L ACID CAN FD	03003,A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	NRL	SRL	SRL	SRL	SRL	--	DEN	KAN	ARL	PRS	PRS	SAN	PRN
IMP CHEESE PRODUCTS (Filth)	03037B	SRL	NRL	SRL	ARL	SRL	ARL	ARL	--	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRN	PRS	SAN	PRN
DOM ACID/L ACID CAN FD	03803A	NRL	NRL	SRL	ARL	SRL	DEN	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	KAN	--	--	PRS	SAN	PRN
DOMESTIC FOOD SAFETY (Filth)	03803B	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	KAN	DEN	KAN	--	--	PRS	PRS	PRN
DOMESTIC FOOD SAFETY	03803C	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	KAN	DEN	KAN	--	--	PRS	SAN	PRN
DOMESTIC FOOD SAFETY (Allergen)	03803C	NRL	NRL	DET	DET	DET	DET	DET	DET	DET	SRL	SRL	SRL	SRL	ARL	ARL	ARL	--	--	PRS	PRS	PRS
IMPORTED FDS-GENERAL (Filth)	03819A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	NRL	SRL	SRL	SRL	SRL	--	DEN	KAN	ARL	PRS	PRS	PRS	PRN
IMPORTED FDS-GENERAL	03819B	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	NRL	SRL	SRL	SRL	SRL	--	DEN	KAN	ARL	PRS	PRS	SAN	PRN
IMPORTED FDS GENERAL (Allergen)	03819B	NRL	NRL	DET	DET	DET	DET	DET	DET	DET	SRL	SRL	SRL	SRL	ARL	ARL	ARL	ARL	PRS	PRS	PRS	PRS
DOM FISH & FISHERY PROD (Filth)	03842B	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL	--	--	PRS	PRS	PRN
DOM FISH & FISHERY PROD	03842C	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL	--	--	PRS	SAN	PRN
ORGANOLEPTIC ANALYSIS +	03842C	NRL	NRL	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	PRN
IMPORT SEAFOOD PROD	03844B	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	NRL	SRL	SRL	SRL	SRL	--	ARL	ARL	ARL	PRS	PRS	PRS	PRN
IMPORT SEAFOOD PROD	03844C	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	NRL	SRL	SRL	SRL	SRL	--	ARL	ARL	ARL	PRS	PRS	SAN	PRN
ORGANOLEPTIC ANALYSIS ++	03844C	NRL	NRL	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	PRN
JUICE HACCP	03847H	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL	--	--	PRS	SAN	PRN
FOOD DEFENSE (Imp/Dom)	03R845	NRL	NRL	WEA	WEA	KAN	FCC	FCC	FCC	NRL	SRL	SRL	SRL	DEN	ARL	DEN	KAN	ARL	PRS	PRS	SAN	PRN
04 PESTICIDES & CHEM CONTAM.																						
PEST & CHEM DOM FDS & SEAFD	04004A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	--	--	PRS	PRS	PRN
DIOXIN ANALYSIS	04004D	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	--	--	-ARL-	-ARL-	-ARL-
IMP FOODS - PESTICIDES	04004A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	SRL	SRL	SRL	SRL	SRL	--	ARL	ARL	ARL	PRS	PRS	PRS	PRN
IMP FDS - PESTICIDES SEAFOOD	04004A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	--	SRL	SRL	SRL	SRL	SRL	--	KAN	KAN	ARL	PRS	PRS	PRS	PRN
TOXIC ELM IN FDS D/I	04019A	NRL	NRL	SRL	KAN	SRL	KAN	KAN	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	SAN	SAN	SAN
TOXIC ELM TBL&CK WARE-D/I	04019B	NRL	NRL	SRL	KAN	SRL	KAN	KAN	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	PRS	SAN	SAN
RADIONUCLIDES IN FDS-D/I	04019C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
TOTAL DIET STUDY	04839	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	KAN	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	--	--	-KAN-	-KAN-	-KAN-
07 MOL BIO & NATURAL TOXINS																						
MYCOTOXINS DOM FDS (AFLA)	07001	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
MYCOTOXINS DOM FDS (FUM)	07001	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	--	--	-KAN-	-KAN-	-KAN-
MYCOTOXINS DOM FDS (OCHRA)	07001	NRL	NRL	NRL	KAN	NRL	KAN	KAN	NRL	NRL	KAN	KAN	KAN	KAN	KAN	KAN	KAN	--	--	PRN	PRN	PRN
MYCO DOM FDS (DON,PATULIN)	07001	NRL	NRL	NRL	SRL	NRL	SRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	--	--	PRN	PRN	PRN
MYCOTOXINS IMP FDS (AFLA)	07001	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	PRN	PRN	PRN
MYCOTOXINS IMP FDS (FUM)	07001	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-
MYCOTOXINS IMP FDS (OCHRA)	07001	NRL	NRL	NRL	SRL	NRL	SRL	SRL	NRL	NRL	SRL	KAN	SRL	SRL	KAN	KAN	KAN	KAN	KAN	PRN	PRN	PRN
MYCO IMP FDS (DON, PATULIN)	07001	NRL	NRL	NRL	SRL	NRL	SRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	KAN	KAN	PRN	PRN	PRN
MYCO IMP FDS (SPEC SURV)	07001	-SRL-	SRL-	-SRL-	-SRL-	-SRL-	SRL	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
09 FOOD & COLOR ADDITIVES																						
IMPORT FOODS (FD ADDS)	09006A	NRL	NRL	NRL	ARL	NRL	DET	ARL	--	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	DEN	DEN	SAN	SAN	SAN
IMPORT FOODS (COLOR)	09006B	NRL	NRL	NRL	ARL	NRL	DET	ARL	--	NRL	SRL	SRL	SJN	SJN	DEN	DEN	DEN	DEN	DEN	SAN	SAN	SAN
DOM FD SAFETY (COLOR)	09803,E	NRL	NRL	NRL	ARL	NRL	DET	ARL	--	NRL	SRL	SRL	SJN	SJN	DEN	DEN	DEN	--	--	SAN	SAN	SAN
DOM FD SAFETY (FD ADDS)	09803,F	NRL	NRL	NRL	ARL	NRL	DET	ARL	--	NRL	SRL	SRL	SRL	SJN	DEN	DEN	DEN	--	--	SAN	SAN	SAN
21 FOOD COMP STDS LABEL & ECON																						
MEDICAL FOODS	21002	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
NLEA ENFORCEMENT DOM	21005	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
NLEA ENFORCEMENT IMP	21005	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
INFANT FORMULA DOM/IMP	21006	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
DIETARY SUPPLEMENTS	21008	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-
SELECT NUTR IN FOOD SURVEY	21839	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	-KAN-	--	--	-KAN-	-KAN-	-KAN-
29 COSMETICS																						
DOM/IMP COSMETICS	29001	NRL	NRL	NRL	ARL	NRL	DET	ARL	NRL	NRL	SRL	SRL	SRL	SRL	ARL	ARL	ARL	ARL	ARL	SAN	SAN	SAN

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

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

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

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.

SERVICING LABORATORIES

FY 2007

CHEMISTS / ENTOMOLOGISTS/BIOLOGISTS

REGIONS>>>>>>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT>>>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
HUMAN DRUGS																		TX&NM	CA&AZ			
46 NEW DRUG EVALUATION																						
NDA CHEM INSP	46832	NRL	NRL	PHI	DET	FCC	DET	DET	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	PRN	PRN
PRE APPROVAL PROFILE	46832B,C	NRL	NRL	FCC	FCC	FCC	FCC	FCC	FCC	FCC	NRL	NRL	NRL	NRL	FCC	FCC	FCC	--	--	FCC	FCC	FCC
PRE APPR FOREIGN CHEM INSP	46832	NRL	NRL	PHI	PHI	FCC	PHI	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	SAN	PRN
PRE APPR FOREIGN PROFILE	46832B,C	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	--	--	NRL	NRL	NRL
52 GENERIC DRUG EVALUATION																						
ANDA CHEM INSP	52832	NRL	NRL	PHI	PHI	FCC	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	SAN	PRN
GEN PRE APPROV PROFILE	52832B,C	NRL	NRL	FCC	FCC	FCC	FCC	FCC	FCC	FCC	NRL	NRL	NRL	NRL	FCC	FCC	FCC	--	--	FCC	FCC	FCC
PRE APPR FOREIGN CHEM INSP	52832	NRL	NRL	PHI	PHI	PHI	PHI	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	PRN	PRN
PRE APPR FOREIGN PROFILE	52832B,C	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	NRL	--	--	NRL	NRL	NRL
56 DRUG QUALITY ASSURANCE																						
DPI CHEM ON INSP	56002 A-F	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	PRN	PRN
DRUG PROCESS INSP (DSA)	56002 A-F	NRL	NRL	PHI	PHI	PHI	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	DEN	--	--	PRN	PRN	PRN
FOREIGN CHEM INSP	56002 A-F	PHI	NRL	PHI	PHI	FCC	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	SAN	PRN
DRG PROD SURVEY (API)	56008A	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-	-SJN-
DRG PROD SURVEY (DPS)	56008A	NRL	NRL	PHI	PHI	PHI	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	PRN	PRN
DPS API	56008H	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SJN	SJN	SJN	---	---	---	DEN	DEN	PRS	PRN	PRN
DPS FINISHED DOSAGE	56008H	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	---	---	---	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-
DQRS/NDA FLD ALERT REPT	56021A,B	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SRL	SJN	SJN	DEN	DEN	DEN	--	--	PRN	PRN	PRN
RX DRG MKTG ACT (PDMA)	560022,A	NRL	NRL	PHI	PHI	PHI	PHI	PHI	PHI	PHI	SJN	SJN	SJN	SJN	DEN	DEN	DEN	--	--	PRN	PRN	PRN
63 INTERNET, FRAUD, OTC MONO	63001A	PHI	NRL	PHI	PHI	PHI	DET	PHI	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRN	PRN	PRN

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

The Analyzing Laboratories for Samples Collected Under 56008A/H, Drug Product Surveillance will be assigned by DFS (HFC-140) based on expertise of drug lab for each specific drug sampled.
SWID - TX & NM Column: Samples collected in TX or NM will be analyzed by the Labs listed.
SWID - CA & AZ Column: Samples collected in CA or AZ will be analyzed by the Labs listed.

SERVICING LABORATORIES

FY 2007

CHEMISTS / ENTOMOLOGISTS/BIOLOGISTS

REGIONS>>>>>>>>>>>>>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT>>>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID TX&NM	SWID CA&AZ	LOS	SAN	SEA
ANIMAL DRUGS & FEEDS																						
68 PRE APPR MON ANIMAL DGS FEEDS																						
NADA PRE APPROVAL INSP	68001	NRL	NRL	KAN	KAN	KAN	KAN	KAN	KAN	KAN	SRL	SRL	SRL	SRL	KAN	KAN	KAN	--	--	PRN	PRN	PRN
METHOD VALIDATION	68001	NRL	NRL	KAN	KAN	KAN	KAN	KAN	KAN	KAN	SRL	SRL	SRL	SRL	DEN	DEN	KAN	--	--	PRN	PRN	PRN
GLP NON-CLINICAL	68808	NRL	NRL	KAN	ARL	KAN	ARL	ARL	SRL	KAN	SRL	SRL	SRL	SRL	KAN	DEN	KAN	--	--	PRN	PRN	PRN
71 POST APPR MON ANIMAL DGS FEEDS																						
DRUG PROCESS INSPECTIONS	71001	NRL	NRL	SRL	KAN	SRL	KAN	KAN	SRL	SRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	--	--	PRN	PRN	PRN
DOM/IMP FEED CONTAMIN	71003A,B	NRL	NRL	SRL	KAN	SRL	ARL	KAN	NRL	NRL	SRL	SRL	SRL	SRL	KAN	KAN	KAN	ARL	ARL	PRS	PRS	PRN
FEED CONT MYCOTOXINS/D	71003C	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	SRL	SRL	SRL	SRL	KAN	KAN	KAN	--	--	PRN	PRN	PRN
FEED CONT MYCOTOXINS/I	71003C	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-	-PRN-
FEED CONT DIOXIN ANALY D/I	71003G	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-	-ARL-
MEDICATED FEEDS	71004	-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-
ILL RESIDUES-MEAT & PLTRY	71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
METHOD VALIDATION	71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
BSE PROGRAM DOMESTIC	71009	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	PRS	PRN
BSE PROGRAM IMPORT	71009	PRN	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	ARL	PRS	PRS	PRN
MEDICAL DEV & RAD HLTH																						
81 POSTMKT ASSURANCE: DEVICES																						
PM/DEN F/U CH & SER TEST	81010	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
PM/DEN F/U RADIONUCLIDES	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																						
MFRS - REAGANTS	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	82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS - SPORICIDAL	82845C	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-
MFRS - TUBERCULOCIDAL	82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	DEN	DEN	DEN	DEN	DEN	DEN	DEN	DEN
CONDOM ASSIG DOM / IMP	82Z002	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-
SURGICAL EXAM GLOVES	82Z003	--	--	-WEA-	--	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-	-PRS-
CTR INIT ASGN TEST KT/REAG	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
CTR INIT ASGN RADIOIMMUN	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-

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

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

SERVICING LABORATORIES

FY 2007

MICROBIOLOGISTS

REGIONS>>>>>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT>>>>>>>>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
FOOD & COSMETICS																		TX&NM	CA&AZ			
03 FOODBORNE BIOLOG HAZARDS																						
IMPORT ACID/L ACID	03003,A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	---	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
DOM ACID/L ACID CAN FD	03803A	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
SPORE HEAT DETERMTN	03803A	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
DOMESTIC FOOD SAFETY	03803D	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
IMP FOODS GENERAL*	03819C	NRL	NRL	SRL	DEN	SRL	DEN	DEN	---	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRN	PRS	SAN	PRN
DOM CHEESE PRODUCTS	03037D	SRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
IMP CHEESE PRODUCTS	03037D	SRL	NRL	SRL	ARL	SRL	ARL	ARL	--	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	NRL	NRL	PRS	SAN	PRN
DOM FISH & FISHERY PROD	03842D	NRL	NRL	SRL	ARL	SRL	ARL	ARL	NRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
IMPORT SEAFOOD PROD	03844D	NRL	NRL	SRL	ARL	SRL	ARL	ARL	---	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
IMP DOMESTIC MICRO ASSIGN	03F098	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	DEN	PRS	SAN	PRN
FOOD DEFENSE (Imp/Dom)	03R845	NRL	NRL	NRL	NRL	NRL	SRL	SRL	SRL	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
JUICE HACCP	03847H	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
04 PESTICIDES & CHEM CONTAM.																						
GENETICALLY MODIFIED CORN	04F102	NRL	NRL	SRL	NRL	NRL	NRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	PRN	PRN	NRL	--	--	PRN	PRN	PRN
18 TECH ASSIST: FOOD & COSMETICS		NRL	NRL	SRL	SRL	SRL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
MILK SAFETY PROGRAM	18003	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN
INTERSTATE TRAVEL SANIT	18029A-F	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRN	PRN	PRN
21 FOOD COMP STDS LABEL & ECON																						
MEDICAL FOODS DOM/IMP	21002	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
INFANT FORMULA DOM/IMP	21006	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
SELECT NUTR IN FOOD SURVEY MARKET BASKET	21839	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	-SRL-	--	--	-SRL-	-SRL-	-SRL-
29 DOM/IMP COSMETICS/COLOR	29001	NRL	NRL	SRL	ARL	SRL	ARL	ARL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	DEN	DEN	PRS	SAN	SAN
HUMAN DRUGS																						
56 DRUG QUALITY ASSURANCE																						
DRUG PROC INSP, DSA/CHEM INSP	56002	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN
DRUG PROD SURVEY	56008A	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN
DQRS/NDA FLD ALERT REPT	56021A,B	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN
63 FRAUDULENT DRUGS	63001	NRL	NRL	SRL	NRL	SRL	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN

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

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

SERVICING LABORATORIES
FY 2007

MICROBIOLOGISTS

REGIONS >>>>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT >>>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
ANIMAL DRUGS & FEED																		TX&NM	CA&AZ			
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-
TYPE "A" MED ARTICLES	71005	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
ILL RES IN MEAT/POULTRY	71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
METHOD VALIDATION	71006	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
MEDICAL DEV & RAD HLTH																						
81 POSTMKT ASSURANCE:DEVICES																						
PR MDR/DEN F/U-STERILITY	81010	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
82 COMPLIANCE: DEVICES																						
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	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
CTR INIT ASGN-MEDIA TEST	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
84 SCIENCE: DEVICES																						
METHODS VALIDATION	84Z002	-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.

SERVICING LABORATORIES

FY 2007

ENGINEERS/PHYSICISTS

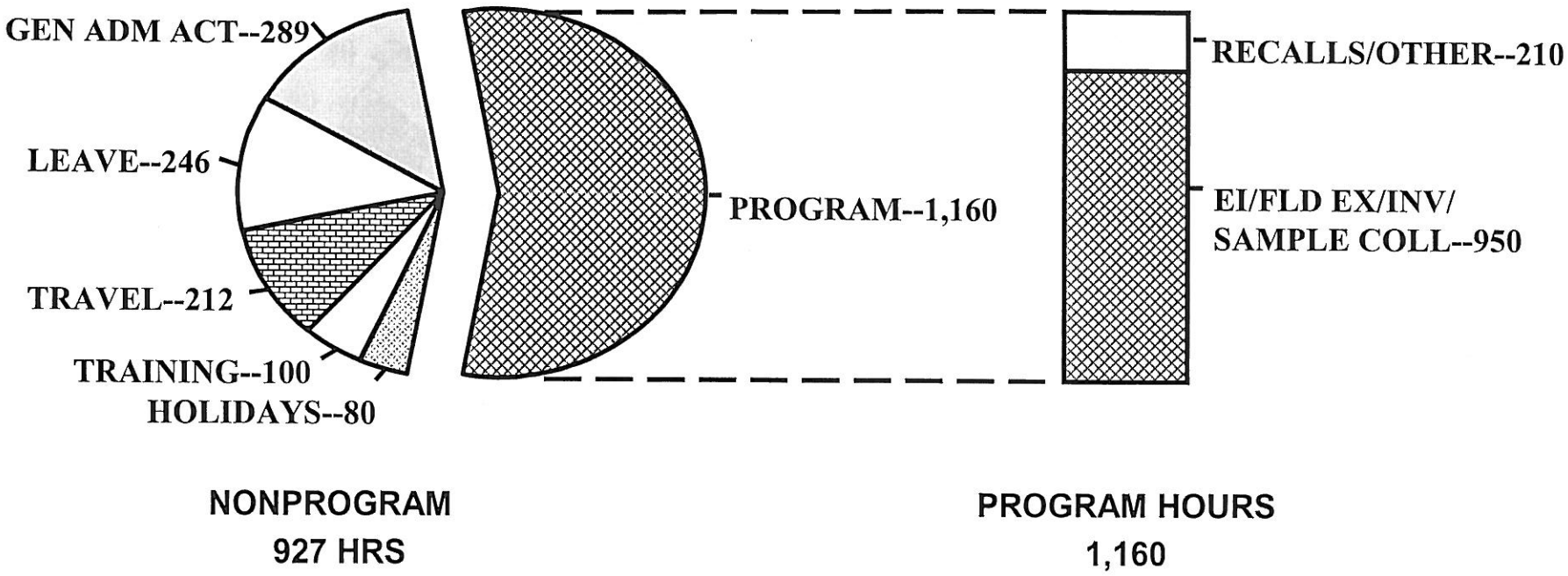
REGIONS >>>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
MEDICAL DEV & RAD HLTH																		TX&NM	CA&AZ			
81 POSTMKT ASSURANCE: DEVICES																						
PROB REPORT MDR/DN F/U	81010	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
82 COMPLIANCE: DEV																						
MON DEV FOREIGN ORIG	82008	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS	82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
SURGICAL EXAM GLOVES	82Z003	-WEA-	-WEA-	---	-WEA-	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
CTR INITIATED ASGNMTS	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
84 SCIENCE: DEVICES																						
METHODS VALIDATION	84Z002	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
84 RCHSA AUTHORITY																						
COMP TEST ELECT PROD	86006A-E	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-

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.

INVESTIGATIVE/INSPECTIONAL

FY 2007 PROGRAM/NONPROGRAM TIME

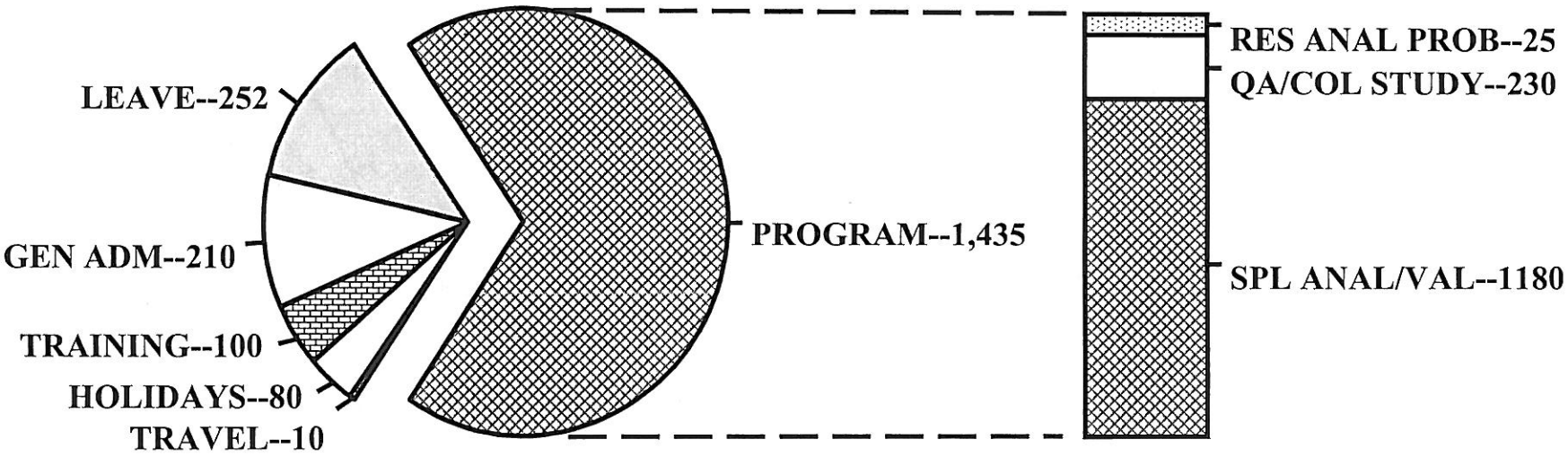
- 2,087 TOTAL HOURS -



ANALYTICAL

FY 2007 PROGRAM/NONPROGRAM TIME

- 2087 TOTAL HOURS -



NONPROGRAM
652 HOURS

PROGRAM
1,435 HOURS

FY 2007

PART II - WORKPLAN SUMMARY
OPERATIONS & POSITIONS

DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE MANAGEMENT BRANCH

ORA/ORM/DPEM

Total Field
INVESTIGATION SUMMARY TABLE
FY 2007

	DOMESTIC INVESTIGATION FTE	IMPORT INVESTIGATION FTE	TOTAL INVESTIGATION FTE
FIELD TOTAL	933.64	384.91	1318.55
HQ	23.96	34.99	58.95
NE REGN	119.65	81.12	200.77
NE RO	10.28	0.00	10.28
NWE	56.51	18.03	74.54
NYK	52.86	63.09	115.95
NRL	0.00	0.00	0.00
WEAC	0.00	0.00	0.00
CE REGN	290.06	51.21	341.27
CE RO	15.10	0.00	15.10
BLT	38.37	10.07	48.44
CIN	34.28	5.01	39.29
DET	33.11	15.08	48.19
CHI	34.14	7.40	41.54
MIN	55.50	7.09	62.59
NWJ	41.08	0.68	41.76
PHI	38.48	5.88	44.36
FCC	0.00	0.00	0.00
SE REGN	161.99	46.05	208.04
SE RO	12.21	0.00	12.21
ATL	46.60	7.05	53.65
FLA	44.13	22.14	66.27
NOL	40.75	12.90	53.65
SJN	18.30	3.96	22.26
SRL	0.00	0.00	0.00
SW REGN	137.77	72.57	210.34
SW RO	15.89	0.00	15.89
DAL	54.31	0.23	54.54
DEN	25.62	0.23	25.85
KAN	41.88	0.20	42.08
SWID	0.07	71.91	71.98
ARL	0.00	0.00	0.00
PA REGN	200.21	98.97	299.18
PA RO	13.07	0.00	13.07
LOS	82.16	48.94	131.10
SAN	53.44	23.00	76.44
SEA	51.54	27.03	78.57
PRL-SW	0.00	0.00	0.00
PRL-NW	0.00	0.00	0.00

PART II
WORKPLAN SUMMARY

POSITION CLASS

COMBINED ANALYTICAL & DISTRICT RESOURCES

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

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

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

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

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

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

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

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESOURCES)
FY 2007

Output Reflects: OPR FTE'S

REGION: NE REGN

FIELD	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	200.77	56.39	46.11	11.13	0.00	1.00	315.40	335574.70
FOOD SAFETY/COS	107.58	36.43	39.71	0.00	0.00	0.00	183.72	198847.60
03	83.31	11.83	38.38	0.00	0.00	0.00	133.52	142728.40
04	5.41	17.75	0.00	0.00	0.00	0.00	23.16	26094.00
07	1.46	3.03	0.00	0.00	0.00	0.00	4.49	4974.00
09	0.97	3.24	0.00	0.00	0.00	0.00	4.21	4736.80
18	12.12	0.00	0.10	0.00	0.00	0.00	12.22	13938.50
21	3.19	0.00	0.00	0.00	0.00	0.00	3.19	3021.10
29	1.12	0.58	1.23	0.00	0.00	0.00	2.93	3354.80
BIOLOGICS	11.10	0.00	0.00	0.00	0.00	0.00	11.10	10673.50
41	3.13	0.00	0.00	0.00	0.00	0.00	3.13	2970.80
42	7.45	0.00	0.00	0.00	0.00	0.00	7.45	7210.70
45	0.52	0.00	0.00	0.00	0.00	0.00	0.52	492.00
HUMAN DRUGS	41.26	13.02	1.51	0.00	0.00	0.00	55.79	56341.50
46	2.36	1.61	0.09	0.00	0.00	0.00	4.06	3962.00
48	5.48	0.00	0.00	0.00	0.00	0.00	5.48	5202.20
52	2.19	5.45	0.00	0.00	0.00	0.00	7.64	8268.50
53	1.51	0.00	0.00	0.00	0.00	0.00	1.51	1431.00
56	28.61	5.89	1.42	0.00	0.00	0.00	35.92	36345.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.11	0.07	0.00	0.00	0.00	0.00	1.18	1132.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	13.11	2.21	0.63	0.00	0.00	0.00	15.95	16977.50
68	0.97	0.04	0.00	0.00	0.00	0.00	1.01	951.80
71	12.14	2.17	0.63	0.00	0.00	0.00	14.94	16025.70
DEVICES & RAD H	27.72	4.73	4.26	11.13	0.00	1.00	48.84	52734.60
81	0.10	0.03	0.02	0.03	0.00	0.00	0.18	186.90
82	17.74	4.70	3.56	3.52	0.00	0.00	29.52	31470.40
83	4.49	0.00	0.00	0.00	0.00	0.00	4.49	4262.40
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	2.07	0.00	0.00	0.00	0.00	0.00	2.07	2400.00
86	3.32	0.00	0.00	4.54	0.00	0.00	7.86	8844.90

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

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

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

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

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

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

REGION: CE REGN

FIELD	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	341.27	55.96	0.00	0.00	0.00	0.00	397.23	399007.50
FOOD SAFETY/COS	126.92	14.60	0.00	0.00	0.00	0.00	141.52	144219.30
03	92.83	0.94	0.00	0.00	0.00	0.00	93.77	92129.50
04	6.00	12.75	0.00	0.00	0.00	0.00	18.75	21047.20
07	3.00	0.00	0.00	0.00	0.00	0.00	3.00	2852.00
09	0.49	0.87	0.00	0.00	0.00	0.00	1.36	1486.80
18	17.30	0.00	0.00	0.00	0.00	0.00	17.30	19699.50
21	6.48	0.00	0.00	0.00	0.00	0.00	6.48	6150.00
29	0.82	0.04	0.00	0.00	0.00	0.00	0.86	854.30
BIOLOGICS	36.27	0.00	0.00	0.00	0.00	0.00	36.27	34628.40
41	8.51	0.00	0.00	0.00	0.00	0.00	8.51	8089.30
42	25.72	0.00	0.00	0.00	0.00	0.00	25.72	24601.10
45	2.04	0.00	0.00	0.00	0.00	0.00	2.04	1938.00
HUMAN DRUGS	87.64	40.06	0.00	0.00	0.00	0.00	127.70	129859.30
46	7.33	3.53	0.00	0.00	0.00	0.00	10.86	10718.00
48	15.21	0.00	0.00	0.00	0.00	0.00	15.21	14455.20
52	4.42	3.85	0.00	0.00	0.00	0.00	8.27	8446.00
53	3.55	0.00	0.00	0.00	0.00	0.00	3.55	3372.00
56	55.38	23.48	0.00	0.00	0.00	0.00	78.86	80344.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.75	0.20	0.00	0.00	0.00	0.00	1.95	1904.00
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
ANIMAL D & F	32.78	1.00	0.00	0.00	0.00	0.00	33.78	32927.70
68	3.50	0.00	0.00	0.00	0.00	0.00	3.50	3326.90
71	29.28	1.00	0.00	0.00	0.00	0.00	30.28	29600.80
DEVICES & RAD H	57.66	0.30	0.00	0.00	0.00	0.00	57.96	57372.80
81	0.15	0.00	0.00	0.00	0.00	0.00	0.15	135.60
82	33.63	0.30	0.00	0.00	0.00	0.00	33.93	32778.80
83	11.32	0.00	0.00	0.00	0.00	0.00	11.32	10759.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.70	0.00	0.00	0.00	0.00	0.00	4.70	5473.00
86	7.86	0.00	0.00	0.00	0.00	0.00	7.86	8226.20

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

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

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

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

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

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

REGION: SE REGN

FIELD	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	208.04	58.72	37.21	0.00	0.00	3.00	306.97	320956.10
FOOD SAFETY/COS	86.80	40.45	33.92	0.00	0.00	3.00	164.17	179216.90
03	62.47	7.60	32.11	0.00	0.00	0.00	102.18	109042.60
04	5.23	14.26	0.00	0.00	0.00	0.00	19.49	21801.90
07	1.36	6.50	0.00	0.00	0.00	3.00	10.86	12505.00
09	0.16	0.45	0.00	0.00	0.00	0.00	0.61	668.00
18	14.80	0.00	0.29	0.00	0.00	0.00	15.09	17019.00
21	2.28	11.57	0.89	0.00	0.00	0.00	14.74	16860.20
29	0.50	0.07	0.63	0.00	0.00	0.00	1.20	1320.20
BIOLOGICS	21.79	0.00	0.00	0.00	0.00	0.00	21.79	20879.70
41	4.82	0.00	0.00	0.00	0.00	0.00	4.82	4579.40
42	15.39	0.00	0.00	0.00	0.00	0.00	15.39	14797.90
45	1.58	0.00	0.00	0.00	0.00	0.00	1.58	1502.40
HUMAN DRUGS	53.25	16.05	2.03	0.00	0.00	0.00	71.33	71596.20
46	3.69	0.99	0.00	0.00	0.00	0.00	4.68	4510.50
48	10.29	0.00	0.00	0.00	0.00	0.00	10.29	9777.20
52	1.98	0.85	0.00	0.00	0.00	0.00	2.83	2728.00
53	1.57	0.00	0.00	0.00	0.00	0.00	1.57	1488.00
56	34.01	11.05	2.03	0.00	0.00	0.00	47.09	47756.50
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.71	0.16	0.00	0.00	0.00	0.00	1.87	1796.00
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
ANIMAL D & F	12.59	2.22	1.26	0.00	0.00	0.00	16.07	16046.80
68	1.62	0.05	0.00	0.00	0.00	0.00	1.67	1576.20
71	10.97	2.17	1.26	0.00	0.00	0.00	14.40	14470.60
DEVICES & RAD H	33.61	0.00	0.00	0.00	0.00	0.00	33.61	33216.50
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	74.00
82	20.39	0.00	0.00	0.00	0.00	0.00	20.39	19745.70
83	6.03	0.00	0.00	0.00	0.00	0.00	6.03	5720.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.75	0.00	0.00	0.00	0.00	0.00	2.75	3189.00
86	4.36	0.00	0.00	0.00	0.00	0.00	4.36	4487.60

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

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

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

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

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

REGION: SW REGN

FIELD	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	210.34	97.21	28.75	0.00	0.00	8.50	344.80	368728.50
FOOD SAFETY/COS	94.61	80.43	25.50	0.00	0.00	5.00	205.54	227602.60
03	65.66	7.98	24.88	0.00	0.00	0.00	98.52	105347.90
04	9.70	61.91	0.00	0.00	0.00	5.00	76.61	88209.70
07	2.03	4.62	0.00	0.00	0.00	0.00	6.65	7367.00
09	0.72	2.49	0.00	0.00	0.00	0.00	3.21	3624.80
18	12.30	0.00	0.06	0.00	0.00	0.00	12.36	14322.00
21	3.84	3.35	0.00	0.00	0.00	0.00	7.19	7607.50
29	0.36	0.08	0.56	0.00	0.00	0.00	1.00	1123.70
BIOLOGICS	19.99	0.00	0.00	0.00	0.00	0.00	19.99	19019.00
41	5.00	0.00	0.00	0.00	0.00	0.00	5.00	4748.50
42	13.70	0.00	0.00	0.00	0.00	0.00	13.70	13057.30
45	1.29	0.00	0.00	0.00	0.00	0.00	1.29	1213.20
HUMAN DRUGS	35.02	7.57	0.98	0.00	0.00	0.00	43.57	42517.70
46	2.23	1.26	0.44	0.00	0.00	0.00	3.93	3848.50
48	9.23	0.00	0.00	0.00	0.00	0.00	9.23	8768.50
52	1.86	0.62	0.00	0.00	0.00	0.00	2.48	2349.50
53	0.60	0.00	0.00	0.00	0.00	0.00	0.60	570.00
56	20.18	5.57	0.54	0.00	0.00	0.00	26.29	25975.20
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.92	0.12	0.00	0.00	0.00	0.00	1.04	1006.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	20.47	9.21	1.75	0.00	0.00	3.50	34.93	36516.70
68	3.18	0.18	0.00	0.00	0.00	0.00	3.36	3195.30
71	17.29	9.03	1.75	0.00	0.00	3.50	31.57	33321.40
DEVICES & RAD H	40.25	0.00	0.52	0.00	0.00	0.00	40.77	43072.50
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	68.40
82	25.98	0.00	0.52	0.00	0.00	0.00	26.50	28042.70
83	4.99	0.00	0.00	0.00	0.00	0.00	4.99	4731.70
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.88	0.00	0.00	0.00	0.00	0.00	2.88	3344.00
86	6.32	0.00	0.00	0.00	0.00	0.00	6.32	6885.70

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

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WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESOURCES)
FY 2007

Output Reflects: OPR FTE'S

REGION: PA REGN

FIELD	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	299.18	62.14	57.00	0.00	0.00	6.50	424.82	444552.60
FOOD SAFETY/COS	171.02	46.94	55.58	0.00	0.00	6.00	279.54	300627.30
03	133.60	17.51	54.70	0.00	0.00	4.00	209.81	223901.10
04	8.49	25.57	0.00	0.00	0.00	0.00	34.06	38267.10
07	1.81	1.95	0.00	0.00	0.00	1.00	4.76	5198.00
09	0.56	1.71	0.00	0.00	0.00	0.00	2.27	2545.60
18	20.62	0.00	0.23	0.00	0.00	0.00	20.85	22847.00
21	5.20	0.00	0.00	0.00	0.00	1.00	6.20	6103.00
29	0.74	0.20	0.65	0.00	0.00	0.00	1.59	1765.50
BIOLOGICS	18.91	0.00	0.00	0.00	0.00	0.00	18.91	18150.50
41	5.46	0.00	0.00	0.00	0.00	0.00	5.46	5179.20
42	12.25	0.00	0.00	0.00	0.00	0.00	12.25	11844.50
45	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1126.80
HUMAN DRUGS	43.00	7.89	0.81	0.00	0.00	0.00	51.70	50746.60
46	2.00	1.10	0.00	0.00	0.00	0.00	3.10	2980.50
48	10.71	0.00	0.00	0.00	0.00	0.00	10.71	10171.70
52	2.11	0.51	0.00	0.00	0.00	0.00	2.62	2477.00
53	1.52	0.00	0.00	0.00	0.00	0.00	1.52	1440.00
56	24.13	5.82	0.81	0.00	0.00	0.00	30.76	30743.40
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.53	0.46	0.00	0.00	0.00	0.00	2.99	2934.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	17.65	3.69	0.61	0.00	0.00	0.50	22.45	22937.60
68	1.14	0.03	0.00	0.00	0.00	0.00	1.17	1113.40
71	16.51	3.66	0.61	0.00	0.00	0.50	21.28	21824.20
DEVICES & RAD H	48.60	3.62	0.00	0.00	0.00	0.00	52.22	52090.60
81	0.05	0.00	0.00	0.00	0.00	0.00	0.05	44.40
82	30.51	3.62	0.00	0.00	0.00	0.00	34.13	33817.90
83	9.70	0.00	0.00	0.00	0.00	0.00	9.70	9206.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.51	0.00	0.00	0.00	0.00	0.00	2.51	2916.00
86	5.83	0.00	0.00	0.00	0.00	0.00	5.83	6105.80

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESOURCES)
FY 2007

Output Reflects: OPR FTE'S

TOTAL FIELD

	INVEST	METH VAL & ANALYTICAL CHEM	METH VAL & ANALYTICAL MICRO	METH VAL & ANALYTICAL ENG/PHY	DISTRICT METHODS VAL/DEV	APPLIED TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	1318.55	330.42	169.07	11.13	0.00	19.00	1848.17	1933578.10
FOOD SAFETY/COS	625.05	218.85	154.71	0.00	0.00	14.00	1012.61	1095481.70
03	475.99	45.86	150.07	0.00	0.00	4.00	675.92	718117.50
04	34.83	132.24	0.00	0.00	0.00	5.00	172.07	195419.90
07	9.66	16.10	0.00	0.00	0.00	4.00	29.76	32896.00
09	2.90	8.76	0.00	0.00	0.00	0.00	11.66	13062.00
18	77.14	0.00	0.68	0.00	0.00	0.00	77.82	87826.00
21	20.99	14.92	0.89	0.00	0.00	1.00	37.80	39741.80
29	3.54	0.97	3.07	0.00	0.00	0.00	7.58	8418.50
BIOLOGICS	121.08	0.00	0.00	0.00	0.00	0.00	121.08	115721.10
41	26.92	0.00	0.00	0.00	0.00	0.00	26.92	25567.20
42	82.91	0.00	0.00	0.00	0.00	0.00	82.91	79492.70
45	11.25	0.00	0.00	0.00	0.00	0.00	11.25	10661.20
HUMAN DRUGS	264.19	84.59	5.33	0.00	0.00	0.00	354.11	354878.00
46	18.28	8.49	0.53	0.00	0.00	0.00	27.30	26652.00
48	52.07	0.00	0.00	0.00	0.00	0.00	52.07	49464.00
52	12.77	11.28	0.00	0.00	0.00	0.00	24.05	24469.00
53	9.00	0.00	0.00	0.00	0.00	0.00	9.00	8541.00
56	164.05	51.81	4.80	0.00	0.00	0.00	220.66	222820.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	8.02	1.01	0.00	0.00	0.00	0.00	9.03	8772.00
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	96.60	18.33	4.25	0.00	0.00	4.00	123.18	125406.30
68	10.41	0.30	0.00	0.00	0.00	0.00	10.71	10163.60
71	86.19	18.03	4.25	0.00	0.00	4.00	112.47	115242.70
DEVICES & RAD H	211.63	8.65	4.78	11.13	0.00	1.00	237.19	242091.00
81	0.46	0.03	0.02	0.03	0.00	0.00	0.54	509.30
82	132.04	8.62	4.08	3.52	0.00	0.00	148.26	149459.50
83	36.53	0.00	0.00	0.00	0.00	0.00	36.53	34680.00
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	14.91	0.00	0.00	0.00	0.00	0.00	14.91	17322.00
86	27.69	0.00	0.00	4.54	0.00	0.00	32.23	34550.20

PART II
WORKPLAN SUMMARY

POSITION CLASS

SEPARATE LAB RESOURCES

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

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

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

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

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

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

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

REGION: NE REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	200.77	54.41	42.62	11.13	5.48	1.00	315.41	335574.70
FOOD SAFETY/COS	107.58	35.57	37.22	0.00	3.36	0.00	183.73	198847.60
03	83.31	11.83	35.89	0.00	2.49	0.00	133.52	142728.40
04	5.41	17.08	0.00	0.00	0.67	0.00	23.16	26094.00
07	1.46	2.84	0.00	0.00	0.20	0.00	4.50	4974.00
09	0.97	3.24	0.00	0.00	0.00	0.00	4.21	4736.80
18	12.12	0.00	0.10	0.00	0.00	0.00	12.22	13938.50
21	3.19	0.00	0.00	0.00	0.00	0.00	3.19	3021.10
29	1.12	0.58	1.23	0.00	0.00	0.00	2.93	3354.80
BIOLOGICS	11.10	0.00	0.00	0.00	0.00	0.00	11.10	10673.50
41	3.13	0.00	0.00	0.00	0.00	0.00	3.13	2970.80
42	7.45	0.00	0.00	0.00	0.00	0.00	7.45	7210.70
45	0.52	0.00	0.00	0.00	0.00	0.00	0.52	492.00
HUMAN DRUGS	41.26	13.02	1.51	0.00	0.00	0.00	55.79	56341.50
46	2.36	1.61	0.09	0.00	0.00	0.00	4.06	3962.00
48	5.48	0.00	0.00	0.00	0.00	0.00	5.48	5202.20
52	2.19	5.45	0.00	0.00	0.00	0.00	7.64	8268.50
53	1.51	0.00	0.00	0.00	0.00	0.00	1.51	1431.00
56	28.61	5.89	1.42	0.00	0.00	0.00	35.92	36345.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.11	0.07	0.00	0.00	0.00	0.00	1.18	1132.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	13.11	2.09	0.63	0.00	0.12	0.00	15.95	16977.50
68	0.97	0.04	0.00	0.00	0.00	0.00	1.01	951.80
71	12.14	2.05	0.63	0.00	0.12	0.00	14.94	16025.70
DEVICES & RAD H	27.72	3.73	3.26	11.13	2.00	1.00	48.84	52734.60
81	0.10	0.03	0.02	0.03	0.00	0.00	0.18	186.90
82	17.74	3.70	2.56	3.52	2.00	0.00	29.52	31470.40
83	4.49	0.00	0.00	0.00	0.00	0.00	4.49	4262.40
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	2.07	0.00	0.00	0.00	0.00	0.00	2.07	2400.00
86	3.32	0.00	0.00	4.54	0.00	0.00	7.86	8844.90

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

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

REGION: CE REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	341.27	55.21	0.00	0.00	0.75	0.00	397.23	399007.50
FOOD SAFETY/COS	126.92	13.85	0.00	0.00	0.75	0.00	141.52	144219.30
03	92.83	0.94	0.00	0.00	0.00	0.00	93.77	92129.50
04	6.00	12.00	0.00	0.00	0.75	0.00	18.75	21047.20
07	3.00	0.00	0.00	0.00	0.00	0.00	3.00	2852.00
09	0.49	0.87	0.00	0.00	0.00	0.00	1.36	1486.80
18	17.30	0.00	0.00	0.00	0.00	0.00	17.30	19699.50
21	6.48	0.00	0.00	0.00	0.00	0.00	6.48	6150.00
29	0.82	0.04	0.00	0.00	0.00	0.00	0.86	854.30
BIOLOGICS	36.27	0.00	0.00	0.00	0.00	0.00	36.27	34628.40
41	8.51	0.00	0.00	0.00	0.00	0.00	8.51	8089.30
42	25.72	0.00	0.00	0.00	0.00	0.00	25.72	24601.10
45	2.04	0.00	0.00	0.00	0.00	0.00	2.04	1938.00
HUMAN DRUGS	87.64	40.06	0.00	0.00	0.00	0.00	127.70	129859.30
46	7.33	3.53	0.00	0.00	0.00	0.00	10.86	10718.00
48	15.21	0.00	0.00	0.00	0.00	0.00	15.21	14455.20
52	4.42	3.85	0.00	0.00	0.00	0.00	8.27	8446.00
53	3.55	0.00	0.00	0.00	0.00	0.00	3.55	3372.00
56	55.38	23.48	0.00	0.00	0.00	0.00	78.86	80344.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.75	0.20	0.00	0.00	0.00	0.00	1.95	1904.00
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
ANIMAL D & F	32.78	1.00	0.00	0.00	0.00	0.00	33.78	32927.70
68	3.50	0.00	0.00	0.00	0.00	0.00	3.50	3326.90
71	29.28	1.00	0.00	0.00	0.00	0.00	30.28	29600.80
DEVICES & RAD H	57.66	0.30	0.00	0.00	0.00	0.00	57.96	57372.80
81	0.15	0.00	0.00	0.00	0.00	0.00	0.15	135.60
82	33.63	0.30	0.00	0.00	0.00	0.00	33.93	32778.80
83	11.32	0.00	0.00	0.00	0.00	0.00	11.32	10759.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.70	0.00	0.00	0.00	0.00	0.00	4.70	5473.00
86	7.86	0.00	0.00	0.00	0.00	0.00	7.86	8226.20

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

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

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

Output Reflects: OPR FTE'S

WORKPLAN SUMMARY / POSITION CLASS (SEPARATE LAB RESOURCES)
FY 2007

REGION: SE REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	208.04	57.89	36.71	0.00	1.32	3.00	306.96	320956.10
FOOD SAFETY/COS	86.80	39.75	33.42	0.00	1.20	3.00	164.17	179216.90
03	62.47	7.60	31.61	0.00	0.50	0.00	102.18	109042.60
04	5.23	13.76	0.00	0.00	0.50	0.00	19.49	21801.90
07	1.36	6.30	0.00	0.00	0.20	3.00	10.86	12505.00
09	0.16	0.45	0.00	0.00	0.00	0.00	0.61	668.00
18	14.80	0.00	0.29	0.00	0.00	0.00	15.09	17019.00
21	2.28	11.57	0.89	0.00	0.00	0.00	14.74	16860.20
29	0.50	0.07	0.63	0.00	0.00	0.00	1.20	1320.20
BIOLOGICS	21.79	0.00	0.00	0.00	0.00	0.00	21.79	20879.70
41	4.82	0.00	0.00	0.00	0.00	0.00	4.82	4579.40
42	15.39	0.00	0.00	0.00	0.00	0.00	15.39	14797.90
45	1.58	0.00	0.00	0.00	0.00	0.00	1.58	1502.40
HUMAN DRUGS	53.25	16.05	2.03	0.00	0.00	0.00	71.33	71596.20
46	3.69	0.99	0.00	0.00	0.00	0.00	4.68	4510.50
48	10.29	0.00	0.00	0.00	0.00	0.00	10.29	9777.20
52	1.98	0.85	0.00	0.00	0.00	0.00	2.83	2728.00
53	1.57	0.00	0.00	0.00	0.00	0.00	1.57	1488.00
56	34.01	11.05	2.03	0.00	0.00	0.00	47.09	47756.50
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.71	0.16	0.00	0.00	0.00	0.00	1.87	1796.00
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
ANIMAL D & F	12.59	2.09	1.26	0.00	0.12	0.00	16.06	16046.80
68	1.62	0.05	0.00	0.00	0.00	0.00	1.67	1576.20
71	10.97	2.04	1.26	0.00	0.12	0.00	14.39	14470.60
DEVICES & RAD H	33.61	0.00	0.00	0.00	0.00	0.00	33.61	33216.50
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	74.00
82	20.39	0.00	0.00	0.00	0.00	0.00	20.39	19745.70
83	6.03	0.00	0.00	0.00	0.00	0.00	6.03	5720.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.75	0.00	0.00	0.00	0.00	0.00	2.75	3189.00
86	4.36	0.00	0.00	0.00	0.00	0.00	4.36	4487.60

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

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

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

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

REGION: SW REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	210.34	95.03	27.35	0.00	3.59	8.50	344.81	368728.50
FOOD SAFETY/COS	94.61	78.74	24.10	0.00	3.10	5.00	205.55	227602.60
03	65.66	7.98	23.48	0.00	1.40	0.00	98.52	105347.90
04	9.70	60.32	0.00	0.00	1.60	5.00	76.62	88209.70
07	2.03	4.52	0.00	0.00	0.10	0.00	6.65	7367.00
09	0.72	2.49	0.00	0.00	0.00	0.00	3.21	3624.80
18	12.30	0.00	0.06	0.00	0.00	0.00	12.36	14322.00
21	3.84	3.35	0.00	0.00	0.00	0.00	7.19	7607.50
29	0.36	0.08	0.56	0.00	0.00	0.00	1.00	1123.70
BIOLOGICS	19.99	0.00	0.00	0.00	0.00	0.00	19.99	19019.00
41	5.00	0.00	0.00	0.00	0.00	0.00	5.00	4748.50
42	13.70	0.00	0.00	0.00	0.00	0.00	13.70	13057.30
45	1.29	0.00	0.00	0.00	0.00	0.00	1.29	1213.20
HUMAN DRUGS	35.02	7.57	0.98	0.00	0.00	0.00	43.57	42517.70
46	2.23	1.26	0.44	0.00	0.00	0.00	3.93	3848.50
48	9.23	0.00	0.00	0.00	0.00	0.00	9.23	8768.50
52	1.86	0.62	0.00	0.00	0.00	0.00	2.48	2349.50
53	0.60	0.00	0.00	0.00	0.00	0.00	0.60	570.00
56	20.18	5.57	0.54	0.00	0.00	0.00	26.29	25975.20
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.92	0.12	0.00	0.00	0.00	0.00	1.04	1006.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	20.47	8.72	1.75	0.00	0.49	3.50	34.93	36516.70
68	3.18	0.18	0.00	0.00	0.00	0.00	3.36	3195.30
71	17.29	8.54	1.75	0.00	0.49	3.50	31.57	33321.40
DEVICES & RAD H	40.25	0.00	0.52	0.00	0.00	0.00	40.77	43072.50
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	68.40
82	25.98	0.00	0.52	0.00	0.00	0.00	26.50	28042.70
83	4.99	0.00	0.00	0.00	0.00	0.00	4.99	4731.70
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.88	0.00	0.00	0.00	0.00	0.00	2.88	3344.00
86	6.32	0.00	0.00	0.00	0.00	0.00	6.32	6885.70

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WORKPLAN SUMMARY / POSITION CLASS (SEPARATE LAB RESOURCES)
FY 2007

Output Reflects: OPR FTE'S

REGION: PA REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	299.18	60.39	52.90	0.00	5.85	6.50	424.82	444552.60
FOOD SAFETY/COS	171.02	45.44	51.48	0.00	5.61	6.00	279.55	300627.30
03	133.60	17.51	50.60	0.00	4.11	4.00	209.82	223901.10
04	8.49	24.07	0.00	0.00	1.50	0.00	34.06	38267.10
07	1.81	1.95	0.00	0.00	0.00	1.00	4.76	5198.00
09	0.56	1.71	0.00	0.00	0.00	0.00	2.27	2545.60
18	20.62	0.00	0.23	0.00	0.00	0.00	20.85	22847.00
21	5.20	0.00	0.00	0.00	0.00	1.00	6.20	6103.00
29	0.74	0.20	0.65	0.00	0.00	0.00	1.59	1765.50
BIOLOGICS	18.91	0.00	0.00	0.00	0.00	0.00	18.91	18150.50
41	5.46	0.00	0.00	0.00	0.00	0.00	5.46	5179.20
42	12.25	0.00	0.00	0.00	0.00	0.00	12.25	11844.50
45	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1126.80
HUMAN DRUGS	43.00	7.89	0.81	0.00	0.00	0.00	51.70	50746.60
46	2.00	1.10	0.00	0.00	0.00	0.00	3.10	2980.50
48	10.71	0.00	0.00	0.00	0.00	0.00	10.71	10171.70
52	2.11	0.51	0.00	0.00	0.00	0.00	2.62	2477.00
53	1.52	0.00	0.00	0.00	0.00	0.00	1.52	1440.00
56	24.13	5.82	0.81	0.00	0.00	0.00	30.76	30743.40
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.53	0.46	0.00	0.00	0.00	0.00	2.99	2934.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	17.65	3.44	0.61	0.00	0.24	0.50	22.44	22937.60
68	1.14	0.03	0.00	0.00	0.00	0.00	1.17	1113.40
71	16.51	3.41	0.61	0.00	0.24	0.50	21.27	21824.20
DEVICES & RAD H	48.60	3.62	0.00	0.00	0.00	0.00	52.22	52090.60
81	0.05	0.00	0.00	0.00	0.00	0.00	0.05	44.40
82	30.51	3.62	0.00	0.00	0.00	0.00	34.13	33817.90
83	9.70	0.00	0.00	0.00	0.00	0.00	9.70	9206.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.51	0.00	0.00	0.00	0.00	0.00	2.51	2916.00
86	5.83	0.00	0.00	0.00	0.00	0.00	5.83	6105.80

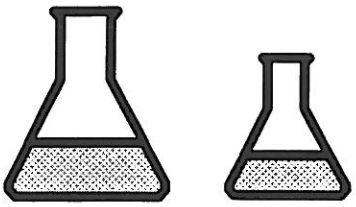
WORKPLAN SUMMARY / POSITION CLASS (SEPARATE LAB RESOURCES)
FY 2007

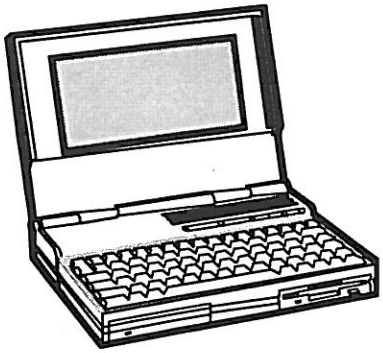
Output Reflects: OPR FTE'S

TOTAL FIELD

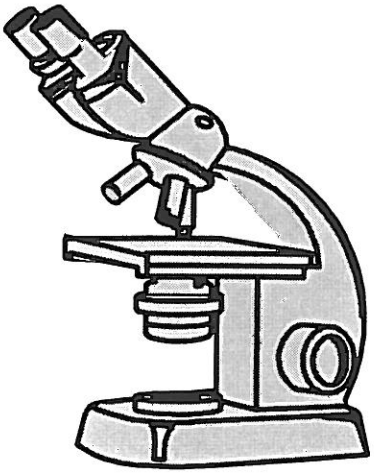
	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	METHODS VAL/DEV	TECH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	1318.55	322.93	159.58	11.13	16.99	19.00	1848.18	1933578.10
FOOD SAFETY/COS	625.05	213.35	146.22	0.00	14.02	14.00	1012.64	1095481.70
03	475.99	45.86	141.58	0.00	8.50	4.00	675.93	718117.50
04	34.83	127.23	0.00	0.00	5.02	5.00	172.08	195419.90
07	9.66	15.61	0.00	0.00	0.50	4.00	29.77	32896.00
09	2.90	8.76	0.00	0.00	0.00	0.00	11.66	13062.00
18	77.14	0.00	0.68	0.00	0.00	0.00	77.82	87826.00
21	20.99	14.92	0.89	0.00	0.00	1.00	37.80	39741.80
29	3.54	0.97	3.07	0.00	0.00	0.00	7.58	8418.50
BIOLOGICS	121.08	0.00	0.00	0.00	0.00	0.00	121.08	115721.10
41	26.92	0.00	0.00	0.00	0.00	0.00	26.92	25567.20
42	82.91	0.00	0.00	0.00	0.00	0.00	82.91	79492.70
45	11.25	0.00	0.00	0.00	0.00	0.00	11.25	10661.20
HUMAN DRUGS	264.19	84.59	5.33	0.00	0.00	0.00	354.11	354878.00
46	18.28	8.49	0.53	0.00	0.00	0.00	27.30	26652.00
48	52.07	0.00	0.00	0.00	0.00	0.00	52.07	49464.00
52	12.77	11.28	0.00	0.00	0.00	0.00	24.05	24469.00
53	9.00	0.00	0.00	0.00	0.00	0.00	9.00	8541.00
56	164.05	51.81	4.80	0.00	0.00	0.00	220.66	222820.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	8.02	1.01	0.00	0.00	0.00	0.00	9.03	8772.00
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	96.60	17.34	4.25	0.00	0.97	4.00	123.16	125406.30
68	10.41	0.30	0.00	0.00	0.00	0.00	10.71	10163.60
71	86.19	17.04	4.25	0.00	0.97	4.00	112.45	115242.70
DEVICES & RAD H	211.63	7.65	3.78	11.13	2.00	1.00	237.19	242091.00
81	0.46	0.03	0.02	0.03	0.00	0.00	0.54	509.30
82	132.04	7.62	3.08	3.52	2.00	0.00	148.26	149459.50
83	36.53	0.00	0.00	0.00	0.00	0.00	36.53	34680.00
84	0.00	0.00	0.68	3.04	0.00	1.00	4.72	5570.00
85	14.91	0.00	0.00	0.00	0.00	0.00	14.91	17322.00
86	27.69	0.00	0.00	4.54	0.00	0.00	32.23	34550.20

PART II
WORKPLAN SUMMARY





OPERATIONS



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REGION: NE REGN

FIELD	DOMESTIC INSPECTION		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 *
TOTAL	2617	82.54 *	137	70.99 *	1278	5.88 *	7584	17.55 *	734	0.82 *
FOOD SAFETY/COS	1493	27.90 *	137	46.14 *	869	3.84 *	6853	15.60 *	585	0.26 *
03	1227	24.44 *	137	42.91 *	211	1.12 *	4495	10.86 *	0	0.00 *
04	0	0.00 *	0	0.75 *	389	1.56 *	1416	3.10 *	10	0.01 *
07	0	0.00 *	0	0.00 *	168	0.71 *	359	0.76 *	0	0.00 *
09	0	0.00 *	0	0.39 *	0	0.00 *	392	0.58 *	0	0.00 *
18	221	2.44 *	0	0.25 *	14	0.05 *	0	0.00 *	0	0.00 *
21	32	0.80 *	0	1.19 *	80	0.36 *	62	0.10 *	575	0.25 *
29	13	0.22 *	0	0.65 *	7	0.04 *	129	0.20 *	0	0.00 *
BIOLOGICS	204	10.35 *	0	0.73 *	0	0.00 *	0	0.00 *	0	0.00 *
41	62	3.13 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	137	6.77 *	0	0.67 *	0	0.00 *	0	0.00 *	0	0.00 *
45	5	0.45 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	371	24.15 *	0	11.85 *	256	1.19 *	63	0.19 *	0	0.00 *
46	15	0.89 *	0	0.00 *	4	0.03 *	0	0.00 *	0	0.00 *
48	62	5.14 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	21	1.27 *	0	0.45 *	26	0.14 *	19	0.06 *	0	0.00 *
53	23	1.38 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	239	15.12 *	0	10.77 *	197	0.88 *	44	0.13 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	11	0.35 *	0	0.63 *	29	0.14 *	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	198	3.87 *	0	6.49 *	136	0.73 *	478	1.26 *	0	0.00 *
68	9	0.51 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	189	3.36 *	0	6.49 *	136	0.73 *	478	1.26 *	0	0.00 *
DEVICES & RAD H	351	16.27 *	0	5.78 *	17	0.12 *	190	0.50 *	149	0.56 *
81	3	0.05 *	0	0.02 *	3	0.03 *	0	0.00 *	0	0.00 *
82	209	11.52 *	0	3.77 *	13	0.09 *	190	0.50 *	0	0.00 *
83	61	3.96 *	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	58	0.41 *	0	0.87 *	0	0.00 *	0	0.00 *	0	0.00 *
86	20	0.33 *	0	1.12 *	1	0.00 *	0	0.00 *	149	0.56 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2007

REGION: NE REGN

FIELD	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 *
TOTAL	0	1.16 *	1267	28.09 *	8697	73.43 *	551	26.78 *	139	8.15 *
FOOD SAFETY/COS	0	1.16 *	787	12.31 *	7373	60.15 *	550	16.06 *	9	0.29 *
03	0	1.16 *	289	6.72 *	5003	40.69 *	0	5.36 *	9	0.29 *
04	0	0.00 *	272	4.33 *	1502	12.75 *	0	0.67 *	0	0.00 *
07	0	0.00 *	205	1.04 *	302	1.79 *	0	0.20 *	0	0.00 *
09	0	0.00 *	0	0.00 *	435	3.24 *	0	0.00 *	0	0.00 *
18	0	0.00 *	14	0.10 *	0	0.00 *	210	9.36 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	340	0.47 *	0	0.00 *
29	0	0.00 *	7	0.12 *	131	1.68 *	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 *	221	9.71 *	177	4.02 *	1	0.81 *	63	3.90 *
46	0	0.00 *	9	1.61 *	0	0.00 *	1	0.09 *	24	1.46 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	5	0.34 *
52	0	0.00 *	30	2.14 *	155	3.31 *	0	0.00 *	5	0.26 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	2	0.13 *
56	0	0.00 *	178	5.89 *	22	0.71 *	0	0.72 *	27	1.71 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	4	0.07 *	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 *	96	0.83 *	363	1.89 *	0	0.39 *	7	0.50 *
68	0	0.00 *	0	0.04 *	0	0.00 *	0	0.00 *	6	0.46 *
71	0	0.00 *	96	0.79 *	363	1.89 *	0	0.39 *	1	0.04 *
DEVICES & RAD H	0	0.00 *	163	5.24 *	784	7.37 *	0	9.52 *	60	3.46 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	53	2.08 *	784	7.37 *	0	2.34 *	27	1.85 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.53 *
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	0.75 *	5	0.03 *
86	0	0.00 *	107	3.08 *	0	0.00 *	0	1.71 *	19	1.05 *

REGION: NE REGN

	TOTALS	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	315.39	335574.70
FOOD SAFETY/COS	183.71	198847.60
03	133.55	142728.40
04	23.17	26094.00
07	4.50	4974.00
09	4.21	4736.80
18	12.20	13938.50
21	3.17	3021.10
29	2.91	3354.80
BIOLOGICS	11.08	10673.50
41	3.13	2970.80
42	7.44	7210.70
45	0.51	492.00
HUMAN DRUGS	55.82	56341.50
46	4.08	3962.00
48	5.48	5202.20
52	7.63	8268.50
53	1.51	1431.00
56	35.93	36345.80
58	0.00	0.00
61	0.00	0.00
63	1.19	1132.00
88	0.00	0.00
ANIMAL D & F	15.96	16977.50
68	1.01	951.80
71	14.95	16025.70
DEVICES & RAD H	48.82	52734.60
81	0.18	186.90
82	29.52	31470.40
83	4.49	4262.40
84	4.72	5570.00
85	2.06	2400.00
86	7.85	8844.90

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REGION: CE REGN

	DOMESTIC INSPECTION		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	6748	203.06 *	124	64.09 *	4026	18.27 *	3615	8.46 *	2034	2.51 *
FOOD SAFETY/COS	2678	50.95 *	124	37.65 *	2429	10.48 *	3050	6.95 *	1515	0.66 *
03	2212	44.03 *	124	34.81 *	598	2.89 *	1834	4.37 *	0	0.00 *
04	0	0.00 *	0	0.51 *	964	3.81 *	733	1.68 *	0	0.00 *
07	0	0.00 *	0	0.00 *	605	2.54 *	216	0.46 *	0	0.00 *
09	0	0.00 *	0	0.17 *	0	0.00 *	197	0.29 *	0	0.00 *
18	327	3.60 *	0	0.40 *	21	0.08 *	0	0.00 *	0	0.00 *
21	106	2.78 *	0	1.66 *	220	1.04 *	46	0.11 *	1515	0.66 *
29	33	0.54 *	0	0.10 *	21	0.12 *	24	0.04 *	0	0.00 *
BIOLOGICS	634	32.01 *	0	1.60 *	0	0.00 *	0	0.00 *	0	0.00 *
41	173	8.51 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	441	21.69 *	0	1.39 *	0	0.00 *	0	0.00 *	0	0.00 *
45	20	1.81 *	0	0.21 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	960	63.30 *	0	11.61 *	757	3.47 *	73	0.22 *	0	0.00 *
46	55	3.23 *	0	0.00 *	15	0.08 *	0	0.00 *	0	0.00 *
48	170	14.52 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	38	2.29 *	0	0.95 *	49	0.27 *	50	0.15 *	0	0.00 *
53	56	3.36 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	619	39.20 *	0	9.84 *	644	2.88 *	23	0.07 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	22	0.70 *	0	0.82 *	49	0.24 *	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	1735	18.89 *	0	5.83 *	819	4.16 *	291	0.75 *	0	0.00 *
68	46	2.52 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	1689	16.37 *	0	5.83 *	819	4.16 *	291	0.75 *	0	0.00 *
DEVICES & RAD H	741	37.91 *	0	7.40 *	21	0.16 *	201	0.54 *	519	1.85 *
81	7	0.11 *	0	0.03 *	0	0.00 *	0	0.00 *	0	0.00 *
82	459	26.43 *	0	2.82 *	20	0.16 *	201	0.54 *	0	0.00 *
83	149	10.16 *	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	93	0.65 *	0	2.24 *	0	0.00 *	0	0.00 *	0	0.00 *
86	33	0.56 *	0	2.31 *	1	0.00 *	0	0.00 *	519	1.85 *

REGION: CE REGN

FIELD	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 *
TOTAL	0	0.51 *	541	51.51 *	133	1.50 *	531	31.11 *	275	16.11 *
FOOD SAFETY/COS	0	0.51 *	0	11.56 *	122	1.15 *	531	20.69 *	27	0.88 *
03	0	0.51 *	0	0.56 *	0	0.24 *	0	5.51 *	27	0.88 *
04	0	0.00 *	0	11.00 *	0	0.00 *	0	1.75 *	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 *	117	0.87 *	0	0.00 *	0	0.00 *
18	0	0.00 *	0	0.00 *	0	0.00 *	362	13.18 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	169	0.25 *	0	0.00 *
29	0	0.00 *	0	0.00 *	5	0.04 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	3	0.13 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	3	0.13 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	0	0.00 *	541	38.65 *	11	0.35 *	0	1.06 *	147	9.01 *
46	0	0.00 *	31	3.53 *	0	0.00 *	0	0.00 *	66	4.01 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.67 *
52	0	0.00 *	68	3.85 *	0	0.00 *	0	0.00 *	14	0.72 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.19 *
56	0	0.00 *	430	22.07 *	11	0.35 *	0	1.06 *	54	3.42 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	12	0.20 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	9.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	0	1.00 *	0	0.00 *	0	1.94 *	18	1.19 *
68	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	13	0.99 *
71	0	0.00 *	0	1.00 *	0	0.00 *	0	1.94 *	5	0.20 *
DEVICES & RAD H	0	0.00 *	0	0.30 *	0	0.00 *	0	4.92 *	80	4.90 *
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 *	54	3.70 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	21	1.17 *
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	1.77 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	3.15 *	0	0.00 *

REGION: CE REGN

	TOTALS	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	397.13	399007.50
FOOD SAFETY/COS	141.48	144219.30
03	93.80	92129.50
04	18.75	21047.20
07	3.00	2852.00
09	1.33	1486.80
18	17.26	19699.50
21	6.50	6150.00
29	0.84	854.30
BIOLOGICS	36.24	34628.40
41	8.51	8089.30
42	25.71	24601.10
45	2.02	1938.00
HUMAN DRUGS	127.67	129859.30
46	10.85	10718.00
48	15.19	14455.20
52	8.23	8446.00
53	3.55	3372.00
56	78.89	80344.10
58	0.00	0.00
61	0.00	0.00
63	1.96	1904.00
88	9.00	10620.00
ANIMAL D & F	33.76	32927.70
68	3.51	3326.90
71	30.25	29600.80
DEVICES & RAD H	57.98	57372.80
81	0.14	135.60
82	33.95	32778.80
83	11.33	10759.20
84	0.00	0.00
85	4.69	5473.00
86	7.87	8226.20

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WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2007

REGION: SE REGN

FIELD	DOMESTIC INSPECTION		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 *
TOTAL	3187	108.91 *	84	49.99 *	2114	9.48 *	3628	9.26 *	1080	1.48 *
FOOD SAFETY/COS	1496	27.76 *	84	29.63 *	1411	6.13 *	3251	8.27 *	738	0.32 *
03	1107	22.94 *	84	28.19 *	308	1.45 *	2284	5.92 *	0	0.00 *
04	0	0.00 *	0	0.26 *	704	2.94 *	786	2.02 *	0	0.00 *
07	0	0.00 *	0	0.00 *	275	1.16 *	93	0.20 *	0	0.00 *
09	0	0.00 *	0	0.06 *	0	0.00 *	60	0.09 *	0	0.00 *
18	336	3.71 *	0	0.40 *	22	0.09 *	0	0.00 *	0	0.00 *
21	33	0.78 *	0	0.64 *	91	0.42 *	13	0.02 *	738	0.32 *
29	20	0.33 *	0	0.08 *	11	0.07 *	15	0.02 *	0	0.00 *
BIOLOGICS	411	20.41 *	0	1.26 *	0	0.00 *	0	0.00 *	0	0.00 *
41	104	4.82 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	291	14.13 *	0	1.14 *	0	0.00 *	0	0.00 *	0	0.00 *
45	16	1.46 *	0	0.12 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	523	34.27 *	0	11.21 *	387	1.77 *	68	0.20 *	0	0.00 *
46	18	1.07 *	0	0.00 *	5	0.03 *	0	0.00 *	0	0.00 *
48	112	9.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	14	0.84 *	0	0.44 *	19	0.11 *	33	0.10 *	0	0.00 *
53	24	1.44 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	336	20.51 *	0	9.90 *	316	1.41 *	35	0.10 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	19	0.60 *	0	0.87 *	47	0.22 *	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	358	5.75 *	0	3.31 *	303	1.50 *	16	0.04 *	0	0.00 *
68	18	0.93 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	340	4.82 *	0	3.31 *	303	1.50 *	16	0.04 *	0	0.00 *
DEVICES & RAD H	399	20.72 *	0	4.58 *	13	0.08 *	293	0.75 *	342	1.16 *
81	5	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	253	14.74 *	0	2.21 *	12	0.08 *	293	0.75 *	0	0.00 *
83	78	5.29 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	44	0.31 *	0	1.26 *	0	0.00 *	0	0.00 *	0	0.00 *
86	19	0.30 *	0	1.11 *	1	0.00 *	0	0.00 *	342	1.16 *

REGION: SE REGN

	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	0.26 *	3718	50.87 *	4925	42.71 *	230	23.20 *	186	10.72 *
FOOD SAFETY/COS	0	0.26 *	2864	30.98 *	4849	41.89 *	230	18.17 *	23	0.74 *
03	0	0.26 *	668	12.54 *	3317	26.36 *	0	3.81 *	23	0.74 *
04	0	0.00 *	880	4.78 *	964	8.98 *	0	0.50 *	0	0.00 *
07	0	0.00 *	926	4.71 *	269	1.60 *	0	3.20 *	0	0.00 *
09	0	0.00 *	0	0.00 *	60	0.45 *	0	0.00 *	0	0.00 *
18	0	0.00 *	43	0.29 *	0	0.00 *	166	10.58 *	0	0.00 *
21	0	0.00 *	324	8.26 *	218	4.20 *	64	0.08 *	0	0.00 *
29	0	0.00 *	23	0.40 *	21	0.30 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.13 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.13 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	0	0.00 *	476	16.82 *	17	0.54 *	0	0.71 *	94	5.75 *
46	0	0.00 *	3	0.99 *	0	0.00 *	0	0.00 *	43	2.60 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	7	0.47 *
52	0	0.00 *	2	0.85 *	0	0.00 *	0	0.00 *	9	0.46 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	2	0.13 *
56	0	0.00 *	462	11.82 *	17	0.54 *	0	0.71 *	33	2.09 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	9	0.16 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	3.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	378	3.07 *	59	0.28 *	0	1.39 *	10	0.73 *
68	0	0.00 *	0	0.05 *	0	0.00 *	0	0.00 *	9	0.69 *
71	0	0.00 *	378	3.02 *	59	0.28 *	0	1.39 *	1	0.04 *
DEVICES & RAD H	0	0.00 *	0	0.00 *	0	0.00 *	0	2.93 *	56	3.37 *
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 *	38	2.60 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	13	0.74 *
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	1.14 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.79 *	0	0.00 *

REGION: SE REGN

TOTALS

	OPR FTE'S	PERSNHRS
FIELD TOTAL	306.88	320956.10
FOOD SAFETY/COS	164.15	179216.90
03	102.21	109042.60
04	19.48	21801.90
07	10.87	12505.00
09	0.60	668.00
18	15.07	17019.00
21	14.72	16860.20
29	1.20	1320.20
BIOLOGICS	21.80	20879.70
41	4.82	4579.40
42	15.40	14797.90
45	1.58	1502.40
HUMAN DRUGS	71.27	71596.20
46	4.69	4510.50
48	10.28	9777.20
52	2.80	2728.00
53	1.57	1488.00
56	47.08	47756.50
58	0.00	0.00
61	0.00	0.00
63	1.85	1796.00
88	3.00	3540.00
ANIMAL D & F	16.07	16046.80
68	1.67	1576.20
71	14.40	14470.60
DEVICES & RAD H	33.59	33216.50
81	0.08	74.00
82	20.38	19745.70
83	6.03	5720.20
84	0.00	0.00
85	2.74	3189.00
86	4.36	4487.60

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REGION: SW REGN

	DOMESTIC INSPECTION		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	3323	90.29 *	48	68.83 *	2060	9.25 *	7403	15.10 *	1057	1.40 *
FOOD SAFETY/COS	900	17.07 *	48	42.89 *	1254	5.30 *	7135	14.41 *	736	0.32 *
03	691	13.75 *	48	40.72 *	167	0.86 *	2635	6.32 *	0	0.00 *
04	0	0.00 *	0	0.28 *	606	2.36 *	3907	7.06 *	7	0.00 *
07	0	0.00 *	0	0.00 *	357	1.51 *	245	0.52 *	0	0.00 *
09	0	0.00 *	0	0.29 *	0	0.00 *	297	0.44 *	0	0.00 *
18	142	1.78 *	0	0.14 *	9	0.04 *	0	0.00 *	0	0.00 *
21	54	1.32 *	0	1.38 *	107	0.49 *	36	0.05 *	729	0.32 *
29	13	0.22 *	0	0.08 *	8	0.04 *	15	0.02 *	0	0.00 *
BIOLOGICS	381	19.04 *	0	0.80 *	0	0.00 *	0	0.00 *	0	0.00 *
41	107	5.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	261	12.86 *	0	0.71 *	0	0.00 *	0	0.00 *	0	0.00 *
45	13	1.18 *	0	0.09 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	395	26.55 *	0	3.84 *	270	1.25 *	25	0.08 *	0	0.00 *
46	12	0.72 *	0	0.00 *	3	0.03 *	0	0.00 *	0	0.00 *
48	100	8.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	17	1.03 *	0	0.39 *	21	0.11 *	19	0.06 *	0	0.00 *
53	10	0.60 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	246	15.07 *	0	2.97 *	221	0.99 *	6	0.02 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	10	0.32 *	0	0.48 *	25	0.12 *	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	1254	12.07 *	0	3.12 *	528	2.64 *	54	0.14 *	0	0.00 *
68	37	2.04 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	1217	10.03 *	0	3.12 *	528	2.64 *	54	0.14 *	0	0.00 *
DEVICES & RAD H	393	15.56 *	0	18.18 *	8	0.06 *	189	0.47 *	321	1.08 *
81	3	0.05 *	0	0.03 *	0	0.00 *	0	0.00 *	0	0.00 *
82	168	9.79 *	0	14.01 *	7	0.06 *	189	0.47 *	0	0.00 *
83	62	4.42 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	143	1.00 *	0	0.92 *	0	0.00 *	0	0.00 *	0	0.00 *
86	17	0.30 *	0	3.22 *	1	0.00 *	0	0.00 *	321	1.08 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2007

REGION: SW REGN

FIELD	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 *
TOTAL	0	0.32 *	6075	71.47 *	6058	49.20 *	408	31.58 *	124	7.42 *
FOOD SAFETY/COS	0	0.32 *	4989	54.41 *	5757	47.67 *	403	22.68 *	17	0.54 *
03	0	0.32 *	399	8.79 *	2457	21.90 *	0	5.35 *	17	0.54 *
04	0	0.00 *	3064	39.57 *	2574	20.75 *	0	6.60 *	0	0.00 *
07	0	0.00 *	460	2.34 *	367	2.18 *	0	0.10 *	0	0.00 *
09	0	0.00 *	0	0.00 *	334	2.49 *	0	0.00 *	0	0.00 *
18	0	0.00 *	9	0.06 *	0	0.00 *	187	10.35 *	0	0.00 *
21	0	0.00 *	1040	3.35 *	0	0.00 *	216	0.28 *	0	0.00 *
29	0	0.00 *	17	0.30 *	25	0.35 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.13 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.13 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	0	0.00 *	179	7.81 *	3	0.10 *	5	0.64 *	54	3.32 *
46	0	0.00 *	0	1.26 *	0	0.00 *	5	0.44 *	25	1.51 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.41 *
52	0	0.00 *	0	0.62 *	0	0.00 *	0	0.00 *	5	0.26 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	0	0.00 *	172	5.81 *	3	0.10 *	0	0.20 *	18	1.14 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	7	0.12 *	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 *	897	8.73 *	298	1.43 *	0	5.59 *	17	1.23 *
68	0	0.00 *	0	0.18 *	0	0.00 *	0	0.00 *	15	1.15 *
71	0	0.00 *	897	8.55 *	298	1.43 *	0	5.59 *	2	0.08 *
DEVICES & RAD H	0	0.00 *	10	0.52 *	0	0.00 *	0	2.67 *	33	2.20 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	10	0.52 *	0	0.00 *	0	0.00 *	24	1.64 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.56 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.96 *	0	0.00 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.71 *	0	0.00 *

REGION: SW REGN

	TOTALS	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	344.86	368728.50
FOOD SAFETY/COS	205.61	227602.60
03	98.55	105347.90
04	76.62	88209.70
07	6.65	7367.00
09	3.22	3624.80
18	12.37	14322.00
21	7.19	7607.50
29	1.01	1123.70
BIOLOGICS	19.97	19019.00
41	5.00	4748.50
42	13.70	13057.30
45	1.27	1213.20
HUMAN DRUGS	43.59	42517.70
46	3.96	3848.50
48	9.22	8768.50
52	2.47	2349.50
53	0.60	570.00
56	26.30	25975.20
58	0.00	0.00
61	0.00	0.00
63	1.04	1006.00
88	0.00	0.00
ANIMAL D & F	34.95	36516.70
68	3.37	3195.30
71	31.58	33321.40
DEVICES & RAD H	40.74	43072.50
81	0.08	68.40
82	26.49	28042.70
83	4.98	4731.70
84	0.00	0.00
85	2.88	3344.00
86	6.31	6885.70

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REGION: PA REGN

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
FIELD	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	4832	140.01 *	207	94.57 *	3048	12.80 *	7926	19.48 *	1625	1.62 *
FOOD SAFETY/COS	2707	51.12 *	207	73.19 *	2373	9.38 *	7192	17.51 *	1351	0.60 *
03	2093	42.12 *	207	69.86 *	532	2.42 *	5452	13.54 *	0	0.00 *
04	0	0.00 *	0	0.84 *	1323	4.70 *	1152	2.94 *	8	0.01 *
07	0	0.00 *	0	0.00 *	305	1.30 *	251	0.53 *	0	0.00 *
09	0	0.00 *	0	0.23 *	0	0.00 *	229	0.34 *	0	0.00 *
18	524	7.01 *	0	0.45 *	34	0.14 *	0	0.00 *	0	0.00 *
21	69	1.65 *	0	1.57 *	166	0.74 *	61	0.09 *	1343	0.59 *
29	21	0.34 *	0	0.24 *	13	0.08 *	47	0.07 *	0	0.00 *
BIOLOGICS	351	17.70 *	0	1.20 *	0	0.00 *	0	0.00 *	0	0.00 *
41	114	5.46 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	225	11.15 *	0	1.11 *	0	0.00 *	0	0.00 *	0	0.00 *
45	12	1.09 *	0	0.09 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	417	28.44 *	0	8.95 *	277	1.27 *	31	0.10 *	0	0.00 *
46	12	0.71 *	0	0.00 *	3	0.02 *	0	0.00 *	0	0.00 *
48	112	10.01 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	20	1.21 *	0	0.43 *	25	0.14 *	19	0.06 *	0	0.00 *
53	20	1.20 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	236	14.76 *	0	6.81 *	186	0.84 *	12	0.04 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	17	0.55 *	0	1.71 *	63	0.27 *	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	726	9.75 *	0	4.53 *	377	2.00 *	236	0.63 *	0	0.00 *
68	15	0.83 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	711	8.92 *	0	4.53 *	377	2.00 *	236	0.63 *	0	0.00 *
DEVICES & RAD H	631	33.00 *	0	6.70 *	21	0.15 *	467	1.24 *	274	1.02 *
81	3	0.05 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	404	23.08 *	0	3.17 *	20	0.15 *	467	1.24 *	0	0.00 *
83	134	8.77 *	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	0.33 *	0	1.30 *	0	0.00 *	0	0.00 *	0	0.00 *
86	44	0.77 *	0	2.23 *	1	0.00 *	0	0.00 *	274	1.02 *

REGION: PA REGN

	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	1.12 *	2409	31.37 *	11588	80.65 *	564	34.15 *	153	9.06 *
FOOD SAFETY/COS	0	1.12 *	1885	22.09 *	10610	73.86 *	564	30.00 *	21	0.67 *
03	0	1.12 *	640	15.74 *	7128	51.40 *	0	12.94 *	21	0.67 *
04	0	0.00 *	1079	5.29 *	2979	18.79 *	0	1.50 *	0	0.00 *
07	0	0.00 *	119	0.60 *	226	1.34 *	0	1.00 *	0	0.00 *
09	0	0.00 *	0	0.00 *	229	1.71 *	0	0.00 *	0	0.00 *
18	0	0.00 *	34	0.23 *	0	0.00 *	208	13.03 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	356	1.53 *	0	0.00 *
29	0	0.00 *	13	0.23 *	48	0.62 *	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 *	170	6.90 *	67	1.50 *	0	0.30 *	68	4.24 *
46	0	0.00 *	2	1.10 *	0	0.00 *	0	0.00 *	21	1.27 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.68 *
52	0	0.00 *	0	0.51 *	0	0.00 *	0	0.00 *	5	0.26 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	5	0.32 *
56	0	0.00 *	141	4.83 *	67	1.50 *	0	0.30 *	27	1.71 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	27	0.46 *	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 *	354	2.38 *	355	1.67 *	0	1.14 *	5	0.34 *
68	0	0.00 *	0	0.03 *	0	0.00 *	0	0.00 *	4	0.30 *
71	0	0.00 *	354	2.35 *	355	1.67 *	0	1.14 *	1	0.04 *
DEVICES & RAD H	0	0.00 *	0	0.00 *	556	3.62 *	0	2.71 *	59	3.81 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	0	0.00 *	556	3.62 *	0	0.00 *	42	2.88 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	17	0.93 *
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	0.89 *	0	0.00 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.82 *	0	0.00 *

REGION: PA REGN

	TOTALS	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	424.83	444552.60
FOOD SAFETY/COS	279.54	300627.30
03	209.81	223901.10
04	34.07	38267.10
07	4.77	5198.00
09	2.28	2545.60
18	20.86	22847.00
21	6.17	6103.00
29	1.58	1765.50
BIOLOGICS	18.90	18150.50
41	5.46	5179.20
42	12.26	11844.50
45	1.18	1126.80
HUMAN DRUGS	51.70	50746.60
46	3.10	2980.50
48	10.69	10171.70
52	2.61	2477.00
53	1.52	1440.00
56	30.79	30743.40
58	0.00	0.00
61	0.00	0.00
63	2.99	2934.00
88	0.00	0.00
ANIMAL D & F	22.44	22937.60
68	1.16	1113.40
71	21.28	21824.20
DEVICES & RAD H	52.25	52090.60
81	0.05	44.40
82	34.14	33817.90
83	9.70	9206.50
84	0.00	0.00
85	2.52	2916.00
86	5.84	6105.80

TOTAL FIELD

	DOMESTIC INSPECTION		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	20744	633.14 *	600	391.84 *	12526	55.68 *	30156	69.85 *	6530	7.83 *
FOOD SAFETY/COS	9274	174.80 *	600	267.50 *	8336	35.13 *	27481	62.74 *	4925	2.16 *
03	7330	147.28 *	600	254.49 *	1816	8.74 *	16700	41.01 *	0	0.00 *
04	0	0.00 *	0	2.64 *	3986	15.37 *	7994	16.80 *	25	0.02 *
07	0	0.00 *	0	0.00 *	1710	7.22 *	1164	2.47 *	0	0.00 *
09	0	0.00 *	0	1.14 *	0	0.00 *	1175	1.74 *	0	0.00 *
18	1550	18.54 *	0	1.64 *	100	0.40 *	0	0.00 *	0	0.00 *
21	294	7.33 *	0	6.44 *	664	3.05 *	218	0.37 *	4900	2.14 *
29	100	1.65 *	0	1.15 *	60	0.35 *	230	0.35 *	0	0.00 *
BIOLOGICS	2018	106.29 *	0	8.19 *	0	0.00 *	0	0.00 *	0	0.00 *
41	560	26.92 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	1377	69.92 *	0	7.62 *	0	0.00 *	0	0.00 *	0	0.00 *
45	81	9.45 *	0	0.57 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	2666	178.26 *	0	47.46 *	1947	8.95 *	260	0.79 *	0	0.00 *
46	112	6.62 *	0	0.00 *	30	0.19 *	0	0.00 *	0	0.00 *
48	556	49.04 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	110	6.64 *	0	2.66 *	140	0.77 *	140	0.43 *	0	0.00 *
53	133	7.98 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	1676	105.46 *	0	40.29 *	1564	7.00 *	120	0.36 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	79	2.52 *	0	4.51 *	213	0.99 *	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	4271	50.33 *	0	23.28 *	2163	11.03 *	1075	2.82 *	0	0.00 *
68	125	6.83 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	4146	43.50 *	0	23.28 *	2163	11.03 *	1075	2.82 *	0	0.00 *
DEVICES & RAD H	2515	123.46 *	0	45.41 *	80	0.57 *	1340	3.50 *	1605	5.67 *
81	21	0.34 *	0	0.08 *	3	0.03 *	0	0.00 *	0	0.00 *
82	1493	85.56 *	0	28.75 *	72	0.54 *	1340	3.50 *	0	0.00 *
83	484	32.60 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	384	2.70 *	0	6.59 *	0	0.00 *	0	0.00 *	0	0.00 *
86	133	2.26 *	0	9.99 *	5	0.00 *	0	0.00 *	1605	5.67 *

TOTAL FIELD

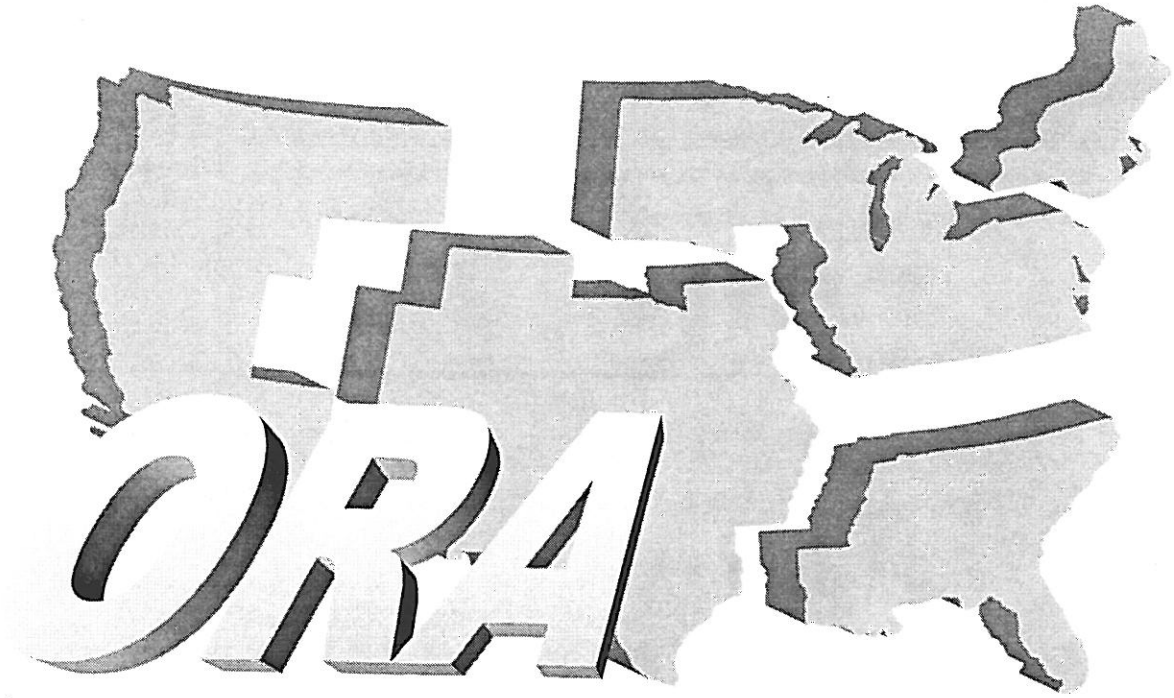
FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	3.37 *	14010	233.31 *	31401	247.49 *	2284	146.85 *	957	58.71 *
FOOD SAFETY/COS	0	3.37 *	10525	131.35 *	28711	224.72 *	2278	107.63 *	100	3.22 *
03	0	3.37 *	1996	44.35 *	17905	140.59 *	0	33.00 *	100	3.22 *
04	0	0.00 *	5295	64.97 *	8019	61.27 *	0	11.02 *	0	0.00 *
07	0	0.00 *	1710	8.69 *	1164	6.91 *	0	4.50 *	0	0.00 *
09	0	0.00 *	0	0.00 *	1175	8.76 *	0	0.00 *	0	0.00 *
18	0	0.00 *	100	0.68 *	0	0.00 *	1133	56.50 *	0	0.00 *
21	0	0.00 *	1364	11.61 *	218	4.20 *	1145	2.61 *	0	0.00 *
29	0	0.00 *	60	1.05 *	230	2.99 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	31	4.03 *
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 *	23	2.87 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	8	1.16 *
HUMAN DRUGS	0	0.00 *	1587	79.89 *	275	6.51 *	6	3.52 *	466	28.70 *
46	0	0.00 *	45	8.49 *	0	0.00 *	6	0.53 *	190	11.52 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	44	2.97 *
52	0	0.00 *	100	7.97 *	155	3.31 *	0	0.00 *	42	2.17 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	16	1.02 *
56	0	0.00 *	1383	50.42 *	120	3.20 *	0	2.99 *	174	11.02 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	59	1.01 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	12.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	1725	16.01 *	1075	5.27 *	0	10.45 *	57	3.99 *
68	0	0.00 *	0	0.30 *	0	0.00 *	0	0.00 *	47	3.59 *
71	0	0.00 *	1725	15.71 *	1075	5.27 *	0	10.45 *	10	0.40 *
DEVICES & RAD H	0	0.00 *	173	6.06 *	1340	10.99 *	0	22.75 *	303	18.77 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	63	2.90 *	1340	10.99 *	0	2.34 *	200	13.70 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	69	3.93 *
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	5.51 *	15	0.09 *
86	0	0.00 *	107	3.08 *	0	0.00 *	0	10.18 *	19	1.05 *

TOTAL FIELD

FIELD	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	1848.07	1933578.10
FOOD SAFETY/COS	1012.62	1095481.70
03	676.05	718117.50
04	172.09	195419.90
07	29.79	32896.00
09	11.64	13062.00
18	77.76	87826.00
21	37.75	39741.80
29	7.54	8418.50
BIOLOGICS	121.01	115721.10
41	26.92	25567.20
42	82.91	79492.70
45	11.18	10661.20
HUMAN DRUGS	354.08	354878.00
46	27.35	26652.00
48	52.01	49464.00
52	23.95	24469.00
53	9.00	8541.00
56	220.74	222820.00
58	0.00	0.00
61	0.00	0.00
63	9.03	8772.00
88	12.00	14160.00
ANIMAL D & F	123.18	125406.30
68	10.72	10163.60
71	112.46	115242.70
DEVICES & RAD H	237.18	242091.00
81	0.53	509.30
82	148.28	149459.50
83	36.53	34680.00
84	4.72	5570.00
85	14.89	17322.00
86	32.23	34550.20

FY 2007

PART III - PROGRAM FORECASTS



DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE MANAGEMENT BRANCH

ORA/ORM/DPEM

PART III
RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2007

	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
	DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
TOTAL ALL PROGRAMS	1146.2	628.0	74.0	1848.2	1969.3	1102.5	128.2	3200.0
FOOD AND COSMETICS	488.2	520.7	4.2	1013.1	829.8	916.9	7.3	1754.0
BIOLOGICS	113.9	3.0	4.1	121.0	196.6	5.2	7.2	209.0
HUMAN DRUGS	276.5	34.5	43.0	354.0	478.9	59.6	74.5	613.0
ANIMAL DRUGS AND FEEDS	97.3	21.8	4.0	123.1	168.4	37.7	6.9	213.0
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	170.3	48.0	18.7	237.0	295.6	83.1	32.3	411.0

"Operational FTEs" are those FTEs specifically planned in the Workplan.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2007

October 1, 2006

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	488.2	520.7	4.2	1013.1	829.8	916.9	7.3	1754.0
03	FOODBORNE BIOLOGICAL HAZARDS	265.8	406.0	4.2	676.0	447.3	716.2	7.3	1170.8
04	PESTICIDES AND CHEMICAL CONTAMINANTS	92.5	79.6		172.1	158.0	140.1		298.1
07	MOLECULAR BIOLOGY AND NATURAL TOXINS	20.4	9.4		29.8	35.3	16.3		51.6
09	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		11.6		11.6		20.1		20.1
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	77.8			77.8	134.7			134.7
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	28.6	9.6		38.2	49.1	16.4		65.5
29	COLOR AND COSMETICS TECHNOLOGY	3.1	4.5		7.6	5.4	7.8		13.2

"Operational FTE's" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs."

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

PROJECT SUMMARY SHEET October 1, 2006
FY 2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Foods and Cosmetics	Foodborne Biological Hazards - 03

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		**265.8**	**406.0**	**4.2**	**676.0**	**1170.8**	
1	Import Acidified and Low Acid Canned Foods	03003,A,		14.8		14.8	25.6	2-3
2	Domestic and Imported Cheese & Cheese Products	03037,D	11.3	11.4		22.7	39.3	4-5
3	Domestic Acidified and Low Acid Canned Food	03803A	14.7			14.7	25.5	6-7
4	Domestic Food Safety	03803,B	96.1			96.1	166.4	8-9
5	Import Foods - General	03819A,B		277.1		277.1	480.0	10-11
6	Domestic Fish and Fishery Products Inspection	03842,B	69.7			69.7	120.7	12-13
7	Import Seafood Products	03844,B		80.3		80.3	139.1	14-15
8	Juice HACCP Inspection Program	03847H	10.0			10.0	17.3	16-17
9	Import & Domestic Micro Assignment	03F098	10.9	11.0		21.9	37.9	18-19
10	Foreign Inspections/Assessments	03R233			4.2	4.2	7.3	20-21
11	Methods Validation/Development Program	03R816	12.5			12.5	21.7	22-23
12	Contract Management	03R843	14.0			14.0	24.2	24-25
13	Food Defense	03R845	26.6	11.4		38.0	65.8	26-27

NTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
nald R. Roy 301-436-2061	Stephen F. Burt 301-827-1633

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Acidified and Low-Acid Canned Foods, CP 7303.003, FY 07	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

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. As in FY 06, the number of planned hours for Import Field Exams will remain at 3200 and the number of Import Sample Collections will remain at 1400.

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: 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 530.04 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)	d. INDUSTRY/PRODUCT CODE (S)
Refer to Compliance Program (7303.003)	03-04, 09, 12-18, 20-25, 27, 29, 30-31, 33-41

e. EXAM TYPE: [X] CHEMICAL [X] 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	2. PPS PROJECT NAME/NUMBER
Import Acidified and Low Acid Canned Foods	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03003, 03003A	[X] ORA [X] CENTER	14.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		2 IMPORT FIELD EXAMS (Hours) *	4 IMPORT SAMPLE COLLECTION	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 **
	TOTAL FIELD		3200	1400	1230	170		1230		170
	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									
	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		3200	2520				8610		1700
	CONVERSION FACTOR		950	950				1180		1180
	TOTAL OPERATIONAL FTEs		3.37	2.65				7.30		1.44

9. REMARKS

* Workload : Spreads for Field Exams and Import Sample Collections were determined by CFSAN using previous planned and accomplished data for each district and ORADSS line entry data 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.

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 530.04 for additional information on Food & Cosmetic activities.

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

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.

**** NOTE: SWID SAMPLES COLLECTED FROM TX & NM ARE SENT TO ARL. SWID SAMPLES COLLECTED FROM CA & AZ ARE SENT TO PRS.**

1. PROGRAM/ASSIGNMENT TITLE	2. PMS PROJECT NAME/NUMBER
Domestic and Imported Cheese and Cheese Products 03037 FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

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.

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.

New for FY 07: 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Hard and Soft Cheeses	12

e. EXAM TYPE: [ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Salmonella, Listeria, E. coli, Enterotoxigenic E. Coli (ETEC), Enterohemmorhagic E. Coli EHEC 0157:H7 - S. Aureus, And Phosphatase and Filth

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic and Imported Cheese and Cheese Products	Foodborne Biological Hazards

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03037, 03037B, 03037D	[X] ORA [ ] CENTER	22.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1)	2 INVESTI-GATIONS (Hours) (3)	3 DOMESTIC SAMPLE COLLECTION (2)		4 IMPORT SAMPLE COLL MICRO (5)	4 IMPORT SAMPLE COLL CHEM GUIDANCE	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	8 IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (7)
	TOTAL FIELD	300	350	300		700	75	300	75	700
	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	17.0		4.0		2.0		17.0	6.1	16.0
	TOTAL HOURS	5100	350	1200		1400		5100	458	11200
	CONVERSION FACTOR	950	950	950		950		1180	1180	1180
	TOTAL OPERATIONAL FTEs	5.37	0.37	1.26		1.47		4.32	0.39	9.49

9. REMARKS

(1) INSPECTIONS: DISTRIBUTED BY CFSAN.

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. ARTISNAL 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.

(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.

(3) INVESTIGATION HOURS DISTRIBUTED BY CFSAN. TIME IS PROVIDED FOR ASSIGNMENTS TO COVER THE INVESTIGATION OF "BATHTUB CHEESE" AND SUITCASE CHEESE".

(4) DOMESTIC SAMPLE ANALYSIS: BASED ON DOMESTIC SAMPLE COLLECTIONS AND THE CURRENT SERVICING LABORATORIES CHART UNDER THE APPENDIX III OF THE ORA FIELD WORKPLAN.

(5) IMPORT SAMPLE COLLECTIONS WERE DETERMINED BY CFSAN. (b)(2) & (b)(7)(E)
(b)(2) & (b)(7)(E)

NOTE: SWID SAMPLES COLLECTED FROM TX & NM ARE SENT TO NRL. SWID SAMPLES COLLECTED FROM CA & AZ SENT TO NRL.

(6) FILTH ANALYSIS SHOULD BE DONE AS NEEDED ON SPLIT IMPORT SAMPLES COLLECTED FOR MORE THEN ONE ATTRIBUTE

(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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Acidified and Low-Acid Canned Foods, CP 7303.803A, FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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

Low-Acid Canned Foods: Inspections conducted in prior year's programs have demonstrated that the degree of compliance of 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 is needed to establish and maintain compliance with the low-acid canned food regulations.

Acidified Foods: To improve the acidified food industry's degree of freedom from public health hazard and their degree of 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 400 FDA inspections are needed to fulfill program obligations FY 07. 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT (S)	d. INDUSTRY/PRODUCT CODE(S)
See Compliance Program	16, 20-22, 24-25, 27, 35, 37, 38, 40-41

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Domestic Acidified and Low Acid Canned Food	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03803A (2)	[X] ORA [ ] CENTER	14.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1) (3)	3 INVESTI-GATIONS (HOURS) (1)	4 DOMESTIC SAMPLE COLLECTION (1) (5)	4 DOMESTIC SAMPLE COLLECTION MICRO GUIDANCE	4 DOMESTIC SAMPLE COLLECTION CHEM GUIDANCE		7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 BETTER PROCESS-ING SCHOOL (Training Hours) (4)
	TOTAL FIELD	400	400	200	180	20		20	180	950
	HEADQUARTERS	(b)(2) & (b)(7)(E)						(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		25.0		5.0				8.0	10.0	
TOTAL HOURS		10000	400	1000				160	1800	950
CONVERSION FACTOR		950	950	950				1180	1180	950
TOTAL OPERATIONAL FTEs		10.53	0.42	1.05				0.14	1.53	1.00

9. REMARKS

(1) Source of workload: Inspections, Investigation Hours and DSC's provided by CFSAN. Resource distribution based on CFSAN's LACF database as of 3/2006.
(2) Report all resources expended for NLEA under PAC 21005.
(3) Inspect NAI firms on 3-year inspection cycle. State inspections may be conducted in addition to the number of inspections assigned per district.
(4) Attendence at Better Processing Schools (BPS).
(5) Planned collections are for projected "for cause" sampling.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Food Safety 03803 FY 2007	Foodborne Biological Hazards – 03

3. PROGRAM TYPE: [X] COMPLIANCE [ ] PROGRAM [ ] 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 2007 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 *Salmonella* 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).

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, and 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. Sample collections will typically be "for cause," i.e., no surveillance sampling is to be conducted. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations. Only those "for cause" collections needed to support regulatory inspections are to be conducted.
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 *Clostridium botulinum, Yersinia enterocolitica* 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.

Survelliance 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT (S)	d. INDUSTRY/PRODUCT CODE (S)
All Food Products (Except 12 & 16)	02-11, 13-15, 17-41, 45-46, 50

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING
[X] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Filth, Decomposition and Microbiological Contamination (See Compliance Program)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See compliance program.

FY 2007 ORA WORKPLANNING SHEET

October 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Food Safety	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03803, B, C, D, E; 04803; 09803E,F (2) (5) (8)	X ORA ____ CENTER	96.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS INCLUDING HIGH RISK (1) (3) (6)	1 NON CLINICAL GLP INSPECTIONS (4)	4 INVESTIGATIONS (HOURS) INCLUDES NAT'L EXPERTS (1)	3 DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL MICRO GUIDANCE	DOMESTIC SAMPLE COLL MICRO GUIDANCE	DSAs MICRO SALMONELLA SEROTYPING (HOURS) (6)	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	FOOD SAFETY METHOD VALIDATION MICRO (7)	FOOD SAFETY METHOD VALIDATION CHEM (7)
	TOTAL FIELD	4000	10	13860	400	240	160	1180	240	160	1500	1500
	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											
	ATLANTA											
SE	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
SW	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
PA	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW											
	PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION		17.0			5.6				12.0	12.0		
TOTAL HOURS		68000		13860	2240			1180	2880	1920	1500	1500
CONVERSION FACTOR		950		950	950			1180	1180	1180	1180	1180
OPERATIONAL FTEs		71.58		14.59	2.36			1.00	2.44	1.63	1.27	1.27

7. REMARKS

(1) FY 2007 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 February 28, 2006. Includes time for National Experts (3 FTEs). Resources have been allocated for 4000 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.

(2) Resources for 04803 and 09803E,F are included. Resources for audits are under State Contracts Program, 03R843.

(3) Allergen Inspections may be assigned upon the issuance of an Allergen Program for FY07.

* 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.

(4) Non-Clinical Good Laboratory Practice Inspections: CFSAN will contact affected Districts to arrange inspections during the course of the year.

(5) Assignments for sprout producers and egg farms, if needed in FY 07, will be taken from this Program.

(6) Salmonella Serotyping: Samples generated from NRL, SRL & ARL go to ARL; Samples generated from other labs go to Denver.

(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.

(8) Non Seafood Inspections for EU and Chilean Certification will be handled by CFSAN Assignment and counted against the inspectional obligations of this program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Foods – General 03819 FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or 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 the compliance program. The Compliance Program prioritizes high risk products (raw produce, RTE foods, ice cream products, dried milk products, tahini, sesame seed and halva candy, bush meat, baked goods, custard or cream-filled (egg containing), and BSE at-risk products), imported foods of regional significance, foods with a high frequency of contamination with filth which presents a public health hazard, and foods subject to decomposition which presents a public health hazard. Districts should deemphasize coverage of products that are not consistent with the Compliance Program priorities. (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 [ ] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: NA [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products (except seafood and cheese)	02-09, 13-15, 17-41

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Microbiological Contamination, Filth, and Decomposition (See Compliance Program)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

FY 2007 ORA WORKPLANNING SHEET

October 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Foods General	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03819A,B,C (03R833/99R/833/03R824)(1)	[X] ORA [ ] CENTER	277.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HRS OPR 14 03R833 (2)	2 PRIOR NOTICE REVIEW HOURS OPER 14 03R833 (6)	2 INVESTI-GATION HOURS	2 BSE ENTRY REVIEW & FOLLOW UP (4)	4 IMPORT SAMPLE COLL PHYSICAL	4 IMPORT SAMPLE COLL CHEM (ACKEE SUBSET) (7)	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 (7)	8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED SALM RESIST (5)
	TOTAL FIELD	92000	42000	82380	9000	7750	40	5080	2630	5080	40	2670	1180
	HEADQUARTERS PRIOR NOTICE	(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												
	ATLANTA												
SE	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
SW	DENVER												
	KANSAS CITY												
	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
PA	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LAB - SW												
	PACIFIC REGIONAL LAB - NW												
	HOURS PER OPERATION					2.2				8.2		7.5	
	TOTAL HOURS	92000	42000	82380	9000	17050				41656		20025	1180
	CONVERSION FACTOR	1200	1200	950	1200	950				1180		1180	1180
	OPERATIONAL FTEs	76.67	35.00	86.72	7.50	17.95				35.30		16.97	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 530.04 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES.

(4) BSE Entry Review& follow-up resources planned are to cover entry review products from BSE-affected or at-risk countries for product ingredients to determine whether they include ruminant material subject to USDA/APHIS prohibition. Entries of a product that appears to contain ruminant materials from BSE-affected or at-risk countries are referred to APHIS.

(5) Denver Laboratory: Salmonella Resistance

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

(7) Import Sample Analysis/Collection ACKEE, if necessary: Column for guidance only. Collection is for Chem analysis per assignment.

(8) Please review the latest program sampling priorities available at CFSAN OC Intranet site. Sample collections & analysis may also be utilized for chloropropanols in fermented soy products assignments late in FY 07.

NOTE: ADJUSTMENTS IN IMPORT INVESTIGATIONAL RESOURCES HAVE BEEN MADE TO ACCOUNT FOR ON-BOARD IMPORT STAFFING IN SOME DISTRICTS.

ISA CHEM AND ISA MICRO BASED ON ISC AND LAB SERVICING TABLE

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Fish and Fishery Products Inspection Program (03842) FY 07	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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.

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

Starting in FY07 High Risk Potential Products (HRPP) processors whose last two inspections were 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.

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 scombroid fish should be analyzed for histamine not for parasites or micro; 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Domestic Fish and Fishery Products	16

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING

[X] MICROANALYTICAL [X] OTHERS *(Specify)* (PSP, ASP, Standards, Economic Deception, Labeling)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

2007 ORA WORKPLAN

OCTOBER 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	
Domestic Fish and Fishery Products Inspection Program	Foodborne Biological Hazards - 03	
3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03842, B, C, D, H (1)	ORA [X] CENTER	69.7

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS INCLUDING HIGH RISK (4) (5)	3 DOMESTIC SAMPLES COLL VIBRIO ASSIGNMENT (7)	3 DOMESTIC SAMPLES COLL (3) (5)	3 DOMESTIC SAMPLES COLL MICRO GUIDANCE	3 DOMESTIC SAMPLES COLL CHEM GUIDANCE	7 DSA VIBRIO ASSIGNMENT (7)	7 DSAs ORGANO EXAMS (Hours) (2)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 EU CERTIFICATION (HOURS) (6)
	TOTAL FIELD	2330	36	280	210	70	216	400	70	210	1860
	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
NE	NEW YORK										
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
CE	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
SW	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		22.0	5.0	5.0			45.0		11.0	16.5	
TOTAL HOURS		51260	180	1400			9720	400	770	3465	1860
CONVERSION FACTOR		950	950	950			1180	1180	1180	1180	950
TOTAL OPERATIONAL FTEs		53.96	0.19	1.47			8.24	0.34	0.65	2.94	1.96

9. REMARKS

(1) ADDITIONAL PACs: 04842A, H, 07842, H; 09842E, F, H; 21005; 21842; 21R811; 21R829 .

(2) ORGANOLEPTIC NATIONAL EXPERT

(3) SEAFOOD COLLECTIONS ARE PLANNED "FOR CAUSE ONLY." VERIFICATION SAMPLES ARE NOT TO BE COLLECTED.

(4) STARTING IN FY 07 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) OEI OF SEAFOOD FIRMS FLAGGED IN FACTS AS HIGH RISK EXCLUDING FIRMS WITH INDUSTRY CODE 12 AS OF FEBRUARY 28, 2006.

INPSECTIONS AND DSCs BASED ON OEI.

(6) E.U. CERTIFICATION PROCESSING HOURS. USE REPORTING OPERATION 92.

(7) THE MAJORITY OF THE SAMPLES FOR THE SPECIAL VIBRIO ASSIGNMENT WIILL BE COLLECTED BY AND PAID FOR BY STATE REPRESENTATIVES OF ISSC.

THERE WILL BE 324 SAMPLES COLLECTED/ANALYZED BUT 1/3 OF THE ANALYSIS WILL BE DONE BY THE GULF COAST SEAFOOD LABORATORY.

DFS ASSIGNED THE LABORATORY DISTRIBUTION.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Seafood Program 03844 FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

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 in conjunction with non-safety inspection for decomposition, filth, etc. 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 – i.e. raw scombroid fish should be analyzed for histamine not for parasites or micro; 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.
NOTE: *Ciguatera toxin* confirmation which requires animals will be done at Pacific Regional Laboratory-NW.

NOTE: Confirmation tests which require animals for *Clostridium botulinum* will be split between Southeast Regional Laboratory (SRL) & Pacific Regional Laboratory-NW (PRL-NW). SRL will be the confirmation-servicing laboratory for NE, CE & SE. Regions. PRL-NW will be the confirmation-servicing laboratory for SW & PA Regions.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	16

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [X] OTHERS *(Specify)* (PSP, ASP, Standards, Labeling)

f. CHECK THE FOLLOWING ATTRIBUTES

See the HACCP Guidance for hazards associated with each specific seafood product.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE
Import Seafood Products

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03844B, C, D, H; 07844: 09844E,F

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
80.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP * 03844H (1)	4 IMPORT SAMPLE COLL PHYSICAL (2) / (6)	4 IMPORT SAMPLE COLL MICRO GUIDANCE	4 IMPORT SAMPLE COLL CHEM GUIDANCE	9 INVESTIGATION HOURS (3)	8 ISAs ORGANO ANALYSES (Hours) (5)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (4) / (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (4) / (6)	
	TOTAL FIELD	500	6400	4480	3050	950	1180	3050	4480	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	13.0	2.6					5.3	10.6	
	TOTAL HOURS	6500	16640			950	1180	16165	47488	
	CONVERSION FACTOR	950	950			950	1180	1180	1180	
	TOTAL OPERATIONAL FTEs	6.84	17.52			1.00	1.00	13.70	40.24	

9 REMARKS

(1) FY 2007 : 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 IN WITH SPECIAL EMPHASIS TOWARDS THE OFFICE OF SEAFOOD'S 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 SCROMBROTOXIC FISH SHOULD BE ANALYZED FOR HISTAMINE NOT FOR MICRO; RAW SHRIMP SHOULD BE ANALYZED FOR UNDECLARED SULFITE (AND/OR CHEMOTHERAPEUTICS) 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.);
(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 530.04 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 (BASED ON 2007 WORKPLAN) 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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Juice HACCP Inspection Program 03847, 03847H FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 shelf-stable according to the regulation. The collection of verification samples will be implemented this fiscal year to help further validate firms' HACCP plans.

6. FIELD OBLIGATIONS

Inspectional priority should be the following: Firms associated with recent outbreaks, unpasteurized juice firms whose previous inspections were OAI, and followed by firms that have not been inspected. HACCP-trained investigators will also review importers' verification procedures and product specifications, which demonstrate that the foreign processor's product was produced according to HACCP principles.

Resources have been provided for "for cause" samples and "verification" samples (pending issuance of revised compliance program).

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: [x] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [x] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT (S)	d. INDUSTRY/PRODUCT CODE (S)
Juice Products	20-22, 24, 25

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[X] MICROANALYTICAL [X] 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	2. PPS PROJECT NAME/NUMBER
Juice HACCP Inspection Program	Foodborne Biological Hazards -03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03847H, 03847 (1)	[X] ORA [X] CENTER	10.0

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS (2)	4 DOMESTIC SAMPLE COLLECTION (3)	DOMESTIC SAMPLE COLLECTION CHEM GUIDE ONLY	DOMESTIC SAMPLE COLLECTION MICRO GUIDE ONLY	7 DOMESTIC SAMPLES ANALYZED CHEM		7 DOMESTIC SAMPLES ANALYZED MICRO	1 IMPORTER INSPECTIONS (4)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	300	150	37	113	37		113	100	
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	18.5	6.2			11.0		15.0	13.0	
	TOTAL HOURS	5550	930			407		1695	1300	
	CONVERSION FACTOR	950	950			1180		1180	950	
	TOTAL OPERATIONAL FTEs	5.84	0.98			0.34		1.44	1.37	

9. REMARKS

(1) Additional related PAC's: 03847, 04847H, 07847H, 09847H, 21847H. 03847 would be used for general sanitation issues (non-HACCP) and the "H" PACs for HACCP verification samples and the HACCP component of inspection. Non "H" PACs would be used for "For Cause" samples and filth/sanitation component of inspection.

(2) Per CFSAN, Domestic Inspections based on OEI juice processor data as of 3/24/06. State inspections may be conducted in addition to the number of inspections assigned per district (PAC 03S004). Resources have been added to cover food security issues at all domestic processor inspections. Inspectional priority is as follows: firms associated with recent outbreaks, unpasteurized juice firms, firms whose previous inspections were OAI, and firms that have not yet been inspected. OEI inventory will be provided to each district prior to the beginning of each year.

(3) Per CFSAN, DSC resources have been provided for anticipated "for cause" and "verification" samples (pending issuance of revised compliance program).

(4) Per CFSAN, Importer inspections based on ORADSS data as of April 2006 (physical location of juice importers).

(5) Please refer to the list of juice importers distributed by the program monitor and follow the same inspectional priority as above.

(6) 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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import and Domestic Micro Assignments 03F098 (Domestic), 03F100 (Import) FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

To collect and analyze selected food commodities 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 has 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.

6. FIELD OBLIGATIONS

To collect samples and perform analyses as specified in the FY 07 produce assignments issued by CFSAN.

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

b. INSPECTION TYPE: NA [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fresh fruits and vegetables as specified in the assignment.	20-22, 24-25

e. EXAM TYPE: [ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import and Domestic Micro Assignments	Foodborne Biological Hazards -03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F098 (Import) 03F100 (Domestic)	[ ] ORA [X] CENTER	21.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLLECTION	DOMESTIC SAMPLE COLLECTION	IMPORT SAMPLE ANALYSIS MICRO	DOMESTIC SAMPLE ANALYSIS MICRO					9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	450	450	450	450					
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		3.0	3.0	25.0	25.0					
TOTAL HOURS		1350	1350	11250	11250					
CONVERSION FACTOR		950	950	1180	1180					
TOTAL OPERATIONAL FTEs		1.42	1.42	9.53	9.53					

9. REMARKS

Assignments will be issued by CFSAN for the collection of cantaloupe, green onions, tomatoes, loose-leaf lettuce, spinach, cilantro, basil, parsley.

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.

Domestic and Import Sample Analysis based on Domestic and Import Sample collection(s) and Laboratory Servicing Table.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections/Assessments 03R233 FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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, will 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

The number of illnesses and deaths related to food borne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. To the best of our knowledge, approximately half of the foods that have been associated with food borne illness have been imported. 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. An important aspect of this new initiative is to increase our knowledge of the conditions under which a variety of foods are manufactured in foreign countries.

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 Imports 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 07, 100 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection outbreaks, infant formulas, seafood, cheese, etc.	02-50, 54

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Foreign Inspections/Assessments	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R233	[X] ORA [ ] CENTER	4.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FOREIGN	2 INVESTIGATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) *						9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	100		950						
	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	30.0								
	TOTAL HOURS	3000		950						
	CONVERSION FACTOR	950		950						
	TOTAL OPERATIONAL FTEs	3.16		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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program 03R816 FY 2007	Foodborne Biological Hazards - 03

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: N/A ☐ 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: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R816	[X] ORA [ ] CENTER	12.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV MICRO (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)							
	TOTAL FIELD	**10245**	**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									
	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	10245	4720							
	CONVERSION FACTOR	1205	1180							
	TOTAL OPERATIONAL FTEs	8.50	4.00							

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Contract Management 03R843 FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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 8000 food inspections are anticipated to be contracted out in FY 07 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED Audits

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products	02-41, 45-46, 50

e. EXAM TYPE: [ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Audits of State Contract Food Inspections.

f. CHECK THE FOLLOWING ATTRIBUTES

Follow DFSR guidance.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Contract Management	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R843	[X] ORA [ ] CENTER	14.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		INFO ONLY NUMBER OF FOOD STATE CONTRACT AUDITS (1)	2007 DOMESTIC FOOD STATE CONTRACTS LESS SEAFOOD (3)	2007 DOMESTIC SEAFOOD STATE CONTRACTS IND 16 (3)	2007 TOTAL STATE CONTRACTS (3)				9 CONTRACT MANAGE-MENT HOURS (2)
	TOTAL FIELD		629	8111	879	8990				13300
	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									
	TOTAL HOURS									13300
	CONVERSION FACTOR									950
	TOTAL OPERATIONAL FTEs									14.00

9 REMARKS

(1) Food State Contract Audits to be conducted at about 7% of state contract food firm inspections.
Number of Food State Contract Audits is for informational purposes.
Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.
(2) Time planned for contract management includes resources to conduct audits.
(3) Food State Contract inventory per Division of Federal State Relations.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Food Defense 03R845 FY 2007	Foodborne Biological Hazards

3. PROGRAM TYPE: NA [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENTS & Preparedness Activities

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 expediously.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All food products.	All food industry/product codes.

e. EXAM TYPE: [X] CHEMICAL [x] MICROBIOLOGICAL [X] PHYSICAL [X] ENGINEERING [X] MICROANALYTICAL [x] 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	2. PPS PROJECT NAME/NUMBER
Food Defense	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R845	[X] ORA [ ] CENTER	38.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 CSO DOMESTIC HOURS	2 CSO IMPORT HOURS	8 IMPORT CHEM HOURS	8 IMPORT MICRO HOURS	DOMESTIC CHEM HOURS	DOMESTIC MICRO HOURS	CHEM HOURS FD METHOD VALIDATION * INFO ONLY	MICRO HOURS FD METHOD VALIDATION * INFO ONLY
	TOTAL FIELD	15960	6840	2830	2128	6610	4956	2500	1750
	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 LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS	15960	6840	2830	2128	6610	4956		
	CONVERSION FACTOR	950	950	1180	1180	1180	1180		
	TOTAL OPERATIONAL FTEs	16.80	7.20	2.40	1.80	5.60	4.20		

9. REMARKS

Reporting: Food Defense activities are reported under 03R845, expanded time should be reported under 04R845, 07R845, 09R845, 21R845.

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.

Resources are to be used for CFSAN food defense assignments for inspections, sample collections and analyses, including those to support the FERN. Resources for lead FERN Lab (FCC, NRL, WEAC) activities are funded separately. Total lab time may be used for maintaining general food defense capabilities.

* Resources for food defense method validation are a subset of the total Chemist and Microbiologist resources planned.

Note: SWID samples collected from TX & NM are sent to ARL. SWID samples collected from CA & AZ are sent to PRS.

CSO DOMESTIC HOURS BASED ON TOTAL FOODS M/R OEI INCLUDING IND CODE 02-51 DATED 2/28/06
CSO IMPORT HOURS BASED ON TOTAL FOODS ACS FDA REVIEW LINES
LAB RESOURCES PRE-PLANNED BY ORA
LABORATORY RESOURCES PLANNED BY DFS.

PROJECT SUMMARY SHEET
FY 2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME-NUMBER
Food and Cosmetics	Pesticides and Chemical Contaminants - 04

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		92.5	79.6		172.1	298.1	
1	Pesticides and Industrial Chemicals in Domestic and Imported Foods	04004A,D *	38.2	38.9		77.1	133.6	2-5
2	Chemotherapeutic in Seafood	04018	3.0	22.2		25.2	43.6	6-7
3	Toxic Elements in Food and Foodware		4.8	12.9		17.7	30.7	
	Toxic Elements in Foods (Domestic and Import)**	04019A	(4.4)	(8.9)		(13.3)		8-13
	Toxic Elements in Foodware (Domestic and Import)	04019B	(0.2)	(3.5)		(3.7)		
	Radionuclides in Foods (Domestic and Import)	04019C	(0.2)	(0.5)		(0.7)		
4	Total Diet Study	04839	23.4			23.4	40.5	14-15
5	Field Assignments for Chemical Contaminants	04F800	1.1	5.6		6.7	11.6	16-17
6	Methods Validation/Development Program	04R816	10.0			10.0	17.3	18-19
7	Forensic Evaluation and Sample Analysis	04R838	12.0			12.0	20.8	20-21

* 04R833, 99R833, 04R824

** Includes DISC and DISA FTEs

CENTER PROJECT MANAGER-TELEPHONE	ORA PLANNER-TELEPHONE
Ronald R. Roy (301)436-2061	Lorraine B. Jefferson, 301-827-1631

FORM FDA 2622 (9-98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Domestic and Imported Foods	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To enforce tolerances and other regulatory limits for pesticides in domestic and imported foods. To determine incidence and levels of pesticides and industrial chemicals in domestic and imported foods. Continued emphasis on dioxins to obtain comprehensive data on background levels of dioxin in a variety of foods. Conduct follow-up assignments to determine source of remarkable findings. The data 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 and enforce legal residue limits.

Findings are also used to estimate dietary exposure for risk assessments performed by FDA, EPA, and 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 portion of each district's 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 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All human foods.	All human food codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Domestic and Imported Foods	Pesticides and Chemical Contaminants -04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04004A,D, 99R833, 04R824	[X] ORA [ ] CENTER	77.1 (38.2)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs			DSCs DIOXINS	DSAs DIOXINS *	DSAs DIOXINS **	DSCs SEAFOOD	DSAs SEAFOOD
	TOTAL FIELD	1100	2400	2400			750	750	232	100	100
	HEADQUARTERS	(b)(2) & (b)(7)(E)					(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										
	ATLANTA										
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
W	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		3.0	5.2			4.0	20.0	11.6	3.0	5.2
	TOTAL HOURS	1100	7200	12480			3000	15000	2691	300	520
	CONVERSION FACTOR	950	950	1180			950	1180	1180	950	1180
	TOTAL OPERATIONAL FTEs	1.16	7.58	10.58			3.16	12.71	2.28	0.32	0.44

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.

** Kansas City will analyze 232 of the 750 dioxin DSCs.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Domestic and Imported Foods	Pesticides and Chemical Contaminants -04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04004A,D, 99R833, 04R824	[X] ORA [ ] CENTER	(38.9)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY				ISCs	ISAs		ISCs SEAFOOD	ISAs SEAFOOD	
	TOTAL FIELD				**5300**	**5300**		**300**	**300**	
	HEADQUARTERS				(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
MA	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW									
HOURS PER OPERATION					1.6	6.2		1.6	6.2	
TOTAL HOURS					8480	32860		480	1860	
CONVERSION FACTOR					950	1180		950	1180	
TOTAL OPERATIONAL FTEs					8.93	27.85		0.51	1.58	

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	2. PPS PROJECT NAME/NUMBER
Chemotherapeutics in Seafood	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To sample and analyze selected import and domestic aquacultured seafood products. To determine the presence of unapproved chemical compounds such as drugs or anit-fungals 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. With the advent of this trend, there will be incentives to protect investments and/or gain a competitive edge through the use of chemotherapeutic agents. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the U.S. and do not have adequate regulatory controls to prevent their export to 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 07 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or additional validated methods are ready to implement.

As a budget relief, two agent analyses may be run per sample provided the second agent is one of interest for that product. Please refer to the FY 07 Collection Schedule and Compliance Program (both when issued) for species to collect, assigned servicing laboratories, and agents of interest.

Individual subsample analyses will only be required for 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 07 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	16

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Unapproved drugs per the Compliance Program

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Chemotheropeutics in Seafood	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04018	[ ] ORA [x] CENTER	25.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		DSCs	DSAs	DSAs IND SUBS	DSAs COMPOSITES	ISCs	ISAs	ISAs IND SUBS	ISAs COMPOSITES
	TOTAL FIELD		150	150	45	105	1150	1175	445	730
	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									
	ATLANTA									
	FLORIDA									
SE	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			4.0	19.0			3.0	18.6		
TOTAL HOURS			600	2850			3450	21855		
CONVERSION FACTOR			950	1180			950	1180		
TOTAL OPERATIONAL FTEs			0.63	2.42			3.63	18.52		

7. REMARKS

CFSAN spread the number of sample collections per district based on ORADSS line entry data and domestic OEI data. DFS spreads the laboratory analyses. Individual sub sample analyses will be for Chloramphenicol and Nitrofurans samples. All remaining residue analyses will be a composite of 12 subsamples. The analytical module is a field wide average based on number of total samples planned for individual subsample analysis and for composite analysis. Refer to the FY 07 Collection Schedule for specific commodities to collect (when issued). Domestic samples can be collected as D/I samples if district cannot meet sample obligations with OEI firms or if samples are being collected fresh.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic)	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To determine the incidence and levels of lead, cadmium, mercury and other toxic elements of significance and radionuclides in domestic imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in foodware.

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

Imported agricultural products and their processed derivatives, candy, chocolate/cocoa, and seafood 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 directed other FY 07 food work. Import field exams should be focused upon foodware (b)(2) & (b)(7)(E) (b)(2) & (b)(7)(E) Sample collections and 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 radionuclide. 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:
[X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All human food products. Ceramic foodware.	02-41, 52A

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING
[ ] MICROANALYTICAL [X] 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	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Foods (Domestic and Import)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019A	[X] ORA [X] CENTER	17.7 (8.5)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSC NON-SEAFOOD	ISC NON-SEAFOOD	DSA NON-SEAFOOD	ISA NON-SEAFOOD	DSCs SEAFOOD	DSAs SEAFOOD	DSC MERCURY IN SEAFOOD	DSA MERCURY IN SEAFOOD	ISC SEAFOOD
	TOTAL FIELD	100	280	100	280	100	100	100	100	170
	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		3.5	1.8	12.0	12.0	4.5	12.0	4.5	12.0	4.5
TOTAL HOURS		350	504	1200	3360	450	1200	450	1200	765
CONVERSION FACTOR		950	950	1180	1180	950	1180	950	1180	950
TOTAL OPERATIONAL FTEs		0.37	0.53	1.02	2.85	0.47	1.02	0.47	1.02	0.81

7. REMARKS

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

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Foods (Domestic and Import)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019A	[X] ORA [X] CENTER	(4.8)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ISA SEAFOOD	DISC MERCURY IN TUNA *	DISA MERCURY IN TUNA *			DISC MERCURY IN SEAFOOD *	DISA MERCURY IN SEAFOOD *		
	TOTAL FIELD	170	75	75			135	135		
	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 LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION		12.0	3.5	12.0			4.5	12.0		
TOTAL HOURS		2040	263	900			608	1620		
CONVERSION FACTOR		1180	950	1180			950	1180		
TOTAL OPERATIONAL FTEs		1.73	0.28	0.76			0.64	1.37		

7. REMARKS

* To be issued as CFSAN Field Assignment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Foodware (Domestic and Import)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019B	[X] ORA [ ] CENTER	(3.7)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		3 DSCs (Houseware)	4 ISCs (Houseware)	5 DOMESTIC FIELD EXAMS	6 IMPORT INV HOURS *	7 DSAs	8 ISAs		
	TOTAL FIELD		10	200	25	1400	10	200		
	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			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	2. PPS PROJECT NAME/NUMBER
Radionuclides in Foods (Domestic and Import)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019C	X ORA X CENTER	(0.7)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 Inspections	2 INV	3 DSC	4 ISC	5 Field Exams	6 Import Field Exams	7 DSAs	8 ISAs	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD			16	84			16	84	
	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 LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION				2.5	1.7			13.0	4.2	
TOTAL HOURS				40	143			208	353	
CONVERSION FACTOR				950	950			1180	1180	
TOTAL OPERATIONAL FTEs				0.04	0.15			0.18	0.30	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Total Diet Study	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 been often 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 which each consisting of three separate samplings of 284 food items 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, and toxic elements. WEAC will analyze all foods from one market basket for radionuclides.

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

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Various Human Foods	All Human Food Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Radiochemical Analysis

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Total Diet Study	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04839	[ ] ORA [X] CENTER	23.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DSCs (TOTAL) (DIET) (1)	2 DOMESTIC SAMPLE TO BE ANALYZED (2)	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) (3)						
	TOTAL FIELD	**60**	**1136**	**1**						
	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									
	ATLANTA									
	FLORIDA									
SE	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 LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION		26.0	20.1	2800.0						
TOTAL HOURS		1560	22834	2800						
CONVERSION FACTOR		950	1180	1180						
TOTAL OPERATIONAL FTEs		1.64	19.35	2.37						

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.
(3) All TDS food items from one market basket analyzed by WEAC for selected radionuclides.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Field Assignments for Chemical Contaminants	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

To collect and analyze selected food products of domestic and foreign origin for chemical contaminants as directed by CFSAN field assignments. Assignments are anticipated for perchlorate in foods, contaminants in honey, and general pesticides and toxic elements in dietary supplements.

5. PROGRAM JUSTIFICATION

Monitoring of foods for suspected chemical contaminants is necessary to ensure a safe food supply. Perchlorates have recently been identified as suspect contaminants and monitoring is required to provide the Agency with incidence and level data to properly evaluate their presence in the food supply. Contaminants like fluoroquinilone and nitrofuran 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 [ ] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Selected human foods and dietary supplements	As directed by CFSAN assignments

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Field Assignments for Chemical Contaminants	Pesticides and Chemical Contaminants -04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04F800	[X] ORA [X] CENTER	6.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSC PERCHLORATE IN FOODS	DSA PERCHLORATE IN FOODS			ISC CONTAMINANTS IN HONEY	ISA CONTAMINANTS IN HONEY	ISC/DISC PES & TE DIETARY SUPPL. *		ISA/DISA PES & TE DIETARY SUPPL. **
	TOTAL FIELD	200	200			100	100	200		200
	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									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW									
HOURS PER OPERATION		3.0	3.0			3.0	6.5	3.0		24.0
TOTAL HOURS		600	600			300	650	600		4800
CONVERSION FACTOR		950	1180			950	1180	950		1180
TOTAL OPERATIONAL FTEs		0.63	0.51			0.32	0.55	0.63		4.07

7. REMARKS

*Collection of samples for both Pesticides and Toxic Elements analysis.

** The Analytical module includes resources for both Pesticides and Toxic Elements

Collections for Perchlorate and Dietary Supplements will be directed by CFSAN field assignments.

Contaminants in honey include chloroamphenicol (See Import Bulletin) and CFSAN assignment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04R816	[X] ORA [ ] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)							
	TOTAL FIELD	6025	5900							
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	6025	5900							
	CONVERSION FACTOR	1205	1180							
	TOTAL OPERATIONAL FTEs	5.00	5.00							

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☐ 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: ☐ BY DISTRICT OFFICE ☐ BY CENTER ☐ BY BOTH

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	

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

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04R838	[X] ORA [ ] CENTER	12.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION							
	TOTAL FIELD	**1205**	**13255**							
	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									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - 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.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Molecular Biology & Natural Toxins - 07

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		20.4	9.4		29.8	51.6	
1	Mycotoxins in Domestic and Import Foods	07001	15.9	9.4		25.3	43.8	2/5
2	Methods Validation/Development Program	07R816	4.5			4.5	7.8	6/7

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy, 301-436-2061	Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mycotoxins in Domestic and Import Foods PAC 07001	Molecular Biology and Natural Toxins - 07

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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

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.

Fumonisins B_1 and B_2 are naturally occurring toxic metabolites produced mainly by the fungus, *Fusarium verticilloides*, 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.

Deoxynivalenol (DON) is a trichothecene mycotoxin produced by several strains of *Fusarium*, 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.

Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera *Aspergillus* and *Penicillium*. 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.

Patulin is a mold metabolite produced by several species of mold fungi including *Penicillium expansum*, 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.

6. FIELD OBLIGATIONS

The Field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic products as directly by the Compliance Program.

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Attachment "A" C.O. 7307.001 for list of Products.	See Attachment "A" C.O. 7307.001 for Product Codes.

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Aflatoxins, Fumonisins B_1 and B_2, Deoxynivalenol (DON), Ochratoxin A, and Patulin.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program (C.O.) 7307.001

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mycotoxin in Domestic and Import Foods	Molecular Biology & Natural Toxins - 07

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001 (DOMESTIC)	X ORA ____ CENTER	Total (25.3) 15.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DSCs AFLA-TOXIN	3 DSCs FUMON-ISON	3 DSCs DON	3 DSCs OCHRA TOXIN	3 DSCs PATULIN	7 ALL DOMESTIC SAMPLE ANALYSES	7 DSAs AFLA-TOXIN	7 DSAs FUMON-ISON	7 DSAs DON
	TOTAL FIELD	800	320	250	100	240	1710	800	320	250
	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	4.0	4.0	4.0	4.0	4.0	6.0			
	TOTAL HOURS	3200	1280	1000	400	960	10260			
	CONVERSION FACTOR	950	950	950	950	950	1180			
	TOTAL OPERATION FTEs	3.37	1.35	1.05	0.42	1.01	8.69			

7. REMARKS

Report all Domestic and Import operations under PAC 07001.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mycotoxin in Domestic and Import Foods PAGE 2	Molecular Biology & Natural Toxins - 07

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001 (DSA, ISCs)	X ORA ____ CENTER	2.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	7 DSAs OCHRA TOXIN	7 DSAs PATULIN	4 ISCs AFLA TOXIN	4 ISCs PEANUT BUTTER	4 ISCs FUMON-ISON	4 ISCs DON	4 ISCs OCHRA TOXIN	4 ISCs PATULIN	4 ISCs SPECIAL SURVEY
	TOTAL FIELD	100	240	500	(105)	160	160	64	240	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			2.0		2.0	2.0	2.0	2.0	2.0
	TOTAL HOURS			1000		320	320	128	480	80
	CONVERSION FACTOR			950		950	950	950	950	950
	TOTAL OPERATION FTEs			1.05		0.34	0.34	0.13	0.51	0.08

7. REMARKS

* Peanut Butter ISCs were spread by CFSAN

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mycotoxin in Domestic and Import Foods PAGE 3	Molecular Biology & Natural Toxins - 07

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001 (ISAs)	X ORA ___ CENTER	6.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	8 ALL IMPORT SAMPLE ANALYSES	8 ISAs AFLA TOXIN	8 ISAs FUMON-ISON	8 ISAs DON	8 ISAs OCHRA TOXIN	8 ISAs PATULIN	8 ISAs SPECIAL SURVEY	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERAT-TIONS (HOURS)
	TOTAL FIELD	**1164**	**500**	**160**	**160**	**64**	**240**	**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	7.0								
	TOTAL HOURS	8148								
	CONVERSION FACTOR	1180								
	TOTAL OPERATION FTEs	6.91								

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Molecular Biology and Natural Toxins - 07

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Molecular Biology and Natural Toxins - 07

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07R816	[X] ORA [ ] CENTER	4.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)						
	TOTAL FIELD	**600**	**4130**	**590**						
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	600	4130	590						
	CONVERSION FACTOR	1205	1180	1180						
	TOTAL OPERATIONAL FTEs	0.50	3.50	0.50						

9. REMARKS

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Food & Color Additive Petition Review & Policy Development - 09

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			11.6		11.6	20.1	
1	Imported Foods - Food & Color Additives	09006A, B		11.6		11.6	20.1	2/3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy, 301-436-2061	Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported Foods - Food and Color Additives PAC 09006A,B	Food and Color Additives - 09

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To direct coverage of imported food products to determine their compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its 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 and undeclared food and color additives to ensure that these foods meet the requirements of the Act.

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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All human foods	All food codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Label Reviews

f. CHECK THE FOLLOWING ATTRIBUTES

Unapproved or undeclared food and color additives

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported Foods - Food and Color Additives	Food & Color Additive Petition Review & Policy Development - 09

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
09006A (Foods), 09006B (Colors)	[X] ORA [ ] CENTER	11.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	4 ISCs FOOD ADDITIVES	8 ISAs FOOD ADDITIVES		4 ISCs COLOR ADDITIVES	8 ISAs COLOR ADDITIVES		IMPORT INVESTI-GATIONS (HOURS) *		9 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									
	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		1.4	11.0		1.4	8.0				
TOTAL HOURS		434	3410		1211	6920		1087		
CONVERSION FACTOR		950	1180		950	1180		950		
OPERATIONAL FTEs		0.46	2.89		1.27	5.86		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.

PROJECT SUMMARY SHEET
FY2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Technical Assistance: Food and Cosmetics - 18

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		77.8			77.8	134.7	
1	Retail Food Protection - State Program	18002	23.0			23.0	39.8	2-5
2	Milk Safety Program	18003	19.1			19.1	33.1	6-9
3	Molluscan Shellfish Evaluation	18004	13.0			13.0	22.5	10-13
4	Interstate Travel Program - Conveyances and Support Facilities	18029A-E	22.7			22.7	39.3	14-17

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (301)436-2061	Lorraine B. Jefferson (301)827-1631

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Retail Food Protection - State Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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, prestandardization workshops, HACCP, and Retail Specialist certification, etc. Maintain a cadre of trained FDA Food Specialists.

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

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Foods	Inspections: 51 NY

e. EXAM TYPE: [ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)* N/A

f. CHECK THE FOLLOWING ATTRIBUTES

Reduction in the occurrence of CDC identified risk factors associated with foodborne illness in retail establishments and 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 Food Code provisions and related program documents.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Retail Food Protection - State Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18002	[ ] ORA [X] CENTER	23.0 (22.0)

REGION	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)	FOOD DEVELOP-MENT (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	8412	1926	1788	460	1200	2760	1380	2070	6454
	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									
	TOTAL HOURS	8412	1926	1788	460	1200	2760	1380	2070	6454
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	7.01	1.61	1.49	0.38	1.00	2.30	1.15	1.73	5.38

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 CFSAN in the development and issuance of regulatory language for the Supplement to the 2005 Food Code.

(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.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Retail Food Protection - State Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18002	[ ] ORA [X] CENTER	(1.0)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	CONFERENCE FOR FOOD PRO-ACTIVITIES (10)	FOOD DEFENSE COORDINATION & CFSAN DIRECTED PROJECTS (11)							
	TOTAL FIELD	**460**	**690**							
	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									
	TOTAL HOURS	460	690							
	CONVERSION FACTOR	1200	1200							
	TOTAL OPERATIONAL FTEs	0.38	0.58							

7. REMARKS:

(10) Includes all committee work for the Conference for Food Protection and preliminary work on issues/position paper development for 2008 CFP.

(11) Time allocated for the presentation and distribution of FDA materials related to food defense, 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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Milk Safety Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 U.S. This program enables FDA to exert influence on the application of Uniform Sanitary Standards for Grade "A" Milk produced in the U.S. This program provides a mechanism for reciprocity between states, thereby eliminating the need for costly *duplicative inspection* across jurisdictional lines. Without this program, FDA would have direct responsibility for inspecting all 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Grade "A" Milk and Milk Products, (Cheese, Butter, Dry Milk and Frozen Dessert - when produced in IMS Plants)	09, 13, 14

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Listeria, Yersinia, Salmonella, Coliform and animal drug residues in milk and milk products.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Work assigned in this program is to be conducted by persons who are standardized in the use of the Grade "A" Pasteurized Milk Ordinance and related documents and in the case of non-IMS products, persons trained to conduct GMP inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Milk Safety Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18003	[ ] ORA [X] CENTER	19.1 (16.8)

REGION	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 CERTIFICATION 2	TECHNICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION [3]	STATE MILK SAMPLING SURVEILLANCE OFFICER INITIAL CONT [1]	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER [4]
	TOTAL FIELD	146	34	253	58	37	51	17	35	31
	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	24.0	12.0	20.0	8.0	40.0	100.0	120.0	24.0	40.0
	TOTAL HOURS	3504	408	5060	464	1480	5100	2040	840	1240
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	2.92	0.34	4.22	0.39	1.23	4.25	1.70	0.70	1.03

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).

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Milk Safety Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	OPERATIONAL FTE POSITIONS
18003	[ ] ORA [x] CENTER	(2.3)

REGION	DISTRICT/ SPECIALIZED LABORATORY	NCMS [5]	Food Defense [6] COORDINATION	TRAINING GIVEN [7]						
	TOTAL FIELD	19	19	19						
	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	60.0	25.0	60.0						
	TOTAL HOURS	1140	475	1140						
	CONVERSION FACTOR	1200	1200	1200						
	TOTAL OPERATIONAL FTEs	0.95	0.40	0.95						

5/ Activities include time for RMS to prepare for and attend the NCIMS biennial conference.
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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Molluscan Shellfish Evaluation	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Evaluate the shellfish sanitation program of 30 states and 5 nations for 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 Vibrio vulnificus and Vibrio parahaemolyticus management programs and to assist in the EU audit of the NSSP.

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

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fresh and fresh frozen molluscan shellfish	16, 52 B, Y

e. EXAM TYPE: N/A [ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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
[X] ORA [X] CENTER

5. OPERATIONAL FTE POSITIONS
13.0 (10.3)

R 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-STAN-IZATION (9)
	TOTAL FIELD	167	22	500	2789	5	2	14	132				10
	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 LAB - SW												
	PACIFIC REGIONAL LAB - NW												
	HOURS PER OPERATION	20.0	80.0			200.0	400.0	50.0	8.0				40.0
	TOTAL HOURS	3340	1760	500	2789	1000	800	700	1056				400
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200				1200
	TOTAL OPERATIONAL FTEs	2.78	1.47	0.42	2.32	0.83	0.67	0.58	0.88				0.33

REMARKS:

(1) Time is allocated for planning, field evaluations, file reviews (Comprehensive Growing Area Sanitary Surveys, Triennial Evaluations and Annual Updates), growing areas data reviews and report writings to determine state program conformity to the requirements of the National Shellfish Sanitation Program(NSSP) Model Ordinance (MO). The overwhelming majority of shellfish related illness have been attributed to shellfish contamination due to the conditions in the shellfish growing area.

(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* education 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

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Molluscan Shellfish Evaluation	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18004	X	(2.7)

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM WORKSHOP (10)	CENTER INITIA-TIVES/LAB (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE COORDINATION (13)	ISSC COMMITTEE (14)
	TOTAL FIELD	12	11	13	13	13
	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					
	ATLANTA					
SE	FLORIDA					
	NEW ORLEANS					
	SAN JUAN					
	REGIONAL LAB					
	REGIONAL STAFF					
	DALLAS					
SW	DENVER					
	KANSAS CITY					
	SOUTHWEST IMPORT DISTRICT					
	REGIONAL LAB					
	REGIONAL STAFF					
	LOS ANGELES					
PA	SAN FRANCISCO					
	SEATTLE					
	PACIFIC REGIONAL LAB - SW					
	PACIFIC REGIONAL LAB - NW					
	HOURS PER OPERATION	30.0	80.0	40.0	15.0	100.0
	TOTAL HOURS	360	880	520	195	1300
	CONVERSION FACTOR	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTE	0.30	0.73	0.43	0.16	1.08

(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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To inspect and investigate passenger conveyances and their support facilities based on the Public Health Service Act, the Food Drug and Cosmetic Act (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, 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 industry, trade associates, and others to promote voluntary compliance, coordinate activities with FAA, CDC, DOT, EPA, Department of Homeland Security (USCG, TSA) and other domestic and foreign government health officials as much as possible to enhance the protection of the traveling public and crew of conveyances both during construction and in operation at watering points, caterers, commissaries, and service areas of 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 regulations.

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 with 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human food, water, and waste; conveyance environmental conditions	Inspections/Investigations: Industry 51, All food codes including water 29W (Y30).

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [X] MICROANALYTICAL [ ] 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 in FDA procedures and specific guidelines established for the Interstate Travel Program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18029 A - F	X ORA X CENTER	22.7 (22.3)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS	CONVEY UNDER CONSTRUCTION HOURS (**)	WATERING POINTS INSP (A)	CATERING POINTS INSP (B) (*)	VESSELS INSP (C))	DSCs	DSAs MICRO	INV (HOURS)	ITP SPECIALIST TIME (HOURS) (***)
	TOTAL FIELD	1550	1360	(666)	(466)	(308)	100	100	1550	950
	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									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	10.5					4.0	8.0		
	TOTAL HOURS	16275	1360				400	800	1550	950
	CONVERSION FACTOR	950	950				950	1180	950	950
	TOTAL OPERATIONAL FTEs	17.13	1.43				0.42	0.68	1.63	1.00

7. REMARKS:

Inspections in Columns A-C are included in Column 1. Columns will not add across since other firms may be covered under this program.
Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B.
(*)Catering Point Insp. (B) is High Risk Priority.
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.
Districts should focus inspections on new caterers per mandatory registration.
(b)(2) & (b)(7)(E)
Districts should use INV hours to correct OEI, coordinate with other federal agencies and other 3RD parties within the district.
(***)ITP Specialist hours are provided to each of the districts (SAN, LOS and SEA) for specialized inspections of aircraft constructions, ship constructions and galley components.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18029 A - F	X ORA X CENTER	(.4)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	STEERING COMMITTEE (HOURS) (****)
	TOTAL FIELD	400
	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		
TOTAL HOURS		400
CONVERSION FACTOR		950
TOTAL OPERATIONAL FTEs		0.42

7. REMARKS:

(****)Steering Committee- 80 hours provided to each of the districts (NWE, CIN,FLA,DAL and LOS) for developing/revising industry guidance and inspection guides, and other possible program initiatives. Includes time for committee conference calls.

PROJECT SUMMARY SHEET
FY 2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME-NUMBER
Food and Cosmetics	Food Composition, Standards, Labeling and Economics - 21

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		28.6	9.6		38.2	65.5	
1	Medical Foods - Domestic and Import	21002	3.6	0.7		4.3	7.1	2-3
2	Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Program	21005*	4.7	4.6		9.3	16.1	4-5
3	Infant Formula Program	21006	2.9	1.4		4.3	7.1	6-7
4	Dietary Supplements	21008	13.0	2.9		15.9	27.6	8-11
5	Selected Nutrients in Food Survey	21839	3.4			3.4	5.9	12-13
6	Methods Validation/Development Program	21R816	1.0			1.0	1.7	14-15

*03R833,99R833, 21R824, 21R829(Health Fraud) and FPLA

CENTER PROJECT MANAGER-TELEPHONE	ORA PLANNER-TELEPHONE
Ronald R. Roy (301)436-2061	Lorraine B. Jefferson, 301-827-1631

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Foods - Domestic and Import	Foods Composition Standard Labeling and Economics-21

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods.

5. PROGRAM JUSTIFICATION

Medical foods are formulated to be consumed or administered entirely under the supervision of a physician and are intended for the specific dietary management of a 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 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/CPB 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: N/A [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Medical Foods	41G[][] Use appropriate product identification number

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Nutrient declarations. Micro exam fo*Listeria monocytogenes, Salmonella, Staphylococcus aureus, Bacillus cereus, Escherichia coli*and Aerobic Plate Count (APC).

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Foods - Domestic and Import	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21002	X ORA X CENTER	4.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM	4 DOMESTIC SAMPLE COLL MICRO	5 IMPORT SAMPLE COLL *	7 DSAs MICRO	7 DSAs CHEM	8 ISAs CHEM **	8
	TOTAL FIELD	22	44	25	19	8	19	25	8	
	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									
W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - 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	2. PPS PROJECT NAME/NUMBER
Domestic and Import NLEA Nutrient Sample/Analysis and General Food Labeling Program	Foods Composition Standard Labeling and Economics-21

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 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

FALCPA requires that all domestic and imported foods labeled on or after January 1, 2006 disclose the presence of a major food allergen in plain English. In addition, most food products entering interstate commerce on or after January 1, 2006 must list trans fat in the nutrition label. The Act also mandates other required label information on food labels. Continuous monitoring of food labels will ensure compliance with regulations established under the Act and identify potential problem areas with the implementation of the new labeling requirements.

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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All food products (except vitamins/minerals)	02-41

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] 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	2. PPS PROJECT NAME/NUMBER
Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21005, 03R833, 99R833 21R824, 21R829(Health Fraud)	[X] ORA [ ] CENTER	9.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DSC	2 DSCs (DOCUMENTARY)	3 DSCs (PHYSICAL) *	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	4000	125	125	2225	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 OPERATION									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION		4.2			18.0	0.4	1.2	10.0		1.2
TOTAL HOURS		1428			1800	1600	150	1250	2225	942
CONVERSION FACTOR		950			1180	950	950	1180	950	950
TOTAL OPERATIONAL FTEs		1.50			1.53	1.68	0.16	1.06	2.34	0.99

7. REMARKS

*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.

**Domestic operations to be conducted during inspections conducted under CP 7303.803,7303.803A,7303.037 and 7303.842.

***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.

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

*****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.

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 530.04 for additional information on Food and Cosmetic Security Activities.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Infant Formula - Domestic and Import	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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. Food security issues are to be covered during all inspections.

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/CPB 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Infant Formula	40C

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Nutrients as required by the Act. Micro exam for *Listeria monocytogenes, Salmonella, Staphylococcus aureus, Bacillus cereus, Escherichia coli,* Aerobic Plate Count (APC).

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Infant Formula Program	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21006	[X] ORA [X] CENTER	4.3

REGION	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		30	20	10	20	10	15	15
	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 LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION	37.0		5.3			100.0	30.0	5.0	100.0
	TOTAL HOURS	814		159			2000	300	75	1500
	CONVERSION FACTOR	950		950			1180	1180	950	1180
	TOTAL OPERATIONAL FTEs	0.86		0.17			1.69	0.25	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 beginining 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	2. PPS PROJECT NAME/NUMBER
Dietary Supplements - Domestic and Import	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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 guidance 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Dietary supplements	54

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* 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	2. PPS PROJECT NAME/NUMBER
Dietary Supplements	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21008, 21R829 (Health Fraud)	[ ] ORA [X] CENTER	15.9 (13.0)

REGION	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	900	200	100	50	50				3000
	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 LABORTORY-SW										
	PACIFIC REGIONAL LABORTORY-NW										
HOURS PER OPERATION		22.0	0.5	4.2	20.0	4.2	20.0				
TOTAL HOURS		5500	450	840	2000	210	1000				3000
CONVERSION FACTOR		950	950	950	1180	950	1180				950
TOTAL OPERATIONAL FTEs		5.79	0.47	0.88	1.69	0.22	0.85				3.16

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.
Additional resources have been planned in the Field Assignments for Chemical Contaminants (04F800) for a pesticide contaminant assignments for selected supplement products.
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.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Dietary Supplements	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21008, 21R829 (Health Fraud)	[ ] ORA [X] CENTER	(2.9)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ISC PAPER OASIS #41 **	ISC PHYSICAL ***	IMPORT INV HOURS *	ISA PHYSICAL CHEM						
	TOTAL FIELD	360	70	900	70						
	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	1.6	1.6		20.0						
	TOTAL HOURS	576	112	900	1400						
	CONVERSION FACTOR	950	950	950	1180						
	TOTAL OPERATIONAL FTEs	0.61	0.12	0.95	1.19						

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 assesment 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	2. PPS PROJECT NAME/NUMBER
Selected Nutrients in Food Survey	Foods Composition Standard Labeling and Economics-21

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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.

Note: In FY 07 folic acid analysis by the Atlanta Center for Nutrient Analysis (ACNA) has been cancelled.

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

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Various foods as required by the Total Diet Studies Program	37, 40

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING
[X] MICROANALYTICAL [X] OTHERS *(Specify)* Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Calcium, phosphorus, iron, selenium, zinc, copper, magnesium, manganese, nickel, potassium, sodium, iodine, water, and folate.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Selected Nutrient in Foods Survey - Total Diet	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21839	[ ] ORA [X] CENTER	3.4

REGION	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		
	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							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	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21R816	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		APPLIED TECHNOLOGY CENTER CHEM (Hours)							
	TOTAL FIELD		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									
	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			1180							
CONVERSION FACTOR			1180							
TOTAL OPERATIONAL FTEs			1.00							

9. REMARKS

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Colors and Cosmetics Technology - 29

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		3.1	4.5		7.6	13.2	
1	Cosmetics: Domestic and Imports	29001; 29F099; 29R833; 29R824 99R833	3.1	4.5		7.6	13.2	2/3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy, 301-436-2061	Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics: Domestic and Import PACs 29001, 29R833, 29R824, 99R833	Colors and Cosmetics Technology - 29

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Cosmetic Products	53

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* 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	2. PPS PROJECT NAME/NUMBER
Cosmetics: Domestic and Imports	Colors and Cosmetics Technology - 29

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
29001, 29R833, 29R824, 99R833	X ORA [ ] CENTER	7.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECT-IONS	2 DOMESTIC INVESTI-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT ENTRY REVIEW (HOURS) *		4 IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	8 IMPORT SAMPLE ANALYSIS (CHEM)	8 IMPORT SAMPLE ANALYSIS (MICRO)
	TOTAL FIELD	100		60	60	1411		230	115	115
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(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									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		15.6		5.5	20.7			1.5	10.0	20.7
TOTAL HOURS		1560		330	1242	1411		345	1150	2381
CONVERSION FACTOR		950		950	1180	1200		950	1180	1180
OPERATIONAL FTEs		1.64		0.35	1.05	1.18		0.36	0.97	2.02

7. REMARKS

* Import Entry Review Hours include time for Filer Evaluation (PAC 99R833) and Follow Up to Refusal (PAC 29R824) and **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 2007

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	113.9	3.0	4.1	121.0	196.6	5.2	7.2	209.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	26.9			26.9	46.5			46.5
42	BLOOD AND BLOOD PRODUCTS	77.0	3.0	2.9	82.9	132.9	5.2	5.1	143.2
45	VACCINES AND ALLERGENIC PRODUCTS	10.0		1.2	11.2	17.2		2.1	19.3

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		26.9			26.9	46.5	
1	Tissue Establishments	41002B,C,D	19.5			19.5	33.7	2/3
2	Bioresearch Monitoring Programs *		7.4			7.4	12.8	4/5
	Good Laboratory Practices	41808	*			*		
	(Nonclinical Labs)							
	Institutional Review Board	41809	*			*		
	Sponsors, Contract Research Organizations,	41810	*			*		
	and Monitors							
	Clinical Investigators *	41811	(7.4)			(7.4)		

* All resources planned under PAC 41811.

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Anita Richardson, 301 827-6220	Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) // Tissue Establishments	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To determine if human cells, tissue, and cellular & tissue-based product (HCT/P) establishments are in compliance with the regulations (21 CFR, Parts 1270 and 1271), promulgated under the Public Health Service Act, Section 361, to assure that HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing.

C.P. 7341.002 - Inspection 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)

5. PROGRAM JUSTIFICATION

Human cells, tissues, and cellular & tissue-based products (HCT/Ps) are important products for medical treatment. Monitoring the recovery and processing of HCT/Ps and the testing and screening of the donors is critical to assure consumer protection from unsuitable products which may endanger public health.

6. FIELD OBLIGATIONS

ORA will perform the inspections, prepare and submit EIRs to the Center for Biologics Evaluation and Research (CBER), and recommend administrative/regulatory actions when appropriate.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	for PAC 41002B 57 K Reproductive Tissue for PAC 41002C 57 M Hematopoietic Stem Cells for PAC 41002D 57 J, 57 L, 57 O All other HCT/Ps 57 P 99 is used for all Human Tissues, n.e.c.

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

FY 2007 ORA WORKPLANNING SHEET October 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps) Inspection of Tissue Establishments	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41002B, C, D	[X] ORA [ ] CENTER	19.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 CBER PRIORITY ESTABs *	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	**484**	**(178)**							
	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	38.3								
	TOTAL HOURS	18537								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	19.51								

9. REMARKS

* CBER requests Districts to inspect Priority Establishments on CBER 7-25-06 memo Attachment.

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)

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs (Nonclin. Lab), IRBs, Spon/Mon/CROs, Clinical Investigators (PDUFA)	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57 / 99 99 is used for products n.e.c.

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	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor-Monitors, Clinical Investigators (PDUFA Domestic & Foreign)	Human Cellular, Tissue & Gene Therapies - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41808-GLP, 41809-IRB, 41810-Spon./ Monitor, 41811 Clinical Investigator *	[X] ORA [ ] CENTER	7.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS *	2 DOMESTIC INVESTIGATIONS (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	**76**								
	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	92.5								
	TOTAL HOURS	7030								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	7.40								

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Blood and Blood Products - 42

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE DOMESTIC	IMPORT	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. TOTAL PROGRAM FTEs	9. PAGE
	TOTAL		77.0	3.0	2.9	82.9	143.2	
1	Inspection of Licensed & Unlicensed Blood Banks	42001F, G;	53.9		0.4	54.3	93.8	2/3
	(National Experts)	42R825	2.6		0.1	2.7	4.7	
	Inspection of Donor Centers							
	Inspection of Reference Laboratories							
	Inspection of Blood/Plasma Brokers							
	Inspection of Blood Produ							
	Technical Assistance and Coordination *		2.5			2.5	4.3	
2	Inspection of Source Plasma Establishments	42002,A	9.9			9.9	17.1	4/5
3	Examination of Blood & Blood Components	42007, 42R833,		3.0		3.0	5.2	6/7
	Offered for Import	42R824,99R833						
4	Inspection of Licensed Viral Marker Test Kits	42008,A	1.5		0.9	2.4	4.2	8/9
	(Core Team Biologics)							
	Field Investigations		0.6			0.6	1.0	
5	Bioresearch Monitoring Programs **		3.5			3.5	6.0	10/11
	Institutional Review Board	42809	*					
	Sponsors, Contract Research Organizations,	42810	*					
	and Monitors							
	Clinical Investigators **	42811	(3.2)				(5.5)	
	(National Experts)	42808, 42811	(0.3)				(0.5)	
		45808, 45811						
6	Inspection of Medical Device Manufacturers	42845A,B,C	1.0			1.0	1.7	12/13
7	Inspection of Plasma Derivatives of							
	Human Origin (Core Team Biologics)	42848A,F,G	1.5		1.5	3.0	5.2	14/15

* For BLT-DO to Assist & Coordinate ARC Information

** All Domestic & Foreign Resources Planned Under Domestic PAC 42811

Foreign Resources to cover PPS 41, 42, 45

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Anita Richardson, 301 827-6220	Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed and Unlicensed Blood Banks	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations: (a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products: (b) 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Blood and Blood Products	55, 57

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	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign) *	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42001F,G 42R825	[X] ORA [ ] CENTER	59.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSPECTIONS	1	2 DOMESTIC INVESTIGATIONS (Hours) **	1 FOREIGN BLOOD BANK INSPECTIONS ***	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDINATION (Hours)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	1130		2469	12			2375		
	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									
	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		45.3			40.0					
TOTAL HOURS		51189		2469	480			2375		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		53.88		2.60	0.51			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.

Domestic Inspectional Module Includes Time for AIDS.
Blood Bank PAC's: 42001F, Level 1 Inspection and 42001G, Level 2 Inspection.
Use Operation Code 11 for all Foreign Inspections.
BLT-DO, Report Technical Assistance Time under Operation Code 92.

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

*** Foreign Blood Bank Inspections spread by DFI.

Personnel Types Required: Investigator, National Experts

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Source Plasma Establishments	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Source Plasma	55, 57

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	2. PPS PROJECT NAME/NUMBER
Inspection of Source Plasma Establishments	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42002	[X] ORA [ ] CENTER	9.9

REGION	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)
	TOTAL FIELD	**174**	**1331**							
	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									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	46.4								
	TOTAL HOURS	8074	1331							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATION FTEs	8.50	1.40							

7. REMARKS

The above resources may be used for Follow-Up Inspections, DSCs, and Foreign Inspections as needed.

* Includes some hours for Follow-Up Inspections. (Report Follow-Up Domestic Inspections as Operation 12 under PAC 42002.)

Personnel Types Required: Investigator, Team Biologics

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Examination of Biological Products Offered for Import	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biological Products	57

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	2. PPS PROJECT NAME/NUMBER
Examination of Biological Products Offered for Import	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42007, 42R833, 42R824, 99R833 41R824, 45R824	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 42R833 IMPORT ENTRY REVIEW 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		**3600**							
	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 - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION										
TOTAL HOURS			3600							
CONVERSION FACTOR			1200							
TOTAL OPERATION FTES			3.00							

9. REMARKS

Resources are planned under PAC 42R833. Report accomplishments under appropriate PAC.
Planned Resources Cover: 42R833 Entry Review; 41R824, 42R824, 45R824 Follow-Up to Refusals; 99R833 Filer Evaluation and any inspections needed for PAC 42007.

Note: Title change; and guidance was issued for importation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Licensed Viral Marker Test Kits (Inspections of In Vitro Diagnostic Product Manufacturers)	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To evaluate the manufacturing process for licensed *in vitro* 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), *In Vitro* 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

In Vitro 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
In Vitro Diagnostic Products accordance with the stated objective.	55, 57, 65 & 81 (Device Categories)

e. EXAM TYPE: [ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Device Specific

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42008, A Domestic & Foreign *	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 Post-Licensed DOMESTIC INSPEC-TIONS	1 Post-Licensed FOREIGN INSPEC-TIONS	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	**12**	**4**	**570**						
	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		120.0	210.0							
TOTAL HOURS		1440	840	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.52	0.88	0.60						

7. REMARKS

* 42008 GMP Inspections,
42008A Pre-License Inspections
All inspections will be performed by Core Team Biologics.
No separate resources are planned for 42008A, use above resources as needed.
Report Foreign Inspections under Operation Code 11.

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

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
IRBs, Spon./Mon./ CROs, Clinical Investigators **(PDUFA)**	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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).

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 biological products 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: Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57 / 99 99 is used for products n.e.c.

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	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor-Monitors, Clinical Investigators (PDUFA Domestic & Foreign)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42809-IRB, 42810-Spon./Monitor, 42811 Clinical Investigator *	[X] ORA [ ] CENTER	3.5

REGION	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	38								
	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									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		87.5								
TOTAL HOURS		3325								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		3.50								

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	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers (Biologics) **PACs 42845A,B,C**	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To evaluate the manufacturing processes for those medical devices and *in vitro* 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 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All devices in the product categories transferred to CBER	65 & 81 (Device Categories)

e. EXAM TYPE: [ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)* Device Specific

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42845A, B, C *	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (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	16								
	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		59.4								
TOTAL HOURS		950								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.00								

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	2. PPS PROJECT NAME/NUMBER
Inspections of Plasma Derivatives of Human Origin **PACs 42848A,F,G**	Blood and Blood Products - 42

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fractionation Products	55, 57

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	2. PPS PROJECT NAME/NUMBER
Inspection of Plasma Derivatives of Human Origin	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42848A, F, G; 41848A, F, G Domestic & Foreign *	[X] ORA [ ] CENTER	3.0

REGION	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	7	7							
	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	207.1	200.0							
	TOTAL HOURS	1450	1400							
	CONVERSION FACTOR	950	950							
	OPERATIONAL FTEs	1.53	1.47							

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: Investigator, Core Team Biologics, Investigator

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Vaccines and Allergenic Products - 45

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. TOTAL PROGRAM FTEs	9. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		10.0		1.2	11.2	19.3	
1	Bioresearch Monitoring Programs *		6.0			6.0	10.3	2/3
	Institutional Review Board	45809	*					
	Sponsors, Contract Research Organizations,	45810	*					
	and Monitors							
	Clinical Investigators *	45811	(6.0)					
2	Licensed Allergenic Products	45848A,F,G	0.9		0.3	1.2	2.1	4/5
	(Core Team Biologics)							
3	Licensed Vaccine Products	45848B,C,D	2.5		0.9	3.4	5.9	6/7
	(Core Team Biologics)							
	Field Time		0.6			0.6	1.0	

* All resources planned under PAC 45811

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Anita Richardson, 301 827-6220	Harriet R. Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
IRBs, Spon./Mon./CROs, Clinical Investigators **(PDUFA)**	Vaccines and Allergenic Products - 45

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57 / 99 99 is used for products n.e.c.

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	2. PPS PROJECT NAME/NUMBER
IRBs, Sponsors-Monitors, Clinical Investigators (PDUFA)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45809 IRBs, 45810 Spon/Mon, 45811 Clin. Invest.	[X] ORA [ ] CENTER	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY SPECIALIZED	1 INSPECTIONS *	2 INVESTIGATIONS (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	66								
	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 OPERATION									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	86.4								
	TOTAL HOURS	5702								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	6.00								

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	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Allergenic Products PACs 45848A,F,G	Vaccines and Allergenic Products - 45

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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:
[X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57

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	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Allergenic Products (Post-Market & Pre-License)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45848A,F,G Domestic/Foreign *	[X] ORA [ ] CENTER	1.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 * DOMESTIC INSPECTIONS	1 * FOREIGN INSPECTIONS	2 DOMESTIC INVESTIGATIONS (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	7	2							
	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									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	126.2	130.0							
	TOTAL HOURS	883	260							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	0.93	0.27							

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 - Allergenics
PAC 45848F Level 1 CGMP Inspection - Allergenics
PAC 45848G Level 2 CGMP Inspection - Allergenics
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	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Vaccine Products PACs 45848B,C,D	Vaccines and Allergenic Products - 45

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57

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	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Vaccine Products (Post-Market)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45848B,C,D Domestic/Foreign *	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS	1 FOREIGN INSPECTIONS	2 DOMESTIC INVESTIGATIONS (Hours)	3 DOMESTIC INVESTIGATIONS (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	6	570						
	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		300.0	140.9							
TOTAL HOURS		2400	845	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		2.53	0.89	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 2007 ORA WORKPLAN
October 1, 2006

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	276.5	34.5	43.0	354.0	478.9	59.6	74.5	613.0
46	NEW DRUG EVALUATION	12.3		15.0	27.3	21.3		26.0	47.3
48	BIORESEARCH MONITORING HUMAN DRUGS	49.0		3.0	52.0	84.8		5.2	90.0
52	GENERIC DRUG EVALUATION	15.0		9.0	24.0	26.0		15.6	41.6
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	8.0		1.0	9.0	13.9		1.7	15.6
56	DRUG QUALITY ASSURANCE	171.2	34.5	15.0	220.7	296.5	59.6	26.0	382.1
63	UNAPPROVED AND MISBRANDED DRUGS	9.0			9.0	15.6			15.6
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0	20.8			20.8

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	New Drug Evaluation - 46

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		**12.3**		**15.0**	**27.3**	**47.3**	
1	NDA Pre-Approval Inspections/Investigations - Domestic (PDUFA)	46832/B/C	12.3			12.3	21.3	2-3
2	NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)	46832/B/C			15.0	15.0	26.0	4-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Joseph Famulare, HFD-320; (301) 827-8940	Anita T. McCurdy 301-827-1632

FORM FDA 2622 (9/98)

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations	New Drug Evaluation - 46

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive Drugs	All Human Drug Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations -Domestic (PDUFA)	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832, 46832B, 46832C 46832M ☑	[X] ORA [ ] CENTER	12.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDAs TO INSPECT (Domestic)	1 CHEMIST INSPECT (HOURS) (Domestic) *	2 INVESTI-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL		7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) **	7 DSAs METH. VALID. (MICRO)	7 DSAs METH. VALID CHEM	
	TOTAL FIELD	112	2275		30		30	6	15	
	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									
	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		56.0			5.0		50.0	105.0	105.0	
TOTAL HOURS		6272	2275		150		1500	630	1575	
CONVERSION FACTOR		950	950		950		1180	1180	1180	
TOTAL OPERATIONAL FTES		6.60	2.39		0.16		1.27	0.53	1.33	

7. REMARKS

* Includes Microbiologists on Inspections.

** NRL analyzes profile DSCs in NE & SE Regions. FCC analyzes profile DSCs in CE, SW and PA Regions.

☑46832M Therapeutic Biologics Products PAC- Resources under 56002M.

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations - Foreign	New Drug Evaluation - 46

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive Drugs	All Human Drug Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

FY2007 ORA WORKPLAN

October 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832, 46832B, 46832C, 46832D	[X] ORA [ ] CENTER	15.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS ++ FOREIGN	1 CHEMIST INSPS (Hours) FOREIGN **							9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	190	3325							
	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		57.5								
TOTAL HOURS		10925	3325							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		11.50	3.50							

7. REMARKS

* **Report as follows:** Insps./Chem on Insps 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
FY 2007 ORA WORKPLAN

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		49.0		3.0	52.0	90.0	
1	In Vivo Bioequivalence - ANDAs & NDAs	48001,A	5.0			5.0	8.7	2-3
	PDUFA (NDAs)		(3.0)					
	Foreign Inspections (In Vivo Bioequivalence,	48001,A;			3.0	3.0	5.2	4-5
	GLPs, Clinicial Investigators)	48808; 48811						
	National Experts PDUFA				(0.4)			
	Field PDUFA				(1.3)			
	* Foreign Inspections PEPFAR (AIDS Relief)	48001D,E;						
	(planned under 48001A and 48001)							
	National Experts (NDAs & ANDAs 0.1)	48811D						
2	Bioresearch Monitoring							6-11
	Good Laboratory Practices (Non-Clinical Lab)	48808	5.0			5.0	8.7	
	National Experts		(0.4)					
	** Institutional Review Board	48809, 48809A	8.0			8.0	13.7	
	Sponsors, Contract Research Organizations,	48810	2.7			2.7	4.7	
	and Monitors							
	Clinical Investigators	48811	28.3			28.3	49.0	
	National Experts		(0.4)					

* 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	ORA PLANNER/TELEPHONE
Joanne L. Rhoads, (301) 594-0020	Carrie M. Mampilly, (301) 827-1635

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60 , 61

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	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence (Pre-Approval)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48001 (ANDAs) 48001A (NDAs) (PDUFA)	[X] ORA [ ] CENTER	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPEC-TIONS DOMESTIC	1 48001A NDA INSPEC-TIONS (PDUFA) DOMESTIC	2 IMPORT INVESTIGATION HOURS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9
	TOTAL FIELD	30	36							
	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									
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	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	65.0	78.5							
	TOTAL HOURS	1950	2826							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	2.05	2.97							

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) 41%, PDUFA 48001A (NDA) 59%.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60 , 61

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	2. PPS PROJECT NAME/NUMBER
Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48001,A; 48808; 48811; 48001D,E; 48811D NDA &, ANDA *	X ORA ☐ CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPEC-TIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPEC-TIONS (PRE-APPR)	2 IMPORT INVESTIGATION HOURS	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9	
	TOTAL FIELD	25	19							
	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									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	62.7	67.7							
	TOTAL HOURS	1568	1286							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	1.65	1.35							

7. REMARKS

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

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

HIGH PRIORITY for NDA inspections.

** President's Emergency Plan for AIDS Relief (PEPFAR):
48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator.
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	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practice (Nonclinical Laboratory)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60 , 61

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	2. PPS PROJECT NAME/NUMBER
Institutional Review Board (IRB); Radioactive Drug Research Committee (RDRC)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60 , 61

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	2. PPS PROJECT NAME/NUMBER
Sponsors, Contract Research Organizations, & Monitors	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60 , 61

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	2. PPS PROJECT NAME/NUMBER
Clinical Investigators	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60 , 61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors; Clinical Investigators (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48808, 48809, 48809A, 48810, 48811	[X] ORA [ ] CENTER	44.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 GLP INSPEC-TIONS 48808	2 NAT'L EXPERT INVESTI-GATIONS (Hours) 48808 - GLP	1 SPONSOR, CRO, MONITORS INSPECTIONS 48810 *	1 CLINICAL INVESTIGA-TORS INSPECTIONS 48811	2 NAT'L EXPERT INVESTI-GATIONS (Hours) 48811 - CI **	1 *** IRB INSPECTIONS 48809, 48809A §			
	TOTAL FIELD	50	380	35	282	333	123			
	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	87.8		73.4	94.1		62.0			
	TOTAL HOURS	4390	380	2569	26536	333	7626			
	CONVERSION FACTOR	950	950	950	950	950	950			
	TOTAL OPERATIONAL FTEs	4.62	0.40	2.70	27.93	0.35	8.03			

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 48-5).

* Sponsors, Contract Research Organizations, and Monitors
** Clinical Investigators
*** Institutional Review Board

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Generic Drug Evaluation - 52

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		15.0		9.0	24.0	41.6	
1	ANDA Pre-Approval	52832	15.0			15.0	26.0	2-3
	-Domestic							
2	ANDA Pre-Approval Inspections/Investigations	52832			9.0	9.0	15.6	4-5
	-Foreign							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Joseph Famulare HFD-320; (301) 827-8940	Anita T. McCurdy 301-827-1632

FORM FDA 2622 (9/98)

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA - Pre-Approval Inspections/Investigations	Generic Drug Evaluation - 52

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	All Human Drug Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre - Approval Inspections/Inv. - Domestic	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832, B, C	[X] ORA [ ] CENTER	15.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAs TO INSPECT Domestic	1 CHEMIST INSPECT. (Hours) *	2 DOMESTIC INVEST (Hours)	3 DOMESTIC SAMPLE COLL **	3 PROFILE/ PORTION OF DSCs FOR **	7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	7 BIOTEST (Chem) ***	7 DSAs (METH) (VALID) (Chem)	9 MISC. HOURS
	TOTAL FIELD	**110**	**1931**	**1593**	**140**	**(50)**	**45**	**45**	**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									
	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		57.5			5.0		50.0	30.0	105.0	
TOTAL HOURS		6325	1931	1593	700		2250	1350	1050	
CONVERSION FACTOR		950	950	950	950		1180	1180	1180	
TOTAL OPERATIONAL FTEs		6.65	2.03	1.68	0.74		1.91	1.14	0.89	

7. REMARKS

*Includes microbiologists on inspections. ** DSCs for profile/biotest analyses. Includes 50 Profile DSCs to be analyzed by Division of Drug Analysis (HFD-920). *** NRL-analyzes profile/biotest DSCs collected in NE &SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre-Approval Inspections/Investigations - Foreign	Generic Drug Evaluation - 52

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [x] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [x] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	All Human Drug Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

ANDA Pre - Approval Inspections/Investigations - Foreign	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832, 52832B ,52832C, 52832E	[X] ORA [ ] CENTER	9.0

REGION	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) ****	8 IMPORT SAMPLE ANALYSES METH. VALID ****
	TOTAL FIELD	**42**	**1900**	**950**		**140**		**70**	**70**	**15**
	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(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									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	Southwest Import District									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		50.0				3.0		30.0	15.0	50.0
TOTAL HOURS		2100	1900	950		420		2100	1050	750
CONVERSION FACTOR		950	950	950		950		1180	1180	1180
TOTAL OPERATIONAL FTEs		2.21	2.00	1.00		0.44		1.78	0.89	0.64

7. REMARKS

*** Report as follow: Insps./Chem on Insps. under foreign operation code 11 Pac Code 52832;**

++ PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

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

** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers.

**** NRL analyzes all Profile/Biotest ISCs and methods development ISAs.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		8.0		1.0	9.0	15.6	
1	Enforcement of the Adverse Drug Experience Reporting Regulation	53001A,B	8.0		1.0	9.0	15.6	2-3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ralph J Schmid, HFD-332; 301-827-8929	Anita T. McCurdy, 301-827-1632

FORM FDA 2622 (9/98)

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Adverse Drug Experience Reporting Regulations	Postmarketing Surveillance & Epidemiology: Human Drugs - 53

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To provide assignments, guidance and instructions to field offices for inspecting drug firms to determine compliance with the ADE reporting requirements of 21 CFR 310.305,314.80 and 318.98. 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 54, 56, 60-66

e. EXAM TYPE: [ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Adverse Drug Experience Reporting Regulations	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001A, 53001B *	[X] ORA [X] CENTER	9.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS DOMESTIC	1 INSPECTIONS FOREIGN	2 INVESTIGATION	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 MISC. HOURS
	TOTAL FIELD	**133**	**16**							
	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 - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION		57.0	60.0							
TOTAL HOURS		7581	960							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		7.98	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.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Drug Quality Assurance - 56

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		171.2	34.5	15.0	220.7	382.1	
1	Drug Process Inspections - Domestic	56002A-F, *	120.5			120.5	208.7	2-5
2	Drug Process Inspections - Gas Manufs.	56002E	5.0			5.0	8.6	
3	Foreign Drug Inspections	56002A-F,*			15.0	15.0	26.0	6-7
4	Drug Product Surveillance - Domestic Drugs	56008A,C	25.7			25.7	44.5	8-11
5	Drug Product Surveillance - Import Drugs	56008H***		34.5		34.5	59.7	
6	Drug Quality Reporting System - DQRS	56021A, B	4.0			4.0	6.9	12-13
7	Enforcement of Rx Drug Marketing Act (PDMA)	56022	2.0			2.0	3.5	14-15
8	Pharmacy Compounding Assignments	56D015	4.0			4.0	6.9	16-17
9	Forensic Evaluation and Sample Analysis	56R838****	10.0			10.0	17.3	18-19
	(*) 56832, 56R359							
	(***) 56R824, 56R833, 99R833							
	(****)56R831							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ralph J. Schmid, HFD-330; 301-827-8929	Anita T. McCurdy 301-827-1632

FORM FDA 2622 (9/98)

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process Inspections	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 50, 54-56, 60-66

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002, A, B, C, D, F 56832, 56R359, 56002M*	[X] ORA [ ] CENTER	120.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 INVESTI-GATIONS (Hours) *	1 CHEMIST ON INSPECTIONS (Hours)	1 MICRO ON INSPEC-TIONS (Hours)	3 DOMESTIC SAMPLE COLL **	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	9 CERTIFICATION HOURS For Audits
	TOTAL FIELD	1377	2810	7574	1538	450	229	40	229	40	2850
	HEADQUARTERS	(b)(2) & (b)(7)(E)					(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										
	ATLANTA										
	FLORIDA										
SE	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
SW	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION	65.0				5.0			38.0	28.0	
	TOTAL HOURS	89505	2810	7574	1538	2250			8702	1120	2850
	CONVERSION FACTOR	950	950	950	950	950			1180	1180	950
	TOTAL OPERATIONAL FTEs	94.22	2.96	7.97	1.62	2.37			7.37	0.95	3.00

7. REMARKS

* Investigations hours are for additional drug inspections or investigations as needed.

(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.

[ ] *The shaded area breaks out the sample collections and is only a guideline for Districts.*

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
DRUG Process Inspections- Domestic (Gas Manufacturer)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002E	[X] ORA [ ] CENTER	5.0

REGION	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	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLE ANALYSES	8 IMPORT SAMPLES ANALYSES	9 MISC. HOURS
	TOTAL FIELD	**158**								
	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									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PA	PACIFIC REGIONAL-SW									
	PACIFIC REGIONAL-NW									
HOURS PER OPERATION		30.0								
TOTAL HOURS		4740								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.99								

9. REMARKS

* Total number of planned gas inspections in the Program for FY 2007.

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

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Drug Inspections	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	All Human Drug Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [X] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Drug Inspections	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002,A,B,C,D,E,F 56832	[X] ORA [ ] CENTER	15.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS FOREIGN	1 CHEMIST INSPEC-TIONS (Hours) FOREIGN **							
	TOTAL FIELD	174	3800							
	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		60.0								
TOTAL HOURS		10440	3800							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		10.99	4.00							

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 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 toward drug products, firms, and countries which pose a heightened risk to the consuming public relative to the risk-based management system.

To obtain information about the identifying characteristics (forensic testing) of APIs from domestic/foreign sources in order to establish a forensic database to evaluate formulation changes and uncover possible counterfeiting.

5. PROGRAM JUSTIFICATION

FDA has the mandate to assure that the nation's drug supply is safe and effective. The Drug Product Surveillance program is FDA's primary means for monitoring the quality of finished drug products and APIs through sampling and analysis.

6. FIELD OBLIGATIONS

To collect samples and perform laboratory examinations. Upon assignment from CDER, conduct inspections to obtain specific information, such as analytical results, production data, and formulation.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 50, 54-56 and 60-66

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINERING [X] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance - Domestic Drugs	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008A, C	X ORA X CENTER	25.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTIONS	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	3 DOMESTIC SAMPLE COLLECTIONS (API)	7 DOMESTIC SAMPLES ANALYZED (CHEM) *	7 DOMESTIC SAMPLES ANALYZED (MICRO) *	6 DOMESTIC SAMPLES ANALYZED (API) (Chem)	7 METHODS DEVELOPMENT HOURS (Chem)
	TOTAL FIELD	950	870	750	120	180	750	120	180	3540
	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 LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION			4.0			4.0	19.0	22.0	19.5	
TOTAL HOURS		950	3480			720	14250	2640	3510	3540
CONVERSION FACTOR		950	950			950	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.00	3.66			0.76	12.08	2.24	2.97	3.00

9. REMARKS

*DSAs are assigned by Division of Field Science, ORO per lab expertise for specific Drugs.

The shaded area breaks out the sample collections and is only a guideline for Districts.

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FY 2007 ORA Workplan October 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance - Imported Drugs	Drug Quality Assurance-56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008H, 56R833, 56R824, 99R833	X ORA ☐ CENTER	34.5

REGION	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	14700	7510		10260	120	60	60
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(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							
	ATLANTA							
	FLORIDA							
SE	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
SW	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
PA	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION						2.7	38.0	25.0
TOTAL HOURS		14700	7510		10260	324	2280	1500
CONVERSION FACTOR		1200	950		950	950	1180	1180
TOTAL OPERATIONAL FTEs		12.25	7.91		10.80	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 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Reporting System - DQRS NDA-Field Alert Reporting	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs	All Human Drug Codes

e. EXAM TYPE: [ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56021A, 56021B	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL				7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)		
	TOTAL FIELD	100	300	30				30		
	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 LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		25.0		4.0				35.0		
TOTAL HOURS		2500	300	120				1050		
CONVERSION FACTOR		950	950	950				1180		
TOTAL OPERATIONAL FTEs		2.63	0.32	0.13				0.89		

7. REMARKS

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Prescription Drug Marketing Act (PDMA)	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs	All Human Drug Codes

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Analysis as directed in CDER/district assignments.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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
[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
2.0

REGION	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 (Chem)	8 IMPORT SAMPLES TO BE ANALYZED	
	TOTAL FIELD	41	950	34				34		
	HEADQUARTERS	(b)(2) & (b)(7)(E)						(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									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		15.0		2.0				11.0		
TOTAL HOURS		615	950	68				374		
CONVERSION FACTOR		950	950	950				1180		
TOTAL OPERATIONAL FTEs		0.65	1.00	0.07				0.32		

7. REMARKS

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pharmacy Compounding Assignments	Drug Quality Assurance - 56

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 50, 54, 56 and 60-66

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pharmacy Compounding Assignments	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56D015 *	[X] ORA [ ] CENTER	4.0

REGION	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 Misc. (Hours)
	TOTAL FIELD		3800							
	HEADQUARTERS		(b)(2) & (b)(7)(E) redacted							
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									
	REGIONAL STAFF									
SW	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			3800							
CONVERSION FACTOR			950							
TOTAL OPERATIONAL FTEs			4.00							

7. REMARKS

*A block of hours is planned for pharmacy compounding assignments.

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

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Drug Quality Assurance - 56

3. PROGRAM TYPE: N/A ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☐ 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 56R838 or OCI PAC 56R831.
Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report time spent on these activities as PODS Operation Code 03, PAC 56R838 Petition Validation, Methods Development, or Forensic Evaluation. Please consult DFS and/or DPEM for additional reporting guidance.

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

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATE ☐ DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R838, 56R831	[X] ORA [ ] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION
	TOTAL FIELD	12050
	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		
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.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Unapproved and Misbranded Drugs: - Human Drugs - 63

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		9.0			9.0	15.6	
1	Internet, Health Fraud, & OTC Monographs	63001A, 63D012	6.0			6.0	10.4	2-3
2	New Drugs Rx Not Covered by Approved NDA	63002	3.0			3.0	5.2	4-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
William Nychis HFD-310 301-594-1065	Anita T. McCurdy 301-827-1632

FORM FDA 2622 (9/98)

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Internet, Health Fraud, and OTC Monographs	Unapproved and Misbranded Drugs - 63

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

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 off-shore 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 follow-up.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 50, 54, and 60-66

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Internet, Health Fraud, & OTC Monographs	Unapproved and Misbranded Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63001A, 63D012	[X] ORA [ ] CENTER	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVEST-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL. *	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED Chem	8 IMPORT SAMPLES TO BE ANALYZED	9 MISC. (Hours)
	TOTAL FIELD	**32**	**3325**	**118**				**59**		
	HEADQUARTERS	(b)(2) & (b)(7)(E)						(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									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		30.0		4.0				20.0		
TOTAL HOURS		960	3325	472				1180		
CONVERSION FACTOR		950	950	950				1180		
TOTAL OPERATIONAL FTEs		1.01	3.50	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.

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
New Drug (Prescription) Without Approved NDAs	Unapproved and Misbranded Drugs - 63

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Prescription Drugs	Industry Codes: 54, 56, and 60-66

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	2. PPS PROJECT NAME/NUMBER
New Drugs (Prescription) Without Approved NDAs	Unapproved and Misbranded Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63002	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVEST-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL. *			7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 MISC. (Hours)
	TOTAL FIELD	**47**	**950**	**95**					
	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		30.0		5.0					
TOTAL HOURS		1410	950	475					
CONVERSION FACTOR		950	950	950					
TOTAL OPERATIONAL FTEs		1.48	1.00	0.50					

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.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	ICA (Interagency Cooperative Activities) - 88

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		12.0			12.0	20.8	
1	Shelf Life Extension Projects	*	12.0			12.0	20.8	2-3
	*See Data Codes Manual for appropriate							
	project reporting PACs.							
2	United States Pharmacopeia (USP)		(7.0)			(7.0)	(7.0)	4-5
	Reference Standards							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Donna A. Porter, HFC-140; 301-827-2757	Anita T. McCurdy 301-827-1632

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Shelf Life Extension Projects	Interagency Cooperative Activities - 88

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 50, 54, 56, and 60-66

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Environmental chambers used to stress drug products.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Shelf Life Extension Projects	Interagency Cooperative Activities - 88

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
All Appropriate PACs	[X] ORA [ ] CENTER	12.0

REGION	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 (Chem) Hours	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD							**14160**		
	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									
	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.

FY 2007

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
United States Pharmacopeia (USP) Reference Standards	Interagency Cooperative Activities - 88

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

To formalize a partnership between the USP and the FDA to further ensure the quality and standard of marketed pharmaceutical products. Also, to ensure that high quality reference standards are available in the USA.

5. PROGRAM JUSTIFICATION

The USP Reference Standards Program is essential to the FDA laboratory-based regulatory programs and to the pharmaceutical industry. The Reference Standards serve as a tool to FDA in enforcing the quality requirements for marketed drugs. The Standards are recognized by governments of more than 35 other countries.

6. FIELD OBLIGATIONS

Selected ORA laboratories will receive, analyze, evaluate, review, and report findings on candidate samples.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Codes: 50, 54, 56, and 60-66

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Environmental chambers used to stress drug products.

1. PROGRAM/ASSIGNMENT TITLE
USP Reference Standards

2. PPS PROJECT NAME/NUMBER
Interagency Cooperative Activities - 88

3. PROGRAM/ASSIGNMENT CODE(S)
88R451

4. WORK ALLOCATION PLANNED BY
[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
7.0

REGION	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**		
	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									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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 2007

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	97.3	21.8	4.0	123.1	168.4	37.7	6.9	213.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	7.1		3.6	10.7	12.3		6.2	18.5
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	90.2	21.8	0.4	112.4	156.1	37.7	0.7	194.5

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

PROJECT SUMMARY SHEET
FY 2007 ORA WORKPLAN

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Animal Drugs and Feeds	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

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		7.1		3.6	10.7	18.5	
1	NADA Pre-Approval Inspections	68001	2.1		3.6	5.7	9.9	2-3
2	Bioresearch Monitoring		5.0			5.0	8.6	4-7
	(Pre-Market) GLP and Spon/Mon/Con	68808*	(2.9)			(2.9)		
	*68810 planned under 68808	68810						
	(Pre-Market) Clinical Investigators	68811	(2.1)			(2.1)		

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deborah A. Cera, (240) 276-9209	Carrie M. Mampilly, (301) 827-1635

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NADA Pre-Approval Inspections	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Animal Drugs, Type A Medicated Feed Articles	56, 67, 68

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Petition validation work.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NADA Pre-Approval Inspections	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68001	[X] ORA [X] CENTER	5.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	1 CHEMIST ON INSP **	1 INSPEC-TIONS (Foreign) ***	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED	9			
	TOTAL FIELD	**38**	**285**	**47**						
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	45.4		72.5						
	TOTAL HOURS	1725	285	3408						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	1.82	0.30	3.59						

7. REMARKS

** Analyst will participate on inspections as necessary.

Districts and Laboratories should collect and analyze samples as needed by the program, time for these operations is planned under inspections and chemist on inspections.

*** Foreign inspections spread by DFI. Use Operation Code 11 to report foreign inspections.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practice (Non-clinical Laboratory)	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Animal Drugs	67, 68, or 69

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	2. PPS PROJECT NAME/NUMBER
Sponsors, Contract Research Organizations, and Monitors	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Animal Drugs	67, 68, or 69

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	2. PPS PROJECT NAME/NUMBER
Clinical Investigators	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Animal Drugs	67, 68, or 69

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	2. PPS PROJECT NAME/NUMBER
GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68808, 68810, 68811	[X] ORA [ ] CENTER	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 68808 INSPEC-TIONS (GLPs) (SPON/MON) *	1 68811 INSPEC-TIONS (CLINICAL INVEST)							
	TOTAL FIELD	**43**	**44**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	63.3	46.0							
	TOTAL HOURS	2722	2024							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	2.87	2.13							

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"; 3-year inspectional data from OPAS (PAC 68811)).

PROJECT SUMMARY SHEET
FY 2007 ORA WORKPLAN

PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Animal Drugs and Feeds	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

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		**90.2**	**21.8**	**0.4**	**112.4**	**194.5**	
1	Drug Process and New Animal Drug Inspections	71001/71R841	9.2		0.4	9.6	16.5	2-3
2	Feed Contaminants	71003A-J	12.0	2.2		14.2	24.5	4-7
3	Feed Manufacturing	71004/A	6.1			6.1	10.6	8-9
4	Illegal Drug Residues in Meat and Poultry	71006	12.0			12.0	20.8	10-11
5	Ruminant Feed Ban Rule (BSE) Program *	71009, 71R844	39.9	19.6		59.5	103.0	12-15
6	Methods Validation/Development Program	71R816	5.0			5.0	8.7	16-17
7	Forensic Evaluation and Sample Analysis	71R831/71R838	1.0			1.0	1.7	18-19
8	Center Initiated Assignments, Pandemic Preparedness		5.0			5.0	8.7	20-21
	Center Initiated Assignments	71V800	(1.0)			(1.0)		
	Pandemic Preparedness	71R852	(4.0)			(4.0)		
	*Includes: 71R833, 99R833, and 71R824							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deborah A. Cera, (240) 276-9209	Carrie M. Mampilly, (301) 827-1635

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process and New Animal Drug Inspections / Type A Medicated Articles	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21 CFR 211 for dosage form products and 21 CFR 226 for Type A Medicated Articles. To obtain accurate listing and labeling information for veterinary 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 approval New Animal Drug Application (NADA).

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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.	56, 60-66, 67-69

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES
Sterility, purity, identify, potency, decomposition

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
N/A

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process and New Animal Drug Inspections / Type A Medicated Articles	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71001 /A /B, 71005 /A, 71R841	[X] ORA [ ] CENTER	9.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	1	1 CHEM ON INSP (Hours)	1 INSPEC-TIONS (Foreign)	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	DOMESTIC SAMPLE COLL (Micro)	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	7 DOMESTIC SAMPLES TO BE ANALYZED (Micro)
	TOTAL FIELD	194		475	10	250	76	30	15	30	15
	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	35.9			35.0		5.5			18.4	21.1
	TOTAL HOURS	6965		475	350	250	418			552	317
	CONVERSION FACTOR	950		950	950	950	950			1180	1180
	TOTAL OPERATIONAL FTEs	7.33		0.50	0.37	0.26	0.44			0.47	0.27

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.
Type A Medicated Articles program (71005 / A is now under 71001); continue to report work to PAC 71005 / A.

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: FACTS database (registered firms in IND 56, 67, 68 with Status of "Operational" and Workload Obligation of "Yes".)
Foreign Inspections spread by Division of Field Investigations, ORO.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Complete animal feeds and feed ingredients.	69-72

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - DOMESTIC	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003 A-J	X ORA X CENTER	TOTAL 14.2 DOMESTIC 12.0 IMPORT 2.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (Dioxin) *	3 DOMESTIC SAMPLE COLL ** , ***	3 DOMESTIC SAMPLE COLL Metals 71003B	3 DOMESTIC SAMPLE COLL Myco 71003C	3 DOMESTIC SAMPLE COLL Micro 71003E	3 DOMESTIC SAMPLE COLL Chem 71003A	3 DOMESTIC SAMPLE COLL Dioxin 71003G	7 DOMESTIC SAMPLE ANALYSIS Metals 71003B	7 DOMESTIC SAMPLE ANALYSIS Myco 71003C	7 DOMESTIC SAMPLE ANALYSIS Micro *** 71003E	7 DOMESTIC SAMPLE ANALYSIS Chem 71003A	7 DOMESTIC SAMPLE ANALYSIS Dioxin 71003G
	TOTAL FIELD	10	1005	20	250	200	200	135	20	250	200	200	135
	HEADQUARTERS												
	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												
	ATLANTA												
SE	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
SW	DENVER												
	KANSAS CITY												
	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
PA	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LABORATORY-SW												
	PACIFIC REGIONAL LABORATORY-NW												
	HOURS PER OPERATION	17.0	4.2						12.0	7.7	16.0	5.5	16.7
	TOTAL HOURS	170	4221						240	1925	3200	1100	2255
	CONVERSION FACTOR	950	950						1180	1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.18	4.44						0.20	1.63	2.71	0.93	1.91

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

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: 200 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.

***Domestic Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods.

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

NOTE: Continued on Page 71-7

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-5	Monitoring of Marketed Animal Drugs, Feeds and Devices -71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003 A-H (99R833, 71R833, 71R824)	X ORA X CENTER	2.2

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL *	4 IMPORT SAMPLE COLL Chem	4 IMPORT SAMPLE COLL Micro	4 IMPORT SAMPLE ANALYSIS Chem	8 IMPORT SAMPLE ANALYSIS Micro *				
	TOTAL FIELD	220	155	65	155	65				
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	2.5			7.5	12.0				
	TOTAL HOURS	550			1163	780				
	CONVERSION FACTOR	950			1180	1180				
	TOTAL OPERATIONAL FTEs	0.58			0.99	0.66				

9 REMARKS

Dioxin Samples, 71003G, will be analyzed by ARL and chem samples, 71003 A/B, will follow the distibution 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.

Workload Source: FACTS and OASIS databases.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Manufacturing	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Medicated Feeds	69

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Drug analysis (potency) and drug contamination

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Manufacturing	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71004 / A	[X] ORA [ ] CENTER	6.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FEED ESTABS	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED (Chem)	7 DOMESTIC SAMPLES ANALYZED (Micro)	1 VSIP INSPECTIONS (Hours) *				
	TOTAL FIELD	**220**	**52**	**15**	**5**	**238**				
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		19.7	7.8	49.0	44.0					
TOTAL HOURS		4334	406	735	220	238				
CONVERSION FACTOR		950	950	1180	1180	950				
TOTAL OPERATIONAL FTEs		4.56	0.43	0.62	0.19	0.25				

9. REMARKS

Resources are allocated for 20 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 347 State Contract inspections.

* Resources are for the Voluntary Self Inspection Program (VSIP)

Workload Source: FACTS database (registered firms in IND 69); Workload Obligation is "YES", Firm Status is "Operational".

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Illegal Drug Residues in Meat and Poultry	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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.

Starting in FY 07 CVM will issue assignments for Repeat Violators, (b) Tolerance Residues, and AMDUCA Prohibited residues.

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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Meat and Poultry, Animal Feeds and Drugs	16, 17, 67, 68, 69

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] 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	2. PPS PROJECT NAME/NUMBER
Illegal Residues in Meat & Poultry	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71006	[X] ORA [X] CENTER	12.0

REGION	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	233	950	175	600	500	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									
	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		35.0		6.6						
TOTAL HOURS		8155	950	1155	600	500	360			
CONVERSION FACTOR		950	950	950	1180	1180	1180			
TOTAL OPERATIONAL FTEs		8.58	1.00	1.22	0.51	0.42	0.31			

9. REMARKS

Planned analytical time may be converted to methods development per CVM's concurrence. Methods development work will be assigned by CVM.
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.

Investigation hours: Hours not utilized for investigations may be used for inspections.

The Center will issue FACTS assignments to request Federal inspections of repeat violators, residues involving AMDUCA prohibited drugs, residues of drugs not approved for food animal use, and very high level residues. Districts should contact CVM to discuss a regulatory strategy before expending resources on other cases.

Workload Source: Inspections and investigation hours are assigned by Center.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
BSE/Ruminant Feed Ban Inspections	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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.

5. PROGRAM JUSTIFICATION

Bovine Spongiform Encephalophy (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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Animal feeds and feed ingredients	67-72

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

N/A

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS		
71009, 71R844, 71R843 (99R833, 71R833, 71R824)	[X] ORA [X] CENTER	Domestic	39.9	59.5
		Import	19.6	

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSPECTIONS *	BSE PARTNERSHIP INSEPCTIONS	DOMESTIC INVESTIGATION HOURS	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INVESTIGATION HOURS **	3 DOMESTIC SAMPLE COLLECTIONS	4 IMPORT SAMPLES COLLECTIONS	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES ANALYZED	9 TECHNICAL SUPPORT (HOURS) ***
	TOTAL FIELD	2594	895	2850	11700	3800	855	855	855	855	4921
	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										
	ATLANTA										
SE	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
SW	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	7.5	2.5				5.0	2.5	6.0	5.0	
	TOTAL HOURS	19455	2238	2850	11700	3800	4275	2138	5130	4275	4921
	CONVERSION FACTOR	950	950	950	1200	950	950	950	1180	1180	950
	TOTAL OPERATIONAL FTEs	20.48	2.36	3.00	9.75	4.00	4.50	2.25	4.35	3.62	5.18

9. REMARKS

* 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.

BSE inspections are based on CVM's risk based analysis.

*** Technical support hours includes supporting state activities under the Ruminant Feed Ban Regulation, and for supporting state activites under the Feed Manufacturing Program, 71004. These hours also include resources for audits of state contract inspections.

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)

** 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 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).

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	Monitoring of Marketed Animal Drugs Feeds and Devices - 71

Inspection Priorities.

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. While 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 should 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. Certain higher risk firm types, such as renderers, protein blenders, and feed mills, generally require regular re-inspections, even if the firm did not manufacture with prohibited material at their last inspection. Efforts should also be placed on regulatory agencies in identifying additional firms to be inspected under this program. In the identification, planning, and prioritization of inspections conducted under this program, the following firm / industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- 'For Cause' inspections
- Firms that have a violative history
- Renderers, Protein Blenders, and Feed Mills manufacturing with prohibited materials (Performance Goal Firms)
- Rendering operations (involving any product)
- Protein Blenders (involving any product)
- Commercial feed mills (ruminant feeds involved)
- Commercial feed mills (non-ruminant feeds involved)
- Animal feed distributors/retailers (ruminant feed or feed ingredients involved)
- Pet food/animal feed salvage operations
- Commercial feed mills (pet food manufacturing ONLY)
- Haulers/transporters of animal feeds (ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (non-ruminant feed or feed ingredients involved)
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Mobile feed mixers
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feed or feed ingredients involved)
- Haulers/transporters of animal feeds (no ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (pet foods ONLY involved)
- On-farm feed mixers (ONLY ruminant OR no ruminant animals on farm premises)

Inspection planning should generally be based on the priority of firms as listed above. Information should be collected on whether a firm has been documented as receiving, processing or distributing prohibited material. This information can be obtained directly through FACTS database, and through the BSE District Coordinator. A listing of these firms can also be found through the CVM website (http://www.fda.gov/cvm/RuminantFeedInspections.htm).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71R816	[X] ORA [ ] CENTER	5.0

REGION	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									
	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	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	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analyses	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71R838	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	1205								
	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 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	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments, Pandemic Preparedness	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All veterinary products	54, 56, 67-72

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

N/A

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments / Pandemic Preparedness	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71V800, 71R852	[X] ORA [ ] CENTER	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI-GATIONS 71V800 (Hours)	PANDEMIC PREPAREDNESS 71R852 (Hours)							
	TOTAL FIELD	950	3800							
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		950	3800							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.00	4.00							

9. REMARKS

These resources include time for a Center-directed assignment to inspect pharmacies coumpounding animal drug products.

PANDEMIC PREPAREDNESS: Resources for investigating avian flu incidents at domestic sites by examining poultry products used in animal feed/feed ingredients including poultry litter (this may require inspections at renderers to determine distribution of poultry products from diseased poultry). Gather Import information on receipt and distribution of adamantine class antiviral drugs; investigate the use of these drugs in domestic status. Investigational details will be provided via directed assignments from CVM.

71R852: Workload Source: Based on poultry production data obtained from USDA/AMS but also ensuring minimal coverage for all Districts. Hours are assigned by CVM.

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 2007

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	170.3	48.0	18.7	237.0	295.6	83.1	32.3	411.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	94.7	39.8	13.7	148.2	163.9	68.9	23.7	256.5
83	PRODUCT EVALUATION: DEVICES	32.6		3.9	36.5	56.4		6.7	63.1
84	SCIENCE: DEVICES	4.7			4.7	8.1			8.1
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.8		0.1	14.9	26.5		0.2	26.7
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	23.0	8.2	1.0	32.2	39.8	14.2	1.7	55.7

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

PROJECT SUMMARY SHEET

FY 2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Postmarket Assurance: Devices - 81

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		0.5			0.5	0.9	
1	Medical Device Problem Reporting - MDR	81010	0.5			0.5	0.9	2-3
	Follow-up							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Susan N. Gardner 301-594-1708	John Aydinian 301-827-1634

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Problem Reporting – MDR Follow-up	Postmarket Assurance: Devices - 81

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73-91

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

Sterility Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Problem Reporting - MDR Follow-Up	Postmarket Assurance: Devices - 81

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
81010	[X] ORA [ ] CENTER	0.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1)	2 INVESTI-GATIONS (Hours) (2)	3 DOMESTIC SAMPLE COLL ENG	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL STER	7 DOMESTIC SAMPLES TO BE ANALYZED ENG (3)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (4)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (5)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	21	74	1	1	1	1	1	1	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		14.8		10.5	10.5	10.5	37.0	36.0	20.0	
TOTAL HOURS		311	74	11	11	11	37	36	20	
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.33	0.08	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.

PROJECT SUMMARY SHEET

FY 2007

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

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		94.7	39.8	13.7	148.2	256.5	
1	Monitoring Devices of Foreign Origin - Import	82008 *		28.1		28.1	48.6	2-3
2	Inspection of Medical Device Manufacturers:		90.7		13.7	104.4	180.6	4-9
	GMP Inspections	82845ABCGS	(88.4)		(13.7)	(102.1)	(176.7)	
	Accredited Persons Audit Investigations	82845J	(0.3)			(0.3)	(0.5)	
	Accredited Persons Audit Inspections	82845P	(2.0)			(2.0)	(3.4)	
3	Condom Assignment	82Z002		4.1		4.1	7.1	10-11
4	Manufacturers and Importers of Surgical/ Examination Gloves	82Z003		7.6		7.6	13.2	12-13
5	BSE Assignment	82Z005	0.2			0.2	0.4	14-15
6	Center Initiated Assignments	82Z800	1.5			1.5	2.6	14-15
7	Methods Validation/Development Program	82R816	2.0			2.0	3.5	16-17
8	Forensic Evaluation & Sample Analysis	82R838	0.3			0.3	0.5	18-19

* In addition to PAC 82008, includes reporting PACs 82R824, 82R833, and 99R833.

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Tim Ulatowski 301-594-4692	John Aydinian 301-827-1634

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Monitoring Devices of Foreign Origin - Import	Compliance: Devices - 82

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [X] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73-91

e. EXAM TYPE: [ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Refer to Compliance Program for procedures to handle initial distributors and/or foreign establishments which are not registered.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Monitoring Devices of Foreign Origin - Import	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82008, 82R824, 82R833, 99R833	[X] ORA [ ] CENTER	28.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 IMPORT INV HOURS *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (Physical) ENG	4 IMPORT SAMPLE COLL (Physical) MICRO **	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		23111	5663		60	60	60	60	
	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									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION					2.2	2.2	25.5	25.5	
	TOTAL HOURS		23111	5663		132	132	1530	1530	
	CONVERSION FACTOR		1200	950		950	950	1180	1180	
	TOTAL OPERATIONAL FTEs		19.26	5.96		0.14	0.14	1.30	1.30	

9. REMARKS

* Import investigation hours are for field exams, filer evalutions, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

** 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).

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers	Compliance: Devices - 82

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Class II and III Devices and all Class I Devices which have been finally classified for one year.	73-91

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS ***(Specify)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845A,B,C,G,J,K,P,S, 81845R,T, 81011	[X] ORA [ ] CENTER	104.4 [101.6]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS LEVEL I DOMESTIC 82845A	1 INSPECTIONS LEVEL II DOMESTIC 82845B	1 INSPECTIONS LEVEL III COMPLIANCE DOMESTIC 82845C	1 INSPECTIONS FOREIGN 82845B	1 INSPECTIONS FOR CAUSE DOMESTIC 82845G	1 INSPECTIONS FOR CAUSE HIGH RISK DOMESTIC 82845G	1 INSPECTIONS ACCRED PERSONS DOMESTIC 82845P	2 INVESTIGATIONS (Hours) 82845B	2 INVESTIGATIONS (Hours) A.P. AUDITS MDUFMA 82845J
	TOTAL FIELD	707	470	107	200	75	75	24	3103	255
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		36.0	65.0	89.0	65.0	71.0	100.0	78.0		
TOTAL HOURS		25452	30550	9523	13000	5325	7500	1872	3103	255
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		26.79	32.16	10.02	13.68	5.61	7.89	1.97	3.27	0.27

9. REMARKS

For FY 2007, the hours/operation module for Level I inspections has been planned at 36 hours/operation to include additional time for MDR review. Level II inspection hours/operation modules have also been adjusted to reflect increased levels of 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.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845A,B,C,G,J,K,P,S, 81845R,T, 81011	[X] ORA [ ] CENTER	104.4 [2.3]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL 82845C	3 DOMESTIC SAMPLE COLL ENG 82845C	3 DOMESTIC SAMPLE COLL MICRO 82845C	3 DOMESTIC SAMPLE COLL CHEM 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C		
	TOTAL FIELD	41	10	24	7	10	24	7		
	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									
W	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	6.0				72.0	62.0	32.5		
	TOTAL HOURS	246				720	1488	228		
	CONVERSION FACTOR	950				1180	1180	1180		
	TOTAL OPERATIONAL FTEs	0.26				0.61	1.26	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 Reagant Testing to support GMP observations at WEAC.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845A,B,C,G,J,K,P,S, 81845R,T, 81011	[X] ORA [ ] CENTER	104.4 [0.5]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL 82845S	3 DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR 82845S	3 DOMESTIC SAMPLE COLL STERILITY 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82845S	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	17	11	6	11	6				
	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									
W	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	6.0			25.0	25.0				
	TOTAL HOURS	102			275	150				
	CONVERSION FACTOR	950			1180	1180				
	TOTAL OPERATIONAL FTEs	0.11			0.23	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	2. PPS PROJECT NAME/NUMBER
Condom Assignment	Compliance: Devices - 82

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
	85

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Condom Assignment	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z002	[X] ORA [ ] CENTER	4.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL CHEM	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	3			315				315	
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
V	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	24.0			2.3				12.2	
	TOTAL HOURS	72			725				3843	
	CONVERSION FACTOR	950			950				1180	
	TOTAL OPERATIONAL FTEs	0.08			0.76				3.26	

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	2. PPS PROJECT NAME/NUMBER
Manufacturers and Importers of Surgical/Examination Gloves	Compliance: Devices - 82

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
	85

e. EXAM TYPE: [X] CHEMICAL [ ] MICROBIOLOGICAL [X] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Manufacturers and Importers of Surgical/Examination Gloves	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z003	[X] ORA [ ] CENTER	7.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL ENG (PHYSICAL)	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
	TOTAL FIELD				**225**	**680**			**225**	**680**
	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									
W	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				2.6	2.6			6.7	6.7
	TOTAL HOURS				585	1768			1508	4556
	CONVERSION FACTOR				950	950			1180	1180
	TOTAL OPERATIONAL FTEs				0.62	1.86			1.28	3.86

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
BSE Assignment/Center Initiated Assignments	Compliance: Devices - 82

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

BSE: To enhance FDA's uniformity in inspection and compliance of BSE firms subject to the regulation and to determine compliance with the BSE regulation.

Center Initiated Assignments: Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.

5. PROGRAM JUSTIFICATION

BSE: FDA seeks to protect the public through the development of a comprehensive strategy of education, inspection and enforcement action on industry. These activities were initiated to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) regulations.

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

BSE: Districts will, upon assignment, conduct inspections of firms whose devices may contain or be exposed to BSE risk material to implement the objectives of this assignment.

Center Initiated Assigments: Conduct inspections and investigations as directed by Center assignments.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Center Initiated Assignments: All Devices	Center Initiated

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Center Initiated Assignments: Sterility/Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
BSE Assignment, Center Initiated Assignments	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z005, 82Z800	[X] ORA [ ] CENTER	1.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS BSE (1) 82Z005	1 INSPECTIONS CENTER-INITIATED 82Z800	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL (2) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (3) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY(4) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (5) 82Z800	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) METH DEV ENG (6) 82Z800
	TOTAL FIELD	10	22		14	1	2	2		400
	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									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	20.0	36.0		10.0	15.0	50.0	50.0		
	TOTAL HOURS	200	792		140	15	100	100		400
	CONVERSION FACTOR	950	950		950	1180	1180	1180		1180
	TOTAL OPERATIONAL FTEs	0.21	0.83		0.15	0.01	0.08	0.08		0.34

9. REMARKS

(1) BSE Inspections (82Z005):Districts will, upon assignment, conduct inspections of firms whose devices may contain, or be exposed to, BSE risk material.
(2) Includes Documentary Samples and Analytical Samples.
(3) WEAC--Ad Hoc testing of test kits or reagents.
(4) WEAC--Sterility samples.
(5) WEAC--Ad Hoc testing of media.
(6) WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Compliance: Devices - 82

3. PROGRAM TYPE: N/A [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82R816	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV MICRO (Hours)	METHODS VAL/DEV CHEM (Hours)							
	TOTAL FIELD	**1205**	**1205**							
	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									
	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	1205							
	CONVERSION FACTOR	1205	1205							
	TOTAL OPERATIONAL FTEs	1.00	1.00							

9. REMARKS

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

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

3. PROGRAM TYPE: N/A ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☐ 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 ☐ BY DISTRICT OFFICE ☐ BY CENTER ☐ BY BOTH

b. INSPECTION TYPE: N/A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
	N/A

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82R838	[X] ORA [ ] CENTER	0.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	360								
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	360								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.30								

9. REMARKS

PROJECT SUMMARY SHEET

FY 2007

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

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		32.6		3.9	36.5	63.1	
1	Medical Device Premarket Approval and		8.1		3.1	11.2	19.3	2-3
	Postmarket Inspections:							
	MDUFMA User Fee	83001	(5.0)			(5.0)	(8.6)	
	PreMarket Approval Inspections	83001	(1.0)		(1.7)	(2.7)	(4.7)	
	Postmarket Approval Inspections	83001A	(2.1)		(1.4)	(3.5)	(6.0)	
2	Bioresearch Monitoring		24.5		0.8	25.3	43.8	4-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Daniel Schultz 301-594-2022	John Aydinian 301-827-1634

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Premarket Approval and Postmarket Inspections	Product Evaluation: Devices - 83

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73-91

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	2. PPS PROJECT NAME/NUMBER
Medical Device Premarket Approval and Postmarket Inspections	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83001, A	[X] ORA [ ] CENTER	11.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS PRE-APPROVAL 83001	1 INSPEC-TIONS POST-APPROVAL 83001A	1 FOREIGN INSPEC-TIONS PRE-APPROVAL 83001	1 FOREIGN INSPEC-TIONS POST-APPROVAL 83001A	1 INSPEC-TIONS MDUFMA USER FEE 83001	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	20	65	32	27	99				
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		48.2	30.2	50.7	49.4	48.2				
TOTAL HOURS		964	1963	1622	1334	4772				
CONVERSION FACTOR		950	950	950	950	950				
TOTAL OPERATIONAL FTEs		1.01	2.07	1.71	1.40	5.02				

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Product Evaluation: Devices - 83

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73Z, 74Z and 94Z, 95Z

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	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring (Pre-Market)	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83808, 83809, 83810, 83811	[X] ORA [ ] CENTER	25.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS DOMESTIC	1 INSPECTIONS FOREIGN	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	300	10							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	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 Matthew Tarosky at (240) 276-0243 with any questions.

.P, IRB, Sponsor/Monitor, and Clinical Investigator Inspections have been consolidated for planning purposes, with a column for Domestic and Foreign inspections. Continue to report time against PACs 83808 (GLP), 83809 (IRB), 83810 (Sponsor/Monitor), and 83811 (Clinical Investigator), depending on the type of inspection.

PROJECT SUMMARY SHEET

FY 2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Science: Devices - 84

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		4.7			4.7	8.1	
1	Test Method Development and Evaluation	84Z002	3.7			3.7	6.4	2-3
2	Methods Validation/Development Program	84R816	1.0			1.0	1.7	4-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Larry Kessler 301-827-4777	John Aydinian 301-827-1634

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Test Method Development and Evaluation	Science: Devices - 84

3. PROGRAM TYPE: N/A [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
To be assigned	73-91

e. EXAM TYPE: [ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Test Method Development and Evaluation	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84Z002	[ ] ORA [X] CENTER	3.7

REGION	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	9 OTHER OPERATIONS (Hours)	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	TOTAL FIELD								**800**	**3590**
	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									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS									800	3590
CONVERSION FACTOR									1180	1180
TOTAL OPERATIONAL FTEs									0.68	3.04

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Science: Devices - 84

3. PROGRAM TYPE: N/A [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84R816	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY				APPLIED TECHNOLOGY CENTERS MICRO (Hours)					
	TOTAL FIELD				**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									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
W	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					1180					
CONVERSION FACTOR					1180					
TOTAL OPERATIONAL FTEs					1.00					

9. REMARKS

PROJECT SUMMARY SHEET

FY 2007

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Mammography Quality Standards Acts (MQSA) Authority - 85

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		14.8		0.1	14.9	26.7	
1	Mammography Facilities Inspection Program	85014 A,C,F	14.8		0.1	14.9	26.7	2-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Lynne L. Rice 301-443-2845	John Aydinian 301-827-1634

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mammography Facilities Inspection Program	Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Mammography equipment	90

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	2. PPS PROJECT NAME/NUMBER
Mammography Facilities Inspection Program	Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
85014 A,C,F	[X] ORA [ ] CENTER	14.9 [9.4]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 85014 (1)	1 INSPEC-TIONS FOREIGN 85014 (2)	1 INSPEC-TIONS 85014 (3)	1 INSPEC-TIONS 85014 (4)	1 INSPEC-TIONS 85014F (5)	1 INSPEC-TIONS 85014F (6)	2 INVESTI-GATIONS (Hours) 85014A (7)	2 INVESTI-GATIONS (Hours) 85014F (8)	
	TOTAL FIELD	213	15	122	31	9	9	2321	5334	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
W	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	8.0	8.0	8.0	8.0	11.0	11.0			
	TOTAL HOURS	1704	120	976	248	99	99	2321	5334	
	CONVERSION FACTOR	1160	1160	1160	1160	1160	1160	1160	1160	
	TOTAL OPERATIONAL FTEs	1.47	0.10	0.84	0.21	0.09	0.09	2.00	4.60	

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) Inspection Follow-Up Activities (Non-Warning Letter).

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mammography Facilities Inspection Program	Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
85014 A,C,F	[X] ORA [ ] CENTER	14.9 [5.5]

REGION	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	9 OTHER OPERATIONS (Hours) 85014 (9)	9 OTHER OPERATIONS (Hours) 85014 (10)	9 OTHER OPERATIONS (Hours) 85014C (11)
	TOTAL FIELD							1200	5162	59
	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									
W	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								1200	5162	59
CONVERSION FACTOR								1200	1160	1160
TOTAL OPERATIONAL FTEs								1.00	4.45	0.05

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

9) Technical Assistance and Coordination Activities: RRHRs.
10) Technical Assistance and Coordination Activities.
11) Compliance Activities.

PROJECT SUMMARY SHEET

FY 2007

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		23.0	8.2	1.0	32.2	55.7	
1	Optical Electronic Products:		4.5		0.2	4.7	8.1	2-3
	Inspection of Manufacturers of Laser Products	86001	(4.2)		(0.2)	(4.4)	(7.6)	
	Field Implementation of the Sunlamp & Sunlamp	86002	(0.3)			(0.3)	(0.5)	
	Products Peformance Standard as Amended							
2	X-Ray Surveillance Programs:		10.0			10.0	17.3	4-11
	Field Compliance Testing of Diagnostic X-Ray	86003	(9.0)			(9.0)	(15.6)	
	Equipment							
	Field Compliance Testing of Cabinet X-Ray	86004	(1.0)			(1.0)	(1.7)	
	Equipment							
3	Compliance Testing of Electronic Products	86006, A, B,	3.1		0.8	3.9	6.8	12-13
	at WEAC	D, E						
4	Imported Electronic Products	86007 *		8.2		8.2	14.2	14-15
5	Radiological Health Control Activities:		5.4			5.4	9.3	16-19
	Medical Device and Radiological Health Use	86008	(3.4)			(3.4)	(5.9)	
	Control and Policy Implementation							
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	(3.4)	
	* In addition to PAC 86007, includes reporting							
	PACs 86R824, 86R833, and 99R833.							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Lynne L. Rice 301-443-2845	John Aydinian 301-827-1634

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Optical Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Inspection of Manufacturers of Laser Products:
To determine if laser products are in compliance with the radiation emissions requirement of the "laser performance standard."

Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:
To conduct a field enforcement program to determine the compliance of sunlamp and sunlamp products with both the performance standard and Agency issued recommendations.

5. PROGRAM JUSTIFICATION

Inspection of Manufacturers of Laser Products: FDA conducts a program effort to protect the public from the dangerous emission of radiation from laser products. Under the authority of Public Law 90-602 the FDA published a Laser Product Performance Standard designed to control dangerous emissions from these products and is applicable to laser products manufactured after August 2, 1976. In addition, those laser products that are used in medical applications are covered under this Agency's medical device authority.
Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: FDA conducts program efforts to minimize radiation emissions from electronic products and devices that have proven to have harmful biological effects. Under the authority of Public Law 90-602 and the Medical Device Amendments to the Food, Drug and Cosmetic Act, FDA has published a performance standard and separate recommendations designed to control the emission of light radiation from sunlamp products. The performance standard for sunlamp products became effective May 7, 1980, and the amended standard on September 7, 1986. Recent studies suggest that exposure to excessive UVA radiation has resulted in malignant melanoma.

6. FIELD OBLIGATIONS

Inspection of Manufacturers of Laser Products: Electro-Optic specialists will initiate and schedule their own inspections of laser manufacturers listed in the compliance program. In addition, the Electro-Optic Specialist will participate on joint CDRH/ORA inspections when such inspections are scheduled by the Center.
Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: Districts will identify and schedule inspections of sunlamp product manufacturers for compliance with the FD&C Act. Districts will initiate and conduct field testing of suntanning facilities per the guidance set out in the compliance program. In addition, in that most states and local radiological health bureaus have no regulation on these products, the field should establish communications with them and offer assistance if they choose to develop such regulations.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Lasers and laser products Sunlamp, suntanning booths, and sunlamp products.	95LS-99 95 US-11

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

f. CHECK THE FOLLOWING ATTRIBUTES

Sunlamp Products: The investigator should use the inspectional Check-List (Review of Product Compliance) located in the compliance program when conducting field tests under this compliance program.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Caution: laser product *may* be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Optical Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86001, 86002	[X] ORA [X] CENTER	4.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 86001 (1)	1 INSPEC-TIONS FOREIGN 86001 (2)	1 INSPEC-TIONS 86002 (3)	2 INVESTI-GATIONS (Hours) 86001 (4)	3 DOMESTIC SAMPLE COLL 86001	5 FIELD EXAMS/ TESTS 86001 (5)	5 FIELD EXAMS/ TESTS 86002 (6)	9 OTHER OPERATIONS (Hours) 86001 (7)	9 OTHER OPERATIONS (Hours) 86002
	TOTAL FIELD	100	5	7	638	5	75	30	1216	75
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	17.2	52.4	13.8		3.0	5.0	3.9		
	TOTAL HOURS	1720	262	97	638	15	375	117	1216	75
	CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	1.81	0.22	0.10	0.67	0.02	0.39	0.12	1.28	0.08

9. Remarks

Inspection of Manufacturers of Laser Products:

1) Comprehensive Inspections can only be claimed for manufacturers of radiation-emitting products on a recurring basis.
2) Number of inspections for Engineering Analyst.
4) Investigation Hours--refer to Compliance Program for reporting information.
5) Will include laser products located at a user facility and laser light shows.
7) To include all other activities such as technical assistance, coordination, and training.

Sunlamps and Sunlamp Products:

3) Inspectional figures are only for biennial inspections of manufacturers of sunlamp products (to include sunlamps, booth beds, etc.). Inspections are to be conducted in conjunction with a GMP inspection. Examination of booth beds at tanning parlors, athletic clubs, etc. should be reported as field exams and not inspections.
6) The field test of each sunlamp product should be counted as a separate operation.

NOTE: RRHR's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
X-Ray Surveillance Programs	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Field Compliance Testing of Diagnostic X-Ray Equipment:
To determine if certified dental and medical x-ray diagnostic equipment meet the Federal performance requirement for diagnostic x-ray equipment (21 CFR 1020.30), in order to monitor the compliance of x-ray equipment component manufacturers and assemblers.

Field Compliance Testing of Cabinet X-Ray Equipment:
To determine compliance with the performance standard for cabinet x-ray equipment with respect to radiation emissions under conditions of use.

5. PROGRAM JUSTIFICATION

Field Compliance Testing of Diagnostic X-Ray Equipment:
Under the authority of Public Law 90-602, FDA has published a performance standard designed to control unnecessary radiation associated with diagnostic x-ray equipment. The promulgated standard became effective August 1, 1974, and this authority extends to all diagnostic x-ray equipment manufactured after that date.

Field Compliance Testing of Cabinet X-Ray Equipment:
Under the authority of Public Law 90-602 FDA published a performance for cabinet x-ray equipment which became effective on April 10, 1975, (and on April 25, 1974, for carry-on baggage systems). This performance standard is designed to control the emission levels of radiation from cabinet x-ray systems and baggage x-ray equipment and to assure that radiation exposure will be reduced to, or maintained at, acceptable levels in accessible areas from those systems manufactured after the effective date of the standard. In addition, the standard will have the effect of minimizing incidences of system failure and associated excessive radiation exposure.

6. FIELD OBLIGATIONS

Diagnostic X-Rays: Assemblers will be inspected to ensure their capabilities to properly install diagnostic x-ray components. Field personnel will conduct tests using their discretion as far as site selection except where the CDRH identifies priorities. Equipment at each site will be tested per the instruction of the compliance program. ORA will monitor both State and Federal inspectors to assure quality and consistency in the collected test data. **Cabinet X-Rays**: Districts will conduct record reviews of manufacturers in their inventory to determine locations of cabinet x-ray systems. Identified site locations will be sent to appropriate DDs so they can schedule field tests. Field personnel will conduct tests at locations identified by the district. Each site shall be investigated per the instructions of the compliance program.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Diagnostic X-Ray Equipment Cabinet x-ray and baggage x-ray	94DS--- 94 IS-11 94 IS-21

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Diagnostic X-Rays: 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	2. PPS PROJECT NAME/NUMBER
X-Ray Surveillance Programs	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86003, 86004	[X] ORA [X] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 86003	1 INSPEC-TIONS * 86004	2 INVESTI-GATIONS (Hours) 86003	2 INVESTI-GATIONS (Hours) 86004	5 FIELD EXAMS/ TESTS 86003	5 FIELD EXAMS/ TESTS 86004	5B AUDITS 86003	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) 86003
	TOTAL FIELD	**18**	**8**	**1030**	**40**	**1307**	**163**	**30**		**3225**
	HEADQUARTERS	(b)(2) & (b)(7)(E)								(b)(2) & (b)(7)(E)
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
W	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	16.0	8.0			3.0	5.2	4.0		
	TOTAL HOURS	288	64	1030	40	3921	848	120		3225
	CONVERSION FACTOR	950	950	950	950	950	950	950		950
	TOTAL OPERATIONAL FTEs	0.30	0.07	1.08	0.04	4.13	0.89	0.13		3.39

9. REMARKS

* CSO trained for surveying X-Ray equipment. Inspections to be performed during first quarter of fiscal year.

Planning guidance:

1st quarter: Contact all X-Ray manufacturers in the District, and conduct an onsite inspection of 50% of the manufacturers (rather than phone contact only).

2nd quarter: Complete one-third of field tests.

3rd quarter: Complete two-thirds of field tests.

4th quarter: Complete remaining field tests.

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

Diagnostic X-Rays (86003):

1) Inspections are spread based on the number of x-ray assemblers. (b)(2) & (b)(7)(E)

2) Investigation hours are for review of assembler reports.

3) Field Tests and Audits are obtained from Attachment A, and are provided by CDRH's Compliance X-Ray Products Branch, HFZ 300. Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor to verify both Federal and State data.

1) Other Operations includes Coordination/Technical Assistance resources for Field Test Review.

ources of Diag. X-Ray Workloads: Inspections are based on the OEI of Diag. X-Ray Assemblers;Investigation Hours are based on review-ng 2579 Reports (Assembler Reports of X-Ray Equip. Installations);Coordination Hours are based on the Total Field Test Records to review.

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ATTACHMENT A
2007 WORKPLAN FOR FIELD COMPLIANCE TESTING OF DIAGNOSTIC X-RAY SYSTEMS
(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2007)

NEW ENGLAND DISTRICT

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

BALTIMORE DISTRICT

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

CHICAGO DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
IL	(b)(2) & (b)(7)(E)				

CINCINNATI DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
KY	(b)(2) & (b)(7)(E)				
OH					
Total					

DETROIT DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
IN	(b)(2) & (b)(7)(E)				
MI					
Total					

MINNEAPOLIS DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
MN	(b)(2) & (b)(7)(E)				
ND					
SD					
WI					
Total					

NEW JERSEY DISTRICT

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

PHILADELPHIA DISTRICT

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

ATLANTA DISTRICT

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

FLORIDA DISTRICT

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

NEW ORLEANS DISTRICT

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

SAN JUAN DISTRICT

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

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
AR	(b)(2) & (b)(7)(E)				
OK					
TX					
Total					

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
CO	(b)(2) & (b)(7)(E)				
NM					
UT					
WY					
Total					

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
IA	(b)(2) & (b)(7)(E)				
KS					
NE					
MO					
Total					

LOS ANGELES DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
AZ	(b)(2) & (b)(7)(E)				
CA					
Total					

SAN FRANCISCO DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
CA	(b)(2) & (b)(7)(E)				
HI					
NV					
Total					

SEATTLE DISTRICT

State	Number Systems Installed	Partner-ship Tests	FDA Tests	FDA F/U	Audits
AK	(b)(2) & (b)(7)(E)				
ID					
MT					
OR					
WA					
Total					

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure, through laboratory testing, that electronic products meet the FDA performance standards.

5. PROGRAM JUSTIFICATION

Public Law 90-602 and subsequent regulations (21 Subchapter J) are intended to safeguard the public from radiation hazards associated with electronic products. The Act specifically authorizes the Secretary to promulgate performance standards imposing additional requirements on specific electronic products of special concern from a radiation safety standpoint. Such performance standards have been issued: 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).

6. FIELD OBLIGATIONS

WEAC will test all products in accordance with the appropriate compliance program circular and submit each report to the Center. WEAC will return equipment to lenders when advised by the Center. In addition, WEAC will advise the Center with the status of all equipment on hand, being tested and returned to lenders. WEAC will conduct inspections to confirm conformance to the Radiological Health Standards Act.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Microwaves, TV Receivers, Diagnostic X-Ray Equipment, Mercury Vapor/Sunlamp, Ultrasonic Therapy Equipment	96MS, 94VS, 94DS, 95US, 97US

e. EXAM TYPE: [ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [X] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86006 A,B,D,E	[ ] ORA [X] CENTER	3.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS (PL 90-602 STANDARD)	7 DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	7 DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY SOURCE	7 DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	14	75	15	4	1	12			
	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									
W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	70.0	23.6	39.0	245.0	120.0	15.0			
	TOTAL HOURS	980	1770	585	980	120	180			
	CONVERSION FACTOR	1180	1180	1180	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	0.83	1.50	0.50	0.83	0.10	0.15			

9. REMARKS

All samples to be shipped by distributors/manufacturers to WEAC.

-Diagnostic X-Ray

Whole - For analysis of entire diagnostic X-Ray systems for compliance;

Source - Leakage test of diagnostic source assembly only.

Foreign Inspections--PL 90-602 Standard Inspections:

Report accomplishments in PAC 86006;

To ensure conformance to Rad Health Standards; to be conducted by Engineering Analyst.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure that imported electronic products presented for entry into the U.S. are certified to be in compliance with appropriate standards where applicable.

To provide a mechanism through which imported electronic products found to be in noncompliance with FDA regulations can be precluded from introduction into commerce in the United States.

5. PROGRAM JUSTIFICATION

FDA under the authority of Public Law 90-602 conducts program effort to minimize the effects of harmful radiation from electronic products and radiation emitting medical devices. The Act is very specific about restrictions and safeguards concerning such electronic products from foreign countries.

6. FIELD OBLIGATIONS

The district import program manager will monitor all custom entries of electronic products for which performance standards are in effect and determine whether imported models are contained on lists provided by CDRH and that these models are not among those which have been determined to be noncompliant. All information gathered as a result of these activities will be furnished to the Office of Compliance in accordance with the compliance program.

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

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All electronic products or devices that emit radiation.	94-97

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	2. PPS PROJECT NAME/NUMBER
Imported Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86007, 86R824, 86R833, 99R833	[X] ORA [ ] CENTER	8.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 IMPORT INV HOURS *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		7790	1620						
	HEADQUARTERS		(b)(2) & (b)(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
W	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS		7790	1620						
	CONVERSION FACTOR		1200	950						
	TOTAL OPERATIONAL FTEs		6.49	1.71						

9. REMARKS

* Import investigation hours are for field exams, filer evalutions, 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	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Use Control:
Provide technical assistance to State and Federal radiological health programs implementing FDA use control programs, including DENT (see the compliance program for a more complete statement of objectives and laboratory support); Maintain liaison with State radiological health programs; Provide support for regional training activities and regional videotape library; Promote implementation of programs to optimize radiation exposure; Communicate FDA policies to State and local health agencies.

Emergency Planning & Response Activities:
To act as a focal point for emergency readiness response planning by States.

5. PROGRAM JUSTIFICATION

Medical Device and Radiological Health Use Control and Policy Implementation:
Rapidly changing technology requires that the FDA develop use control programs whose effective implementation will require training beyond that possessed by most State radiological health program personnel.

Emergency Planning & Response Activities:
The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.

6. FIELD OBLIGATIONS

Use Control: RRHRs will maintain liaison and provide technical assistance to State/Federal radiological health program personnel; assist in the planning and presentation of quality assurance training with the region; help select State participants in new use control programs; serve as managers of the regional videotape library; and attend the following meetings: National Conference of State Program Directors; Regional meetings with state and local radiological health agencies; and Rockville, MD HQ annual meetings with CDRH, ORA and other FDA officials. WEAC will provide Laboratory Support for the DENT programs.

Emergency Planning & Response Activities: Provide consultation to states and attend regional emergency planning meetings.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:
Emergency Planning & Response Activities
[ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
	Emergency Planning & Response Activities: 94YN-99

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	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86008, 86009	[ ] ORA [X] CENTER	5.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL		9 TECHNICAL ASSISTANCE (Hours) RRHR 86009		9 MISC (Hours) DENT * 86008	9 MISC (Hours) RRHR ** 86008
	TOTAL FIELD						2400		475	3600
	HEADQUARTERS						(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)	
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS							2400		475	3600
CONVERSION FACTOR							1200		1180	1200
TOTAL OPERATIONAL FTEs							2.00		0.40	3.00

9. REMARKS

See Continuation Sheet for footnotes, guidance, etc.

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

Remarks

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

* This block of time provides laboratory support for the DENT program; this include the following activities:
a) reading exposed personnel radiation monitors (i.e. badges) from participating agencies;
b) calibrating and checking the accuracy of DENT survey kits upon request.

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

This block of time also includes coordination, technical assistance, and other activities performed by RRHRs under the following programs:
- Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended (PAC 86002);
- Field Compliance Testing of Diagnostic X-Ray Equipment (PAC 86003);
- Field Compliance Testing of Cabinet X-Ray Equipment (PAC 86004);
- Medical Device and Radiological Health Use Control and Policy Implementation (PAC 86008);
- Emergency Planning and Response Activities (PAC 86009);

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

FOOTENOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):

Technical Assistance hours will be performed by RRHRs.

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