FY 2005

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 February 1, 2005

From Director, Program Planning & Workforce Management Branch

Subject Final FY 2005 ORA Field Workplan

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

The enclosed Final FY 2005 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 preliminary FY 2005 Workplan. The Workplan is based on the FY 2005 FDA Appropriation passed by Congress in December 2004. This Workplan supersedes the Interim Workplan dated September 17, 2004. 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 2005 Program Forecasts.

The FY 2005 ORA Field Workplan is based on ORA's planning base of 1,992 Operational (3,485 Total) FTEs. This represents an overall reduction of 71 Operational FTEs from the FY 2004 Workplan. ORA's budget resources have been steadily eroded due to increasing payroll, rent, and shared services taps that are not adequately funded in the base budget. Any targeted increases in appropriations are more than offset by these increasing costs, and 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. The Total FTEs are considerably lower than FY 2004 because of declining budget resources and the transfer of FTEs to Shared Services.

Foods and Cosmetics

There are 1,105 Operational FTEs for FY 2005. This is a reduction of 29 Operational FTEs from FY 2004. To reflect the continued emphasis on imported products, and to meet Congressional mandates for food defense activities, resources have been shifted from domestic to import foods programs. Significant changes include:

Import Acidified & LACF (03003/A): Field exams increased from 1,500 to 3,000; sample collections and analyses increased from 1,000 to 1,300.

Domestic and Imported Cheese (03037): Inspections reduced from 700 to 500 and NAI firms should be covered every other year. Domestic sample collections and analyses reduced from 600 to 400 and import sample collections and analyses reduced from 1,000 to 700. Investigation hours have been planned for an unpasteurized cheese assignment.

Domestic Acidified & LACF (03803A): Inspections reduced from 500 to 400; sample collections and analyses reduced from 300 to 200.

Domestic Food Safety (03803): Inspections reduced from 4,500 to 3,500; sample collections and analyses reduced from 1,075 to 600.

Import Foods (03819): Field exams increased from 48,000 to 65,000.

Import Seafood (03844): Inspections reduced from 700 to 500.

Import and Domestic Micro Assignments (03F098/100): Samples collections and analyses doubled to 500 import and 500 domestic.

Foreign Inspections (03R233): Inspections reduced from 250 to 200.

Toxic Elements in Foodware (04019B): Domestic sample collections reduced from 210 to 50; domestic field exams reduced from 485 to 100.

Mycotoxins (07001): Domestic and import programs combined into a single program.

Biologics

There are 119 Operational FTEs for FY 2005. This is a reduction of 4 Operational FTEs from FY 2004. Significant changes include:

Source Plasma Establishments (42002): Inspections reduced from 228 to 193.

Examination of Blood Offered for Import (42007/42R833): Entry review hours reduced from 8,280 to 3,480.

Inspection of Medical Device Manufacturers (Biologics): NEW PACS. 42845A (Level 1); 42845B (Level 2); 42845C (Level 3). Refer to C.P. 7382.845 for inspectional guidance.

Human Drugs

There are 408 Operational FTEs for FY 2005. This is a reduction of 23 Operational FTEs from FY 2004. Significant changes include:

A total of 4.5 FTEs of foreign work has been planned for the President's Emergency Plan for AIDS Relief (PEPFAR). This is to conduct inspections of foreign drugs destined to third-world countries. Operations are planned for PACs 46832D, 48001D, and 52832E.

In Vivo Bioequivalence – Foreign (48001A): Foreign NDA (PDUFA) inspections reduced from 57 to 30.

Institutional Review Board (48809): Inspections reduced from 168 to 145.

ANDA Methods Validation – Domestic (52832): Sample analyses reduced from 95 to 50.

Drug Process Inspections – Domestic non-gas (56002): 9.5 additional FTEs allocated to inspectional activities.

Drug Product Surveillance – Domestic (56008A): Increased by 7.6 FTEs and revised for FY 2005 CDER surveillance sampling assignments.

Drug Product Surveillance – Import (56008H): Increased by 10 FTEs to reflect increased emphasis on imported drug products.

Drug Product Surveillance – Domestic Import (56008J): Discontinued as a separate program. Resources have been redistributed to other programs.

Prescription Drug Marketing (56002): Reactivated with 2 FTEs.

Animal Drugs and Feeds

There are 133 Operational FTEs for FY 2005. This is a reduction of 2 Operational FTEs from FY 2004. There is an increase in the BSE program as a result of Congressional directives in the FY 2005 Appropriation. Significant changes include:

NADA Pre-Approval (68001): Domestic inspections reduced from 67 to 50; sample collections and analyses reduced from 40 to 15.

Clinical Investigators (68811): Inspections reduced from 71 to 51.

Drug Process Inspections (71001/71R841): Domestic inspections reduced from 255 to 220.

Feed Contaminants – Domestic (71003): Domestic sample collections and analyses reduced from 1,150 to 760; dioxin inspections reduced from 100 to 60.

Feed Manufacturing (71004): Inspections reduced from 305 to 258.

Illegal Residues (71006): Inspections reduced from 240 to 225; sample analysis hours reduced from 3,361 to 2201; technical support hours eliminated.

Ruminant Feed Ban/BSE (71009): Inspections increased from 2,840 to 3,760; domestic sample collections and analyses increased from 600 to 900; import sample collections and analyses increased from 600 to 900; technical support hours eliminated.

Devices and Radiological Health

There are 227 Operational FTEs for FY 2005. This is a reduction of 12 Operational FTEs from FY 2004. There is an MDUFMA User Fee increase for the Medical Device Preapproval program. There are increases for the Medical Device Preapproval program and the Bioresearch Monitoring program as a result of Congressional directives in the FY 2005 Appropriation. Significant changes include:

Inspection of Medical Device Manufacturers: GMP program (82845): Level 1 inspections reduced from 770 to 714; Level 2 inspections reduced from 515 to 483; Domestic Sample Collections reduced from 177 to 89; Domestic Sample Analyses (ENG) reduced from 25 to 18; Domestic Sample Analyses (MICRO) reduced from 110 to 43; Domestic Sample Analyses (CHEM) reduced from 37 to 18. All Mutual Recognition Agreement (MRA) operations (Inspections and Technical Assistance/Coordination hours) eliminated in FY 2005. National Expert hours increased from 773 in FY 2004 to 2,042. New in FY 2005 are MDUFMA Accredited Person (AP) Audits, with 255 hours planned for this operation.

Center Initiated Assignments (82Z800): Inspections reduced from 40 to 25; Misc ENG hours reduced from 850 to 500 hours.

Medical Device Premarket Approval and Postmarket Inspections (83001): MDUFMA User Fee Inspections increased from 64 to 86.

Bioresearch Monitoring (83808-11): Good Laboratory Practices (GLP) Inspections increased from 18 to 35; Clinical Investigator (CI) Inspections increased from 126 to 168.

Test Method and Development (84Z002): Misc Hours (MICRO) reduced from 1,495 to 775; Misc Hours (ENG) reduced from 3,930 to 3,540; Misc Hours (CHEM) eliminated in FY 2005.

Mammography Facilities Inspection (85014 A,C,F): Investigation Hours reduced from 8,043 to 6,965.

Optical Electronic Products (86001): Investigation Hours reduced from 2,101 to 1,147.

Emergency Planning and Response Activities (86009): Misc Hours reduced from 1,305 to 925.

Workplan Changes between FY 2004 and FY 2005 - a listing of programs and research projects compared to the FY 2004 ORA Field Workplan; these are listed by Center and Program with FTEs, and will enable you to identify where resource shifts and programmatic cuts occurred. (See "Reasons for Change" Excel spreadsheets.)

There has been a terminology change in the FTE Summary Tables. FTEs that were previously categorized as "Supported" are now called "Program" to reflect the dynamic and varied nature of the non-planned FTEs which are an essential part of ORA's workforce.

The FY 2005 Servicing Laboratories Table continues to reflect the laboratory servicing changes consistent with ORA's Laboratory capabilities determined by Division of Field Science. Please review this table carefully and note the latest changes.

The FY05 ORA Workplan has been published to a CD format. Your CD is a non-writable CD 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

Attachments- See "Reasons for Change" files

CFSAN: FY 2005 WORKPLAN - REASONS FOR CHANGE

FEBRUARY 1, 2005

PAC	PROGRAM	FTEs FY 2004	FTEs FY 2005	FTEs Differ-ence	Reason for Change
03003	Import Acidified and Low Acid Canned Foods	9.8	13.9	4.1	Budget/ Reprogramming
03037	Domestic and Imported Cheese and Cheese Products	40.5	28.5	-12.0	Budget/ Reprogramming
03039	National Drug Residue Milk Monitoring Program	3.6	3.6	0.0	
03803A	Domestic Acidified and Low Acid Canned Food	19.2	14.9	-4.3	Budget/ Reprogramming
03803B	Domestic Food Safety	123.6	94.9	-28.7	Budget/ Reprogramming
03819	Import Foods	261.6	288.8	27.2	Budget/ Reprogramming
03842	Domestic Fish and Fishery Products	83.1	75.0	-8.1	Budget/ Reprogramming
03844	Import Seafood Products	103.5	101.4	-2.1	Budget/ Reprogramming
03847H	Juice HACCP Inspection Program (HACCP)	14.0	14.0	0.0	
03R233	Foreign Inspection/Assessments	9.1	7.5	-1.6	Budget/ Reprogramming
03F098	Import & Domestic Micro Assignments	12.2	27.8	15.6	Budget/ Reprogramming
03839	Emergency Response to Foodborne Outbreaks	11.0	7.0	-4.0	Budget/ Reprogramming
03843	Food State Contract Audits	22.8	22.8	0.0	
03R816	ORA/Center Directed Research Projects	14.0	12.0	-2.0	Budget/ Reprogramming
03R845	CT Preparedness	23.1	11.6	-11.5	Budget/ Reprogramming
03	**Food Safety**	**751.1**	**723.7**	-27.4	
04004A,D	Pesticides and Industrial Chemical -Domestic/Import	82.9	85.1	2.2	Budget/ Reprogramming
04018	Chemotherapeutics In Seafood	19.2	17.9	-1.3	Budget/ Reprogramming
04019A,B,C	Toxic Elements Foods & Foodware (Dom. and Imp.)	23.8	23.7	-0.1	Budget/ Reprogramming
04839	Total Diet Study	23.4	23.4	0.0	
04R816	ORA-Center Directed Research Projects	9.6	9.6	0.0	
04R838	Forensic Evaluation and Sample Analysis	10.7	10.8	0.1	
04F800	Field Assignments for Chemical Contaminants	13.1	14.9	1.8	Budget/ Reprogramming
04	**Pesticides and Industrial Contaminants**	**182.7**	**185.4**	2.7	
07001	Mycotoxins Domestic and Imported	29.6	29.6	0.0	Budget/ Reprogramming
07R816	ORA-Center Directed Research Projects	6.5	6.5	0.0	Budget/ Reprogramming
07	**Molecular Biology and Natural Toxins**	**36.1**	**36.1**	0.0	
09006A,B	Imported Foods-Food and Color Additives	9.5	10.0	0.5	Budget/ Reprogramming
09R816	ORA-Center Directed Research Projects	1.1	1.1	0.0	Budget/ Reprogramming
09	**Food and Color Additives**	**10.6**	**11.1**	0.5	
18002	Retail Food Protection - State Program	30.0	26.0	-4.0	Budget/ Reprogramming
18003	Milk Safety Program	28.0	26.0	-2.0	Budget/ Reprogramming
18004	Molluscan Shellfish Evaluation	14.0	14.0	0.0	
18029 A -E	Interstate Travel Program	26.3	27.8	1.5	Budget/ Reprogramming
18	**Technical Assistance**	**98.3**	**93.8**	-4.5	
21002	Medical Foods Import and Domestic	5.0	5.1	0.1	
21005	NLEA, Nutrient Sample Analysis	9.4	9.4	0.0	
21006	Infant Formula Import and Domestic	5.3	6.3	1.0	Budget/ Reprogramming
21008	Dietary Supplements	20.7	19.5	-1.2	Budget/ Reprogramming
21839	Selected Nutrient in Foods survey- Total Diet	4.2	4.2	0.0	
21R816	ORA-Center Directed Research Projects	2.4	2.4	0.0	
21	**Food Composition, Standards, Labeling & Economics**	**47.0**	**46.9**	-0.1	
29001,29002	Cosmetics-Domestic and Import	8.1	8.1	0.0	Budget/ Reprogramming
29	**Colors and Cosmetics Technology**	**8.1**	**8.1**	0.0	
TOTAL FOR PPS 03, 04 ,07 ,09 18, 21 ,29		**1133.9**	**1105.1**	-28.7	

CBER: FY 2005 Workplan - Reason For Change

PAC	Program/Assignment	BASE FTEs FY 2004	BASE FTEs FY 2005	Differ-ence	Reason for Change
41002	Tissue Establishments	15.5	15.5		
41808	Good Laboratory Practices	*	*		
41809	Institutional Review Board	*	*		
41810	Sponsors, CROs, Monitors	1.0	*	-1.0	
41811	Clinical Investigators	6.4	7.4	1.0	
41	**Human Cellular, Tissue & Gene Therapies**	**22.9**	**22.9**		
42001F,G	Blood Bank Inspections	58.0	59.5	1.5	Reprogramming
	Foreign Blood Bank Inspections	1.0	1.0		
	Pre-Licensed Inspections (41,42,45)	1.0			
42002,A	Source Plasma Establishments	12.5	11.4	-1.1	Budget Reduction
42007	Exam of Blood/Components - Import	6.9	4.0	-2.9	Budget Reduction
42008,A	Licensed Viral Marker Test Kits	3.0	3.0		
42809	Institutional Review Board	*	*		
42810	Sponsors, CROs, Monitors	*	*		
42811	Clinical Investigators	3.0	3.5	0.5	Reprogramming
42811 **	Foreign BIMO Inspections	1.0		-1.0	Reprogramming
42845A,B,C	Medical Device Manufacturers (Biol) (was PAC 42830)	2.5	2.5		
42848A,F,G	Plasma Derivatives of Human Origin (was PAC 42006)	3.0	3.0		
42	**Blood & Blood Products**	**91.9**	**87.9**	**-4.0**	
45809	Institutional Review Board	*	*		
45810	Sponsors, CROs, Monitors	*	*		
45811	Clinical Investigators	3.0	3.0		
45848A,F,G	Licensed Allergenic Products (was PAC 45001,A)	1.2	1.2		
45848B,C,D	Vaccine Products (was PAC 45001,A)	4.0	4.0		
45	**Vaccines & Allergenic Products**	**8.2**	**8.2**		
	BIOLOGICS TOTALS	**123.0**	**119.0**	**-4.0**	

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

CBER: FY 2005 Workplan - Reason For Change

PAC	Program/Assignment	BASE FTEs FY 2004	BASE FTEs FY 2005	Differ-ence	Reason for Change
41002	Tissue Establishments	15.5	15.5		
41808	Good Laboratory Practices	*	*		
41809	Institutional Review Board	*	*		
41810	Sponsors, CROs, Monitors	1.0	*	-1.0	
41811	Clinical Investigators	6.4	7.4	1.0	
41	**Human Cellular, Tissue & Gene Therapies**	**22.9**	**22.9**		
42001F,G	Blood Bank Inspections	58.0	59.5	1.5	Reprogramming
	Foreign Blood Bank Inspections	1.0	1.0		
	Pre-Licensed Inspections (41,42,45)	1.0			
42002,A	Source Plasma Establishments	12.5	11.4	-1.1	Budget Reduction
42007	Exam of Blood/Components - Import	6.9	4.0	-2.9	Budget Reduction
42008,A	Licensed Viral Marker Test Kits	3.0	3.0		
42809	Institutional Review Board	*	*		
42810	Sponsors, CROs, Monitors	*	*		
42811	Clinical Investigators	3.0	3.5	0.5	Reprogramming
42811 **	Foreign BIMO Inspections	1.0		-1.0	Reprogramming
42845A,B,C	Medical Device Manufacturers (Biol) (was PAC 42830)	2.5	2.5		
42848A,F,G	Plasma Derivatives of Human Origin (was PAC 42006)	3.0	3.0		
42	**Blood & Blood Products**	**91.9**	**87.9**	**-4.0**	
45809	Institutional Review Board	*	*		
45810	Sponsors, CROs, Monitors	*	*		
45811	Clinical Investigators	3.0	3.0		
45848A,F,G	Licensed Allergenic Products (was PAC 45001,A)	1.2	1.2		
45848B,C,D	Vaccine Products (was PAC 45001,A)	4.0	4.0		
45	**Vaccines & Allergenic Products**	**8.2**	**8.2**		
	BIOLOGICS TOTALS	**123.0**	**119.0**	**-4.0**	

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

CDER: FY 2005 WORKPLAN - REASON FOR CHANGE

PAC	*PROGRAM/ASSIGNMENTS*	FTEs 2004	FTEs 2005	FTE DIFF	Reason for CHANGE
46832	NDA Pre-Approval/Meth Valid.(Domestic)	19.0	17.0	-2.0	*budget decrease*
46832	NDA Pre-Approval/Meth. Valid. (Foreign)	16.0	15.0	-1.0	*budget decrease*
46	**New Drug Evaluation**	**35.0**	**32.0**	**-3.0**	
48001	In Vivo Bioequivalence (Domestic)	5.4	5.4	0.0	
48001A	In Vivo Bioequivalence Foreign)	5.4	4.6	-0.8	*budget decrease*
48808	Good Laboratory Practices	5.5	5.5	0.0	
48809	Institutional Review Boards	11.1	9.1	-2.0	*budget decrease*
48810	Sponsors, Contract Research Orgs./Monitors	2.9	2.7	-0.2	*budget decrease*
48811	Clinical Investigators	27.0	27.0	0.0	
48	**Bioresearch Monitoring**	**57.3**	**54.3**	**-3.0**	
52002	New Drugs RX Without Approved NDAs	7.5	5.5	-2.0	*budget decrease*
52832	ANDA Pre-Approval/Meth Valid (Domestic)	30.7	24.7	-6.0	*budget decrease*
52832	ANDA Pre-Approval/Meth Valid (Foreign)	15.6	12.1	-3.5	*budget decrease*
52R816	ORA/Center Directed Research Project	1.0	1.0		
52	**Generic Drug Evaluation**	**54.8**	**43.3**	**-11.5**	
53001A,B	Adverse Drg. Exp. Rpt. Regul.Domestic	6.3	6.3	0.0	
53001A,B	Adverse Drg. Exp. Rpt. Regul.Foreign	1.7	1.7	0.0	
53001A,B	Medication Errors	4.0	2.0	-2.0	*budget decrease*
53	**Postmarket Surv. & Epidemiology**	**12.0**	**10.0**	**-2.0**	
56002	Drug Process Inspections-Domestic non-gas	121.6	132.1	10.5	*reprogramming*
56002E	Drug Process Inspections-Domestic-gas	5.0	5.0	0.0	*reprogramming*
56002	Drug Process Inspections-Foreign Non-MRA	20.0	18.0	-2.0	*reprogramming*
56008A	Drug Prdt. Surveillance- Domestic Surveys	21.1	28.7	7.6	*reprogramming*
56008H	Drug Product Surveillance- Import Drugs	31.1	41.1	10.0	*reprogramming*
56008J	Drug Product Surveillance-(Domestic Import)	27.6	0.0	-27.6	*budget decrease/remaing ftes (4.1) absorbed into 56008A*
56021A/B	Drug Quality Reporting Systems-DQRS	5.0	5.0	0.0	
56022	Prescription Drug Marketing - Ctr Initiated	0.0	2.0	2.0	*reprogramming*
56D015	Pharmacy Compounding Assignments	2.0	3.0	1.0	*reprogramming*
56R816	ORA/Center Directed Research Project	3.0	3.0	0.0	
56R838	Forensic Evaluation/Sample Analysis	9.0	9.0	0.0	
56	**Drug Quality Assurance**	**245.4**	**246.9**	**1.5**	
61003	OTC Drug Monographs	2.0	2.0	0.0	*reprogramming*
61	**OTC DRUG EVALUATION**	**2.0**	**2.0**	**0.0**	
63001	Fraudulent Drugs	4.5	3.5	-1.0	*budget decrease*
63D012	Internet Sales Investigations	8.0	4.0	-4.0	*budget decrease*
63	**Health Fraud: Human Drugs**	**12.5**	**7.5**	**-5.0**	
88---	Shelf Life Extension Projects (No FTEs prior to 2003)	12.0	12.0	0.0	*homeland security*
88	**Interagency Cooperative Activities**	**12.0**	**12.0**	**0.0**	
	CDER Total Operational FTEs	**431.0**	**408.0**	**-23.0**	

CVM: FY 2005 Workplan - Reason For Change

PAC	Program/Assignment	FTEs FY 2004	FTEs FY 2005	FTEs Difference	Reason for Change
68001	NADA Preapproval Inspections	7.6	5.7	**-1.9**	Budget Reduction
	Foreign Inspections	(2.0)	(2.0)		
68808*	(Pre-Market) GLP	3.2	2.9	**-0.3**	Budget Reduction
68810*	Sponsors, Contract Research Org. (CROs), Monitors	*	*		
68811	(Pre-Market) Clinical Investigators	2.9	2.1	**-0.8**	Budget Reduction
68	**Pre-Approval Evaluation of Animal Drugs and Food Additives**	**13.7**	**10.7**	**-3.0**	
71001/71R841	Drug Process Inspections	13.0	10.9	**-2.1**	Budget Reduction
71003A-H	Feed Contaminants	21.7	16.3	**-5.4**	Budget Reduction
71004/A	Feed Manufacturing	7.3	6.5	**-0.8**	Budget Reduction
71006	Illegal Tissue Residues in Meat & Poultry	14.7	12.0	**-2.7**	Budget Reduction
71009	Ruminant Feed Ban Rule (BSE) Program	55.7	66.8	**11.1**	Budget Increase
71R816	ORA/Center Directed Research Projects	5.6	6.0	**0.4**	Program Increase
71R831/71R838	Forensic Evaluation & Analysis	0.7	0.7		
71V800	Center Initiated Assignments	3.0	3.0		
71	**Monitoring of Marketed Animal Drugs, Feeds, and Devices**	**121.7**	**122.2**	**0.5**	
TOTAL Operational FTEs		**135.4**	**132.9**	**-2.5**	

*** Includes resources for 68810 Sponsors Contract Research Orgs./Monitors**

CDRH: FY 2005 FINAL WORKPLAN - REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENT	FTEs FY 2004	FTEs FY 2005	FTEs Differ-ence	REASON FOR CHANGE
81010	Med Dev Problem Reporting-MDR F/U	0.5	0.5	0.0	
81	**Postmarket Assurance: Devices**	**0.5**	**0.5**	**0.0**	
82008	Monitoring Device of Foreign Origin-Imports	25.0	25.0	0.0	
82845 A,B,C,G,S	Inspection of Medical Dev Mfgrs: GMP	81.3	73.8	-7.5	Decrease: Budget Reduction
82845B	Foreign Inspection of Medical Dev Mfgrs: GMP	12.5	11.1	-1.4	Decrease: Budget Reduction
82845J,K,P	Auditing of Accredited Persons: MDUFMA	7.2	7.5	0.3	New in '05: AP Audit Investigation Hours
82R841	Mutual Recognition Agreement (MRA)	1.4		-1.4	Program Cancelled
82Z002	Condom Assignment	5.0	5.0	0.0	
82Z003	Mfgrs & Importers of Surgical/Exam Gloves	9.5	9.5	0.0	
82Z005	BSE Assignment	1.0	1.0	0.0	
82Z800	Center Initiated Assignments	3.0	2.0	-1.0	Decrease: Budget Reduction
82R816	ORA/Center Directed Research Projects	0.9	0.9	0.0	
82R838	Forensic Analysis	0.3	0.3	0.0	
82	**Compliance: Devices**	**147.1**	**136.1**	**-11.0**	
83001/A	Med Dev Premkt Approval & Postmkt Inspec	6.8	7.8	1.0	Increase: MDUFMA User Fee
83001/A	Foreign Med Dev Premkt Approval & Postmkt Insp	3.2	3.2	0.0	
83808-11	Bioresearch Monitoring	23.3	25.3	2.0	Increase: Medical Device Review
83	**Project Evaluation: Devices**	**33.3**	**36.3**	**3.0**	
84Z002	Test Method Development & Evaluation	5.2	3.7	-1.5	Decrease: Budget Reduction
84R816	ORA/Center Directed Research Projects	1.4	1.4	0.0	
84	**Science: Devices**	**6.6**	**5.1**	**-1.5**	
85014 A,C,F	Mammography Facilities Inspection Program	16.5	15.5	-1.0	Decrease: Budget Reduction
85014	Foreign Mammography Facilities Inspections	0.1	0.1	0.0	
85	**Mammography Quality Standards Act (MQSA)**	**16.6**	**15.6**	**-1.0**	
86001	Inspection of Mfgrs of Laser Products	6.7	5.7	-1.0	Decrease: Budget Reduction
86001	Foreign Inspection of Mfgrs of Laser Products	0.2	0.2	0.0	
86002	Field Implementation of Sunlamp Products	0.8	0.8	0.0	
86003	Field Compliance Testing of Diag X-Ray Equip	9.0	9.0	0.0	
86004	Field Compliance Testing of Cab X-Ray Equip	2.0	2.0	0.0	
86006 A-F	Compliance Testing of Elec Prod at WEAC	3.4	3.4	0.0	
86006 A-F	Foreign Inspections: Comp Testing of Elec Prod	0.8	0.8	0.0	
86007	Imported Electronic Products	5.5	5.5	0.0	
86008	Med Dev & Rad Hlth Use Control & Pol Implem	4.6	4.6	0.0	
86009	Emergency Planning & Response Activities	2.4	2.0	-0.4	Decrease: Budget Reduction
86	**Radiation Control & Health Safety Act (RCHSA)**	**35.4**	**34.0**	**-1.4**	
Total Operational FTEs		**239.5**	**227.6**	**-11.9**	

FY 2005

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, 2004 to September 30, 2005.

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 2005, 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 breakdown 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 Examined, etc.

Appendix I lists all FY 2005 PPS Projects.

4. RESOURCE MANAGEMENT

ORA is replacing its historic planning tool, the operational/support split of FTE, with a model that more clearly reflects the mission orientation of staff positions. FY05 is the second year of this new model and features of the model are still under development. This revision will identify the staffing requirements that are fixed and variable, and specify those positions that are essential to achieve mission objectives.

This new model characterizes FTE as either [1] Mission Direct or [2] Program Direction and Assistance [PDA]. Mission Direct includes the previous "operational" category with the addition of those positions that also directly work on mission related tasks but whose work is not specifically planned during the annual Workplanning process. Many positions are essential even though they do not perform inspections and sample analyses. All Mission Direct FTE perform mission critical activities; some FTE are pre-planned by ORA; some are pre-planned in cooperation with the centers; and some are planned during the annual Workplanning process.

The Mission Direct: Pre-Planned and Mission Direct: Other FTE are in specialized position descriptions; these individuals are specialists and are not easily reassigned to other duties. Examples of Mission Direct: Other FTE are compliance officers, public affairs specialists, and recall & emergency coordinators. Mission Direct: Pre-Planned FTE are specialized positions that do assignments in center programs that are planned in the Workplan. However, the number of these positions and the work that they perform are determined by the field in consultation with the centers outside of the annual Workplanning process. Examples of these positions are: Team Biologics positions, National Investigational Experts, and Radiological Health Consultants. Mission Direct:

Annual-Planned FTE are available to support center compliance programs and are planned by both the Centers and field through the Field Committees. FTE types are: Investigational CSO; Chemist Analytical; Microbiologist Analytical; and Engineer/Physicists Analytical. These are the positions that are traditionally planned in the annual Workplanning process.

The Program Direction and Assistance [PDA] category contains those management, supervisory, and technical positions that are necessary to the functioning of ORA headquarters and field activities. The exact composition of this category will be continually reviewed and updated. This category has fixed components labeled the Field Management Backbone which include such positions as Regional Director and District Director. The PDA category also has variable components labeled Field Management Mission Coordination which include Compliance Technicians and Consumer Safety Technicians. However, even the fixed components may change as new missions evolve. For example, the full impact of the implementation of Quality Systems and the Bioterrorism Act may require changes in the "fixed" portions. Variable positions such as first line supervisors change as the number of staff change. ORA PDA is comprised of ORA Headquarters and ORA Field Management and Administration.

The new categories are as follows:

PROGRAM DIRECTION & ASSISTANCE

ORA Headquarters: These are the positions that ORA management needs to fulfill headquarters responsibilities.

ORA Field Management and Administration: These are the management and staff positions needed to operate Field offices and laboratories. The Field Management Backbone component is the fixed number of positions that it takes to manage the current number of regions, districts and laboratories. These are the positions needed to open the doors. The variable component of the backbone is first line supervisors. The Field Management Mission Coordination component is other management and administrative positions determined by staffing or other workload.

MISSION DIRECT

Mission Direct: Other
All these positions perform mission critical activities, but are not specifically planned in the Workplan. FTE in specialized position descriptions perform many of these activities; these individuals are specialists and are not easily reassigned to other duties. Examples include:

- Compliance Officers
- Recall & Emergency Coordinators
- Consumer Complaint Coordinators
- Public Affairs Specialists
- State Contract Coordinators
- Laboratory Industrial Hygienist
- QMS Region
- QMS Laboratory
- Pre Approval Managers
- Small Business Representatives

Mission Direct: Pre-Planned: These are positions that ORA (sometimes in collaboration with the centers) have directly assigned to activities supporting ORA's mission.

- Team Biologics
- National Investigational Experts
- Shellfish Safety Specialists
- Milk Safety Specialists
- Retail Food Specialists
- Radiological Health Consultants
- Prior Notice Center
- Forensic Analysis
- Research and Research Center

Mission Direct: Annual Planned: The FTE available to support center compliance programs and planned by both the Centers and field through the field committees. FTE types are:

- Investigational CSOs
- Chemist Analytical
- Microbiologist Analytical
- Engineer/Physicists Analytical

DPEM is incorporating these terms into the Workplan.

5. 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 2005 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 2005 ORA Field Workplan.

6. RELATION TO OTHER PLANS

The FY 2005 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 2005 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 2005 GUIDANCE

This section provides guidance in relation to programmatic objectives and operational requirements related to the FY 2005 Workplan.

The summary tables in the Workplan have been changed to reflect new terminology. The "Operational FTE" category remains and contains the FTE that are specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned.

The "Supported FTE" category has been replaced with "Program FTE" and includes all Mission Direct, Program Direction and Assistance (PDA), user fee, and reimbursable FTE.

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan. The changes were made to better reflect the mission orientation of ORA's professional staff.

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 2005 RESOURCE ACTIVITIES

The FY 2005 ORA Field Workplan is based on a FTE level of 3690 FTEs which is a decrease of 130 FTEs from the FY 2004 ORA Field Workplan level of 3820 FTEs. The FY 2005 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. In the new Staffing Model, national experts are in the category of Mission Direct: Pre-Planned FTE.

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. In the new Staffing Model, Team Biologics are in the category of Mission Direct: Pre-Planned FTE.

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 2005 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 2005. 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 Workplan. Therefore, it is important for data reporting to be both accurate and complete.

4. HARD COPY REPORTING

During FY 2005, 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 2005 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. In May of 2000 the Division of Planning, Evaluation and Management (DPEM) circulated a revised draft FMD-130 to ORA Headquarters Units, and Field, and FDA Centers. The revised draft reflected changes resulting from the implementation of the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System for Import Support (OASIS). The draft FMD is still in effect.

APPENDIX I

PPS
PROGRAM AND PROJECT STRUCTURE
FY 2005 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: Food and Cosmetics
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 Health Fraud: Human 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 2005**

OCTOBER 1, 2004

APPENDIX II

SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2005			FY 2004	
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 2005**

APPENDIX II

SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2005			FY 2004	
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 2005			FY 2004	
NO.	NAME		NO.	NAME
BIOLOGICS				
42	Blood and Blood Products	<	No Change	
41	Human Cellular, Tissue and Gene Therapies			
45	Vaccines and Allergenic Products			
HUMAN DRUGS				
46	New Drug Evaluation	<	No Change	
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	Health Fraud: Human Drugs			

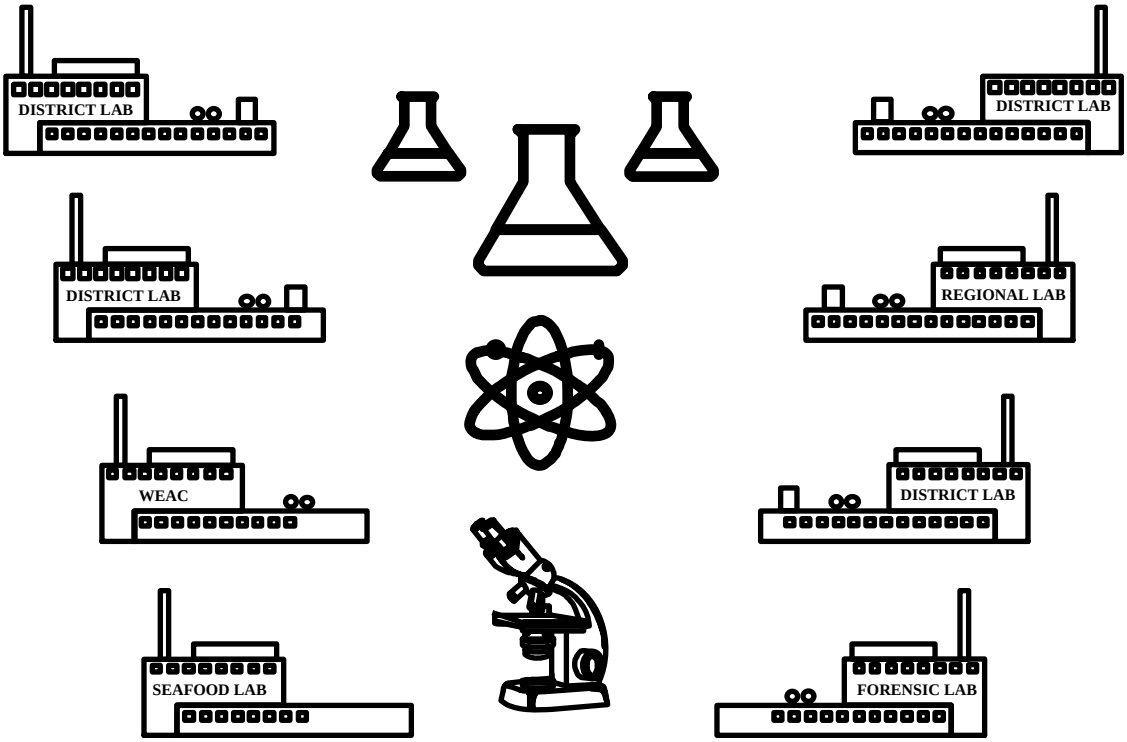
APPENDIX II

SCHEMATIC
PROGRAM AND PROJECT STRUCTURE

FY 2005			FY 2004	
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: Food and Cosmetics			
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 III

FY 2005 SERVICING LABORATORIES



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

FEBRUARY 2005

SERVICING LABORATORIES

**** FY 2005 ****

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
C.T. PREPAREDNESS (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 ELMTS IN FOODS 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	SAN	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	SRL	SRL	DEN	DEN	DEN	DEN	DEN	SAN	SAN	SAN
DOM FD SAFTETY (COLOR)	09803,E	NRL	NRL	NRL	ARL	NRL	DET	ARL	---	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	SAN	SAN	SAN
DOM FD SAFTETY (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	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)

+++ Origin, commodity, and analysis of the 231 KAN Lab Samples will be determined by CFSAN Assignment.

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 2005 **

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	ARL	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	ARL	DEN	KAN	--	--	PRS	PRN	PRN
DRUG PROCESS INSP (DSA)	56002 A-F	NRL	NRL	PHI	DET	PHI	DET	DET	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	ARL	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	DET	PHI	DET	DET	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRS	PRN	PRN
DPS API	56008H	NRL	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SJN	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
61 OTC DRUG EVALUATION	61003	PHI	NRL	PHI	DET	PHI	DET	DET	PHI	PHI	SRL	SRL	SRL	SJN	DEN	DEN	KAN	--	--	PRN	PRN	PRN
63 FRAUDULENT DRUGS	63001	PHI	NRL	PHI	KAN	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/J/K, Drug Product Surveillance will be assigned by DFS (HFC-140) based on expertise of drug lab for each specific drug sampled
46832 Method Validation assigned by CDER review chemist
52832 Method Validation assigned by DFS
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 2005 ****

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
ANIMAL DRUGS & FEEDS																		TX&NM	CA&AZ			
68 PRE APPR MON ANIMAL DGS FEEDS																						
NADA PRE APPROVAL INSP	68001	NRL	NRL	KAN	KAN	KAN	KAN	KAN	KAN	KAN	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	SAN	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-
FEED MICROSCOPY-BSE	71009	SRL	NRL	ARL	ARL	ARL	ARL	NRL	NRL	NRL	SRL	SRL	SRL	SRL	ARL	DEN	DEN	DEN	DEN	PRS	PRS	PRN
BSE IMPORT	71R844	NRL	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 2005 ****

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
SALMONELLA SEROTYPING *	03803D	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	DEN	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-
IMP FOODS GENERAL	03819C	NRL	NRL	SRL	DEN	SRL	DEN	DEN	---	NRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	ARL	PRS	PRS	SAN	PRN
SALMONELLA RESISTANCE	03819C	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-
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
NAT DRUG RES MILK MON	03039	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	DEN	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
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
EMERGENCY RESP FOODBORNE	03R839	NRL	NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	DEN	DEN	DEN	--	--	PRS	SAN	PRN
C.T. PREPAREDNESS (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	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-)

*** Samples generated from SRL & ARL go to ARL and samples generated from other LABS go to DEN.**
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 2005 ****

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	71003	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	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	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 2005 ****

ENGINEERS/PHYSICISTS

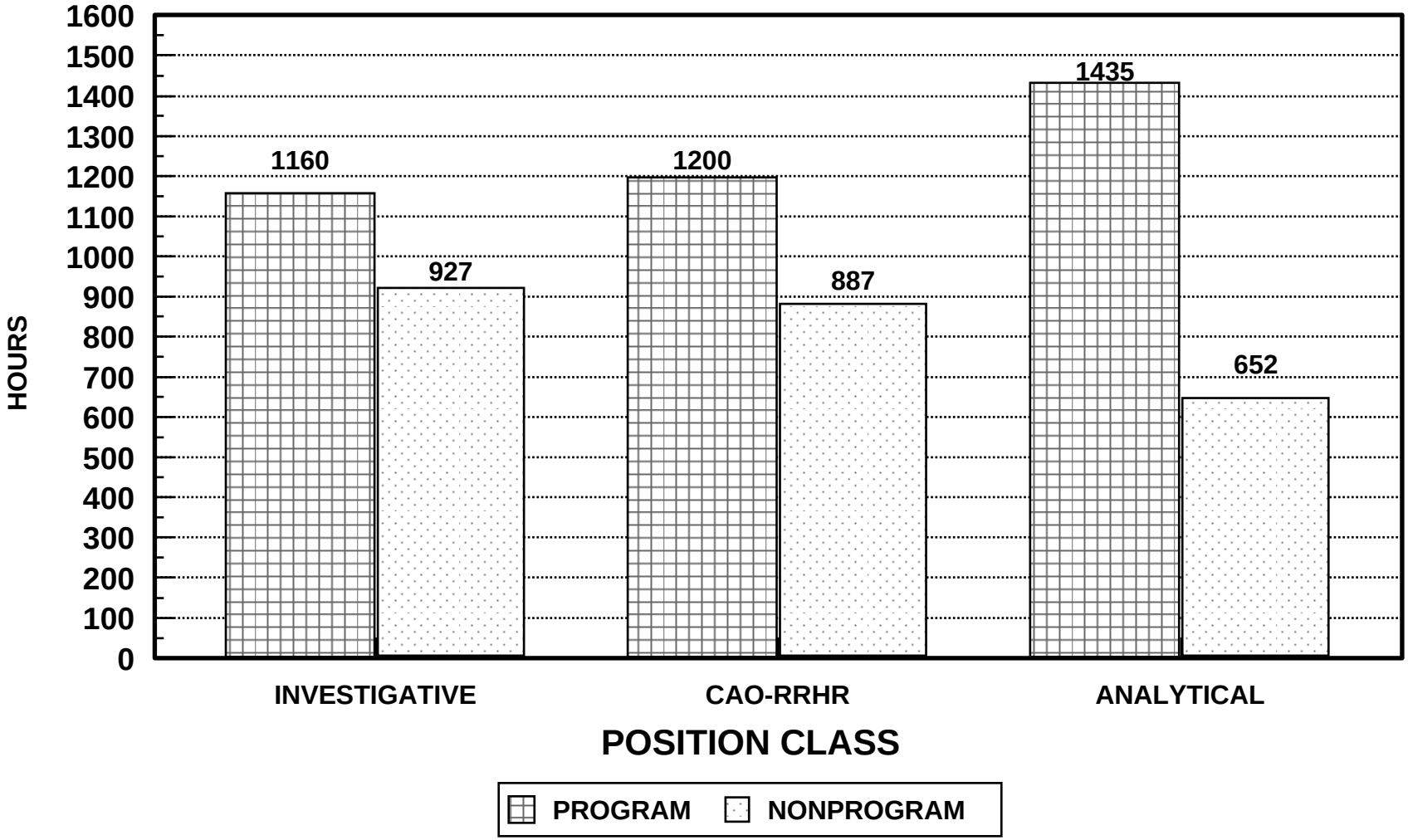
REGIONS >>>>>>>>>		NORTHEAST		CENTRAL							SOUTHEAST				SOUTHWEST					PACIFIC		
COLLECTING DISTRICT>>>		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
MEDICAL DEV & RAD HLTH																		TX&NM	CA&AZ			
81 POSTMKT ASSURANCE: DEVICES																						
PROB 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.

ALL CENTERS - ALL PERSONNEL

FY 2005 PROGRAM/NONPROGRAM OPERATION TIME

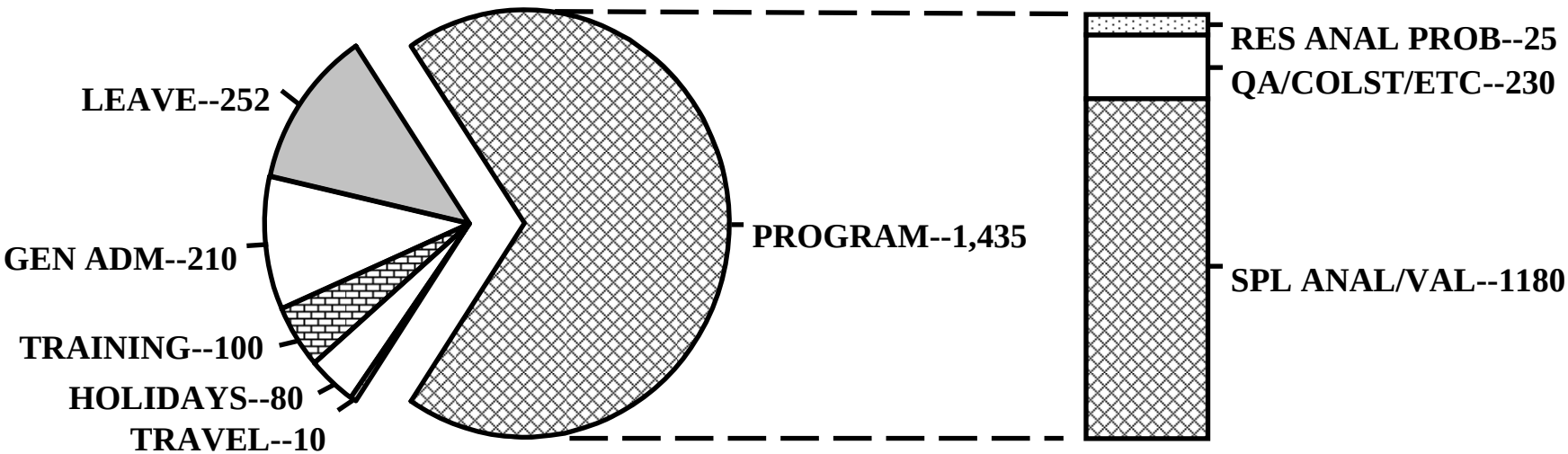
POSITION CLASS TOTALS - 2087 HOURS



ALL CENTERS - ANALYTICAL

FY 2005 PROGRAM/NONPROGRAM TIME

- 2087 TOTAL HOURS -



NONPROGRAM 652 HOURS

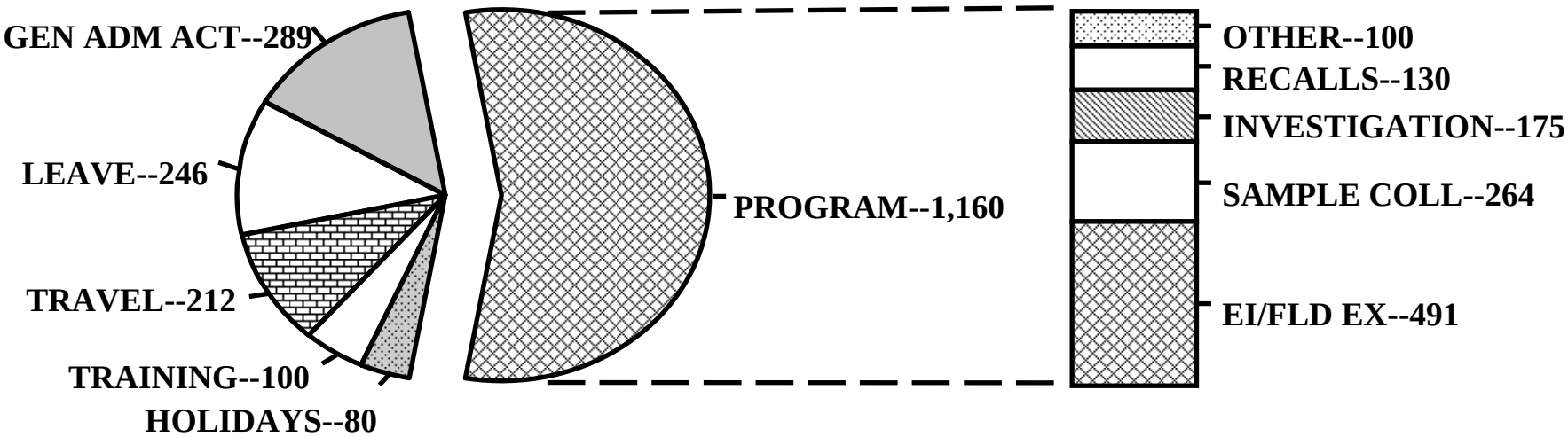
PROGRAM 1,435 HOURS

PROGRAM 1,435 HOURS

CFSAN - INVESTIGATIVE/INSPECTIONAL

FY 2005 PROGRAM/NONPROGRAM TIME

- 2,087 TOTAL HOURS -

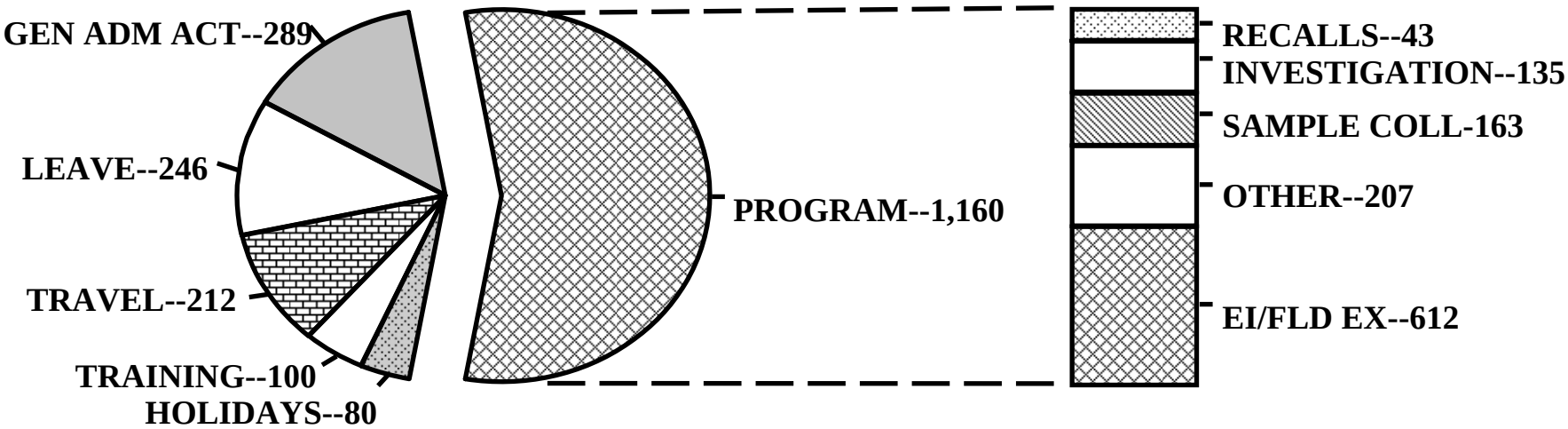


NONPROGRAM	PROGRAM	PROGRAM HOURS
927 HRS	1,160 HRS	1,160

CBER - INVESTIGATIVE/INSPECTIONAL

FY 2005 PROGRAM/NONPROGRAM TIME

- 2,087 TOTAL HOURS -

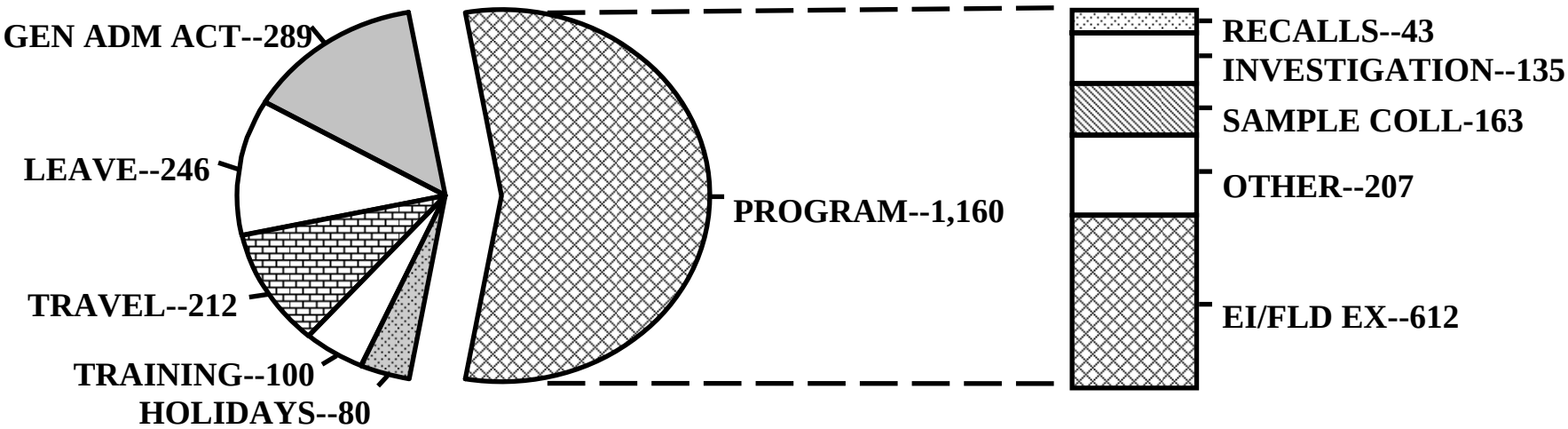


NONPROGRAM	PROGRAM	PROGRAM HOURS
927 HRS	1,160 HRS	1,160

CDER - INVESTIGATIVE/INSPECTIONAL

FY 2005 PROGRAM/NONPROGRAM TIME

- 2,087 TOTAL HOURS -

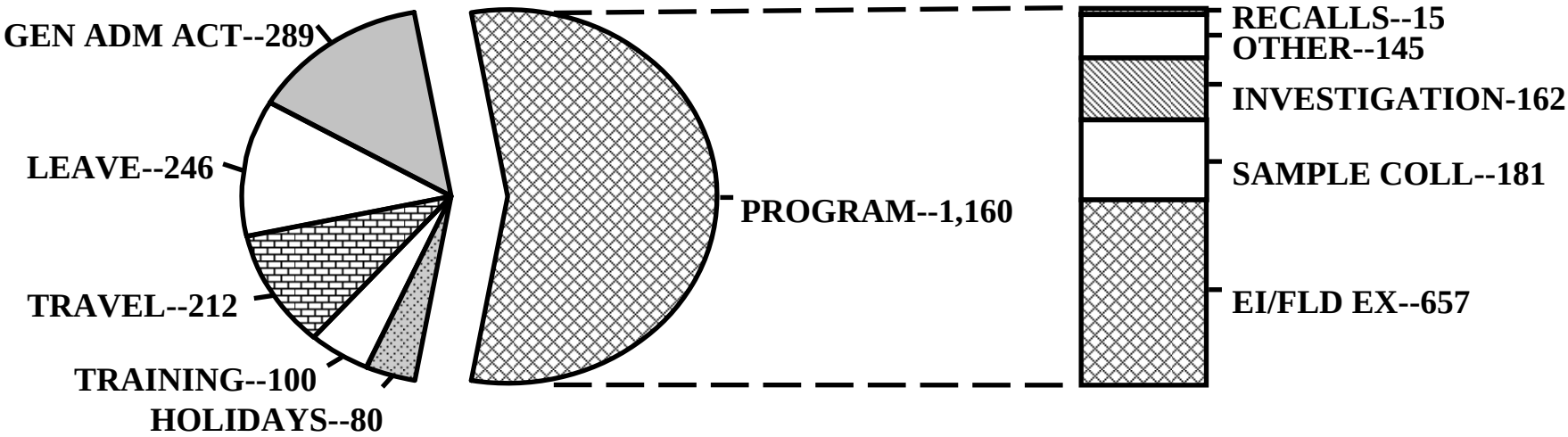


NONPROGRAM	PROGRAM	PROGRAM HOURS
927 HRS	1,160 HRS	1,160

CVM - INVESTIGATIVE/INSPECTIONAL

FY 2005 PROGRAM/NONPROGRAM TIME

- 2,087 TOTAL HOURS -

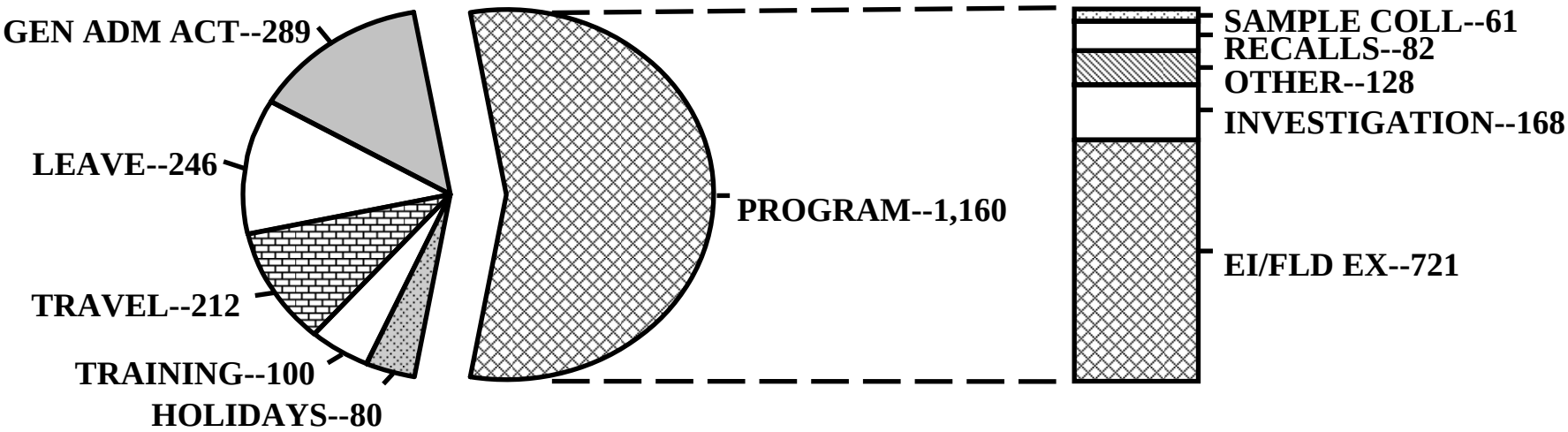


NONPROGRAM	PROGRAM	PROGRAM HOURS
927 HRS	1,160 HRS	1,160

CDRH - INVESTIGATIVE/INSPECTIONAL

FY 2005 PROGRAM/NONPROGRAM TIME

- 2,087 TOTAL HOURS -



NONPROGRAM	PROGRAM	PROGRAM HOURS
927 HRS	1,160 HRS	1,160

FY 2005

PART II - WORKPLAN SUMMARY
OPERATIONS & POSITIONS

DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE MANAGEMENT BRANCH

ORA/ORM/DPEM

PART II
WORKPLAN SUMMARY

POSITION CLASS

COMBINED ANALYTICAL & DISTRICT RESEARCH

(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	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	226.47	63.35	51.21	12.33	7.15	2.00	362.51	383526.90
FOOD SAFETY/COS	127.96	38.07	45.75	0.00	6.11	0.00	217.89	234083.60
03	99.67	15.08	45.44	0.00	3.83	0.00	164.02	174643.80
04	6.95	15.30	0.00	0.00	1.45	0.00	23.70	26270.50
07	1.58	3.44	0.00	0.00	0.58	0.00	5.60	6230.00
09	0.77	2.82	0.00	0.00	0.00	0.00	3.59	4042.00
18	14.33	0.00	0.11	0.00	0.00	0.00	14.44	16252.00
21	3.59	0.00	0.00	0.00	0.25	0.00	3.84	3641.80
29	1.07	1.43	0.20	0.00	0.00	0.00	2.70	3003.50
BIOLOGICS	10.31	0.00	0.00	0.00	0.00	0.00	10.31	9557.00
41	2.13	0.00	0.00	0.00	0.00	0.00	2.13	1939.20
42	7.94	0.00	0.00	0.00	0.00	0.00	7.94	7399.40
45	0.24	0.00	0.00	0.00	0.00	0.00	0.24	218.40
HUMAN DRUGS	46.90	15.44	1.68	0.00	1.04	0.00	65.06	64363.20
46	2.50	3.26	0.09	0.00	0.00	0.00	5.85	5814.00
48	6.01	0.00	0.00	0.00	0.00	0.00	6.01	5465.60
52	3.72	6.00	0.00	0.00	0.00	0.00	9.72	10125.00
53	1.48	0.00	0.00	0.00	0.00	0.00	1.48	1341.00
56	31.22	6.10	1.59	0.00	1.04	0.00	39.95	39739.60
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.46	0.02	0.00	0.00	0.00	0.00	0.48	432.00
63	1.51	0.06	0.00	0.00	0.00	0.00	1.57	1446.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	14.21	4.93	0.32	0.00	0.00	0.00	19.46	21589.00
68	0.74	0.07	0.00	0.00	0.00	0.00	0.81	820.90
71	13.47	4.86	0.32	0.00	0.00	0.00	18.65	20768.10
DEVICES & RAD H	27.09	4.91	3.46	12.33	0.00	2.00	49.79	53934.10
81	0.07	0.03	0.02	0.03	0.00	0.00	0.15	155.00
82	16.68	4.88	2.78	4.23	0.00	0.59	29.16	31239.90
83	4.44	0.00	0.00	0.00	0.00	0.00	4.44	4213.40
84	0.00	0.00	0.66	3.00	0.00	1.41	5.07	5975.00
85	2.17	0.00	0.00	0.00	0.00	0.00	2.17	2523.00
86	3.73	0.00	0.00	5.07	0.00	0.00	8.80	9827.80

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

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

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

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

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

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

WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: CE REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	362.50	55.92	0.00	0.00	1.99	0.00	420.41	416825.50
FOOD SAFETY/COS	143.86	11.89	0.00	0.00	0.00	0.00	155.75	155999.00
03	99.52	0.48	0.00	0.00	0.00	0.00	100.00	95961.60
04	8.54	10.77	0.00	0.00	0.00	0.00	19.31	20921.60
07	3.15	0.00	0.00	0.00	0.00	0.00	3.15	2934.00
09	0.36	0.60	0.00	0.00	0.00	0.00	0.96	1038.30
18	24.02	0.00	0.00	0.00	0.00	0.00	24.02	27408.00
21	7.18	0.00	0.00	0.00	0.00	0.00	7.18	6661.10
29	1.09	0.04	0.00	0.00	0.00	0.00	1.13	1074.40
BIOLOGICS	35.69	0.00	0.00	0.00	0.00	0.00	35.69	32716.80
41	7.22	0.00	0.00	0.00	0.00	0.00	7.22	6560.00
42	27.51	0.00	0.00	0.00	0.00	0.00	27.51	25283.20
45	0.96	0.00	0.00	0.00	0.00	0.00	0.96	873.60
HUMAN DRUGS	95.05	43.00	0.00	0.00	1.99	0.00	140.04	138849.90
46	7.20	4.83	0.00	0.00	0.00	0.00	12.03	11834.00
48	16.72	0.00	0.00	0.00	0.00	0.00	16.72	15189.10
52	10.86	5.47	0.00	0.00	0.00	0.00	16.33	16057.00
53	3.46	0.00	0.00	0.00	0.00	0.00	3.46	3141.00
56	55.98	23.37	0.00	0.00	1.99	0.00	81.34	80871.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.21	0.10	0.00	0.00	0.00	0.00	0.31	306.00
63	0.62	0.23	0.00	0.00	0.00	0.00	0.85	831.00
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
ANIMAL D & F	33.98	0.73	0.00	0.00	0.00	0.00	34.71	35496.50
68	3.70	0.00	0.00	0.00	0.00	0.00	3.70	3695.50
71	30.28	0.73	0.00	0.00	0.00	0.00	31.01	31801.00
DEVICES & RAD H	53.92	0.30	0.00	0.00	0.00	0.00	54.22	53763.30
81	0.13	0.00	0.00	0.00	0.00	0.00	0.13	108.50
82	29.10	0.30	0.00	0.00	0.00	0.00	29.40	28586.40
83	11.51	0.00	0.00	0.00	0.00	0.00	11.51	10917.40
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.94	0.00	0.00	0.00	0.00	0.00	4.94	5743.00
86	8.24	0.00	0.00	0.00	0.00	0.00	8.24	8408.00

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WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: SE REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	213.15	69.37	42.41	0.00	4.31	3.00	332.24	344258.80
FOOD SAFETY/COS	83.95	48.25	39.09	0.00	3.27	3.00	177.56	193225.30
03	54.48	8.16	36.35	0.00	1.53	0.00	100.52	106490.40
04	6.89	16.46	0.00	0.00	0.00	0.00	23.35	25837.90
07	1.60	7.04	0.00	0.00	0.91	3.00	12.55	14430.00
09	0.14	0.45	0.00	0.00	0.33	0.00	0.92	1054.20
18	17.69	0.00	0.24	0.00	0.00	0.00	17.93	19888.50
21	2.53	15.89	1.98	0.00	0.50	0.00	20.90	24032.80
29	0.62	0.25	0.52	0.00	0.00	0.00	1.39	1491.50
BIOLOGICS	22.51	0.00	0.00	0.00	0.00	0.00	22.51	20752.70
41	4.94	0.00	0.00	0.00	0.00	0.00	4.94	4486.30
42	16.70	0.00	0.00	0.00	0.00	0.00	16.70	15469.10
45	0.87	0.00	0.00	0.00	0.00	0.00	0.87	797.30
HUMAN DRUGS	64.33	19.22	2.37	0.00	1.04	0.00	86.96	84995.40
46	4.05	1.61	0.00	0.00	0.00	0.00	5.66	5365.00
48	10.94	0.00	0.00	0.00	0.00	0.00	10.94	9953.60
52	5.93	1.63	0.00	0.00	1.04	0.00	8.60	8316.00
53	1.88	0.00	0.00	0.00	0.00	0.00	1.88	1704.00
56	40.76	12.80	2.37	0.00	0.00	0.00	55.93	55208.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.32	0.07	0.00	0.00	0.00	0.00	0.39	370.00
63	0.45	0.11	0.00	0.00	0.00	0.00	0.56	538.00
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
ANIMAL D & F	9.72	1.90	0.95	0.00	0.00	0.00	12.57	13070.60
68	1.83	0.12	0.00	0.00	0.00	0.00	1.95	1954.70
71	7.89	1.78	0.95	0.00	0.00	0.00	10.62	11115.90
DEVICES & RAD H	32.64	0.00	0.00	0.00	0.00	0.00	32.64	32214.80
81	0.07	0.00	0.00	0.00	0.00	0.00	0.07	67.80
82	18.32	0.00	0.00	0.00	0.00	0.00	18.32	17777.70
83	6.69	0.00	0.00	0.00	0.00	0.00	6.69	6352.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.52	0.00	0.00	0.00	0.00	0.00	2.52	2919.00
86	5.04	0.00	0.00	0.00	0.00	0.00	5.04	5098.10

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WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: SW REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	242.26	105.56	34.34	0.00	4.41	8.98	395.55	420412.10
FOOD SAFETY/COS	120.47	84.30	28.48	0.00	3.41	5.00	241.66	265673.30
03	89.03	10.18	27.97	0.00	0.66	0.00	127.84	135994.60
04	10.07	63.21	0.00	0.00	1.50	5.00	79.78	91649.00
07	1.95	5.20	0.00	0.00	0.50	0.00	7.65	8554.00
09	0.56	2.11	0.00	0.00	0.75	0.00	3.42	3901.70
18	14.39	0.00	0.13	0.00	0.00	0.00	14.52	16715.50
21	4.00	3.27	0.00	0.00	0.00	0.00	7.27	7583.10
29	0.47	0.33	0.38	0.00	0.00	0.00	1.18	1275.40
BIOLOGICS	19.11	0.00	0.00	0.00	0.00	0.00	19.11	17454.30
41	4.49	0.00	0.00	0.00	0.00	0.00	4.49	4088.90
42	14.02	0.00	0.00	0.00	0.00	0.00	14.02	12816.20
45	0.60	0.00	0.00	0.00	0.00	0.00	0.60	549.20
HUMAN DRUGS	42.66	8.97	1.08	0.00	0.00	0.00	52.71	49679.10
46	2.68	0.92	0.44	0.00	0.00	0.00	4.04	3801.00
48	9.63	0.00	0.00	0.00	0.00	0.00	9.63	8760.10
52	3.42	1.05	0.00	0.00	0.00	0.00	4.47	4160.00
53	1.01	0.00	0.00	0.00	0.00	0.00	1.01	924.00
56	24.74	6.74	0.64	0.00	0.00	0.00	32.12	30657.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.10	0.02	0.00	0.00	0.00	0.00	0.12	106.00
63	1.08	0.24	0.00	0.00	0.00	0.00	1.32	1271.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	23.38	12.29	3.41	0.00	1.00	3.98	44.06	47830.00
68	2.83	0.40	0.00	0.00	0.00	0.00	3.23	3256.10
71	20.55	11.89	3.41	0.00	1.00	3.98	40.83	44573.90
DEVICES & RAD H	36.64	0.00	1.37	0.00	0.00	0.00	38.01	39775.40
81	0.06	0.00	0.00	0.00	0.00	0.00	0.06	46.50
82	22.10	0.00	1.37	0.00	0.00	0.00	23.47	24719.00
83	5.51	0.00	0.00	0.00	0.00	0.00	5.51	5227.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.13	0.00	0.00	0.00	0.00	0.00	3.13	3634.00
86	5.84	0.00	0.00	0.00	0.00	0.00	5.84	6148.70

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WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: PA REGN

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	286.99	67.20	58.22	0.00	5.19	7.00	424.60	440822.40
FOOD SAFETY/COS	161.45	50.21	56.96	0.00	4.86	6.00	279.48	298257.20
03	117.16	19.30	56.51	0.00	1.99	4.00	198.96	210620.10
04	11.80	25.61	0.00	0.00	1.63	0.00	39.04	43160.30
07	2.53	3.04	0.00	0.00	0.54	1.00	7.11	7770.00
09	0.51	1.66	0.00	0.00	0.00	0.00	2.17	2427.80
18	22.64	0.00	0.20	0.00	0.00	0.00	22.84	24897.00
21	5.92	0.00	0.00	0.00	0.70	1.00	7.62	7516.80
29	0.89	0.60	0.25	0.00	0.00	0.00	1.74	1865.20
BIOLOGICS	17.86	0.00	0.00	0.00	0.00	0.00	17.86	16645.30
41	4.12	0.00	0.00	0.00	0.00	0.00	4.12	3754.00
42	12.90	0.00	0.00	0.00	0.00	0.00	12.90	12123.70
45	0.84	0.00	0.00	0.00	0.00	0.00	0.84	767.60
HUMAN DRUGS	45.23	9.35	0.84	0.00	0.00	0.00	55.42	52600.70
46	2.12	1.40	0.00	0.00	0.00	0.00	3.52	3344.00
48	9.68	0.00	0.00	0.00	0.00	0.00	9.68	8807.90
52	2.77	1.09	0.00	0.00	0.00	0.00	3.86	3648.00
53	1.84	0.00	0.00	0.00	0.00	0.00	1.84	1674.00
56	25.50	6.23	0.84	0.00	0.00	0.00	32.57	31374.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.70	0.05	0.00	0.00	0.00	0.00	0.75	690.00
63	2.62	0.58	0.00	0.00	0.00	0.00	3.20	3062.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	17.44	3.05	0.42	0.00	0.00	1.00	21.91	23242.90
68	0.93	0.06	0.00	0.00	0.00	0.00	0.99	989.80
71	16.51	2.99	0.42	0.00	0.00	1.00	20.92	22253.10
DEVICES & RAD H	45.01	4.59	0.00	0.00	0.33	0.00	49.93	50076.30
81	0.12	0.00	0.00	0.00	0.00	0.00	0.12	120.10
82	27.65	4.59	0.00	0.00	0.33	0.00	32.57	32575.70
83	8.21	0.00	0.00	0.00	0.00	0.00	8.21	7794.40
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.84	0.00	0.00	0.00	0.00	0.00	2.84	3306.00
86	6.19	0.00	0.00	0.00	0.00	0.00	6.19	6280.10

WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

TOTAL FIELD

FIELD	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	1388.93	361.40	186.18	12.33	23.05	20.98	1992.87	2066613.50
FOOD SAFETY/COS	669.91	232.72	170.28	0.00	17.65	14.00	1104.56	1184765.40
03	492.08	53.20	166.27	0.00	8.01	4.00	723.56	761237.50
04	44.25	131.35	0.00	0.00	4.58	5.00	185.18	207839.30
07	10.81	18.72	0.00	0.00	2.53	4.00	36.06	39918.00
09	2.34	7.64	0.00	0.00	1.08	0.00	11.06	12464.00
18	93.07	0.00	0.68	0.00	0.00	0.00	93.75	105161.00
21	23.22	19.16	1.98	0.00	1.45	1.00	46.81	49435.60
29	4.14	2.65	1.35	0.00	0.00	0.00	8.14	8710.00
BIOLOGICS	119.03	0.00	0.00	0.00	0.00	0.00	119.03	109463.10
41	22.90	0.00	0.00	0.00	0.00	0.00	22.90	20828.40
42	87.94	0.00	0.00	0.00	0.00	0.00	87.94	81166.00
45	8.19	0.00	0.00	0.00	0.00	0.00	8.19	7468.70
HUMAN DRUGS	302.27	95.98	5.97	0.00	4.07	0.00	408.29	397861.10
46	19.52	12.02	0.53	0.00	0.00	0.00	32.07	31043.00
48	54.38	0.00	0.00	0.00	0.00	0.00	54.38	49454.10
52	27.08	15.24	0.00	0.00	1.04	0.00	43.36	42651.00
53	10.00	0.00	0.00	0.00	0.00	0.00	10.00	9084.00
56	183.22	55.24	5.44	0.00	3.03	0.00	246.93	242417.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	1.79	0.26	0.00	0.00	0.00	0.00	2.05	1904.00
63	6.28	1.22	0.00	0.00	0.00	0.00	7.50	7148.00
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	99.18	22.90	5.10	0.00	1.00	4.98	133.16	141678.00
68	10.07	0.65	0.00	0.00	0.00	0.00	10.72	10757.00
71	89.11	22.25	5.10	0.00	1.00	4.98	122.44	130921.00
DEVICES & RAD H	198.54	9.80	4.83	12.33	0.33	2.00	227.83	232845.90
81	0.45	0.03	0.02	0.03	0.00	0.00	0.53	497.90
82	117.09	9.77	4.15	4.23	0.33	0.59	136.16	137980.70
83	36.36	0.00	0.00	0.00	0.00	0.00	36.36	34504.60
84	0.00	0.00	0.66	3.00	0.00	1.41	5.07	5975.00
85	15.60	0.00	0.00	0.00	0.00	0.00	15.60	18125.00
86	29.04	0.00	0.00	5.07	0.00	0.00	34.11	35762.70

PART II
WORKPLAN SUMMARY

POSITION CLASS

SEPARATE RESEARCH RESOURCES

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WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: NE REGN

FIELD	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
TOTAL	226.47	66.67	55.03	12.33	0.00	2.00	362.50	383526.90
FOOD SAFETY/COS	127.96	40.35	49.57	0.00	0.00	0.00	217.88	234083.60
03	99.67	15.08	49.26	0.00	0.00	0.00	164.01	174643.80
04	6.95	16.75	0.00	0.00	0.00	0.00	23.70	26270.50
07	1.58	4.02	0.00	0.00	0.00	0.00	5.60	6230.00
09	0.77	2.82	0.00	0.00	0.00	0.00	3.59	4042.00
18	14.33	0.00	0.11	0.00	0.00	0.00	14.44	16252.00
21	3.59	0.25	0.00	0.00	0.00	0.00	3.84	3641.80
29	1.07	1.43	0.20	0.00	0.00	0.00	2.70	3003.50
BIOLOGICS	10.31	0.00	0.00	0.00	0.00	0.00	10.31	9557.00
41	2.13	0.00	0.00	0.00	0.00	0.00	2.13	1939.20
42	7.94	0.00	0.00	0.00	0.00	0.00	7.94	7399.40
45	0.24	0.00	0.00	0.00	0.00	0.00	0.24	218.40
HUMAN DRUGS	46.90	16.48	1.68	0.00	0.00	0.00	65.06	64363.20
46	2.50	3.26	0.09	0.00	0.00	0.00	5.85	5814.00
48	6.01	0.00	0.00	0.00	0.00	0.00	6.01	5465.60
52	3.72	6.00	0.00	0.00	0.00	0.00	9.72	10125.00
53	1.48	0.00	0.00	0.00	0.00	0.00	1.48	1341.00
56	31.22	7.14	1.59	0.00	0.00	0.00	39.95	39739.60
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.46	0.02	0.00	0.00	0.00	0.00	0.48	432.00
63	1.51	0.06	0.00	0.00	0.00	0.00	1.57	1446.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	14.21	4.93	0.32	0.00	0.00	0.00	19.46	21589.00
68	0.74	0.07	0.00	0.00	0.00	0.00	0.81	820.90
71	13.47	4.86	0.32	0.00	0.00	0.00	18.65	20768.10
DEVICES & RAD H	27.09	4.91	3.46	12.33	0.00	2.00	49.79	53934.10
81	0.07	0.03	0.02	0.03	0.00	0.00	0.15	155.00
82	16.68	4.88	2.78	4.23	0.00	0.59	29.16	31239.90
83	4.44	0.00	0.00	0.00	0.00	0.00	4.44	4213.40
84	0.00	0.00	0.66	3.00	0.00	1.41	5.07	5975.00
85	2.17	0.00	0.00	0.00	0.00	0.00	2.17	2523.00
86	3.73	0.00	0.00	5.07	0.00	0.00	8.80	9827.80

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WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: CE REGN

FIELD	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
TOTAL	362.50	57.91	0.00	0.00	0.00	0.00	420.41	416825.50
FOOD SAFETY/COS	143.86	11.89	0.00	0.00	0.00	0.00	155.75	155999.00
03	99.52	0.48	0.00	0.00	0.00	0.00	100.00	95961.60
04	8.54	10.77	0.00	0.00	0.00	0.00	19.31	20921.60
07	3.15	0.00	0.00	0.00	0.00	0.00	3.15	2934.00
09	0.36	0.60	0.00	0.00	0.00	0.00	0.96	1038.30
18	24.02	0.00	0.00	0.00	0.00	0.00	24.02	27408.00
21	7.18	0.00	0.00	0.00	0.00	0.00	7.18	6661.10
29	1.09	0.04	0.00	0.00	0.00	0.00	1.13	1074.40
BIOLOGICS	35.69	0.00	0.00	0.00	0.00	0.00	35.69	32716.80
41	7.22	0.00	0.00	0.00	0.00	0.00	7.22	6560.00
42	27.51	0.00	0.00	0.00	0.00	0.00	27.51	25283.20
45	0.96	0.00	0.00	0.00	0.00	0.00	0.96	873.60
HUMAN DRUGS	95.05	44.99	0.00	0.00	0.00	0.00	140.04	138849.90
46	7.20	4.83	0.00	0.00	0.00	0.00	12.03	11834.00
48	16.72	0.00	0.00	0.00	0.00	0.00	16.72	15189.10
52	10.86	5.47	0.00	0.00	0.00	0.00	16.33	16057.00
53	3.46	0.00	0.00	0.00	0.00	0.00	3.46	3141.00
56	55.98	25.36	0.00	0.00	0.00	0.00	81.34	80871.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.21	0.10	0.00	0.00	0.00	0.00	0.31	306.00
63	0.62	0.23	0.00	0.00	0.00	0.00	0.85	831.00
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
ANIMAL D & F	33.98	0.73	0.00	0.00	0.00	0.00	34.71	35496.50
68	3.70	0.00	0.00	0.00	0.00	0.00	3.70	3695.50
71	30.28	0.73	0.00	0.00	0.00	0.00	31.01	31801.00
DEVICES & RAD H	53.92	0.30	0.00	0.00	0.00	0.00	54.22	53763.30
81	0.13	0.00	0.00	0.00	0.00	0.00	0.13	108.50
82	29.10	0.30	0.00	0.00	0.00	0.00	29.40	28586.40
83	11.51	0.00	0.00	0.00	0.00	0.00	11.51	10917.40
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.94	0.00	0.00	0.00	0.00	0.00	4.94	5743.00
86	8.24	0.00	0.00	0.00	0.00	0.00	8.24	8408.00

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WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: SE REGN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	213.15	72.15	43.95	0.00	0.00	3.00	332.25	344258.80
FOOD SAFETY/COS	83.95	49.99	40.63	0.00	0.00	3.00	177.57	193225.30
03	54.48	8.16	37.89	0.00	0.00	0.00	100.53	106490.40
04	6.89	16.46	0.00	0.00	0.00	0.00	23.35	25837.90
07	1.60	7.95	0.00	0.00	0.00	3.00	12.55	14430.00
09	0.14	0.78	0.00	0.00	0.00	0.00	0.92	1054.20
18	17.69	0.00	0.24	0.00	0.00	0.00	17.93	19888.50
21	2.53	16.39	1.98	0.00	0.00	0.00	20.90	24032.80
29	0.62	0.25	0.52	0.00	0.00	0.00	1.39	1491.50
BIOLOGICS	22.51	0.00	0.00	0.00	0.00	0.00	22.51	20752.70
41	4.94	0.00	0.00	0.00	0.00	0.00	4.94	4486.30
42	16.70	0.00	0.00	0.00	0.00	0.00	16.70	15469.10
45	0.87	0.00	0.00	0.00	0.00	0.00	0.87	797.30
HUMAN DRUGS	64.33	20.26	2.37	0.00	0.00	0.00	86.96	84995.40
46	4.05	1.61	0.00	0.00	0.00	0.00	5.66	5365.00
48	10.94	0.00	0.00	0.00	0.00	0.00	10.94	9953.60
52	5.93	2.67	0.00	0.00	0.00	0.00	8.60	8316.00
53	1.88	0.00	0.00	0.00	0.00	0.00	1.88	1704.00
56	40.76	12.80	2.37	0.00	0.00	0.00	55.93	55208.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.32	0.07	0.00	0.00	0.00	0.00	0.39	370.00
63	0.45	0.11	0.00	0.00	0.00	0.00	0.56	538.00
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
ANIMAL D & F	9.72	1.90	0.95	0.00	0.00	0.00	12.57	13070.60
68	1.83	0.12	0.00	0.00	0.00	0.00	1.95	1954.70
71	7.89	1.78	0.95	0.00	0.00	0.00	10.62	11115.90
DEVICES & RAD H	32.64	0.00	0.00	0.00	0.00	0.00	32.64	32214.80
81	0.07	0.00	0.00	0.00	0.00	0.00	0.07	67.80
82	18.32	0.00	0.00	0.00	0.00	0.00	18.32	17777.70
83	6.69	0.00	0.00	0.00	0.00	0.00	6.69	6352.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.52	0.00	0.00	0.00	0.00	0.00	2.52	2919.00
86	5.04	0.00	0.00	0.00	0.00	0.00	5.04	5098.10

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WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)

Output Reflects: OPR FTE'S

FY 2005

Date: 26-JAN-2005

REGION: SW REGN

FIELD	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
TOTAL	242.26	109.28	35.01	0.00	0.00	8.98	395.53	420412.10
FOOD SAFETY/COS	120.47	87.03	29.15	0.00	0.00	5.00	241.65	265673.30
03	89.03	10.18	28.64	0.00	0.00	0.00	127.85	135994.60
04	10.07	64.70	0.00	0.00	0.00	5.00	79.77	91649.00
07	1.95	5.70	0.00	0.00	0.00	0.00	7.65	8554.00
09	0.56	2.85	0.00	0.00	0.00	0.00	3.41	3901.70
18	14.39	0.00	0.13	0.00	0.00	0.00	14.52	16715.50
21	4.00	3.27	0.00	0.00	0.00	0.00	7.27	7583.10
29	0.47	0.33	0.38	0.00	0.00	0.00	1.18	1275.40
BIOLOGICS	19.11	0.00	0.00	0.00	0.00	0.00	19.11	17454.30
41	4.49	0.00	0.00	0.00	0.00	0.00	4.49	4088.90
42	14.02	0.00	0.00	0.00	0.00	0.00	14.02	12816.20
45	0.60	0.00	0.00	0.00	0.00	0.00	0.60	549.20
HUMAN DRUGS	42.66	8.97	1.08	0.00	0.00	0.00	52.71	49679.10
46	2.68	0.92	0.44	0.00	0.00	0.00	4.04	3801.00
48	9.63	0.00	0.00	0.00	0.00	0.00	9.63	8760.10
52	3.42	1.05	0.00	0.00	0.00	0.00	4.47	4160.00
53	1.01	0.00	0.00	0.00	0.00	0.00	1.01	924.00
56	24.74	6.74	0.64	0.00	0.00	0.00	32.12	30657.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.10	0.02	0.00	0.00	0.00	0.00	0.12	106.00
63	1.08	0.24	0.00	0.00	0.00	0.00	1.32	1271.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	23.38	13.28	3.41	0.00	0.00	3.98	44.05	47830.00
68	2.83	0.40	0.00	0.00	0.00	0.00	3.23	3256.10
71	20.55	12.88	3.41	0.00	0.00	3.98	40.82	44573.90
DEVICES & RAD H	36.64	0.00	1.37	0.00	0.00	0.00	38.01	39775.40
81	0.06	0.00	0.00	0.00	0.00	0.00	0.06	46.50
82	22.10	0.00	1.37	0.00	0.00	0.00	23.47	24719.00
83	5.51	0.00	0.00	0.00	0.00	0.00	5.51	5227.20
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.13	0.00	0.00	0.00	0.00	0.00	3.13	3634.00
86	5.84	0.00	0.00	0.00	0.00	0.00	5.84	6148.70

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REGION: PA REGN

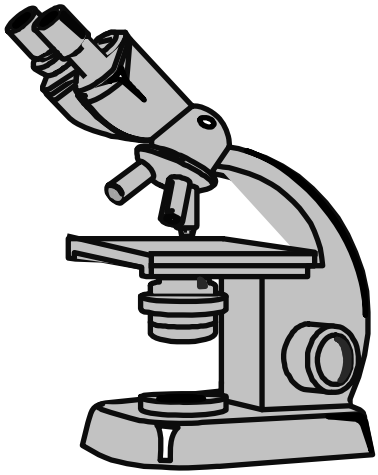
FIELD	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
TOTAL	286.99	70.41	60.21	0.00	0.00	7.00	424.61	440822.40
FOOD SAFETY/COS	161.45	53.09	58.95	0.00	0.00	6.00	279.49	298257.20
03	117.16	19.30	58.50	0.00	0.00	4.00	198.96	210620.10
04	11.80	27.25	0.00	0.00	0.00	0.00	39.05	43160.30
07	2.53	3.58	0.00	0.00	0.00	1.00	7.11	7770.00
09	0.51	1.66	0.00	0.00	0.00	0.00	2.17	2427.80
18	22.64	0.00	0.20	0.00	0.00	0.00	22.84	24897.00
21	5.92	0.70	0.00	0.00	0.00	1.00	7.62	7516.80
29	0.89	0.60	0.25	0.00	0.00	0.00	1.74	1865.20
BIOLOGICS	17.86	0.00	0.00	0.00	0.00	0.00	17.86	16645.30
41	4.12	0.00	0.00	0.00	0.00	0.00	4.12	3754.00
42	12.90	0.00	0.00	0.00	0.00	0.00	12.90	12123.70
45	0.84	0.00	0.00	0.00	0.00	0.00	0.84	767.60
HUMAN DRUGS	45.23	9.35	0.84	0.00	0.00	0.00	55.42	52600.70
46	2.12	1.40	0.00	0.00	0.00	0.00	3.52	3344.00
48	9.68	0.00	0.00	0.00	0.00	0.00	9.68	8807.90
52	2.77	1.09	0.00	0.00	0.00	0.00	3.86	3648.00
53	1.84	0.00	0.00	0.00	0.00	0.00	1.84	1674.00
56	25.50	6.23	0.84	0.00	0.00	0.00	32.57	31374.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.70	0.05	0.00	0.00	0.00	0.00	0.75	690.00
63	2.62	0.58	0.00	0.00	0.00	0.00	3.20	3062.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	17.44	3.05	0.42	0.00	0.00	1.00	21.91	23242.90
68	0.93	0.06	0.00	0.00	0.00	0.00	0.99	989.80
71	16.51	2.99	0.42	0.00	0.00	1.00	20.92	22253.10
DEVICES & RAD H	45.01	4.92	0.00	0.00	0.00	0.00	49.93	50076.30
81	0.12	0.00	0.00	0.00	0.00	0.00	0.12	120.10
82	27.65	4.92	0.00	0.00	0.00	0.00	32.57	32575.70
83	8.21	0.00	0.00	0.00	0.00	0.00	8.21	7794.40
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.84	0.00	0.00	0.00	0.00	0.00	2.84	3306.00
86	6.19	0.00	0.00	0.00	0.00	0.00	6.19	6280.10

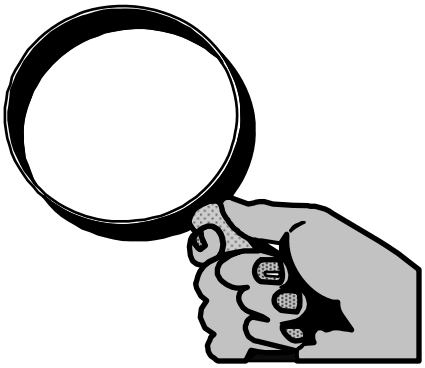
TOTAL FIELD

FIELD	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
TOTAL	1388.93	376.42	194.20	12.33	0.00	20.98	1992.86	2066613.50
FOOD SAFETY/COS	669.91	242.35	178.30	0.00	0.00	14.00	1104.56	1184765.40
03	492.08	53.20	174.29	0.00	0.00	4.00	723.57	761237.50
04	44.25	135.93	0.00	0.00	0.00	5.00	185.18	207839.30
07	10.81	21.25	0.00	0.00	0.00	4.00	36.06	39918.00
09	2.34	8.71	0.00	0.00	0.00	0.00	11.05	12464.00
18	93.07	0.00	0.68	0.00	0.00	0.00	93.75	105161.00
21	23.22	20.61	1.98	0.00	0.00	1.00	46.81	49435.60
29	4.14	2.65	1.35	0.00	0.00	0.00	8.14	8710.00
BIOLOGICS	119.03	0.00	0.00	0.00	0.00	0.00	119.03	109463.10
41	22.90	0.00	0.00	0.00	0.00	0.00	22.90	20828.40
42	87.94	0.00	0.00	0.00	0.00	0.00	87.94	81166.00
45	8.19	0.00	0.00	0.00	0.00	0.00	8.19	7468.70
HUMAN DRUGS	302.27	100.05	5.97	0.00	0.00	0.00	408.29	397861.10
46	19.52	12.02	0.53	0.00	0.00	0.00	32.07	31043.00
48	54.38	0.00	0.00	0.00	0.00	0.00	54.38	49454.10
52	27.08	16.28	0.00	0.00	0.00	0.00	43.36	42651.00
53	10.00	0.00	0.00	0.00	0.00	0.00	10.00	9084.00
56	183.22	58.27	5.44	0.00	0.00	0.00	246.93	242417.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	1.79	0.26	0.00	0.00	0.00	0.00	2.05	1904.00
63	6.28	1.22	0.00	0.00	0.00	0.00	7.50	7148.00
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	99.18	23.89	5.10	0.00	0.00	4.98	133.15	141678.00
68	10.07	0.65	0.00	0.00	0.00	0.00	10.72	10757.00
71	89.11	23.24	5.10	0.00	0.00	4.98	122.43	130921.00
DEVICES & RAD H	198.54	10.13	4.83	12.33	0.00	2.00	227.83	232845.90
81	0.45	0.03	0.02	0.03	0.00	0.00	0.53	497.90
82	117.09	10.10	4.15	4.23	0.00	0.59	136.16	137980.70
83	36.36	0.00	0.00	0.00	0.00	0.00	36.36	34504.60
84	0.00	0.00	0.66	3.00	0.00	1.41	5.07	5975.00
85	15.60	0.00	0.00	0.00	0.00	0.00	15.60	18125.00
86	29.04	0.00	0.00	5.07	0.00	0.00	34.11	35762.70

PART II
WORKPLAN SUMMARY

OPERATIONS





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WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: NE 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	2923	85.42 *	177	55.21 *	1965	8.54 *	9099	22.51 *	758	0.91 *
FOOD SAFETY/COS	1742	30.72 *	177	32.03 *	1557	6.64 *	7956	18.29 *	606	0.27 *
03	1404	26.44 *	177	30.67 *	422	2.01 *	5827	14.05 *	0	0.00 *
04	0	0.00 *	0	0.04 *	851	3.35 *	1197	2.53 *	18	0.01 *
07	0	0.00 *	0	0.00 *	158	0.68 *	419	0.90 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	339	0.51 *	0	0.00 *
18	292	3.29 *	0	0.34 *	16	0.07 *	0	0.00 *	0	0.00 *
21	32	0.71 *	0	0.61 *	96	0.45 *	63	0.12 *	588	0.26 *
29	14	0.28 *	0	0.37 *	14	0.08 *	111	0.18 *	0	0.00 *
BIOLOGICS	190	9.13 *	0	1.05 *	0	0.00 *	0	0.00 *	0	0.00 *
41	41	2.13 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	147	6.82 *	0	0.99 *	0	0.00 *	0	0.00 *	0	0.00 *
45	2	0.18 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	416	26.57 *	0	11.16 *	293	1.27 *	459	1.37 *	0	0.00 *
46	19	1.17 *	0	0.00 *	4	0.03 *	8	0.03 *	0	0.00 *
48	70	5.55 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	43	2.34 *	0	0.62 *	37	0.21 *	16	0.05 *	0	0.00 *
53	17	1.06 *	0	0.22 *	0	0.00 *	0	0.00 *	0	0.00 *
56	253	16.04 *	0	8.87 *	231	0.93 *	435	1.29 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	9	0.26 *	0	0.16 *	8	0.04 *	0	0.00 *	0	0.00 *
63	5	0.15 *	0	1.29 *	13	0.06 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	189	3.43 *	0	6.36 *	90	0.47 *	501	2.30 *	0	0.00 *
68	10	0.54 *	0	0.00 *	2	0.00 *	0	0.00 *	0	0.00 *
71	179	2.89 *	0	6.36 *	88	0.47 *	501	2.30 *	0	0.00 *
DEVICES & RAD H	386	15.57 *	0	4.61 *	25	0.16 *	183	0.55 *	152	0.64 *
81	4	0.05 *	0	0.01 *	0	0.00 *	0	0.00 *	0	0.00 *
82	232	10.70 *	0	2.77 *	24	0.16 *	183	0.55 *	0	0.00 *
83	59	3.87 *	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	65	0.48 *	0	1.13 *	0	0.00 *	0	0.00 *	0	0.00 *
86	26	0.47 *	0	0.70 *	1	0.00 *	0	0.00 *	152	0.64 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: NE 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	23826	21.36 *	1801	32.93 *	10768	88.11 *	2428	39.30 *	145	8.23 *
FOOD SAFETY/COS	21603	19.65 *	1065	12.87 *	9198	70.94 *	1297	25.91 *	18	0.58 *
03	18432	17.65 *	450	6.03 *	6992	54.49 *	105	12.11 *	18	0.58 *
04	1355	1.02 *	357	5.16 *	1369	10.13 *	0	1.45 *	0	0.00 *
07	0	0.00 *	231	1.37 *	349	2.07 *	0	0.58 *	0	0.00 *
09	0	0.00 *	0	0.00 *	379	2.82 *	262	0.26 *	0	0.00 *
18	0	0.00 *	16	0.11 *	0	0.00 *	209	10.62 *	0	0.00 *
21	1816	0.98 *	0	0.00 *	0	0.00 *	330	0.72 *	0	0.00 *
29	0	0.00 *	11	0.20 *	109	1.43 *	391	0.17 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.12 *
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	0.12 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	1684	1.29 *	263	11.35 *	239	5.68 *	900	2.14 *	65	4.22 *
46	0	0.00 *	11	1.99 *	50	1.27 *	1	0.09 *	21	1.28 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.46 *
52	0	0.00 *	35	2.69 *	155	3.31 *	0	0.00 *	8	0.50 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.20 *
56	1684	1.29 *	212	6.59 *	34	1.10 *	899	2.05 *	27	1.78 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	1	0.02 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	4	0.06 *	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	231	0.23 *	278	2.08 *	507	3.17 *	0	1.17 *	6	0.24 *
68	0	0.00 *	2	0.07 *	0	0.00 *	0	0.00 *	5	0.20 *
71	231	0.23 *	276	2.01 *	507	3.17 *	0	1.17 *	1	0.04 *
DEVICES & RAD H	308	0.19 *	195	6.63 *	824	8.32 *	231	10.08 *	53	3.07 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	289	0.18 *	83	3.15 *	824	8.32 *	231	1.92 *	21	1.44 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.56 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	5.06 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.53 *	5	0.03 *
86	19	0.01 *	109	3.40 *	0	0.00 *	0	2.57 *	17	1.04 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: NE REGN

	TOTALS	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	362.52	383526.90
FOOD SAFETY/COS	217.90	234083.60
03	164.03	174643.80
04	23.69	26270.50
07	5.60	6230.00
09	3.59	4042.00
18	14.43	16252.00
21	3.85	3641.80
29	2.71	3003.50
BIOLOGICS	10.30	9557.00
41	2.13	1939.20
42	7.93	7399.40
45	0.24	218.40
HUMAN DRUGS	65.05	64363.20
46	5.86	5814.00
48	6.01	5465.60
52	9.72	10125.00
53	1.48	1341.00
56	39.94	39739.60
58	0.00	0.00
61	0.48	432.00
63	1.56	1446.00
88	0.00	0.00
ANIMAL D & F	19.45	21589.00
68	0.81	820.90
71	18.64	20768.10
DEVICES & RAD H	49.82	53934.10
81	0.14	155.00
82	29.19	31239.90
83	4.43	4213.40
84	5.06	5975.00
85	2.17	2523.00
86	8.83	9827.80

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WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

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	7367	207.49 *	123	49.17 *	5590	24.03 *	4139	10.46 *	1989	2.46 *
FOOD SAFETY/COS	3050	55.94 *	123	22.49 *	3881	15.99 *	3353	7.65 *	1541	0.71 *
03	2541	48.42 *	123	20.23 *	1166	4.95 *	2288	5.47 *	0	0.00 *
04	0	0.00 *	0	0.14 *	1748	6.69 *	637	1.38 *	67	0.04 *
07	0	0.00 *	0	0.00 *	626	2.68 *	215	0.46 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	155	0.23 *	0	0.00 *
18	362	4.09 *	0	0.41 *	20	0.09 *	0	0.00 *	0	0.00 *
21	113	2.75 *	0	1.54 *	287	1.37 *	42	0.09 *	1474	0.67 *
29	34	0.68 *	0	0.17 *	34	0.21 *	16	0.02 *	0	0.00 *
BIOLOGICS	616	30.47 *	0	2.60 *	0	0.00 *	0	0.00 *	0	0.00 *
41	130	7.22 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	478	22.53 *	0	2.36 *	0	0.00 *	0	0.00 *	0	0.00 *
45	8	0.72 *	0	0.24 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	988	65.17 *	0	12.64 *	904	3.73 *	290	0.88 *	0	0.00 *
46	55	3.39 *	0	0.00 *	12	0.09 *	19	0.06 *	0	0.00 *
48	183	15.12 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	117	6.90 *	0	1.70 *	98	0.55 *	50	0.16 *	0	0.00 *
53	37	2.32 *	0	0.77 *	0	0.00 *	0	0.00 *	0	0.00 *
56	582	37.02 *	0	9.91 *	761	2.95 *	221	0.66 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	6	0.18 *	0	0.01 *	6	0.02 *	0	0.00 *	0	0.00 *
63	8	0.24 *	0	0.25 *	27	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	1947	22.18 *	0	4.70 *	760	4.02 *	270	1.23 *	0	0.00 *
68	57	3.17 *	0	0.00 *	6	0.00 *	0	0.00 *	0	0.00 *
71	1890	19.01 *	0	4.70 *	754	4.02 *	270	1.23 *	0	0.00 *
DEVICES & RAD H	766	33.73 *	0	6.74 *	45	0.29 *	226	0.70 *	448	1.75 *
81	7	0.08 *	0	0.01 *	0	0.00 *	0	0.00 *	0	0.00 *
82	460	21.84 *	0	2.51 *	44	0.28 *	226	0.70 *	0	0.00 *
83	150	10.13 *	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	97	0.77 *	0	2.79 *	0	0.00 *	0	0.00 *	0	0.00 *
86	52	0.91 *	0	1.43 *	1	0.01 *	0	0.00 *	448	1.75 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: CE 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	11454	10.29 *	706	53.38 *	139	1.56 *	1556	43.28 *	326	18.17 *
FOOD SAFETY/COS	10181	9.32 *	24	9.87 *	123	1.04 *	894	30.77 *	60	1.93 *
03	8900	8.54 *	24	0.08 *	37	0.40 *	46	9.99 *	60	1.93 *
04	369	0.29 *	0	9.79 *	0	0.00 *	0	0.98 *	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 *	81	0.60 *	121	0.12 *	0	0.00 *
18	0	0.00 *	0	0.00 *	0	0.00 *	504	19.43 *	0	0.00 *
21	912	0.49 *	0	0.00 *	0	0.00 *	169	0.24 *	0	0.00 *
29	0	0.00 *	0	0.00 *	5	0.04 *	54	0.01 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	3	0.12 *
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	0.12 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	856	0.67 *	682	42.48 *	16	0.52 *	457	2.84 *	173	11.14 *
46	0	0.00 *	48	4.83 *	0	0.00 *	0	0.00 *	60	3.64 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	22	1.59 *
52	0	0.00 *	87	5.47 *	0	0.00 *	0	0.00 *	25	1.55 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.40 *
56	856	0.67 *	526	22.85 *	16	0.52 *	457	2.84 *	60	3.96 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	6	0.10 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	15	0.23 *	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	128	0.12 *	0	0.73 *	0	0.00 *	0	0.97 *	18	0.72 *
68	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	13	0.52 *
71	128	0.12 *	0	0.73 *	0	0.00 *	0	0.97 *	5	0.20 *
DEVICES & RAD H	289	0.18 *	0	0.30 *	0	0.00 *	205	6.20 *	72	4.26 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	253	0.16 *	0	0.30 *	0	0.00 *	205	0.76 *	42	2.86 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	25	1.37 *
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	1.33 *	5	0.03 *
86	36	0.02 *	0	0.00 *	0	0.00 *	0	4.11 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: CE REGN

TOTALS

	OPR FTE'S	PERSNHRS
FIELD TOTAL	420.29	416825.50
FOOD SAFETY/COS	155.71	155999.00
03	100.01	95961.60
04	19.31	20921.60
07	3.14	2934.00
09	0.95	1038.30
18	24.02	27408.00
21	7.15	6661.10
29	1.13	1074.40
BIOLOGICS	35.69	32716.80
41	7.22	6560.00
42	27.51	25283.20
45	0.96	873.60
HUMAN DRUGS	140.07	138849.90
46	12.01	11834.00
48	16.71	15189.10
52	16.33	16057.00
53	3.49	3141.00
56	81.38	80871.80
58	0.00	0.00
61	0.31	306.00
63	0.84	831.00
88	9.00	10620.00
ANIMAL D & F	34.67	35496.50
68	3.69	3695.50
71	30.98	31801.00
DEVICES & RAD H	54.15	53763.30
81	0.09	108.50
82	29.41	28586.40
83	11.50	10917.40
84	0.00	0.00
85	4.92	5743.00
86	8.23	8408.00

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WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SE 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	3690	118.24 *	89	29.95 *	2961	12.32 *	3722	9.73 *	1127	1.51 *
FOOD SAFETY/COS	1763	29.82 *	89	12.25 *	2220	8.99 *	2983	7.56 *	803	0.36 *
03	1279	23.74 *	89	10.95 *	540	2.30 *	2019	5.11 *	0	0.00 *
04	0	0.00 *	0	0.08 *	1201	4.56 *	783	2.12 *	6	0.00 *
07	0	0.00 *	0	0.00 *	327	1.41 *	90	0.19 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	60	0.10 *	0	0.00 *
18	433	5.06 *	0	0.50 *	25	0.11 *	0	0.00 *	0	0.00 *
21	33	0.66 *	0	0.61 *	109	0.50 *	16	0.02 *	797	0.36 *
29	18	0.36 *	0	0.11 *	18	0.11 *	15	0.02 *	0	0.00 *
BIOLOGICS	425	20.24 *	0	2.01 *	0	0.00 *	0	0.00 *	0	0.00 *
41	102	4.94 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	314	14.49 *	0	1.95 *	0	0.00 *	0	0.00 *	0	0.00 *
45	9	0.81 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	646	42.05 *	0	10.99 *	477	2.01 *	374	1.11 *	0	0.00 *
46	32	1.96 *	0	0.00 *	7	0.05 *	9	0.02 *	0	0.00 *
48	121	10.28 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	67	3.55 *	0	1.00 *	57	0.31 *	32	0.10 *	0	0.00 *
53	20	1.25 *	0	0.44 *	0	0.00 *	0	0.00 *	0	0.00 *
56	393	24.63 *	0	9.26 *	391	1.55 *	333	0.99 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	9	0.26 *	0	0.02 *	8	0.04 *	0	0.00 *	0	0.00 *
63	4	0.12 *	0	0.27 *	14	0.06 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	400	6.23 *	0	0.92 *	236	1.16 *	23	0.10 *	0	0.00 *
68	26	1.34 *	0	0.00 *	3	0.00 *	0	0.00 *	0	0.00 *
71	374	4.89 *	0	0.92 *	233	1.16 *	23	0.10 *	0	0.00 *
DEVICES & RAD H	456	19.90 *	0	3.78 *	28	0.16 *	342	0.96 *	324	1.15 *
81	4	0.04 *	0	0.01 *	1	0.01 *	0	0.00 *	0	0.00 *
82	268	13.01 *	0	1.63 *	26	0.15 *	342	0.96 *	0	0.00 *
83	93	5.89 *	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	65	0.51 *	0	1.22 *	0	0.00 *	0	0.00 *	0	0.00 *
86	26	0.45 *	0	0.92 *	1	0.00 *	0	0.00 *	324	1.15 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

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	6934	5.99 *	5597	69.76 *	5068	42.01 *	1273	31.65 *	204	10.98 *
FOOD SAFETY/COS	5451	4.87 *	4754	46.46 *	4994	40.87 *	455	24.97 *	44	1.42 *
03	4778	4.47 *	1021	17.54 *	3450	26.97 *	68	8.00 *	44	1.42 *
04	189	0.14 *	2093	8.90 *	1005	7.56 *	0	0.00 *	0	0.00 *
07	0	0.00 *	943	5.59 *	243	1.44 *	0	3.91 *	0	0.00 *
09	0	0.00 *	0	0.00 *	60	0.45 *	46	0.38 *	0	0.00 *
18	0	0.00 *	36	0.24 *	0	0.00 *	203	12.03 *	0	0.00 *
21	484	0.26 *	632	13.67 *	218	4.20 *	89	0.63 *	0	0.00 *
29	0	0.00 *	29	0.52 *	18	0.25 *	49	0.02 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.24 *
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 *	6	0.24 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	1285	1.00 *	603	20.75 *	26	0.84 *	686	1.98 *	96	6.17 *
46	0	0.00 *	9	1.61 *	0	0.00 *	0	0.00 *	33	2.00 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.66 *
52	0	0.00 *	8	1.63 *	0	0.00 *	0	1.04 *	15	0.93 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.20 *
56	1285	1.00 *	575	14.33 *	26	0.84 *	686	0.94 *	36	2.38 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	4	0.07 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	7	0.11 *	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	12	0.00 *	240	2.55 *	48	0.30 *	0	0.81 *	12	0.48 *
68	0	0.00 *	3	0.12 *	0	0.00 *	0	0.00 *	12	0.48 *
71	12	0.00 *	237	2.43 *	48	0.30 *	0	0.81 *	0	0.00 *
DEVICES & RAD H	186	0.12 *	0	0.00 *	0	0.00 *	132	3.89 *	46	2.67 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	164	0.11 *	0	0.00 *	0	0.00 *	132	0.62 *	27	1.85 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	14	0.79 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.76 *	5	0.03 *
86	22	0.01 *	0	0.00 *	0	0.00 *	0	2.51 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SE REGN

TOTALS

	OPR FTE'S	PERSNHRS
FIELD TOTAL	332.14	344258.80
FOOD SAFETY/COS	177.57	193225.30
03	100.50	106490.40
04	23.36	25837.90
07	12.54	14430.00
09	0.93	1054.20
18	17.94	19888.50
21	20.91	24032.80
29	1.39	1491.50
BIOLOGICS	22.49	20752.70
41	4.94	4486.30
42	16.68	15469.10
45	0.87	797.30
HUMAN DRUGS	86.90	84995.40
46	5.64	5365.00
48	10.94	9953.60
52	8.56	8316.00
53	1.89	1704.00
56	55.92	55208.80
58	0.00	0.00
61	0.39	370.00
63	0.56	538.00
88	3.00	3540.00
ANIMAL D & F	12.55	13070.60
68	1.94	1954.70
71	10.61	11115.90
DEVICES & RAD H	32.63	32214.80
81	0.06	67.80
82	18.33	17777.70
83	6.68	6352.20
84	0.00	0.00
85	2.52	2919.00
86	5.04	5098.10

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WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

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	3819	100.92 *	118	55.35 *	2732	12.00 *	7944	16.91 *	1002	1.40 *
FOOD SAFETY/COS	1048	19.41 *	118	35.86 *	1696	7.01 *	7606	15.83 *	705	0.32 *
03	819	16.00 *	118	34.54 *	322	1.43 *	3478	8.41 *	0	0.00 *
04	0	0.00 *	0	0.09 *	846	3.25 *	3673	6.63 *	0	0.00 *
07	0	0.00 *	0	0.00 *	375	1.61 *	156	0.34 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	248	0.37 *	0	0.00 *
18	163	2.05 *	0	0.19 *	10	0.04 *	0	0.00 *	0	0.00 *
21	53	1.10 *	0	0.95 *	130	0.60 *	38	0.06 *	705	0.32 *
29	13	0.26 *	0	0.09 *	13	0.08 *	13	0.02 *	0	0.00 *
BIOLOGICS	371	17.59 *	0	1.15 *	0	0.00 *	0	0.00 *	0	0.00 *
41	93	4.49 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	272	12.56 *	0	1.09 *	0	0.00 *	0	0.00 *	0	0.00 *
45	6	0.54 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	460	31.03 *	0	4.73 *	341	1.42 *	90	0.28 *	0	0.00 *
46	20	1.24 *	0	0.00 *	4	0.03 *	7	0.03 *	0	0.00 *
48	104	8.98 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	34	1.97 *	0	0.54 *	28	0.16 *	21	0.07 *	0	0.00 *
53	8	0.51 *	0	0.33 *	0	0.00 *	0	0.00 *	0	0.00
56	282	17.97 *	0	3.17 *	280	1.11 *	62	0.18 *	0	0.00
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	3	0.09 *	0	0.00 *	2	0.01 *	0	0.00 *	0	0.00 *
63	9	0.27 *	0	0.69 *	27	0.11 *	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	1453	16.30 *	0	1.91 *	675	3.44 *	51	0.24 *	0	0.00 *
68	42	2.18 *	0	0.00 *	3	0.01 *	0	0.00 *	0	0.00 *
71	1411	14.12 *	0	1.91 *	672	3.43 *	51	0.24 *	0	0.00 *
DEVICES & RAD H	487	16.59 *	0	11.70 *	20	0.13 *	197	0.56 *	297	1.08 *
81	3	0.03 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	206	10.11 *	0	8.57 *	19	0.12 *	197	0.56 *	0	0.00 *
83	67	4.68 *	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	188	1.34 *	0	1.13 *	0	0.00 *	0	0.00 *	0	0.00 *
86	23	0.43 *	0	2.00 *	1	0.01 *	0	0.00 *	297	1.08 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SW 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	24310	22.57 *	8445	86.74 *	6902	52.42 *	1596	37.97 *	173	9.27 *
FOOD SAFETY/COS	23047	21.74 *	7165	62.35 *	6607	50.44 *	725	27.54 *	36	1.17 *
03	21670	20.97 *	1064	10.95 *	3300	27.21 *	18	7.18 *	36	1.17 *
04	144	0.11 *	4462	44.33 *	2680	18.88 *	0	6.50 *	0	0.00 *
07	0	0.00 *	555	3.29 *	322	1.91 *	0	0.50 *	0	0.00 *
09	0	0.00 *	0	0.00 *	282	2.11 *	191	0.94 *	0	0.00 *
18	0	0.00 *	19	0.13 *	0	0.00 *	248	12.10 *	0	0.00 *
21	1233	0.66 *	1044	3.27 *	0	0.00 *	221	0.30 *	0	0.00 *
29	0	0.00 *	21	0.38 *	23	0.33 *	47	0.02 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.37 *
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 *	9	0.37 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	240	0.18 *	240	9.44 *	5	0.16 *	133	0.78 *	73	4.70 *
46	0	0.00 *	0	0.92 *	0	0.00 *	5	0.44 *	23	1.39 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.66 *
52	0	0.00 *	4	1.05 *	0	0.00 *	0	0.00 *	11	0.68 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.20 *
56	240	0.18 *	219	7.21 *	5	0.16 *	128	0.34 *	27	1.77 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	1	0.02 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	16	0.24 *	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	24	0.02 *	1014	13.58 *	290	1.82 *	0	5.99 *	19	0.76 *
68	0	0.00 *	9	0.40 *	0	0.00 *	0	0.00 *	16	0.64 *
71	24	0.02 *	1005	13.18 *	290	1.82 *	0	5.99 *	3	0.12 *
DEVICES & RAD H	999	0.63 *	26	1.37 *	0	0.00 *	738	3.66 *	36	2.27 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	918	0.58 *	26	1.37 *	0	0.00 *	738	0.73 *	21	1.44 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	15	0.83 *
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	0.65 *	0	0.00 *
86	81	0.05 *	0	0.00 *	0	0.00 *	0	2.28 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SW REGN

TOTALS

	OPR FTE'S	PERSNHRS
FIELD TOTAL	395.55	420412.10
FOOD SAFETY/COS	241.67	265673.30
03	127.86	135994.60
04	79.79	91649.00
07	7.65	8554.00
09	3.42	3901.70
18	14.51	16715.50
21	7.26	7583.10
29	1.18	1275.40
BIOLOGICS	19.11	17454.30
41	4.49	4088.90
42	14.02	12816.20
45	0.60	549.20
HUMAN DRUGS	52.72	49679.10
46	4.05	3801.00
48	9.64	8760.10
52	4.47	4160.00
53	1.04	924.00
56	32.09	30657.00
58	0.00	0.00
61	0.12	106.00
63	1.31	1271.00
88	0.00	0.00
ANIMAL D & F	44.06	47830.00
68	3.23	3256.10
71	40.83	44573.90
DEVICES & RAD H	37.99	39775.40
81	0.03	46.50
82	23.48	24719.00
83	5.51	5227.20
84	0.00	0.00
85	3.12	3634.00
86	5.85	6148.70

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WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: PA 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	4967	135.28 *	193	50.92 *	4493	18.14 *	8393	21.18 *	1610	1.71 *
FOOD SAFETY/COS	2860	51.57 *	193	31.38 *	3823	14.91 *	7498	18.09 *	1345	0.60 *
03	2227	42.51 *	193	29.01 *	850	3.77 *	5688	13.96 *	0	0.00 *
04	0	0.00 *	0	0.21 *	2327	8.26 *	1083	2.79 *	9	0.00 *
07	0	0.00 *	0	0.00 *	389	1.67 *	400	0.86 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	223	0.33 *	0	0.00 *
18	542	7.19 *	0	0.61 *	29	0.13 *	0	0.00 *	0	0.00 *
21	70	1.46 *	0	1.34 *	207	0.95 *	59	0.08 *	1336	0.60 *
29	21	0.41 *	0	0.21 *	21	0.13 *	45	0.07 *	0	0.00 *
BIOLOGICS	323	15.76 *	0	2.10 *	0	0.00 *	0	0.00 *	0	0.00 *
41	76	4.12 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	239	10.92 *	0	1.98 *	0	0.00 *	0	0.00 *	0	0.00 *
45	8	0.72 *	0	0.12 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	435	28.97 *	0	8.61 *	325	1.39 *	139	0.43 *	0	0.00 *
46	14	0.86 *	0	0.00 *	3	0.02 *	7	0.03 *	0	0.00 *
48	102	8.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	24	1.41 *	0	0.43 *	20	0.11 *	21	0.07 *	0	0.00 *
53	18	1.13 *	0	0.33 *	0	0.00 *	0	0.00 *	0	0.00 *
56	245	15.80 *	0	5.90 *	217	0.88 *	111	0.33 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	7	0.20 *	0	0.46 *	6	0.03 *	0	0.00 *	0	0.00 *
63	25	0.76 *	0	1.49 *	79	0.35 *	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	685	9.64 *	0	3.51 *	299	1.57 *	230	1.05 *	0	0.00 *
68	16	0.80 *	0	0.00 *	1	0.00 *	0	0.00 *	0	0.00 *
71	669	8.84 *	0	3.51 *	298	1.57 *	230	1.05 *	0	0.00 *
DEVICES & RAD H	664	29.34 *	0	5.32 *	46	0.27 *	526	1.61 *	265	1.11 *
81	7	0.08 *	0	0.03 *	2	0.02 *	0	0.00 *	0	0.00 *
82	419	20.06 *	0	2.09 *	39	0.24 *	526	1.61 *	0	0.00 *
83	116	7.63 *	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	64	0.49 *	0	1.74 *	0	0.00 *	0	0.00 *	0	0.00 *
86	58	1.08 *	0	1.46 *	5	0.01 *	0	0.00 *	265	1.11 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

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	19509	17.45 *	2688	29.96 *	13276	95.52 *	1456	45.08 *	163	9.37 *
FOOD SAFETY/COS	18718	16.85 *	2210	19.28 *	12327	87.93 *	1057	37.69 *	36	1.16 *
03	16220	15.36 *	741	11.29 *	8846	64.54 *	163	17.38 *	36	1.16 *
04	693	0.52 *	1280	6.67 *	2847	18.96 *	0	1.63 *	0	0.00 *
07	0	0.00 *	146	0.87 *	366	2.17 *	0	1.54 *	0	0.00 *
09	0	0.00 *	0	0.00 *	223	1.66 *	170	0.16 *	0	0.00 *
18	0	0.00 *	29	0.20 *	0	0.00 *	229	14.71 *	0	0.00 *
21	1805	0.97 *	0	0.00 *	0	0.00 *	336	2.20 *	0	0.00 *
29	0	0.00 *	14	0.25 *	45	0.60 *	159	0.07 *	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	433	0.34 *	220	8.63 *	69	1.56 *	230	0.46 *	77	5.04 *
46	0	0.00 *	6	1.40 *	0	0.00 *	0	0.00 *	20	1.21 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	12	0.89 *
52	0	0.00 *	6	1.09 *	0	0.00 *	0	0.00 *	12	0.75 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.40 *
56	433	0.34 *	167	5.51 *	69	1.56 *	230	0.46 *	27	1.79 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	3	0.05 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	38	0.58 *	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	105	0.11 *	258	2.05 *	230	1.44 *	0	2.43 *	3	0.12 *
68	0	0.00 *	1	0.06 *	0	0.00 *	0	0.00 *	3	0.12 *
71	105	0.11 *	257	1.99 *	230	1.44 *	0	2.43 *	0	0.00 *
DEVICES & RAD H	253	0.15 *	0	0.00 *	650	4.59 *	169	4.50 *	47	3.05 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	211	0.13 *	0	0.00 *	650	4.59 *	169	1.39 *	36	2.46 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	11	0.59 *
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	0.62 *	0	0.00 *
86	42	0.02 *	0	0.00 *	0	0.00 *	0	2.49 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: PA REGN

TOTALS

	OPR FTE'S	PERSNHRS
FIELD TOTAL	424.61	440822.40
FOOD SAFETY/COS	279.46	298257.20
03	198.98	210620.10
04	39.04	43160.30
07	7.11	7770.00
09	2.15	2427.80
18	22.84	24897.00
21	7.60	7516.80
29	1.74	1865.20
BIOLOGICS	17.86	16645.30
41	4.12	3754.00
42	12.90	12123.70
45	0.84	767.60
HUMAN DRUGS	55.43	52600.70
46	3.52	3344.00
48	9.70	8807.90
52	3.86	3648.00
53	1.86	1674.00
56	32.57	31374.80
58	0.00	0.00
61	0.74	690.00
63	3.18	3062.00
88	0.00	0.00
ANIMAL D & F	21.92	23242.90
68	0.98	989.80
71	20.94	22253.10
DEVICES & RAD H	49.94	50076.30
81	0.13	120.10
82	32.57	32575.70
83	8.22	7794.40
84	0.00	0.00
85	2.85	3306.00
86	6.17	6280.10

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

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	22807	660.31 *	700	277.83 *	17741	75.03 *	33297	80.79 *	6486	7.99 *
FOOD SAFETY/COS	10463	187.46 *	700	166.01 *	13177	53.54 *	29396	67.42 *	5000	2.26 *
03	8270	157.11 *	700	157.40 *	3300	14.46 *	19300	47.00 *	0	0.00 *
04	0	0.00 *	0	0.56 *	6973	26.11 *	7373	15.45 *	100	0.05 *
07	0	0.00 *	0	0.00 *	1875	8.05 *	1280	2.75 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	1025	1.54 *	0	0.00 *
18	1792	21.68 *	0	2.05 *	100	0.44 *	0	0.00 *	0	0.00 *
21	301	6.68 *	0	5.05 *	829	3.87 *	218	0.37 *	4900	2.21 *
29	100	1.99 *	0	0.95 *	100	0.61 *	200	0.31 *	0	0.00 *
BIOLOGICS	1966	100.93 *	0	11.99 *	0	0.00 *	0	0.00 *	0	0.00 *
41	442	22.90 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	1474	71.55 *	0	11.45 *	0	0.00 *	0	0.00 *	0	0.00 *
45	50	6.48 *	0	0.54 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	2945	198.64 *	0	48.13 *	2340	9.82 *	1352	4.07 *	0	0.00 *
46	140	8.62 *	0	0.00 *	30	0.22 *	50	0.17 *	0	0.00 *
48	580	49.76 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	285	16.17 *	0	4.29 *	240	1.34 *	140	0.45 *	0	0.00 *
53	100	6.27 *	0	2.09 *	0	0.00 *	0	0.00 *	0	0.00 *
56	1755	115.29 *	0	37.11 *	1880	7.42 *	1162	3.45 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	34	0.99 *	0	0.65 *	30	0.14 *	0	0.00 *	0	0.00
63	51	1.54 *	0	3.99 *	160	0.70 *	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	4674	58.15 *	0	17.40 *	2060	10.66 *	1075	4.92 *	0	0.00 *
68	151	8.03 *	0	0.00 *	15	0.01 *	0	0.00 *	0	0.00 *
71	4523	50.12 *	0	17.40 *	2045	10.65 *	1075	4.92 *	0	0.00 *
DEVICES & RAD H	2759	115.13 *	0	34.30 *	164	1.01 *	1474	4.38 *	1486	5.73 *
81	25	0.28 *	0	0.06 *	3	0.03 *	0	0.00 *	0	0.00 *
82	1585	75.72 *	0	19.72 *	152	0.95 *	1474	4.38 *	0	0.00 *
83	485	32.20 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	479	3.59 *	0	8.01 *	0	0.00 *	0	0.00 *	0	0.00 *
86	185	3.34 *	0	6.51 *	9	0.03 *	0	0.00 *	1486	5.73 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

TOTAL 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 *
FIELD TOTAL	86033	77.66 *	19237	272.77 *	36153	279.62 *	8309	197.31 *	1103	63.38 *
FOOD SAFETY/COS	79000	72.43 *	15218	150.83 *	33249	251.22 *	4428	146.91 *	200	6.45 *
03	70000	66.99 *	3300	45.89 *	22625	173.61 *	400	54.69 *	200	6.45 *
04	2750	2.08 *	8192	74.85 *	7901	55.53 *	0	10.56 *	0	0.00 *
07	0	0.00 *	1875	11.12 *	1280	7.59 *	0	6.53 *	0	0.00 *
09	0	0.00 *	0	0.00 *	1025	7.64 *	790	1.86 *	0	0.00 *
18	0	0.00 *	100	0.68 *	0	0.00 *	1393	68.89 *	0	0.00 *
21	6250	3.36 *	1676	16.94 *	218	4.20 *	1145	4.09 *	0	0.00 *
29	0	0.00 *	75	1.35 *	200	2.65 *	700	0.29 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	39	3.59 *
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 *	32	2.41 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	7	1.18 *
HUMAN DRUGS	4498	3.48 *	2008	92.65 *	355	8.76 *	2406	8.20 *	534	34.52 *
46	0	0.00 *	74	10.75 *	50	1.27 *	6	0.53 *	173	10.49 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	63	4.64 *
52	0	0.00 *	140	11.93 *	155	3.31 *	0	1.04 *	77	4.79 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	26	1.73 *
56	4498	3.48 *	1699	56.49 *	150	4.18 *	2400	6.63 *	195	12.87 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	15	0.26 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	80	1.22 *	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	500	0.48 *	1790	20.99 *	1075	6.73 *	0	11.37 *	60	2.40 *
68	0	0.00 *	15	0.65 *	0	0.00 *	0	0.00 *	50	2.00 *
71	500	0.48 *	1775	20.34 *	1075	6.73 *	0	11.37 *	10	0.40 *
DEVICES & RAD H	2035	1.27 *	221	8.30 *	1474	12.91 *	1475	28.33 *	270	16.42 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	1835	1.16 *	109	4.82 *	1474	12.91 *	1475	5.42 *	163	11.15 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	75	4.14 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	5.06 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	3.89 *	15	0.09 *
86	200	0.11 *	109	3.40 *	0	0.00 *	0	13.96 *	17	1.04 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

TOTAL FIELD

	TOTALS	
	OPR FTE'S	PERSNHRS
FIELD TOTAL	1992.69	2066613.50
FOOD SAFETY/COS	1104.53	1184765.40
03	723.60	761237.50
04	185.19	207839.30
07	36.04	39918.00
09	11.04	12464.00
18	93.74	105161.00
21	46.77	49435.60
29	8.15	8710.00
BIOLOGICS	119.01	109463.10
41	22.90	20828.40
42	87.91	81166.00
45	8.20	7468.70
HUMAN DRUGS	408.27	397861.10
46	32.05	31043.00
48	54.40	49454.10
52	43.32	42651.00
53	10.09	9084.00
56	246.92	242417.00
58	0.00	0.00
61	2.04	1904.00
63	7.45	7148.00
88	12.00	14160.00
ANIMAL D & F	133.10	141678.00
68	10.69	10757.00
71	122.41	130921.00
DEVICES & RAD H	227.78	232845.90
81	0.45	497.90
82	136.23	137980.70
83	36.34	34504.60
84	5.06	5975.00
85	15.58	18125.00
86	34.12	35762.70

FY 2005

PART III - PROGRAM FORECASTS

DEPT OF HEALTH & HUMAN SERVICES
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE MANAGEMENT BRANCH

ORA/ORM/DPEM

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2005

February 1, 2005

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	554.6	543	7.5	1105.1	993.3	959.4	13.3	1966.0
03	FOODBORNE BIOLOGICAL HAZARDS	280.1	436.1	7.5	723.7	494.8	779.5	13.3	1287.6
04	PESTICIDES AND CHEMICAL CONTAMINANTS	112.9	72.5		185.4	210.8	118.6		329.4
07	MOLECULAR BIOLOGY AND NATURAL TOXINS	25.7	10.4		36.1	45.0	19.3		64.3
09	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT	1.1	10.0		11.1	2.0	17.7		19.7
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	93.8			93.8	167.0			167.0
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	37.2	9.7		46.9	66.9	16.7		83.6
29	COLOR AND COSMETICS TECHNOLOGY	3.8	4.3		8.1	6.8	7.6		14.4

"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
FY 2005

FEBRUARY 1, 2005

1.89

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		**280.1**	**436.1**	**7.5**	**723.7**	**1287.6**	
1	Import Acidified and Low Acid Canned Foods	03003,A,		13.9		13.9	24.7	2-3
2	Domestic and Imported Cheese & Cheese Products	03037,D	17.1	11.4		28.5	50.7	4-5
3	National Drug Residue Milk Compliance Program	03039	3.6			3.6	6.4	6-7
4	Domestic Acidified and Low Acid Canned Food	03803A	14.9			14.9	26.5	8-9
5	Domestic Food Safety	03803,B	94.9			94.9	168.8	10-13
6	Import Foods - General	03819A,B		288.8		288.8	514.0	14-15
7	Domestic Fish and Fishery Products Inspection	03842,B	75.0			75.0	133.4	16-17
8	Import Seafood Products	03844,B		101.4		101.4	180.4	18-19
9	Juice HACCP Inspection Program	03847H	14.0			14.0	24.9	20-21
10	Import & Domestic Micro Assignment	03F098	13.9	13.9		27.8	49.5	22-23
11	Foreign Inspections/Assessments	03R233			7.5	7.5	13.3	24-25
12	Emergency Response to Foodborne Outbreaks	03R839	7.0			7.0	12.5	26-27
	and Illnesses							
13	Food State Contract Audits	03R843	22.8			22.8	40.6	28-29
14	Counter Terrorism Preparedness	03R845	4.9	6.7		11.6	20.6	30-31
15	ORA/Center Directed Research Projects	03R816	12.0			12.0	21.3	32-33

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy 301-436-2657	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 2005	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.

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. It is projected that in FY 05, foreign manufacturers will comprise approximately 86% of total number of registered firms. Therefore, in FY 05, the number of Import Field Exams will double in number to 3000 (from 1500 in FY 04) and the number of Import Sample Collections will increase to 1300 (from 1000 in FY 04).

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.

For FY 05 and beyond 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.

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 [X] 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 ☐ CENTER	13.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTION	4 IMPORT SAMPLE COLL	5 FIELD EXAM TESTS	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED CHEM
	TOTAL FIELD				**1300**		**3000**	**1144**		**156**
	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		1.0	7.0		10.0
TOTAL HOURS					2340		3000	8008		1560
CONVERSION FACTOR					930		930	1180		1180
TOTAL OPERATIONAL FTEs					2.52		3.23	6.79		1.32

9. REMARKS

* Workload : April 1, 2003 -May 30, 2004 ACS FDA Review Lines

For FY 05 and beyond all 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, should an additional exam be required the time is to be reported under the CT PAC (03R845, 04R845 etc.). See IOM Section 530.04 for additional information on Food & Cosmetic Activities.

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. PMS PROJECT NAME/NUMBER
Domestic and Imported Cheese and Cheese Products 03037 FY 2005	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, as well as domestic surveillance sampling to meet the workplan obligation. The emphasis is on soft cheese manufacturers (soft, semi-soft, soft-ripened), and as resources permit, coverage of other cheese. The field is also requested to conduct sample collections and analyses of imported cheese. Refer to the guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections. Food security issues (see IOM) are to be covered during all inspections.

NOTE: (For specialized micro testing below, see compliance program or contact DFS for additional details)

DEN will perform Salmonella antibiotic resistance testing.

ARL will perform Salmonella serotyping for isolates originating from all labs with the following exception:

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: Domestic and Imported Cheese and Cheese Products

2. PPS PROJECT NAME/NUMBER: Foodborne Biological Hazards

3. PROGRAM/ASSIGNMENT CODE(S): 03037, 03037B, 03037D

4. WORK ALLOCATION PLANNED BY: [X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS: 28.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1)	2 INVESTI-GATIONS (Hours) (3)	3 DOMESTIC SAMPLE COLLECTION (2)		4 IMPORT SAMPLE COLL PHYSICAL (5)		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	500	350	400		700		400	75	700
	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	16.5		4.0		2.0		18.0	7.1	16.0
	TOTAL HOURS	8250	350	1600		1400		7200	532.5	11200
	CONVERSION FACTOR	930	930	930		930		1180	1180	1180
	TOTAL OPERATIONAL FTEs	8.87	0.38	1.72		1.51		6.10	0.45	9.49

9. REMARKS

(1) INSPECTIONS: BASED ON A 5/19/04 FACTS INVENTORY OF HIGH RISK FIRMS CONTAINING INDUSTRY CODE 12 (CHEESE) BUT NOT CONTAINING INDUSTRY CODE 16 (SEAFOOD). DISTRICTS WITH STATE CONTRACT RESOURCES ARE TO COORDINATE COVERAGE OF HIGH-RISK AND NON-HIGH RISK INVENTORIES PER PROGRAM PRIORITIES. HIGH RISK FIRMS WHOSE LAST INSPECTION WAS NAI MAY BE PLACED ON A 2 YEAR INSPECTION FRQUENCY.

(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 TIME IS PROVIDED FOR AN ASSIGNMENT TO INVESTIGATE THE PRESENCE OF UNPASTEURIZED CHEESE PRODUCTS IN RETAIL STORES. DISTRIBUTION OF HOURS PER CFSAN.

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

(5) IMPORT SAMPLE (PHYSICAL) COLLECTIONS: BASED ON MAY 1, 2003 -APRIL 30, 2004 ACS FDA REVIEW LINES (100%) OF SOFT CHEESES. NOTE: SWID SAMPLES COLLECTED FOR TX & NM ARE SENT TO NRL. SWID SAMPLES COLLECTED FOR CA & AZ SENT TO NRL. SWID IS PROVIDED RESOURCES FOR A DISTRICT INITIATIVE REGARDING PERSONAL IMPORTATION OF (b)(2) & (b)(7)(E)

(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
National Drug Residue Milk Compliance Program 03039 FY 2005	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

The National Drug Residue Milk Compliance Program is a joint effort between CFSAN, CVM and ORA. The program will provide an indication of animal residues in retail milk. Presently, sulfonamides are planned for testing in FY 05 for retail milk.

5. PROGRAM JUSTIFICATION

The National Drug Residue Milk compliance program will provide indications of drug residues in milk and extent of Compliance with Federal regulations. The results will help in the design of future compliance efforts for use by federal, state and local authorities. The initiative will enhance the National Conference on Interstate Milk Shipments (NCIMS) and industry residue testing program and provide information on which to focus regulatory priorities.

6. FIELD OBLIGATIONS

Five hundred (500) retail samples are anticipated for collection. The types of samples and locations for collections, as well as the analytes to be tested for, will be determined in the compliance program. The field is not to initiate any activities until the compliance program is issued.

Denver Laboratory will analyze the retail samples for drugs directed in the compliance program.

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)
Pasteurized Grade "A" whole white milk as noted in the Compliance Program.	09

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

f. CHECK THE FOLLOWING ATTRIBUTES

The analytes will be determined in the Compliance Program.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program for details (when issued).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
National Drug Residue Milk Compliance Program	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03039	[ ] ORA [X] CENTER	3.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL		6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD			500				**500**		
	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				2.0				6.0		
TOTAL HOURS				1000				3000		
CONVERSION FACTOR				930				1180		
TOTAL OPERATIONAL FTEs				1.08				2.54		

9. REMARKS

Resources planned represent CFSAN's requirement under this program. This is a joint venture between CVM and CFSAN. Resources distributed by CFSAN.
Sampling schedule will be developed and issued by CFSAN's Office and Compliance and Office of Plant and Dairy Food.
Work will be directed by issuance of a new Compliance Program. The field should not initiate collections until the program is issued.
Domestic sample collection is based upon regional milk production.
Sample analytes will be directed by the Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Acidified and Low-Acid Canned Foods 03803A FY 2005	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. See 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 inspections are needed to fulfill program obligations in FY 05. 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 at domestic processors.

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	14.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (3)			3 INVESTI-GATIONS (HOURS)	4 DOMESTIC SAMPLE COLLECTION (5)		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**		**20**	**180**	**930**
	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									
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	930
	CONVERSION FACTOR	930			930	930		1180	1180	930
	TOTAL OPERATIONAL FTEs	10.75			0.43	1.08		0.14	1.53	1.00

9. REMARKS

(1) Source of workload: Inspections, Investigation Hours and DSC's based on CFSAN Registration file, provided by CFSAN as of 5/2004.
(2) Report all resources expended for NLEA under PAC 21005.
(3) NAI firms will go to a 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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Food Safety 03803 FY 2005	Food borne 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 2005 remains to inspect all high-risk firms annually, including added coverage for allergens.

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). Allergen sample collections and analyses are planned for FY 05. 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.
During FY 2005, FDA will continue to monitor chicken eggs for *Salmonella* Enteritidis and needed follow-up assignments will utilize resources of this program. Also, needed inspections for FDA E.U. certification will be covered here. Food security issues are to be covered during all inspections.

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.

As of the 3rd quarter in FY 04, 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: *Ciguatera toxin* confirmation test will be done at the Pacific Regional Laboratory – NW.
Confirmation tests for *Clostridium botulinum*, *Yersinia enterocolitica* & paralytic shellfish poison 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.

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.

1. PROGRAM/ASSIGNMENT TITLE
Domestic Food Safety

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

3. PROGRAM/ASSIGNMENT CODE(S)
03803,B,C,D,E; 04803
09803E,F, 03R845 (2)

4. WORK ALLOCATION PLANNED BY
X ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
94.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS Including High Risk (1)	1 NON-CLINCIAL GLP INSPECTIONS (6)	1 INSPECTIONS SPROUT ASSIGN-MENT (TO BE ASSIGNED) (5)	1 EGG FARM INSP (9)	1 INSPEC-TIONS ALLERGEN 03803E (3)	2 INVESTI-GATIONS (HOURS) INCL NATL EXPERTS (1)	3 DOMESTIC SAMPLE COLL ALLERGEN (4)	3 DOMESTIC SAMPLE COLL (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED ALLERGEN (CHEM) (7)
	TOTAL FIELD	3500	(6)	(400)	(5)	375	7207	75	600	240	360	75
	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	18.5				12.5		3.0	5.2	15.0	15.0	4.0
	TOTAL HOURS	64750				4688	7207	225	3120	3600	5400	300
	CONVERSION FACTOR	930				930	930	930	930	1180	1180	1180
	TOTAL OPERATIONAL FTES	69.62				5.04	7.75	0.24	3.35	3.05	4.58	0.25

9. REMARKS

(1) FY 2005 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 MAY 19, 2004.

INCLUDES TIME FOR NATIONAL EXPERTS (4 FTES). RESOURCES HAVE BEEN ALLOCATED FOR 3500 TOTAL INSPECTIONS. HIGH RISK, SPROUT, AND GLP FIRMS ARE INCLUDED IN THIS TOTAL

NUMBER. DISTRICTS SHOULD BE ABLE TO MEET HIGH RISK PERFORMANCE GOALS WITH THE ALLOCATED RESOURCES PLUS STATE CONTRACT INSPECTIONS.

SAMPLE COLLECTIONS ARE "FOR CAUSE" UNLESS DIRECTED BY ASSIGNMENT.

(2) RESOURCES FOR 04803, 09803E, F ARE INCLUDED. RESOURCES FOR AUDITS ARE UNDER STATE CONTRACTS PROGRAM 03R843.

(3) REPORT ALLERGEN INSPECTIONS UNDER PAC 03803E. DO NOT INITIATE INSPECTIONS UNTIL NEW ALLERGEN PROGRAM IS ISSUED.

ALLERGEN INSPECTIONS BASED ON OEI OF ALLERGEN FIRMS PER CFSAN.

(4) ALLERGEN SAMPLES ARE PROJECTED FOR PEANUT CROSS-CONTAMINATION (SEE COMPLIANCE PROGRAM FOR DETAILS.).

(5) SPROUT INSPECTIONS TO BE DIRECTED BY A CFSAN ASSIGNMENT.

(6) NON-CLINICAL GOOD LABORATORY PRACTICES INSPECTIONS: CFSAN WILL CONTACT AFFECTED DISTRICTS TO ARRANGE INSPECTIONS DURING THE COURSE OF THE YEAR.

(7) PER DFS THE ANAYLTE FOR DSA ALLERGEN IS CLASSIFIED AS CHEM.
(8) SALMONELA SEROTYPING: SAMPLES GENERATED FROM SRL & ARL GO TO ARL. SAMPLES GENERATED FROM OTHER LABS GO TO DENVER.
(9) EGG FARM INSPECTION: TO BE CONDUCTED BY A CFSAN FIELD ASSIGNMENT FOR INSPECTION OF EGG FARMS PREVIOUSLY IMPLICATED IN SE AND SH OUTBREAKS.

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1. PROGRAM/ASSIGNMENT TITLE: Domestic Food Safety

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

3. PROGRAM/ASSIGNMENT CODE(S): 03803,B,C,D, E; 04803 09803E,F, 03R845

4. WORK ALLOCATION PLANNED BY: X ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS: N/A

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSA MICRO SALMONELA SEROTYPING [8]	FY 2005 STATE CONTRACTS PER DIVISION FEDERAL STATE RELATIONS (INFO ONLY) (1)							
	TOTAL FIELD	1180	8132							
	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									
	TOTAL HOURS	1180								
	CONVERSION FACTOR	1180								
	TOTAL OPERATIONAL FTES	1.00								

9. REMARKS

(1) RESOURCES FOR AUDITS ARE UNDER STATE CONTRACTS PROGRAM 03R843.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Foods – General 03819 FY 2005	Food borne 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, MOUs, etc…), to ensure that future entries of products are in compliance.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C 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. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC.

NOTE TO LABS: (see compliance program or contact DFS for additional details)

DEN will perform Salmonella antibiotic resistance testing.

ARL will perform Salmonella serotyping for isolates originating from all labs.

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.

2005 ORA WORKPLAN **FEBRUARY 1, 2005**

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 (03R833/99R833/R824) **(1)**	X ORA ☐ CENTER	288.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HRS OPER 14 03R833 (2)	2 PRIOR NOTICE REVIEW HOURS OPER 14 03R833 (10)	9 IMPORT FILER EVAL HOURS OPER 95 99R833 (5)	2 IMPORT FOLLOW - UP-REFUSAL OPER 14 R824 (HOURS) (3)	4 IMPORT SAMPLE COLL PHYSICAL	2 BSE ENTRY REVIEW & FOLLOW UP (HOURS) (4)	4 IMPORT SAMPLE COLL ALLERGEN (9)	6 IMPORT FIELD EXAMS (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED ALLERGEN CHEM (8)	8 IMPORT SAMPLES TO BE (HOURS) ANALYZED SALM RESIST (7)
	TOTAL FIELD	**92000**	**33600**	**20000**	**8000**	**9000**	**9000**	**300**	**65000**	**6430**	**2570**	**300**	**1180**
	HEADQUARTERS (HQ PRIOR NOTICE CTR)	(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						2.2		2.2	0.9	8.2	7.0	2.5	
TOTAL HOURS		92000	33600	20000	8000	19800	9000	660	58500	52726	17990	750	1180
CONVERSION FACTOR		1200	1200	930	930	930	1200	930	930	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		76.67	28.00	21.51	8.60	21.29	7.50	0.71	62.90	44.68	15.25	0.64	1.00

9. 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) Follow-up-to-Refusal hours: additional resources added for marking and tracking the disposition of detained lots.

(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) Import Filer Evaluation based on number of filers. Resources are provided to cover an estimated 1000 filers at 20 hours per evaluation.

(6) For FY 05 and beyond 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.

(7) Denver Laboratory: Salmonella Resistance

(8) Per DFS the analyte for ISA allergens is classified as chem.

(9) Sample collections for Allergens are to be directed by CFSAN assignment.

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

FY 2005 WORKLOAD

IMPORT ENTRY REVIEW HOURS OP 14: BASED ON TOTAL FOODS BY INDUSTRY CODE ELECTRONIC REV LINES.

IMPORT FILER EVALUATION HOURS: BASED ON NUMBER OF FILERS

IMPORT FIELD EXAMS: BASED ON 100% ACS FDA REVIEW LINES

IMPORT FOLLOW-UP-TO REFUSAL HOURS: BASED ON ACCOMPLISHED HOURS/TIME FROM 10/1/02 - 9/30/03.

BSE ENTRY REVIEW AND FOLLOW-UP: BASED ON ACS FDA REVIEW LINES

ISC PHYSICAL & ISC ALLERGEN: BASED ON 100% ACS FDA REVIEW LINES (NOTE: FY 2005 SWID SAMPLES COLLECTED FOR TX & NM ARE SENT TO ARL. SWID SAMPLES COLLECTED FOR CA & AZ SENT TO PRS.)

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

ISA ALLERGEN BASED ON ISC ALLERGEN AND LAB SERVICING TABLE

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Fish and Fishery Products Inspection Program (03842) FY 2005	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.

Inspectional resources should be utilized to cover processors according to the priorities directed in the compliance program. Districts should utilize state contract inspections to assist in inventory coverage.

5. PROGRAM JUSTIFICATION

FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices. Samples will be collected and analyzed only for cause and for HACCP verification when appropriate.

6. FIELD OBLIGATIONS

The field is to conduct inspections, but only make sample collections and analyses for cause or for HACCP verification samples as described in the compliance program. Verification of sampling/analysis must meet specific HACCP criteria.
Total estimated inventory is approximately 4500. Resources have been provided for 3120 FDA inspections. The balance needs to be covered by States under contract to FDA. The high-risk inventory (scombrotoxic, smoked, vacuum packaged or ready-to-eat) of approximately 3,200 firms is to have priority for inspection. Between FDA and available State resources, districts need to ensure coverage of the high risk inventory. Remaining resources are to be applied according to the priorities set forth in the program. Food security issues (see IOM) are to be covered during all inspections.

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.

There are obligations to provide the states with standards and instructions for sampling/analyzing for PSP/ASP in seafood.

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

Refer to the compliance program

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Refer to the compliance program

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)	X ORA ____ CENTER	75.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS INCLUDING HIGH RISK (4)	STATE CONTRACTS IND 16 FY 2005 - INFO ONLY PER DIV FEDERAL STATE RELATIONS (6)	3 INV HOURS	3 DOMESTIC SAMPLES COLL (3)		7 DSAs ORGANO EXAMS (Hours) (2)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 EU CERTIFICATION (HOURS) (7)
	TOTAL FIELD	**3120**	**1137**	**1860**	**800**		**590**	**200**	**600**	**2790**
	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	16.5			4.5			11.0	16.5	
	TOTAL HOURS	51480		1860	3600		590	2200	9900	2790
	CONVERSION FACTOR	930		930	930		1180	1180	1180	930
	TOTAL OPERATIONAL FTEs	55.35		2.00	3.87		0.50	1.86	8.39	3.00

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" and HACCP verification.

Only physical samples for laboratory analysis are to be counted against the goal of 800 samples. Resources for DOC sample collections are included under INV hours. Districts should collect sufficient HACCP Verification samples so that when added to "for cause" samples, meets their full workplan obligation.

(4) Total Seafood inventory is approx. 4500 firms. Resources are provided here for 3120 FDA inspections. The remaining firms are to be covered by state inspections.

SOURCE OF SEAFOOD WORKLOAD:

(5) OEI OF SEAFOOD FIRMS FLAGGED IN FACTS AS HIGH RISK EXCLUDING FIRMS WITH INDUSTRY CODE 12 AS OF MAY 19, 2004 (INFORMATION ONLY).

INPSECTIONS, INVESTIGATION HOURS AND DSCs BASED ON OEI.

(6) DFSR IDENTIFIED STATE CONTRACTS AND ARE LISTED FOR INFORMATIONAL PURPOSES ONLY.

(7) E.U. CERTIFICATION PROCESSING HOURS: RESOURCE DISTRIBUTION PER CFSAN (USE REPORTING OPERATION CODE 92).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Seafood Program 03844 FY 2005	Food borne 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

To provide inspection coverage to importers, focusing on those that import high-risk products that could be health hazards, and to conduct follow-up inspection(s) on importers found to be in non-compliance with the HACCP regulations.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C Act and its regulations. Resources are provided for coverage of Imported seafood products for chemical hazards, pathogen contamination, decomposition, etc.
The program also incorporates 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. Inspections along with import sample collection and analysis, will be conducted to assure conformity with current good manufacturing practices and other regulations promulgated under the FD&C Act.

6. FIELD OBLIGATIONS

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.

Sample collection, analysis, and field exams are to focus on "substantial risk products, including scombrotoxic, smoked, vacuum Packaged or ready-to-eat products.

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, Economic Deception, Labeling)

f. CHECK THE FOLLOWING ATTRIBUTES

See Compliance Program

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03844B, C, D, H; 07844: 09844E,F	[X] ORA [ ] CENTER	101.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP * 03844H (1)	4 IMPORT SAMPLE COLL PHYSICAL (2) / (6)	9 LABEL EXAM (2)	6 IMPORT FIELD EXAMS (2) / (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**	**7500**	**400**	**2000**	**1180**	**5000**	**5750**			
	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	11.0	2.4	0.4	0.4		5.3	10.6			
	TOTAL HOURS	5500	18000	160	800	1180	26500	60950			
	CONVERSION FACTOR	930	930	930	930	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	5.91	19.35	0.17	0.86	1.00	22.46	51.65			

9. REMARKS

(1) FY 2005 : IMPORTER INSPECTIONS: BASED ON OASIS CONSIGNEE DATA AS OF 5/21/04.

PER CFSAN, INSPECTIONS OF IMPORTERS ARE TO ASCERTAIN THAT THE IMPORTER HAS COMPLIED WITH SEAFOOD HACCP REGULATIONS (NOT TO PERFORM FILER INSPECTIONS).

(2) ISC/LABEL EXAMS/IMPORT FIELD EXAMS: BASED ON MAY 1, 2003 - APRIL 30, 2004 FDA REVIEW LINES (DOES NOT INCLUDE LACF): BROKEN OUT BY PRIORITY ACCORDING TO COMPLIANCE PROGRAM (70% OF RESOURCES BASED ON PRIORITIES 1-4 /30% BASED ON LOW PRIORITIES [ALL OTHER] - AS OUTLINED IN THE COMPLIANCE PROGRAM).

(3) FOR FY 05 AND BEYOND ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE:

(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 FOR FY 2005 (CARRIED OVER FROM FY 2004) BETWEEN THE WEAC LAB DIRECTOR AND THE NEW ENGLAND IB DIRECTOR TO HAVE 223 CHEM AND 112 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 2005	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

As of January 20, 2004, all juice processing firms are subject to the Juice HACCP Regulation. Inspectional priority should be the following: Unpasteurized juice firms, large or small 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 Juice HACCP verification samples (see revised Juice HACCP Inspection Program for details *when issued*). Districts should collect sufficient Juice HACCP verification samples, so that when added to their "for cause" collections, meets their full domestic sample collection Workplan obligation.

State inspections may be conducted in addition to the number of inspections assigned per district.

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	14.0

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	**375**	**225**	**60**	**165**	**60**		**165**	**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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	18.5	6.2			11.0		15.0	11.0	
	TOTAL HOURS	6938	1395			660		2475	2200	
	CONVERSION FACTOR	930	930			1180		1180	930	
	TOTAL OPERATIONAL FTEs	7.46	1.50			0.56		2.10	2.37	

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 related food borne biological hazards, pesticides/chem contaminants, mycotoxins, additives, and labeling.

(2) Inspections based on OEI data per CFSAN. State inspections may be conducted in addition to the number of inspections assigned per district.

(3) DSC resources based on OEI data per CFSAN.
Resources have been provided for anticipated "for cause" samples and Juice HACCP verification samples (see Compliance Program for details).
Districts should collect sufficient Juice HACCP verification samples so that when added to their "for cause" collections, meets their full domestic sample collection obligation.
The field should hold off on the collection of verification samples and Juice HACCP Importer inspections until the new CP or other specific guidance addressing these items is issued.

(4) Importer inspections based on FDA review lines (5/1/03- 4/30/04) of juice products.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import and Domestic Micro Assignments 03F098 & 03F100 FY 2005	Food borne Biological Hazards - 03

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

4. OBJECTIVES

To collect and analyze selected food products of domestic and foreign origin for pathogenic microorganisms. Work will be directed by one or more CFSAN field assignments.

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. The assignment(s) will focus on commodities and pathogens that continue to be implicated in food borne outbreaks.

6. FIELD OBLIGATIONS

To collect samples and perform analyses as specified in the assignment(s) issued by CFSAN.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fresh fruits and vegetables as specified in the assignments.	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

Refer to field assignment(s).

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)	X ORA X CENTER	27.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLLECTION	4 IMPORT DOMESTIC COLLECTION	7 DOMESTIC SAMPLE ANALYSIS MICRO	8 IMPORT SAMPLE ANALYSIS MICRO					9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**500**	**500**	**500**	**500**					
	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	29.0	29.0					
	TOTAL HOURS	1500	1500	14500	14500					
	CONVERSION FACTOR	930	930	1180	1180					
	TOTAL OPERATIONAL FTEs	1.61	1.61	12.29	12.29					

9. REMARKS

Import and Domestic assignment's will be issued by CFSAN for the collection of cantaloupe, green onions specific leafy herbs (basil, cilantro, parsley, etc.), lettuce and tomatoes for analysis for pathogens

Note: SWID samples collected for TX & NM are sent to ARL. SWID samples collected for CA & AZ are sent to DEN.

Workload: Import & Domestic Sample Collection 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 2005	Food borne 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 shall provide imported food entry and compliance data to assist CFSAN in determining the countries and firms whose inspections would be of greatest value to the Agency.

ORA shall plan inspections of foreign firms (selected 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).

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 Hazard

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R233	X ORA ☐ CENTER	7.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FOREIGN	2 INVESTIGATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) *						9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**200**		**930**						
	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		6000		930						
CONVERSION FACTOR		930		930						
TOTAL OPERATIONAL FTEs		6.45		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.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Emergency Response to Foodborne Outbreaks and Illnesses 03R839 – FY 2005	Food borne Biological Hazards - 03

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

4. OBJECTIVES

To conduct investigations, inspections, sample collections and sample analyses in response to food borne outbreaks and illnesses from food of domestic or foreign origin.

5. PROGRAM JUSTIFICATION

Approximately 450 food borne outbreaks and 13,000 individual cases of food poisoning, due to microbial pathogens are reported to the Centers for Disease Control annually. FDA must provide an emergency response to serious outbreaks and illnesses to help identify the causative agent(s) and Food(s) involved, and remove the affected foods from commerce to protect the public health.

6. FIELD OBLIGATIONS

The field will conduct investigations, inspections, sample collections and analyses as directed by ORA headquarters and CFSAN. To ensure proper reporting, the field is to use PACs 03R839, 04R839, etc..

Activities will usually be directed by the Office of Crisis Management and/or CFSAN's Emergency Coordination & Response Staff.

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)
To be directed by assignment	All human food codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

As directed by assignment

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

As directed by assignment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Emergency Response to Foodborne Outbreaks and Illnesses	Foodborne Biological Hazards -03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R839; 03R845*	X ORA ☐ CENTER	7.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2000 CENSUS RESIDENT POPULATION DATA INFO ONLY	2 INVESTI-GATIONS (Hours)	2 MICRO-BIOLOGIST ON INVESTIGATION (Hours)						9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**285230516**	**5580**	**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		5580	1180						
	CONVERSION FACTOR		930	1180						
	TOTAL OPERATIONAL FTEs		6.00	1.00						

9. REMARKS

NOTE: This program provides resources for emergency response and containment of foodborne outbreaks and illnesses of foods of both domestic and foreign origin. Resources can be used for Sample Collection, Sample Analysis, Investigations and Inspections. REPORTING: Emergency Response Activities are planned under 03R839, expended time should be reported against the appropriate CFSAN PACs 04R839, 07R839, 09R839 and 21R839.

Workload: 2000 Census Resident Population Data.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Food State Contract Audits 03R843 FY 2005	Food borne Biological Hazards - 03

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

4. OBJECTIVES

To perform joint audit investigations of states that are under contract with FDA to conduct food inspections.

5. PROGRAM JUSTIFICATION

About 9,300 food inspections are anticipated to be contracted out in FY 05 by FDA to the states. The Agency needs to ensure appropriate oversight of state food firm inspections is conducted.

6. FIELD OBLIGATIONS

To perform joint audit investigations of approximately 7% of state contract inspections in FY 05. Guidance for conducting an audit investigation is to be provided by the Division of Federal State Relations. Resources are provided for district management of state contracts.

Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.

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)
All Food Products	02-41, 45-46, 50

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

f. CHECK THE FOLLOWING ATTRIBUTES

Follow DFSR guidance.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Follow DFSR guidance.

1. PROGRAM/ASSIGNMENT TITLE
Food State Contract Audits

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

3. PROGRAM/ASSIGNMENT CODE(S)
03R843

4. WORK ALLOCATION PLANNED BY
[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
22.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INV HOURS FOOD STATE CONTRACT AUDITS (2)	NUMBER OF FOOD STATE CONTRACT AUDITS (1)	2005 DOMESTIC FOOD STATE CONTRACTS LESS SEAFOOD (4)	2005 DOMESTIC SEAFOOD STATE CONTRACTS IND 16 (4)	2005 TOTAL STATE CONTRACTS (4)	7 DSAs ORGANO EXAMS (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 CONTRACT MANAGE-MENT HOURS (3)
	TOTAL FIELD	6305	(650)	8132	1137	9269				14880
	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		(9.7)							
	TOTAL HOURS	6305	(6305)							14880
	CONVERSION FACTOR	930	(930)							930
	TOTAL OPERATIONAL FTEs	6.78	(6.78)							16.00

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: For information purposes and guidance.
(2) Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.
(3) Time planned for contract management.
(4) Food State Contract inventory per Division of Federal State Relations.

1. PROGRAM/ASSIGNMENT TITLE

Counter-Terrorism Preparedness

03R845 FY 2005

2. PPS PROJECT NAME/NUMBER

Food borne Biological Hazards

3. PROGRAM TYPE: NA ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☐ ASSIGNMENT

4. OBJECTIVES

To maintain Counter-terrorism 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.

5. PROGRAM JUSTIFICATION

A secure food supply is considered part of the nation's infrastructure. FDA, along with other federal Agencies, are responsible for responding to threats to the security of the food supply. The resources and activities planned under this program will help maintain a necessary state of readiness to respond to threats and activities planned for periods of heightened alert.

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.

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

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

c. PRODUCT(S)

All food products.

d. INDUSTRY/PRODUCT CODE(S)

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
Counter Terrorism Preparedness	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R845	X ORA ☐ CENTER	11.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 CSO DOMESTIC HOURS	2 CSO IMPORT HOURS	8 IMPORT DOMESTIC CHEM HOURS	8 IMPORT DOMESTIC MICRO HOURS					
	TOTAL FIELD	**1550**	**3100**	**3750**	**4000**					
	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		1550	3100	3750	4000					
CONVERSION FACTOR		930	930	1180	1180					
TOTAL OPERATIONAL FTEs		1.67	3.33	3.18	3.39					

9. REMARKS

Planned resources are for non-emergency and non-code red alert status CT preparedness activities.
Resources may be used for CFSAN issued assignments for inspections, sample collections, and sample analysis for the Food Emergency Response Network (FERN).
Lab resources may also be used for maintaining CT-related analytical capabilities.
Note: SWID samples collected for TX & NM are sent to ARL. SWID samples collected for CA & AZ are sent to PRS.
Resources for the lead FERN laboratory (FCC, NRL, and WEAC) activities have been pre-planned by ORA.
Resources for the FERN lead labs are for general CT preparedness and CFSAN CT-related assignments.
WORKLOAD:
CSO DOMESTIC HOURS BASED ON TOTAL FOODS M/R OEI INCLUDING IND CODE 02-51 DATED 3/17/2004
CSO IMPORT HOURS BASED ON TOTAL FOODS ACS FDA REVIEW LINES (5/1/03 -4/30/04)
LABORATORY RESOURCES PLANNED BY DFS.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects 03R816 FY 2005	Food borne 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

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects. All research will be distributed in-house and/or published in the referred scientific literature.

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
ORA/Center Directed Research Projects	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R816	[X] ORA [ ] CENTER	12.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 DISTRICT RESEARCH CHEMIST (Hours)	9 RESEARCH CENTER RESEARCH CHEMIST (Hours)	9 DISTRICT RESEARCH MICRO (Hours)	9 RESEARCH CENTER RESEARCH MICRO (Hours)					
	TOTAL FIELD			**9659**	**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				9659	4720					
CONVERSION FACTOR				1205	1180					
TOTAL OPERATIONAL FTEs				8.02	4.00					

9. REMARKS

PROJECT SUMMARY SHEET
FY 2005

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		**112.9**	**72.5**		**185.4**	**329.4**	
1	Pesticides and Industrial Chemicals in Domestic and	04004A,D **	46.0	39.1		85.1	151.1	2-5
	Imported Foods							
2	Chemotherapeutic in Seafood	04018	4.3	13.6		17.9	31.7	6-7
3	Toxic Elements in Food and Foodware		7.1	16.6		23.7	42.2	
	Toxic Elements in Foods (Domestic and Import)***	04019A	(6.2)	(9.9)		(16.1)		8-13
	Toxic Elements in Foodware (Domestic and Import)	04019B	(0.7)	(6.2)		(6.9)		
	Radionuclides in Foods (Domestic and Import)	04019C	(0.2)	(0.5)		(0.7)		
4	Total Diet Study	04839	23.4			23.4	41.6	14-15
5	Field Assignments for Chemical Contaminants	04F800	11.7	3.2		14.9	26.5	16-19
6	ORA-Center Directed Research Projects	04R816	9.6			9.6	17.1	20-21
7	Forensic Evaluation and Sample Analysis	04R838	10.8			10.8	19.2	22-23
8								
	** 04R833, 99R833,04R824,04R845							
	*** Includes DISC and DISA FTEs							

CENTER PROJECT MANAGER-TELEPHONE	ORA PLANNER-TELEPHONE
Ronald R. Roy (301)436-2657	Lorraine B. Jefferson, 301-827-1630

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.

There is an ongoing emphasis on dioxins to obtain comprehensive data on background levels of dioxin in a variety of foods; this information will help the Agency to determine how to reduce dietary exposure to dioxin.

5. PROGRAM JUSTIFICATION

The food supply requires monitoring for both pesticides and industrial chemicals to protect the public health. The residue data obtained are also used to estimate dietary exposure for risk assessments performed by the Agency and EPA, as well as by other national and international organizations.

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 quarterly collections schedules issued by CFSAN. Dioxin investigation assignments and follow-up sampling may be issued by CFSAN under this program when there are typically high dioxin levels are found..

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

b. INSPECTION TYPE: NA [ ] 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, 04R833,99R833, 04R824	X ORA X CENTER	85.1 (46.0)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs			DSCs Dioxins	DSAs Dioxins MASS SPEC *	DSAs DIOXINS CALUX	DSCs SEAFOOD	DSAs SEAFOOD
	TOTAL FIELD	**500**	**2700**	**2700**			**1505**	**1537**	**200**	**175**	**175**
	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			3.0	5.2			4.0	11.6	11.6	3.0	5.2
TOTAL HOURS		500	8100	14040			6020	17829	2320	525	910
CONVERSION FACTOR		930	930	1180			930	1180	1180	930	1180
TOTAL OPERATIONAL FTEs		0.54	8.71	11.90			6.47	15.11	1.97	0.56	0.77

7. REMARKS

Report Counter Terrorism work performed only under 04R845

*Includes analysis of 232 Total Diet Study sample homogenates. CFSAN will issue collection schedule

DSCs Seafood: See compliance program for collection details

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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,04R833,99R833, 04R824	[X] ORA [ ] CENTER	(39.1)

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									
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					1.6	6.2		1.6	6.2	
TOTAL HOURS					8480	32860		480	1860	
CONVERSION FACTOR					930	1180		930	1180	
TOTAL OPERATIONAL FTEs					9.12	27.85		0.52	1.58	

9. REMARKS
Page 2 of 2

ISC Seafoods: See compliance program for collection details

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 anti-fungals and to initiate regulatory actions against loss 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 the 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 aquacultured products specified in the program.
Multiple analyses (chemotherapeutic agents) will be run on the majority of samples, therefore sample analyses outnumber sample collections. Only a single sample will need to go to labs assigned to perform multiple analyses. Please refer to revised Chemotherapeutics in Seafood Compliance Program (when issued), and if needed contact the assigned labs and/or DFS.
Individual subsample analyses will only be required for shrimp samples being analyzed for Chloramphenicol. All of the remaining samples will be a composite of 12 sub samples. Collection and analytical resources for Nitrofurans will come from this compliance program in FY 05 in either the form of a field assignment or as a component of this compliance program when re-issued to the field.

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: [Xx] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [ ] MICROANALYTICAL [ ] OTHERS ***(Specify)*** Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Unapproved drugs per the Compliance Program, Non-permitted ingredients, microbiological/contaminants, labeling warnings.

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	17.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		ISCs	DSCs	ISAs	ISA IND SUBS	ISA COMPOSITE	DSAs	DSAs IND SUBS	DSAs COMPOSITE
	TOTAL FIELD		**752**	**224**	**752**	**(432)**	**(320)**	**224**	**(64)**	**(160)**
	HEADQUARTERS		(b)(2)&b(7)(E)							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	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	4.0	17.5			17.5		
TOTAL HOURS			2256	896	13160			3920		
CONVERSION FACTOR			930	930	1180			1180		
TOTAL OPERATIONAL FTEs			2.43	0.96	11.15			3.32		

7. REMARKS

CFSAN spread the number of sample collections per district. DFS spread the laboratory analyses.

Please refer to the FY 05 Aquaculture Program Collection Scedule and the Chloramphenicol and Nitrofurans in Shrimp and Crabmeat Assignment (both to be issued in January 2005 and available @http://intranet.cfsan.fda.gov/OC/ochome.htm) for specific species collections and laboratory assignments. For species calling for coverage of multiple analytes, the labs should alternate the analyte equally among samples received (i.e, 1 analyte per sample), unless needed to meet lab workplan obligation due to sample shortfalls.

Individual sub sample analyses will only be required for domestic and import shrimp and crabmeat samples being analyzed for Chloramphenicol and Nitrofuran (see assignment for details). All remaining species/residue combinations will be a composite of 12 sub samples. The analytical module is a field-wide average based on number of total samples planned for individual subsample analysis and for composite analysis. The above sample collections and analyses include resources for the Choramphenicol and Nitrofurans in Shrimp and Crabmeat Assignment; assignment operations were prorated to account for 8 months remaining for FY 05.

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 and imported foods (including seafood,) and 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 food is necessary to guard against any dangerous level of radiochemical contamination of domestic and imported foods. This monitoring will also provide continuing background data to identify any upward trend in tritium, gamma-ray emitters and Sr levels.

6. FIELD OBLIGATIONS

Raw agricultural products and their processed derivatives and seafood are to be sampled and analyzed for the presence of toxic elements in in accordance with instructions in the "Toxic Element" program and assignments (to be issued). Planned assignments include mercury in tuna and other seafood species. CFSAN issued collection schedules will direct other FY 05 food work. Sample collections, analyses and other activities relating to domestic and imported foodware will continue as directed by the "Toxic Element" program.

Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides.

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)
All human food products. Ceramic foodware.	02 - 41, 52A

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

[ ] MICROANALYTICAL [X] OTHERS ***(Specify)*** Radiochemical Analysis

f. CHECK THE FOLLOWING ATTRIBUTES

Lead, cadmium, mercury and other toxic elements as directed. DOMESTIC - tritium, ^{90}Sr & gamma ray emiters;

IMPORTS: ^{134}Cs, ^{137}Cs and ^{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	16.1 (8.2)

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	**120**	**100**	**120**	**100**	**100**	**100**	**200**	**200**	**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		420	180	1440	1200	450	1200	900	2400	765
CONVERSION FACTOR		930	930	1180	1180	930	1180	930	1180	930
TOTAL OPERATIONAL FTEs		0.45	0.19	1.22	1.02	0.48	1.02	0.97	2.03	0.82

7. REMARKS

* DSC (NON-SEAFOOD): CFSAN TO ISSUE COLLECTION SCHEDULE FOR LEAD IN NON-SEAFOOD.

** ISC RESOURCES FOR SWID ARE "FOR CAUSE" SAMPLING, E.G. MEXICAN CANDY AND BOTTLE WATER FOR LEAD.

***DSC (SEAFOOD): CFSAN WILL ISSUE COLLECTION SCHEDULE FOR CADMIUM IN MOLLUSCS.

***ISC (SEAFOOD): CFSAN WILL ISSUE COLLECTION SCHEDULE FOR BOTH LEAD AND CADMIUM IN SEAFOOD.

**** TO BE ISSUED AS CFSAN FIELD ASSIGNMENT.

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1. PROGRAM/ASSIGNMENT TITLE
Toxic Elements in Foods (Domestic and Import)

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

3. PROGRAM/ASSIGNMENT CODE(S)
04019A

4. WORK ALLOCATION PLANNED BY
[X] ORA [X] CENTER

5. OPERATIONAL FTE POSITIONS
(7.9)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ISA SEAOOD	DISC MERCURY IN TUNA ****	DISA MERCURY IN TUNA			DISC MERCURY IN SEAFOOD ****	DISA MERCURY IN SEAFOOD		
	TOTAL FIELD	170	150	150			270	270		
	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	525	1800			1215	3240		
CONVERSION FACTOR		1180	930	1180			930	1180		
TOTAL OPERATIONAL FTEs		1.73	0.56	1.53			1.31	2.75		

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	(6.9)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		3 DSCs (Houseware)	4 ISCs (Houseware)	5 DOMESTIC FIELD EXAMS	6 IMPORT FIELD EXAMS *	7 DSAs	8 ISAs		
	TOTAL FIELD		**50**	**400**	**100**	**2750**	**50**	**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 LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION			3.5	1.8	0.7	0.7	10.0	10.0		
TOTAL HOURS			175	720	70.0	1925	500	4000		
CONVERSION FACTOR			930	930	930	930	1180	1180		
TOTAL OPERATIONAL FTEs			0.19	0.77	0.08	2.07	0.42	3.39		

7. REMARKS

* For FY 05 and beyond 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 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.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

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				930	930			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 occurrence and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex groups through analyses of table-ready foods, 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 acrylamide and dioxins under the pesticide program.

6. FIELD OBLIGATIONS

The collection and analysis of four market baskets, each consisting of three separate samplings of 286 items food items, which are to be collected from three locales in the region, over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, and toxic elements. WEAC will analyze all foods from the first 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) *	2 DOMESTIC SAMPLE TO BE ANALYZED **	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) ***
	TOTAL FIELD	**60**	**1144**	**1**
	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		25.0	20.0	2800.0
TOTAL HOURS		1500	22880	2800
CONVERSION FACTOR		930	1180	1180
TOTAL OPERATIONAL FTEs		1.61	19.39	2.37

7. REMARKS

* 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.
** Represents the total number of food items analyzed for various attributes.
*** 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

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 perchlorates, acrylamides, chloramphemicol in selected foods, and general pesticide and toxic element analysis in dietary supplements. Resources have been provided for a field assignment for coverage of an additional Contaminant to be determined prior to the start of FY 05.

5. PROGRAM JUSTIFICATION

Monitoring of foods for suspected chemical contaminants is necessary to ensure a safe food supply. Perchlorates and acrylamides 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. Chloramphenicol is a banned drug in the U.S. for food-producing animals but its presence has been detected in imported honey and suspected in imported dried milk. There are concerns regarding pesticides and toxic elements in dietary supplements yet there are minimal monitoritng 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.

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)
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	14.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSC PERCHLORATE IN FOODS	DSA PERCHLORATE IN FOODS		DSAs ACRYLAMIDE ***	ISC CONTAMINANTS IN HONEY	ISA CONTAMINANTS IN HONEY	DSC PESTICIDE & TOXIC ELEMNT IN /DIETARY SUPP. *	DSA PESTICIDE & TOXIC ELEMNT IN /DIETARY SUPP. **	ISC PESTICIDE & TOXIC ELEMNT IN DIETARY SUPP. *
	TOTAL FIELD	**750**	**750**		**400**	**200**	**200**	**50**	**50**	**150**
	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		3.0	3.0		3.0	3.0	6.5	3.5	24.0	2.0
TOTAL HOURS		2250	2250		1200	600	1300	175	1200	300
CONVERSION FACTOR		930	1180		1180	930	1180	930	1180	930
TOTAL OPERATIONAL FTEs		2.42	1.91		1.02	0.65	1.10	0.19	1.02	0.32

7. REMARKS

*Collection of samples for both Pesticides and Toxic Elements analysis.
**The Analytical module includes resources for both Pesticides and Toxic Elements.
***DSA Acrylamide: Kansas City to analyze 400 TDS composites.
Collections for Perchlorate and Dietary Supplements will be directed by CFSAN field assignments.

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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	

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ISA PESTICIDE & TOXIC ELEMNT IN DIETARY SUPP. ***		ISC CAP N' DRIED MILK *	ISA CAP N' DRIED MIL *	DSC NITRO-FURANS IN HONEY **	DSA NITRO FURANS IN HONEY **	DSC FURAN IN FOODS ***	DSA FURAN IN FOODS ***
	TOTAL FIELD	**150**		**25**	**25**	**25**	**25**	**500**	**500**
	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		24.0		3.0	4.0	3.0	6.5	3.0	3.0
TOTAL HOURS		3600		75	100	75	163	1500	1500
CONVERSION FACTOR		1180		930	1180	930	1180	930	1180
TOTAL OPERATIONAL FTEs		3.05		0.08	0.08	0.08	0.14	1.61	1.27

7. REMARKS

* Resources are allocated for either an Import Bulletin or a CFSAN initiated assignment for Chloramphenicol in Dried Milk

** Resources are for continued coverage of CAP in imported honey (Import Bulletin #36-B03) unless superseded by CFSAN assignment and for CFSAN initiated assignment for for coverage of Nitrofurans in honey (domestic to be collected at manufacturers).

***Resources are allocated for CFSAN initiated assignment for Furan in food products (to determined)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Pesticides and Chemical Contaminants - 04

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

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects identified in Part IIA of the Workplan. All research will be distributed in-house and/or published in the referred scientific literature.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/AA ☐ BY DISTRICT OFFICE ☐ BY CENTER ☐ BY BOTH

b. INSPECTION TYPE: N/AA ☐ 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
ORA/Center Directed Research Projects	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04R816	[X] ORA [ ] CENTER	9.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 DISTRICT RESEARCH (CHEM)	9 RESEARCH CENTER (CHEM)							
	TOTAL FIELD	**5517**	**5900**							
	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 OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	5517	5900							
	CONVERSION FACTOR	1205	1180							
	TOTAL OPERATIONAL FTEs	4.58	5.00							

7.REMARKS:

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

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 04R838 or OCI PAC 04R831.

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 04R838; Petition Validation, Methods Development, or Forensic Evaluation.

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
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	10.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION							
	TOTAL FIELD	**1180**	**11800**							
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION										
TOTAL HOURS		1180	11800							
CONVERSION FACTOR		1205	1205							
TOTAL OPERATIONAL FTEs		0.98	9.79							

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
FY 2005

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Molecular Biology and Natural Toxins: Food and Cosmetics - 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		25.7	10.4		36.1	64.3	
1	Mycotoxins in Domestic and Import Foods	07001	19.2	10.4		29.6	52.7	2-5
2	ORA/Center Directed Research Projects	07R816	6.5			6.5	11.6	6-7
3								

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (301)436-2657	Lorraine B. Jefferson (301)827-1631

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

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

4. OBJECTIVES

To collect and analyze domestic samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin.

To remove from interstate commerce those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance.
To detain those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance.

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 verticillioides, 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 putulin 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 directed by the Compliance Program.
Mycotoxins in Domestic Foods (07001) and Mycotoxins in Import (07002) Compliance Programs wil be combined in FY 05 into one Program Mycotoxins in Domestic and Import Foods) under a single Program Assignment code (07001). In FY 05 and beyond, all program activities to be reported under PAC 07001.

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.P. 7307.001 for list of Products.	02, 03, 05, 07, 09, 12, 13, 23, 24

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

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001	X ORA X CENTER	(29.6) 19.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSCs AFLA	DSCs FUM	DSCs DON	DSCs OCHRA	DSCs PATULIN		ALL DOMESTIC ANALYSIS	DSAs AFLA	DSAs FUM	DSAs DON
	TOTAL FIELD	**800**	**400**	**250**	**125**	**300**		**1875**	**(800)**	**(400)**	**(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 LABORTORY-SW										
	PACIFIC REGIONAL LABORTORY-NW										
	HOURS PER OPERATION	4.0	4.0	4.0	4.0	4.0		7.0			
	TOTAL HOURS	3200	1600	1000	500	1200		13125			
	CONVERSION FACTOR	930	930	930	930	930		1180			
	TOTAL OPERATIONAL FTEs	3.44	1.72	1.08	0.54	1.29		11.12			

7. REMARKS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001	X ORA X CENTER	(2.8)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSAs OCHRA	DSAs PATULIN	ISCs AFLA	ISCs PEANUT BUTTER	ISCs FUM	ISCs DON	ISCs OCHRA	ISCs PATULIN	ISCs SPECIAL SURV.
	TOTAL FIELD	**(125)**	**(300)**	**500**	**(105)**	**200**	**160**	**80**	**300**	**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 LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION				2.0		2.0	2.0	2.0	2.0	2.0
TOTAL HOURS				1000		400	320	160	600	80
CONVERSION FACTOR				930		930	930	930	930	930
TOTAL OPERATIONAL FTEs				1.08		0.43	0.34	0.17	0.65	0.09

7. REMARKS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001	X ORA X CENTER	(7.6)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ALL IMPORT SAMPLE ANALYSIS	ISAs AFLA	ISAs FUM	ISAs DON	ISAs OCHRA	ISAs PATULIN	ISAs SPECIAL SURV.			
	TOTAL FIELD	**1280**	**(500)**	**(200)**	**(160)**	**(80)**	**(300)**	**(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 LABORTORY-SW										
	PACIFIC REGIONAL LABORTORY-NW										
	HOURS PER OPERATION	7.0									
	TOTAL HOURS	8960									
	CONVERSION FACTOR	1180									
	TOTAL OPERATIONAL FTEs	7.59									

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PMS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Molecular Biology and Natural Toxins: Foods and Cosmetics - 07

3. PROGRAM TYPE: ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☐ ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

Accomplishments of goals of the individual research projects identified in Part IIA of the Workplan. All research will be distributed in-house and/or published in the referred scientific literature.

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
ORA/Center Directed Research Projects	Molecular Biology and Natural Toxins: Food and Cosmetics - 07

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07R816	[X] ORA [ ] CENTER	6.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEMIST	RESEARCH CENTER RESEARCH MICRO					
	TOTAL FIELD	**3053**		**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 OPERATION									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION										
TOTAL HOURS		3053		4130	590					
CONVERSION FACTOR		1205		1180	1180					
TOTAL OPERATIONAL FTEs		2.53		3.50	0.50					

7.REMARKS:

PROJECT SUMMARY SHEET
FY 2005

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Food and Color Additives Petition Review and 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		1.1	10.0		11.1	19.7	
1	Imported Foods-Food and Color Additives	09006A,B,*		10.0		10.0	17.8	2-3
2	ORA/Center Directed Research Projects	09R816	1.1			1.1	1.9	4-5
	*09R845							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (301)436-2657	Lorraine B. Jefferson (301)827-1631

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported Foods-Foods and Color Additives 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 regulations promulgated under the Act, with respect to food and color additives..

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the Act and the regulations for food and color additives. The compliance program directs sample collections and label review of imported products for unsafe food additives and non-permitted food or undeclared color additives to insure that these foods meet the requirements of the law.

6. FIELD OBLIGATIONS

Districts should conduct label reviews and collect and analyze imported foods for known potential food and color additive violations, and take appropriate regulatory actions when violations are found.

For FY 05 and beyond 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 imporat field 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 (03R845,04845,ETC). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

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

b. INSPECTION TYPE: NA N/A [ ] 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 [ ] OTHERS ***(Specify)***

f. CHECK THE FOLLOWING ATTRIBUTES

Food and color additives

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
09006 A,B	[X] ORA [ ] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2	4 ISCs COLOR ADDITIVIES	9 LABEL REVIEW COLOR ADDITIVES	8 ISAs COLOR ADDITIVES	4 ISCs FOOD ADDITIVES	9 LABEL REVIEW FOOD ADDITIVES	8 ISAs FOOD ADDITIVES		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		**755**	**250**	**755**	**270**	**540**	**270**		
	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 LABORTORY- SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION		1.4	0.5	8.0	1.4	1.1	11.0		
	TOTAL HOURS		1057	125	6040	378	594	2970		
	CONVERSION FACTOR		930	930	1180	930	930	1180		
	TOTAL OPERATIONAL FTEs		1.14	0.13	5.12	0.41	0.64	2.52		

7. REMARKS

NOTE: Resources for Entry Review and Filer Evalution are planned under the Import Foods- General Program (03819).
For FY 05 and beyond all Import Field Exams are to routinely include verification that the imported products is the same as that which was declared (reconciliation exams); an assessment of security concerns related to labeling and source country (including container integrity signs of intentional adulteration, etc.); and traditonal 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 suspicious are raised conducting routine work requiring follow up should and additional exam and time be reported under CT PAC (03R845,04R845, etc.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

1. PROGRAM/ASSIGNMENT TITLE	2. PMS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Food and Color Additives Petition Review Policy Development – 09

3. PROGRAM TYPE: ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☐ ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

Accomplishments of goals of the individual research projects identified in Part IIA of the Workplan. All research will be distributed in-house and/or published in the referred scientific literature.

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

ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Food and Color Additive Petition Review and Policy Development - 09

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
09R816	X ORA ☐ CENTER	1.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH (CHEM)	DISTRICT CENTER (MICRO)	RESEARCH CENTER (CHEM)						
	TOTAL FIELD	**1300**								
	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									
	TOTAL HOURS	1300								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	1.08								

7. REMARKS

PROJECT SUMMARY SHEET
FY2005

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		93.8			93.8	167.0	
2	Retail Food Protection - State Program	18002*	26.0			26.0	46.3	2-3
3	Milk Safety Program	18003	26.0			26.0	46.3	4-7
4	Molluscan Shellfish Evaluation	18004	14.0			14.0	24.9	8-11
5	Interstate Travel Program - Conveyances	18029A-E*	27.8			27.8	49.5	12-15
	and Support Facilities							
	*18R845							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (301)436-2657	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. For FY 04 this program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, the 2004 Baseline Data Collection and Analysis of Foodborne Illness Risk Factors at retail and report thereof, the on-going egg safety initiative, 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 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 the 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 the 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	26.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL FOOD PROGRAM STANDARDS	STANDARD-IZATION (ITP CDC IHS, STATE AN D LOCAL) *	RE-STANDARD-IZATION (ITP, STATE AND LOCAL) **	NATL CFSAN DIRECTED PROJECTS SECURITY	TEAM LEADERS SC/NATIONAL	NATL TEAM WORK GROUP	REGIONAL SEMINARS	TRAINING WORKSHOPS	TECHNICAL ASSISTANCE
	TOTAL FIELD	**11250**	**1960**	**3467**	**600**	**1200**	**2080**	**1040**	**2070**	**7531**
	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	11250	1960	3467	600	1200	2080	1040	2070	7531
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	9.38	1.63	2.89	0.50	1.00	1.73	0.87	1.73	6.28

7. REMARKS:

Report Counter Terrorism work performed only under 18R845.

* Time allocated for Regional Food Specialists to standardize. FDA ITP staff, CDC and IHS staff and state and local counterparts.

**Time allocated for Regional Specialists to Re-Standardize FDA ITP staff and state and local counterparts.

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.

In addition, it is preferable that Regional Milk Specialists conduct GMP inspections of non-IMS dairy products only when produced in IMS 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

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.

FY 2005 ORA WORKPLAN February 1, 2005

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	26.0 (22.3)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANT [1]	CHECK RATINGS TRANSFER AND RECEIVING [1]	CHECK RATING FARMS	SINGLE SERVICE AUDITS	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICATION 2	TECHINCAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION [3]	STATE MILK SAMPLING SURVELLANCE OFFICER INITIAL CONT	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER [4]
	TOTAL FIELD	**214**	**66**	**361**	**78**	**39**	**51**	**17**	**44**	**28**
	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	120.0	120.0	24.0	80.0
	TOTAL HOURS	5136	792	7220	624	1560	6120	2040	1056	2240
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	4.28	0.66	6.02	0.52	1.30	5.10	1.70	0.88	1.87

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.

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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	OPERTIONAL FTE POSITIONS
18003	[ ] ORA [x] CENTER	(3.7)

REGION	DISTRICT/ SPECIALIZED LABORATORY	RMS STANDARD-IZATION [5]	NCMS	TRAINING GIVEN [6]
	TOTAL FIELD	**17**	**22**	**22**
	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	50.0	80.0	80.0
	TOTAL HOURS	850	1760	1760
	CONVERSION FACTOR	1200	1200	1200
	TOTAL OPERATIONAL FTEs	0.71	1.47	1.47

5/ Activities include the Initial and Re-standardiztion (Individual Audits and Group Field Exercise) of RMSs.
6/ 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 of 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
14.0 (10.5)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION	PATROL EVALUATION	VIBRIO SPECIES MANAGE-MENT HOURS	TECHINCAL ASSISTANCE	FOREIGN EVALUATION	NATIONAL TEAM REPS	TRAINING WORKSHOPS	PLANT EVALUATION	STANDARD-IZATION & RE-STAN-IZATION
	TOTAL FIELD	**167**	**17**	**500**	**14**	**5**	**2**	**20**	**122**	**5**
	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	20.0	80.0		248.0	200.0	400.0	50.0	8.0	40.0
	TOTAL HOURS	3340	1360	500	3472	1000	800	1000	976	200
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	2.78	1.13	0.42	2.89	0.83	0.67	0.83	0.81	0.17

7. REMARKS:

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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	(3.5)

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM MEETING	CENTER INITIA-TIVES	REGIONAL SEMINARS	EU AUDIT	ISSC COMMITTEE	LABORATORY EVALUATION			
	TOTAL FIELD	**14**	14	**14**	**14**	**14**	**12**			
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	30.0	80.0	40.0	40.0	100.0	8.0			
	TOTAL HOURS	420	1120	560	560	1400	96			
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200			
	TOTAL OPERATIONAL FTE	0.35	0.93	0.47	0.47	1.17	0.08			

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 interstate passenger conveyances and their support facilities based on the Public Health Service Act, the Food Drug and Cosmetic Act (The Act), regulations, program guidance, and Food Code. Indentify 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 or regulatory actions as appropriate ensure conformance with the public health prinicples embodied in the Act and implementing its regulations. The goal of the program is to cooperate with the regulated industry, trade associations and others to promote voluntary compliance; coordinate activities with CDC,DOT,EPA and other domestic and foreign government health officials as much as possible to enhance the public health protection of the traveling public and crew or conveyances both during construction and in operation, watering points, vessels, and servicing areas.

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 control 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.

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 techinical 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.

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)
Environmental Conditions, Human Food, Water and Wastes	Inspections/Investigations: Industry 51 All food codes, including water 29W (Y30).

e. EXAM TYPE: [ ] 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

These field assignments will be conducted by persons standardized in the use of FDA’s Food Code and in accordance with established FDA procedures and specific guidelines established for the IT 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	27.8 (25.8)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS	CONVEY UNDER CONSTRUC HOURS (**)	WATERING POINTS INSP (A)	CATERING POINTS INSP (B) (***)	VESSELS INSP (C))	DSCs	DSAs MICRO	INV (HOURS)	ITP SPECIALIST TIME (HOURS)
	TOTAL FIELD	1792	1360	(710)	(380)	(300)	100	100	1900	930
	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	10.5					4.0	8.0		
	TOTAL HOURS	18816	1360				400	800	1900	930
	CONVERSION FACTOR	930	930				930	1180	930	930
	TOTAL OPERATIONAL FTEs	20.23	1.46				0.43	0.68	2.04	1.00

7. REMARKS:

Inspections in Columns (A), (B) and (C) are included in Column 1.
Report Counter Terrorism work performed only under 18R845.
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 and full inventory should be inspected per workplan.
DSCs should be randonly collected from on-board conveyances water systems ex. faucets, as close to the water holding tank as possible.
At least 2 of the samples per district should be taken from aircraft.
** Time for Conveyance under Construction- Time to be used for plan review, meetings, and final inspections. It includes galleys in ATL,DAL,LOS and Aircraft/Vessels in SAN & SEA.
*** Includes High Risk and some Potential Food Allergen Firms identified by the District.
**** 5 of these inspections are scheduled for the Nashville Branch.

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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	(1.9)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	STEERING COMMITTEE (HOURS) (*****)	STANDARD & RE-STANDARD FOOD CODES (HOURS) (******)							
	TOTAL FIELD	400	1395							
	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									
	TOTAL HOURS	400	1395							
	CONVERSION FACTOR	930	930							
	TOTAL OPERATIONAL FTEs	0.43	1.50							

7. REMARKS:

*****Steering Committee - 80 hours provided to each districts (NWE,CIN,FLA,DAL and SAN) for discussing Regionalization of ITP.

****** Standardizing and Re-standardizing of ITP Personnel in the Food Code.

PROJECT SUMMARY SHEET
FY 2005

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		**37.2**	**9.7**		**46.9**	**83.6**	
1	Medical Foods - Domestic and Import	21002	4.4	0.7		5.1	9.1	2-3
2	Domestic and Import NLEA, Nutrient Sample Analysis							
	and General Food Labeling Program **	21005**	4.8	4.6		9.4	16.7	4-5
3	Infant Formula Program	21006*	4.9	1.4		6.3	11.2	6-9
4	Dietary Supplements***	21008 *	16.5	3.0		19.5	34.9	10-13
5	Selected Nutrients in Food Survey	21839	4.2			4.2	7.4	14-15
6	ORA-Center Directed Research Projects	21R816	2.4			2.4	4.3	16-17

* 21R845

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

*** Includes DISC and DISA FTEs.

CENTER PROJECT MANAGER-TELEPHONE	ORA PLANNER-TELEPHONE
Ronald R. Roy (301)436-2657	Lorraine B. Jefferson, 301-827-1631

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

Coverage is also provided to imported lots of medical foods from foreign firms not being routinely inspected under the Compliance program.

5. PROGRAM JUSTIFICATION

Medical Foods are nutrition support food products for oral or tube feeding that have associated therapeutic claims and are to be used under medical supervision. The products are often used for life support and are subject to compositional and microbiological errors (as evidenced by four infant deaths in 1986). In addition to the infant deaths in 1986, there have been a number of recalls of medical foods in recent years associated with significant compositional deviations and under processing With potential microbiological hazards.

Medical foods 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 medical foods firms. Inspections of foreign manufacturers 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.

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)
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 for *Listeria monocytogenes, Salmonella, Staphylococcus aureus, Bacillus cereus, Escherichia coli,* and Aerobic Plate Count (APC).

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See compliance program.

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	5.1

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	**27**	**54**	**(32)**	**(22)**	**8**	**12**	**34**	**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									
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		30.0	5.2			5.0	30.0	100.0	100.0	
TOTAL HOURS		810	281			40	360	3400	800	
CONVERSION FACTOR		930	930			930	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.87	0.30			0.04	0.31	2.88	0.68	

7. REMARKS

CFSAN spreads inspections and DSCs.
ORA spreads import operations.
* Includes an estimated 15% overage to allow for compliance follow-up inspections
**Time to investigate import entries for admissability is planned under the Imports Foods General Program (7303.819)
***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	Food Composition Standards Labeling and Economics - 21

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

4. OBJECTIVES

To determine the compliancy of domestic and imported foods with: (1) labeling regulations promulgated by the NLEA of 1990; (2) to monitor the compliancy of FDA's notice to manufacturers regarding label declaration of allergic substances in foods; and (3) regulations promulgated under the Federal Food, Drug, and Cosmetic Act (the Act) and the Fair Packaging and Labeling Act (FPLA) for other mandatory label information. In addition, the program provides for compliance and surveillance sample collections and analyses to assure the products contain appropriate amounts of declared nutrients and that they are in compliance with health claims that a their label.

5. PROGRAM JUSTIFICATION

The Act mandates that certain label information appear on food labels. The NLEA requires nutrition labeling on most foods consumed In the United States. In addition, continuous monitoring ensures compliance with the regulations established under the Act and identifies potential problem areas to NLEA.

6. FIELD OBLIGATIONS

District will review import and domestic product labels for NLEA compliance and other mandatory label requirements by conducting field exams. Districts will collect "violative" labels 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).

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.

For FY 05 and beyond all import field exams are 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 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 and 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.

The planned physical sample collections include both compliance ("for cause") sampling and surveillance sampling. The field should attempt to collect sufficient surveillance samples during the year, that, when added to the needed compliance samples, meets their full workplan obligation. See compliance program for details

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: [X] 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 vitamins/minerals)	20-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

All food products (except vitamins/minerals)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Samples for nutrient analysis to be sent to SRL/ACNA. See compliance program for other 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	9.4

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 FIELD EXAMS (SEE REMARKS) ***	ISCs (PAPER) OASIS #41 (SEE REMARKS) *****
	TOTAL FIELD	**340**	**(240)**	**(100)**	**100**	**4000**	**125**	**125**	**4450**	**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	0.5	1.2
TOTAL HOURS		1428			1800	1600	150	1250	2225	942
CONVERSION FACTOR		930			1180	930	930	1180	930	930
TOTAL OPERATIONAL FTEs		1.54			1.53	1.72	0.16	1.06	2.39	1.01

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 7303.843.

***Import Field Exams are time spent reviewing import labels that do 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.

For FY05 and beyond 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 Defense Activities.

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 imports lots of infant Formula from unregistered foreign manufacturers in plan 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.

Resources are set aside in FY 05 for a special field assignment to investigate ethnic retail establishments for counterfeit, diverted, or unregistered infant formulas. 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	6.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS *	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	4 IMPORT SAMPLES COLL	8 IMPORT SAMPLES TO BE ANALYZED CHEM **
	TOTAL FIELD	**24**		**50**	**(21)**	**(31)**	**21**	**31**	**15**	**15**
	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-									
	PACIFIC REGIONAL LABORTORY-									
HOURS PER OPERATION		37.0		5.3			100.0	30.0	5.0	100.0
TOTAL HOURS		888		276			2100	930	75	1500
CONVERSION FACTOR		930		930			1180	1180	930	1180
TOTAL OPERATIONAL FTEs		0.95		0.28			1.78	0.79	0.08	1.27

7. REMARKS

ORA spreads import operations
* Includes an estimated 15% overage to allow for compliance follow-up inspections and food security during all 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
Numbers in parenthesis are included in DSCs

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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	

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INVEST-GATION (Hours)	2 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE ANALYZED	3	3	7		4	8
	TOTAL FIELD	**200**	**10**	**10**						
	HEADQUARTERS	(b)(2)&b(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-									
	PACIFIC REGIONAL LABORTORY-									
	HOURS PER OPERATION		5.3	100.0						
	TOTAL HOURS	200	53	1000						
	CONVERSION FACTOR	930	930	1180						
	TOTAL OPERATIONAL FTEs	0.22	0.06	0.85						

Resources set aside for a Center-directed field assignment to investigate ethnic retail establishments for counterfeit diverted or unregistered infant formulas. Resources are spread for workplanning purposes only. Actual participating districts may change and will be directed by the assignment when issued

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. Specifically, the Center plans to issue a special assignment to target domestic and import glandular products for Microbiological analyses. In addition, 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. Food security issues are to be covered during all inspections.

6. FIELD OBLIGATIONS

Field obligations include inspections, domestic and import investigations, sample collections and analyses of dietary ingredients in dietary supplements.

7a. SELECTION OF ESTABLISHMENTS TO BE [ ] 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 [X] 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. Analyze botanicals as directed for microbiological Contamination.

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)	X ORA X CENTER	19.5 (16.5)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS	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**	**175**	**175**				**4500**
	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	18.0	0.5	4.2	20.0	4.2	20.0				
	TOTAL HOURS	4500	450	840	2000	735	3500				4500
	CONVERSION FACTOR	930	930	930	1180	930	1180				930
	TOTAL OPERATIONAL FTEs	4.84	0.48	0.90	1.69	0.79	2.97				4.84

7. REMARKS

ORA spreads import Operations. CFSAN spreads the remaining operations.
Field Exams and sample collections may be collected at packers/repackers, distributor, or warehouses if the levels planned cannot be performed during the inspections.
Additional resources have been planned in the Domestic Pesticide Program (7304.004) for a pesticide/contaminant assignments for selected supplement products.
Investigational hours are planned primarily for CFSAN directed assignments.
*Includes resources for a special assignment to target domestic and import animal glandulars for micro contamination.
Import resources planned in page 2.

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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	(3.0)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ISC PAPER OASIS #41 **	ISC PHYSICAL ***	IMPORT FIELD EXAM *	ISA PHYSICAL CHEM						
	TOTAL FIELD	**360**	**70**	**1800**	**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	0.5	20.0						
	TOTAL HOURS	576	112	900	1400						
	CONVERSION FACTOR	930	930	930	1180						
	TOTAL OPERATIONAL FTEs	0.62	0.12	0.97	1.19						

7. REMARKS

Includes resources for a special assignment to target domestic and import botanicals for micro, contamination.
*Time spent reviewing import labels that does not result in an import sample collection.
**Time spent collecting labels, records, or other documentation for submission to Compliance. 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.
***Physical samples collected and forwarded to the laboratory for analyses to support violations.
For FY 05 and beyond, 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 concern related to labeling and source country (including container integrity, signs of intention 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 Section 530.04 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 the nutrients identified below in 7F, and all TDS foods from one market basket annually for moisture.

The Atlanta Center for Nutrient Analysis(ACNA) will analyze selected Total Diet Study food items from one market basket annually for folate.

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	All Food Product Industry Codes

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

See TDS Compliance Program

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	4.2

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							**1044**	**149**	
	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							3.7	7.0	
	TOTAL HOURS							3863	1043	
	CONVERSION FACTOR							1180	1180	
	TOTAL OPERATIONAL FTEs							3.27	0.88	

7. REMARKS

* Represents total number of foods to be analyzed for selected nutrients by KAN-DO labs.
** Folic Acid for one market basket consisting of 149 TDS food items.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Pesticides and Chemical Contaminants - 21

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

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects, identified in Part II A of the Workplan. All research will be distributed in-house and/or published in the referred scientific literature.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/AA ☐ 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

ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER 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	2.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH (CHEM)	DISTRICT CENTER (MICRO)	RESEARCH CENTER (CHEM)						
	TOTAL FIELD	**1740**		**1180**						
	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 OPERATION									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY- NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1740		1180						
	CONVERSION FACTOR	1205		1180						
	TOTAL OPERATIONAL FTEs	1.44		1.00						

7. REMARKS

PROJECT SUMMARY SHEET
FY 2005

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		**3.8**	**4.3**		**8.1**	**14.4**	
1	Cosmetics - Domestic and Import	29001*	3.8	4.3		8.1	14.4	2-3
	*29F099, 29R833, 99R833,29R824							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (301)436-2657	Lorraine B. Jefferson (301)827-1631

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics; Domestic and Import	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 of 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 cosmetic 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 CFR701.

Resources are set aside for assignments to address cosmetics making drug claims on their labels. The Center will issue assignments for special investigations and documentary sample collections as products are identified.

6. FIELD OBLIGATIONS

Districts will perform inspections and conduct import field exams, collect and analyze samples for non-permitted ingredients, conduct microbiological analyses, and perform evaluations for labeling compliance. 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 [X] BY BOTH

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

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

e. EXAM TYPE: [Xx] CHEMICAL [x] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [x] OTHERS ***(Specify)*** Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Non-permitted ingredients(including color additives), microbiological/contaminants, labeling warnings.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics- Domestic and Import	Colors and Cosmetics Technology

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
29001,29R833	[X] ORA [ ] CENTER	8.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REV HOURS 29R833 *	IMPORT LABEL EXAMS	IMPORT SAMPLE COLLECTIONS	IMPORT SAMPLE ANALYSIS (CHEM)	IMPORT SAMPLE ANALYSIS (MICRO)	DOMESTIC INSPECTION	DOMESTIC SAMPLE COLL **	DOMESTIC SAMPLE ANALYSIS (MICRO)	INVESTI-GATIONAL HOURS ***	
	TOTAL FIELD	**700**	**700**	**200**	**100**	**100**	**100**	**100**	**75**	**350**	
	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										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
PA	PACIFIC REGIONAL LABORTORY-SW										
	PACIFIC REGIONAL LABORTORY-NW										
	HOURS PER OPERATION		0.40	1.5	10.0	21.2	18.2	5.5	21.2		
	TOTAL HOURS	700	280	300	1000	2120	1820	550	1590	350	
	CONVERSION FACTOR	1200	930	930	1180	1180	930	930	1180	930	
	TOTAL OPERATIONAL FTEs	0.58	0.30	0.32	0.85	1.80	1.96	0.59	1.35	0.38	

7. REMARKS

*Filer evaluation hours (99R833) and Follow-up to Refusal (29R824) are included in Entry Review Hours.
** Includes resources for approximately 25 samples for special assignment to cover drug claims on cosmetics.
*** Time set aside for special assignment to cover drug claims on cosmetics.
For FY 05 and beyond 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 single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the even 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 inormation on Food and Cosmetic Defense Activities.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2005

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	**111.0**	**4.0**	**4.0**	**119.0**	**198.6**	**7.2**	**7.2**	**213.0**
41	**HUMAN CELLULAR, TISSUE AND GENE THERAPY PRODUCTS**	22.9			22.9	41.0			41.0
42	**BLOOD AND BLOOD PRODUCTS**	81.5	4.0	2.4	87.9	145.8	7.2	4.3	157.3
45	**VACCINES AND ALLERGENIC PRODUCTS**	7.0		1.2	8.2	12.5		2.2	14.7

"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

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Human Cellular, Tissue and Gene Therapies - 41

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**22.9**			**22.9**	**41.0**	
1	Tissue Establishments	41002	15.5			15.5	27.8	2/3
2	Bioresearch Monitoring Programs *		7.4			7.4	13.2	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)	(13.2)	
	* All resources planned under PAC 41811.							

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Tissue Establishments	Human Cellular, Tissue and Gene Therapies - 41

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

4. OBJECTIVES

To determine if human tissue for transplantation establishments are in compliance with the tissue regulations (21 CFR, Part 1270), promulgated under the Public Health Service Act, Section 361, by assuring that tissue is suitable in terms of transplantation through the required testing and screening of the tissue donors.

5. PROGRAM JUSTIFICATION

Human tissues for transplantation are important products for medical treatment. Monitoring the recovery of processing of human tissue and the testing and screening of the donors is critical to assure consumer protection from unsuitable tissue 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	57 J - 57M, 57 O, 57 P

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
Tissue Establishments	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41002	[X] ORA [ ] CENTER	15.5

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	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**368**								
	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		14094								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTES		15.49								

9. REMARKS

Please use "HT" as the Establishment Type Code for Tissue Establishments.

Inventory used does not include establishments dealing with stem cells or reproductive tissues only.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs (Nonclin. Lab), IRBs, Spon./Mon., Clin. 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.: 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. Inv.: 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.: 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. Inv: 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.: Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office.

Clin. Inv.: 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 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	**74**								
	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	91.0								
	TOTAL HOURS	6734								
	CONVERSION FACTOR	910								
	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.

Inspections spread by Biologics Field Committee.

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		**81.5**	**4.0**	**2.4**	**87.9**	**157.3**	
1	Inspection of Licensed & Unlicensed Blood Banks	42001F, G;	53.9		0.9	54.8	98.1	2/3
	(National Experts)	42R825	3.1		0.1	3.2	5.7	
	Inspection of Donor Centers							
	Inspection of Reference Laboratories							
	Inspection of Blood/Plasma Brokers							
	Inspection of Blood Product Contractors							
	Technical Assistance and Coordination *		2.5			2.5	4.5	
2	Inspection of Source Plasma Establishments	42002,A	11.4			11.4	20.4	4/5
3	Examination of Blood & Blood Components	42007, 42R833,		4.0		4.0	7.2	6/7
	Offered for Import	42R824,99R833						
4	Inspection of Licensed Viral Marker Test Kits	42008,A	2.3		0.5	2.8	5.0	8/9
	(Core Team Biologics)							
	Field Investigations		0.2			0.2	0.4	
5	Bioresearch Monitoring Programs **		3.5			3.5	6.2	10/11
	Institutional Review Board	42809	*					
	Sponsors, Contract Research Organizations,	42810	*					
	and Monitors							
	Clinical Investigators **	42811	(3.2)				(5.7)	
	(National Experts)	42808, 42811	(0.3)				(0.5)	
		45808, 45811						
6	Inspection of Medical Device Manufacturers	42845A,B,C	2.5			2.5	4.5	12/13
7	Inspection of Plasma Derivatives of							
	Human Origin (Core Team Biologics)	42848A,F,G	1.7		0.9	2.6	4.6	14/15
	Field Investigations		0.4			0.4	0.7	
	* BLT-DO to Assist & Coordinate ARC Info							
	** All Domestic & Foreign Resources Planned Under Domestic PAC 42811							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Anita Richardson, 301 827-6220	Harriet 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) Reference Laboratories that perform testing on blood products and donors, e.g., hepatitis, HIV antibody, Western Blot on donors for re-entry purposes, serum electrophoresis, and STS; (d) Reference 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	60.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSPEC-TIONS	1	2 DOMESTIC INVESTI-GATIONS (Hours) **	1 FOREIGN BLOOD BANK INSPEC-TIONS	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDIN-ATION (Hours)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**1177**		**4787**	**24**			**2275**		
	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		40.0			37.9					
TOTAL HOURS		47080		4787	910			2275		
CONVERSION FACTOR		910		910	910			910		
TOTAL OPERATIONAL FTEs		51.74		5.26	1.00			2.50		

7. REMARKS

* All listed resources are planned under PAC 42001F. Resources cover all facilities listed in current compliance program. Pre-License Inspections are not planned separately. Use above resources for any Pre-License Inspections in PPS 41, 42, 45 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.

** Domestic Investigative Hours include: Domestic Investigations, National Expert time, and time for Follow-Up Inspections.

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 plasmapheresis 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	11.4

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 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**193**	**1432**							
	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	46.4								
	TOTAL HOURS	8955	1432							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATION FTEs	9.84	1.57							

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 Blood and Blood Components 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 intended for transfusion, or source plasma for further manufacture, by manufacturer NOT holding a US license.
4) Detain all import entries which are intended for further manufacture which are NOT covered by a valid short supply agreement.
5) Examine import entries intended for further manufacture into unlicensed products for adequate labeling.
6) Identify foreign manufacturers of blood and blood components offering import entries.

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 policy on the importation of blood products and ensure consistent handling of imported blood products by the field.

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 the type and amount of product, its intended use, and whether it is licensed or unlicensed: conduct investigations as necessary and determine whether entry is in compliance with Federal Regulations.

Collect documentary samples following the guidance in Section III of the compliance program.
(Contact CBER if an Import Sample is collected.)

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)
Blood and Blood Components	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 Blood and Blood Components 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	[X] ORA [ ] CENTER	4.0

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		**4800**							
	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		4800							
	CONVERSION FACTOR		1200							
	TOTAL OPERATION FTES		4.00							

9. REMARKS

Resources are planned under PAC 42R833. Report accomplishments under appropriate PAC.
Planned Resources Cover: 42R833 Entry Review; 42R824 Follow-Up to Refusals; 99R833 Filer Evaluation.

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 in vitro diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and those used for patient diagnosis, monitoring, or prognosis, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including Device GMP 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. 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	**13**	**3**	**216**						
	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	**160.0**	**145.0**							
	TOTAL HOURS	**2080**	**435**	**216**						
	CONVERSION FACTOR	**910**	**910**	**910**						
	TOTAL OPERATIONAL FTEs	**2.29**	**0.48**	**0.24**						

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 hours spread by Biologics Field Committee.

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
IRBs, Spon./Mon./ CROs, Clinical Investigaors **(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)								
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	83.9								
	TOTAL HOURS	3188								
	CONVERSION FACTOR	910								
	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.

Inspections spread by Biologics Field Committee.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers (Biologics) **NEW 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 which were transferred to the Center for Biologics Evaluation and Research (CBER) under the 4/1/1982 Working Relationships Agreement with CDRH.

5. PROGRAM JUSTIFICATION

As a result of the 4/1/1982 Working Relationship Agreement, the Center for Biologics Evaluation and Research (CBER) became the focal point for the review and evaluation of 23 categories of medical devices. Our strategy for inspecting those firms which manufacture products in the 23 categories 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:

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] 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	2.5

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	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**45**								
	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		50.6								
TOTAL HOURS		2277								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		2.50								

7. REMARKS

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

* PACs changed from 42830C,L to 42845A,B,C
42845A Level 1 Inspections;
42845B Level 2 Inspections;
42845C Level 3 Inspections
Refer to C.P. 7382.845 for inspectional guidance.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Plasma Derivatives of Human Origin **NEW 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 plasma derivatives by evaluating, through inspections, the conditions under which a particular class of biological/drug products, plasma derivatives of human origin, is 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 of human origin 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 **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 as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.

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	**8**	**5**		**336**					
	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		190.0	175.0							
TOTAL HOURS		1520	875		336					
CONVERSION FACTOR		910	910		910					
OPERATIONAL FTEs		1.67	0.96		0.37					

7. REMARKS

* NEW PACs - NEW Compliance Program - 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.

** Field Investigation Hours spread by Biologics Field Committee

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 DOMESTIC	IMPORT	FOREIGN	7. TOTAL OPERATIONAL FTEs	8. TOTAL PROGRAM FTEs	9. PAGE
	TOTAL		**7.0**		**1.2**	**8.2**	**14.7**	
1	Bioresearch Monitoring Programs *		3.0			3.0	5.3	2/3
	Institutional Review Board	45809	*					
	Sponsors, Contract Research Organizations,	45810	*					
	and Monitors							
	Clinical Investigators *	45811	(3.0)					
2	Licensed Allergenic Products	45848A,F,G	1.0		0.2	1.2	2.2	4/5
	(Core Team Biologics)							
3	Licensed Vaccine Products	45848B,C,D	2.5		1.0	3.5	6.3	6/7
	(Core Team Biologics)							
	Field Time		0.5			0.5	0.9	
	* All resources planned under PAC 45811							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Anita Richardson, 301 827-6220	Harriet 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	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY (SPECIALIZED)	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	**33**								
	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	82.7								
	TOTAL HOURS	2729								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTEs	3.00								

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.

Inspections spread by Biologics Field Committee.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Allergenic Products **NEW 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 allergenic products by evaluating, through inspections, the conditions under which a particular class of biological/drug products, allergenic products and unlicensed source materials suppliers, is 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, **comprehensive inspections** that assess the adequacy of all significant processes and systems. Inspections will be conducted as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.

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 INSPEC-TIONS	1 * FOREIGN INSPEC-TIONS	2 DOMESTIC INVESTI-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**7**	**2**							
	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	131.8	85.0							
	TOTAL HOURS	923	170							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	1.01	0.19							

7. REMARKS

* NEW PACs - NEW 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.

Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Vaccine Products NEW 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 licensed vaccines by determining that they are manufactured in compliance with current Good Manufacturing Practice regulations and that they comply with standards and commitments made in license applications and/or supplements.

To encourage voluntary compliance by identifying practices which establish and implement programs.

To give regulatory/administrative guidance to ensure that appropriate enforcement actions are initiated against those manufacturers found to be in significant noncompliance with applicable laws and regulations.

To provide information and guidance to investigators assigned to perform biennial GMP or for cause inspections of manufacturers of licensed vaccines.

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, **comprehensive inspections** that assess the adequacy of all significant processes and systems. These should be performed on **at least a Biennial Basis**. Inspections will be conducted as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.

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 INSPEC-TIONS	1 FOREIGN INSPEC-TIONS	2 DOMESTIC INVESTI-GATIONS (Hours)	3 DOMESTIC INVESTI-GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**10**	**5**	**477**						
	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	227.0	180.0							
	TOTAL HOURS	2270	900	477						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	2.49	0.99	0.52						

7. REMARKS

* NEW Compliance Program NEW PACs Inspection of Biological Drug Products (CBER):
45848B Pre-License Inspection - Vaccines; 45848C Level 1 CGMP Inspection - Vaccines;
45848D Level 2 CGMP Inspection - Vaccines. (Previously covered by PAC 45002)
All inspections will be performed by Core Team Biologics.
Resources are planned under 45848C. Use above Resources As Needed and Report Under Appropriate PAC.
Field Investigation Hours spread by Biologics Field Committee.

Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator, Core Team Biologics

CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2005 ORA WORKPLAN
February 1, 2005

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	315.5	41.1	51.4	408.0	528.2	68.7	86.1	683
46	**NEW DRUG EVALUATION**	17.0		15.0	32.0	28.5		25.2	53.7
48	**BIORESEARCH MONITORING HUMAN DRUGS**	49.7		4.6	54.3	83.2		7.7	90.9
52	**GENERIC DRUG EVALUATION**	31.2		12.1	43.3	52.2		20.3	72.5
53	**POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS**	8.3		1.7	10.0	13.9		2.8	16.7
56	**DRUG QUALITY ASSURANCE**	187.8	41.1	18.0	246.9	314.4	68.7	30.1	413.2
61	**OTC DRUG EVALUATION**	2.0			2.0	3.3			3.3
63	**HEALTH FRAUD: HUMAN DRUGS**	7.5			7.5	12.6			12.6
88	**INTERAGENCY COOPERATIVE ACTIVITIES**	12.0			12.0	20.1			20.1

"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		**17.0**		**15.0**	**32.0**	**53.7**	
1	NDA Pre-Approval Inspections/Investigations	46832/B/C	17.0			17.0	28.5	2-4
	Methods Validation - Domestic (PDUFA)	46R845						
2	NDA Pre-Approval Inspections/Investigations	46832/B/C			15.0	15.0	25.2	5-6
	Methods Validation - Foreign (PDUFA)	46R845						

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 2005

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

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Methods Validations	New Drug Evaluation - 46

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

4. OBJECTIVES

Validate NDA methodology before approval.
This includes NDAs for radioactive drugs.

5. PROGRAM JUSTIFICATION

A validated analytical method is needed for compliance purposes after approval of an NDA.

6. FIELD OBLIGATIONS

Assigned district laboratory performs the validation study according to instructions in the assignment from the Division of Field Science (HFC-140).

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] 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/Inv. Methods Validation-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	17.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDAs TO INSPECT (Domestic)	1 CHEMIST INSPECT (HOURS) (Domestic) *	2 INVESTI-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	5 FIELD EXAMS\ TESTS	7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) **	7 DSAs METH. VALID. (MICRO) ***	7	7 DSAs (METH.) (VALID) CHEM ****
	TOTAL FIELD	**140**	**2275**		**30**		**30**	**6**		**44**
	HEADQUARTERS	(b)(2)&b(7)(E)			(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		7840	2275		150		1500	630		4620
CONVERSION FACTOR		910	910		910		1180	1180		1180
TOTAL OPERATIONAL FTES		8.62	2.50		0.16		1.27	0.53		3.92

7. REMARKS

* Includes Microbiologists on Inspections.

** NRL analyzes profile DSCs in NE & SE Regions. FCC analyzes profile DSCs in CE, SW AND PA Regions.

*** Micro Meth. Val.105 hrs NRL; 525 HRS DEN LAB

**** Meth. Valid DSAs

Use CT PAC 46R845 only when specific CT work is performed.

☑46832M Therapeutic Biologics Products PAC- Resources under 56002M.

FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations (Methods Validation) - 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 INSPEC-TIONS FOREIGN	1 CHEMIST INSPS (Hours) FOREIGN **	1 INSPEC-TIONS AIDS RELIEF ++FOREIGN	4 IMPORT SAMPLE COLL ***	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES ANALYSES PROFILE (CHEM) ****		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**158**	**2788**	**15**	**50**			**50**		
	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		55.0		60.0	3.0			30.0		
TOTAL HOURS		8690	2788	900	150			1500		
CONVERSION FACTOR		910	910	910	910			1180		
TOTAL OPERATIONAL FTEs		9.55	3.06	0.99	0.16			1.27		

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. *** Profile samples are collected at foreign manufacturers.
**** NRL analyzes all Profile ISCs and ISAs.
Use CT PAC 46R845 only when specific CT work is performed.

++Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	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		**31.2**		**12.1**	**43.3**	**72.5**	
1	New Drugs (Prescription) Not Covered	52002	5.5			5.5	9.2	2-3
	By Approved NDAs							
2	ANDA Pre-Approval	52832,52R845	24.7			24.7	41.3	4-6
	Methods Validation -Domestic							
3	ANDA Pre-Approval Inspections/Investigations	52832,52R845			12.1	12.1	20.3	7/8
4	Methods Validation - Foreign							
5	ORA Center Directed Research Projects	52R816	1.0			1.0	1.7	9/10

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 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
New Drug (Prescription) Not Covered by Approved NDAs	Generic Drug Evaluation - 52

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) Not Covered by Approved NDAs	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52002	[X] ORA [ ] CENTER	5.5

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	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	TOTAL FIELD	**109**	**1232**	**100**						
	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		30.0		5.0						
TOTAL HOURS		3270	1232	500						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		3.59	1.35	0.55						

7. REMARKS

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

FY 2005

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

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA - Methods Validation (DESI and Post 1962)	Generic Drug Evaluation - 52

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

4. OBJECTIVES

To validate the methodology of the drug products submitted as Abbreviated New Drug Applications (ANDAs) as described in the submissions.

To examine the drug samples for those ANDAs for any special testing (potency, purity, etc.) as required.

5. PROGRAM JUSTIFICATION

ANDAs are required per (21 CFR 314.55) for:

1) 1938-1962 (DESI) drug products determined by the FDA to be safe, effective, and acceptable, and
2) As a result of the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, for drugs approved after October 10, 1962.

Approval for marketing is contingent upon, among other requirements, adequate analytical methodology and any special testing Requirements.

6. FIELD OBLIGATIONS

Perform tests of methodology (USP or other specifications) on samples submitted to the District Laboratories identified by ORA (HFC-140).

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

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

Validate methods, potency, purity, and other requirements

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre - Approval Inspections/Inv. Methods Validation - 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	24.7

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 DDA **	7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	7 BIOTEST (Chem) ***	7 DSAs (METH) (VALID) (Chem) (Hours)	9 MISC. HOURS
	TOTAL FIELD	**176**	**1931**	**1590**	**140**	**(50)**	**45**	**45**	**50**	
	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		65.0			5.0		50.0	30.0	105.0	
TOTAL HOURS		11440	1931	1590	700		2250	1350	5250	
CONVERSION FACTOR		910	910	910	910		1180	1180	1180	
TOTAL OPERATIONAL FTEs		12.57	2.12	1.75	0.77		1.91	1.14	4.45	

7. REMARKS

*Includes microbiologists on inspections. ** DSCs for profile/biotest analyses. Includes 50 Profile DSCs to be analyzed by DDA (HFH-300). *** NRL-analyzes profile/biotest DSCs collected in NE &SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.
Use CT PAC 52R845 only when specific CT work is performed.

FY 2005

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 (Methods Validation) - Foreign	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B ,52832C, 52832E	4. WORK ALLOCATION PLANNED BY [X] ORA [ ] CENTER
5. OPERATIONAL FTE POSITIONS 12.1	

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (Foreign) *	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS	1 INSPEC-TIONS AIDS RELIEF ++FOREIGN	5 IMPORT SAMPLE COLL ***	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST '(Chem) ****	8 IMPORT SAMPLE ANALYSES METH. VALID. ****
	TOTAL FIELD	**46**	**2095**	**1083**	**31**	**140**		**70**	**70**	**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 LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		55.0			60.0	3.0		30.0	15.0	50.0
TOTAL HOURS		2530	2095	1083	1860	420		2100	1050	750
CONVERSION FACTOR		910	910	910	910	910		1180	1180	1180
TOTAL OPERATIONAL FTEs		2.78	2.30	1.19	2.04	0.46		1.78	0.89	0.64

7. REMARKS

*** Report as follow: Insps./Chem on Insps. under foreign operation code 11 Pac Code 52832;**
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 Validation ISAs.
Use CT PAC 52R845 only when specific CT work is performed.

++Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Project	Generic Drug Evaluation-52

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

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects.
All research will be distributed in-house and/or published in the referred scientific literature.

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)

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
ORA/Center Directed Research Project	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52R816	X ORA ☐ CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS								
	TOTAL FIELD	**1250**								
	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	1250								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	1.04								

7.REMARKS

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		**8.3**		**1.7**	**10.0**	**16.7**	
1	Enforcemement of the Adverse Drug	53001A,B,	6.3		1.7	8.0	13.4	2-3
	Expereience Reporting Regulation	53R845,						
	Medical Errors	53001A,B	2.0			2.0	3.3	

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ralph J Schmid, HFD-332; 301-827-8929	Anita T. McCurdy, 301-827-1632

FY 2005

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 ADR 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 ADR 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 Prescription Drug Compliance and Surveillance/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up.
Issue regulatory letters as approved by DPDCS. Notify DPDSC of findings from other inspectional program activities which are relevant to ADR 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 [ ] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS DOMESTIC	1 INSPEC-TIONS FOREIGN	2 MEDICAL ERRORS 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 MISC. HOURS
	TOTAL FIELD	**100**	**26**	**1824**						
	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		5700	1560	1824						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		6.26	1.71	2.00						

7. REMARKS

*Report both Domestic and Foreign inspections and medical error investigations under 53001A for Center-Initiated. and 53001B for District -Initiated.
Use CT PAC 53R845 only when specific CT work is performed.

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.
Medical errors investigation time is spread evenly to all Districts.
Foreign Inspections are spread by DEIO ITOB HFC-133.
Foreign inspections must be reported under foreign operation code 11.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Bioresearch Monitoring: Human Drugs - 48

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		**49.7**		**4.6**	**54.3**	**91.0**	
1	In Vivo Bioequivalence - ANDAs & NDAs	48001,A	5.4			5.4	9.0	2/3
	PDUFA (NDAs)		(2.8)					
	Foreign Inspections (In Vivo Bioequivalence,	48001,A;			4.6	4.6	7.7	4/5
	GLPs, Clinical Investigators)	48808; 48811						
	National Experts PDUFA				(0.3)			
	Field PDUFA				(2.0)			
	Foreign Inspections PEPFAR (AIDS Relief)	48001D,E;			(1.4)			
	National Experts (NDAs & ANDAs 0.1)	48811D			(0.1)			
2	Good Laboratory Practices (Non-Clinical Lab)	48808	5.5			5.5	9.2	6/7
	National Experts		(0.7)					
3	Institutional Review Board	48809, 48809A	9.1			9.1	15.3	8/9
4	Sponsors, Contract Research Organizations,	48810	2.7			2.7	4.5	10/11
	and Monitors							
5	Clinical Investigators	48811	27.0			27.0	45.3	12/13
	National Experts		(0.3)					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Joanne L. Rhoads, 301 594-0020	Harriet Gerber, 301 827-1630

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 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	5.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPEC-TIONS DOMESTIC	1 48001A NDA INSPEC-TIONS (PDUFA) DOMESTIC	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	**36**	**34**							
	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	65.1	75.6							
	TOTAL HOURS	2344	2570							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	2.58	2.82							

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) 49%, PDUFA 48001A (NDA) 51%.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections **NEW PACs Added 48001,A; 48808; 48811D,E; 48811D**	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	4.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPEC-TIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPEC-TIONS (PRE-APPR)	1 FOREIGN AIDS RELIEF NDA & ANDA INSPEC-TIONS **	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	**30**	**12**	**21**						
	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	70.7	58.3	65.0						
	TOTAL HOURS	2121	700	1365						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	2.33	0.77	1.50						

7. REMARKS

*** Planned inspections include: PAC 48001,A In Vivo Bioequivalence, PAC 48811 Clinical Investigators, 48808 GLPs (PDUFA) and NEW 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):**
PACs 48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator.
ALL PEPFAR Resources are planned under PAC 48001D.
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
Good Laboratory Practices (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48808	X ORA ☐ CENTER	5.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 NAT'L EXPERT 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	**50**	**615**							
	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	88.0								
	TOTAL HOURS	4400	615							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	4.84	0.68							

9. REMARKS

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.

Personnel Types Required: Investigator, National Expert

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
Institutional Review Board (PDUFA), Radioactive Drug Research Committee (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48809; 48809A	[X] ORA [ ] CENTER	9.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 I R B INSPECTIONS	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	**145**								
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
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	57.1								
	TOTAL HOURS	8280								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTES	9.10								

7. REMARKS

Resources for the Radioactive Drug Research Committee (RDRC, PAC 48809A) are not planned, please use above resources as needed.

Personnel Types Required: Investigator

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
Sponsors, Contract Research Organizations and Monitors (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48810	[X] ORA [ ] CENTER	2.7

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	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**39**								
	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	63.0								
	TOTAL HOURS	2457								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTES	2.70								

7. REMARKS

Personnel Types Required: Investigator

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 records 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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Clinical Investigators (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48811	[X] ORA [ ] CENTER	27.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 Nat'l Experts 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	**276**	**315**							
	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		88.0								
TOTAL HOURS		24288	315						315	
CONVERSION FACTOR		910	910						910	
TOTAL OPERATIONAL FTEs		26.69	0.35						0.35	

7. REMARKS

Personnel Types Required: Investigator, National Expert

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		**186.8**	**41.1**	**18.0**	**246.9**	**413.2**	
1	Drug Process Inspections - Domestic	56002A-F, *	132.1			132.1	221.1	2-5
2	Drug Process Inspections- Non-Gas	56002A-F**	(127.1)			(127.1)		
3	Drug Process Inspections - Gas Manufs.	56002E	5.0			5.0	8.4	
4	Foreign Drug Inspects./Equivalence Evaluations	56002A-F,*			18.0	18.0	30.1	6-7
5	Drug Product Surveillance - Domestic Drugs	56008A,C	28.7			28.7	48.0	8-11
6	Drug Product Surveillance - Import Drugs	56008H***		41.1		41.1	68.8	
7	Drug Quality Reporting System - DQRS	56021A, B	5.0			5.0	8.4	12-113
8	Enforcement of Rx Drug Marketing Act (PDMA)	56022	2.0			2.0	3.3	14-15
	NDA Field Alert Reporting							
9	Pharmacy Compounding Assignments	56D015	3.0			3.0	5.0	16-17
10	ORA/Center Directed Research Project	56R816	3.0			3.0	5.0	18-19
11	Forensic Evaluation and Sample Analysis	56R838****	9.0			9.0	15.1	20-21
	(*) 56832, 56R845, 56R359							
	(**) 56832, 56R845, 56R359							
	(***) 56R824, 56R833, 99R832							
	(****)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 2005

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 biennial 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	132.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 INSPECTIONS (Hours)	1 CHEMISTS INSPEC-TIONS HOURS	1 MICRO INSPEC-TIONS (Hours)	3 DOMESTIC SAMPLE COLL **	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	9 CERTIFICATION HOURS For Audits	9 MISC HOURS For Team Biologics Therapeutics INV hours
	TOTAL FIELD	**1430**	**755**	**7574**	**1538**	**450**	**229**	**40**	**4800**	**2730**
	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		65.0				5.0	38.0	28.0		
TOTAL HOURS		92950	755	7574	1538	2250	8702	1120	4800	2730
CONVERSION FACTOR		910	910	910	910	910	1180	1180	910	910
TOTAL OPERATIONAL FTEs		102.14	0.83	8.32	1.69	2.47	7.37	0.95	5.27	3.00

7. REMARKS

The number of inspections anticipated for drug firms in the high risk category represents 55% of RX drug manufacturers including API manufacturers and sterile drug firms.
(b)(2)&b(7)(E)
Investigational resources include 3 FTEs for transfer of therapeutics from Biologics planned as headquarters postions.
Gas firms are under a separate worksheet 56-4 . ** DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.

Use CT PAC 56R845 only when specific CT work is performed. *56002M Therapeutic Biologic Products PAC

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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 Investigations 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	**152**								
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL-SW									
	PACIFIC REGIONAL-NW									
HOURS PER OPERATION		30.0								
TOTAL HOURS		4560								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		5.01								

9. REMARKS

* Total number of planned gas inspections in the Program for 2005

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

Nationwide there are approximately 4000 gas manufacturers.

There are approximately 285 parent companies with 2200 specific sites where medical gas is manufactured/repacked.

FY 2005

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	18.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS FOREIGN	1 CHEMIST INSPEC-TIONS (Hours) FOREIGN **						
	TOTAL FIELD	**195**	**4670**						
	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		11700	4670						
CONVERSION FACTOR		910	910						
TOTAL OPERATIONAL FTEs		12.86	5.13						

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 2005

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 form 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	28.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 CHEMISTON INSPECTIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTIONS **	3 DOMESTIC SAMPLE COLLECTIONS (API) ***	7 DOMESTIC SAMPLES ANALYZED (CHEM) *	7 DOMESTIC SAMPLES ANALYZED (MICRO) *	7 DOMESTIC SAMPLES ANALYZED (API) (Chem)	
	TOTAL FIELD	**310**	**950**	**1150**	**220**	**1000**	**150**	**220**	
	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 DISTRI								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION				3.0	4.0	19.0	22.0	19.5	
TOTAL HOURS		310	950	3450	880	19000	3300	4290	
CONVERSION FACTOR		910	910	910	910	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.34	1.04	3.79	0.97	16.10	2.80	3.64	

9. REMARKS

Work performed under 56008D (Bioassay) and 56008G (Radioactive Drug Sampling) have been discontinued.
*DSAs are assigned by DFS (HFC-140) per lab expertise for specific Drugs.
Includes 591(**) and 138(***) survey assignments planned by the Center (HFD-330).

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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	41.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT FILER EVAL. HOURS	2 REFUSAL Follow-Up HOURS	9 IMPORT LABEL EXAMS	MAIL/ COURIERS REVIEWS INV HOURS **	6 IMPORT FIELD EXAMS	4 IMPORT SAMPLE COLLECT-IONS *	8 IMPORT SAMPLES ANALYZED APIs CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	**18295**	**1593**	**376**	**2400**	**9828**	**4498**	**1162**	**90**	**60**
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	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					0.7		0.7	2.7	38.0	25.0
TOTAL HOURS		18295	1593	376	1680	9828	3149	3137	3420	1500
CONVERSION FACTOR		1200	910	910	910	910	910	910	1180	1180
TOTAL OPERATIONAL FTEs		15.25	1.75	0.41	1.85	10.80	3.46	3.45	2.90	1.27

7. REMARKS

* PAC Reporting: Entry Reviews 56R833; Filer Evaluations 99R833; Follow-Up to Refusals 56R824, 63R824
Import Label Reviews, Import Field Exams under PACs 52002, 56008H, 56014/A, 63001;
Use CT PAC 56R845 only when specific CT work is performed.
Report finished dosage form drugs and APIs collected at the site of entry under 56008H.

Some samples will be documentary and will not require analysis. Planned sample analyses do not match planned sample collections as a result.
ISCs and ISAs of bulk Drugs/API collected at the docks/point of entry are now planned in the workplan.
**Mail entry review time is now planned in the workplan. (Hours for NYK includes 200 hours for Newark Airport.

FY 2005

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	5.0

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	9
	TOTAL FIELD	**134**	**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		3350	300	120				1050		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		3.68	0.33	0.13				0.89		

7. REMARKS

FY 2005

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	2. PPS PROJECT NAME/NUMBER
Enforcement of the Prescription Drug Marketing Act (PDMA)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56022, 56022A	[X] ORA [ ] CENTER	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	9
	TOTAL FIELD	**39**	**910**	**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		15.0		2.0				11.0		
TOTAL HOURS		585	910	60				330		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.64	1.00	0.07				0.28		

7. REMARKS

FY 2005

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. It continues to be FDA's policy to ensure the continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevents manufacturing under the guise of compounding. The agency needs to investigate pharmacy-compounding reports of illnesses associated with compounded drug products. In those 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	3.0

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		**2730**							
	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									
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			2730							
CONVERSION FACTOR			910							
TOTAL OPERATIONAL FTEs			3.00							

7. REMARKS

*A block of hours is planned for pharmacy compounding assignments.

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Project	Drug Quality Assurance - 56

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

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects identified in Part IIA of the workplan.
All research will be distributed in-house and/or published in the referred scientific literature.

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

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

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

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
ORA/Center Directed Research Project	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R816	X ORA ☐ CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS								
	TOTAL FIELD	**3655**								
	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		3655								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		3.03								

7.REMARKS

FY 2005

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 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 center 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	9.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION							
	TOTAL FIELD	**10820**							
	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		10820							
CONVERSION FACTOR		1205							
TOTAL OPERATIONAL FTEs		8.98							

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	Over-the-Counter Drug Evaluation - 61

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		**2.0**			**3.3**	**3.3**	
1	OTC Drug Monograph Implementation	61003	2.0			2.0	3.3	2-3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
William Nychis HFD-310; 301-827-8959	Anita T. McCurdy 301-827-1632

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
OTC Drug Monograph Implementation	Over-the Counter Drug Evaluation -61

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

4. OBJECTIVES

To identify and evaluate OTC drug products and to assure their compliance as related specific OTC drug monographs or other regulations.

5. PROGRAM JUSTIFICATION

The Kefauver-Harris Amendments passed by Congress in 1962 included a requirement that all drugs be proven effective and safe. In the Federal Register of January 5, 1972, (37 FR 85)), the Commissioner announced a proposed review of the safety, Effectiveness, and labeling of all OTC drugs by independent advisory panels. The end result of the review is the publication of final monographs (in 21 CFR Part 330 through Part 358) which established conditions under which various OTC drugs can be Generally recognized as safe and effective and not misbranded (monograph conditions), and regulations (in 21 CFR Part 310) which Establish conditions under which OTC drug products are not generally recognized as safe and effective or are misbranded.

6. FIELD OBLIGATIONS

Field conducts inspections, collect samples, analyze samples, evaluates product labeling and conducts follow-up activities as set forth in the general compliance program and program circulars and responds to specific requests or recommendations from the Center for Drug Evaluation and Research.

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-non-rx	Industry Codes: 50, 54, and 60-66

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
OTC Drug Monograph Implementation	Over-the-Counter Drug Evaluation - 61

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
61003	[X] ORA [ ] CENTER	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	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**34**	**600**	**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 LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		26.0		4.0				20.0		
TOTAL HOURS		884	600	120				300		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.97	0.66	0.13				0.25		

9. REMARKS

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Health Fraud: - 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		7.5			7.5	12.6	
1	Fraudulent Drugs	63001*	3.5			3.5	5.9	2-3
2	Internet Drug Sales	63D012, * *	4.0			4.0	6.7	4-5
		63D013, **						
		63D014, **						
	* Counter-Terrorism 63R845							
	** internet RX Drugs 63D012							
	**internet OTC Drugs 63D013							
	** Internet Drugs GHB,GBL,BD 63D014							

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)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Fraudulent Drugs	Health Fraud: Human Drugs -63

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

4. OBJECTIVES

To detect, investigate and take action against fraudulent drug products which present the public with direct and indirect health hazard and economic fraud.

5. PROGRAM JUSTIFICATION

The activity is FDA's control strategy for combating the deceptive and misleading promotion of fraudulent drug products.

6. FIELD OBLIGATIONS

Conduct surveillance, investigations and compliance follow-up of drugs identified as fraudulent.

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
Fraudulent Drugs	Health Fraud: Human Drugs-63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63001, 63R845	[X] ORA [ ] CENTER	3.5

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	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**51**		**160**				**80**		
	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		28.0		4.0				18.0		
TOTAL HOURS		1428		640				1440		
CONVERSION FACTOR		910		910				1180		
TOTAL OPERATIONAL FTEs		1.57		0.70				1.22		

9. REMARKS

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

Use CT PAC 63R845 only when specific CT work is performed.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Internet Drug Sales	Health Fraud: Human Drugs -63

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

4. OBJECTIVES

Monitoring, investigating and taking regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal pharmacy operations off-shore associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases in an effort to Protect the public from fraudulent drug products.

5. PROGRAM JUSTIFICATION

FDA receives several complaints associated with the Internet, and has located over 200 web sites engaged in either illegal promotion sales and distribution activities. With increased interest in the use of the Internet by consumers, physicians, pharmacists, manufacturers, distribution/wholesalers, FDA must monitor and investigate allegations of wrong doing to determine activities that violate the law and jeopardize the public health.

6. FIELD OBLIGATIONS

Districts will conduct inspections and investigations, collect evidence, samples and develop case in accordance with assignments from CDER.

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

b. INSPECTION TYPE: [ ] COMPREENSIVE [ ] 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 Drug Sales	Health Fraud: Human Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63D012, 63D013, 63D014	[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		**3640**							
	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									
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			3640							
CONVERSION FACTOR			910							
TOTAL OPERATIONAL FTEs			4.00							

7. REMARKS

A block of hours is planned for monitoring drugs sold over the internet without a RX, unapproved or fraudulent.
* Please report under correct operation; Report internet activities as follows; RX Drugs-- 63D012; OTC Drugs-- 63D013; 63D014 GHB/GBL/GD.

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**	**20.1**	
1	Shelf Life Extension Projects	*	12.0			12.0	20.1	2/3
	*See Data Coded manual for appropriate							
	project reporting PACs.							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Donna A. Porter, HFC-140; 301-827-2757	Anita T. McCurdy 301-827-1632

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
*	[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.
*See Data Codes Manual for appropriate project reporting PACs.

CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2005

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	100.4	30.1	2.4	132.9	173.0	51.9	4.1	229.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	8.7		2.0	10.7	15.0		3.4	18.4
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	91.7	30.1	0.4	122.2	158.0	51.9	0.7	210.6

"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 2005 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		8.7		2.0	10.7	18.4	
1	NADA Pre-Approval Inspections	68001	3.7		2.0	5.7	9.8	2-3
	(National Expert)		(0.4)			(0.4)		
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 301-827-0181	Carrie M. Mampilly 301-827-1635

FORM FDA 2622 (9/98)

FY 2005

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 INSPEC-TIONS (Foreign) ***	1 CHEMIST ON INSP **	3 DOMESTIC SAMPLE COLL			7 DOMESTIC SAMPLES TO BE ANALYZED		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**50**	**50**	**400**	**15**			**15**		
	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									
	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		60.3	40.0		3.0			19.4		
TOTAL HOURS		3015	2000	400	45			291		
CONVERSION FACTOR		1000	1000	1000	1000			1180		
TOTAL OPERATIONAL FTEs		3.02	2.00	0.40	0.05			0.25		

9. REMARKS

** Analyst will participate on inspections as necessary.
*** 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".)

FY 2005

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: 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
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 specific (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
N/A
[ ] MICROANALYTICAL [ ] OTHERS ***(Specify)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

FY 2005

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: 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
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 INSPEC-TIONS	1 68811 INSPEC-TIONS (CLINICAL INVEST)	3 DOMESTIC 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	**50**		**51**						
	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	58.3		41.0						
	TOTAL HOURS	2915		2091						
	CONVERSION FACTOR	1000		1000						
	TOTAL OPERATIONAL FTEs	2.92		2.09						

9. 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 2005 ORA WORKPLAN

1. 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		**91.7**	**30.1**	**0.4**	**122.2**	**210.6**	
1	Drug Process and New Animal Drug Inspections	71001/71R841	10.5		0.4	10.9	18.8	2-3
2	Feed Contaminants*	71003A-H	13.3	3.0		16.3	28.1	4-7
3	Feed Manufacturing	71004/A	6.5			6.5	11.2	8-9
4	Illegal Drug Residues in Meat and Poultry	71006	12.0			12.0	20.7	10-11
6	Ruminant Feed Ban Rule (BSE) Program	71009, 71R844	39.7	27.1		66.8	115.1	12-15
7	ORA/Center Directed Research Projects**	71R816	6.0			6.0	10.3	16-17
8	Forensic Evaluation and Sample Analysis	71R831/71R838	0.7			0.7	1.2	18-19
9	Center Initiated Assignments	71V800	3.0			3.0	5.2	20-21

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

**Research FTEs are not supported.

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deborah A. Cera 301-827-0181	Carrie M. Mampilly 301-827-1635

FORM FDA 2622 (9/98)

FY 2005

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 21CFR 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 that manufacture sterile products.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED 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.	54, 56, 67, 68

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

f. CHECK THE FOLLOWING ATTRIBUTES

Sterility, purity, identity, 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	10.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	1 NAT'L EXPERTS ON INSP (Hours)	1 CHEM ON INSP (Hours)	1 INSPEC-TIONS (Foreign)	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	7 DOMESTIC SAMPLES TO BE ANALYZED (Micro)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**220**	**230**	**500**	**10**	**499**	**120**	**60**	**25**	
	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									
SW	DALLAS									
	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	33.0			40.0		5.5	18.4	21.1	
	TOTAL HOURS	7260	230	500	400	499	660	1104	528	
	CONVERSION FACTOR	1000	1000	1000	1000	1000	1000	1180	1180	
	TOTAL OPERATIONAL FTEs	7.26	0.23	0.50	0.40	0.50	0.66	0.94	0.45	

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

Workload Source: FACTS database (registered firms in IND 54,56, 67, and 68 with Status of "Operational" and Workload Obligation of "Yes".)
Foreign Inspections Spread by Division of Field Investigations, ORO.

FY 2005

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.

Outcome: Prevention or containment of a 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
Feed Contaminants - DOMESTIC

2. PPS PROJECT NAME/NUMBER
Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)
71003 A-H
*(99R833, 71R833, 71R824)

[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS

TOTAL	16.3
DOMESTIC	13.3
IMPORT	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS (Dioxin) *	3 DOMESTIC SAMPLES COLL	DOMESTIC SAMPLES COLL Myco 71003C	DOMESTIC SAMPLES COLL Micro 71003E	DOMESTIC SAMPLES COLL Chem 71003A	DOMESTIC SAMPLES COLL Dioxin 71003G	7 DOMESTIC SAMPLES ANALYSIS Myco 71003C	7 DOMESTIC SAMPLES ANALYSIS Micro 71003E	7 DOMESTIC SAMPLES ANALYSIS Chem 71003A	7 DOMESTIC SAMPLES ANALYSIS Dioxin 71003G
	TOTAL FIELD	60	760	220	170	200	170	220	170	200	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 LAB (SW)										
	PACIFIC REGIONAL LAB (NW)										
	HOURS PER OPERATION	25.0	4.2					7.7	19.4	5.5	24.0
	TOTAL HOURS	1500	3192					1694	3298	1100	4080
	CONVERSION FACTOR	1000	1000					1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	1.50	3.19					1.44	2.79	0.93	3.46

9. REMARKS

* Inspections performed as F/U to violative dioxin samples

The shaded area breaks out the sample collections and is only a guideline for Districts.

Workload Source: FACTS database; firms in IND 69-72 with Workload Obligation of "YES" and Firm Status is "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	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVW HRS		4 IMPORT SAMPLE COLL	IMPORT SAMPLE COLL CHEM	IMPORT SAMPLE COLL MICRO	6 IMPORT FIELD EXAM	8 IMPORT SAMPLE ANALYZED CHEM *	8 IMPORT SAMPLE ANALYZED MICRO		
	TOTAL FIELD	**1200**		**175**	**125**	**50**	**500**	**125**	**50**		
	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										
	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				2.5			1.0	5.8	10.7		
TOTAL HOURS		1200		438			500	725	535		
CONVERSION FACTOR		1200		1000			1000	1180	1180		
TOTAL OPERATIONAL FTEs		1.00		0.44			0.50	0.61	0.45		

9. REMARKS

* Dioxin Samples, 71003G, will be analyzed by ARL and Chem Samples, 71003A/B, will follow the distribution of this workplan and Servicing Laboratory Table. Mycotoxin Samples, 71003C, will be analyzed by PRN.

The shaded area breaks out the sample collections and is only a guideline for Districts.

Workload Source: FACTS and OASIS databases.

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PMS 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 analyses (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	6.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 * INSPECTIONS MEDICATED FEED ESTABS	1 INSPECTIONS NATIONAL EXPERTS (Hours)			3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES ANALYZED (Micro)	7 DOMESTIC SAMPLES ANALYZED (Chem)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**258**	**139**			**65**	**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 LAB (SW)								
	PACIFIC REGIONAL LAB (NW)								
	HOURS PER OPERATION	19.0				6.0	44.0	44.0	
	TOTAL HOURS	4902	139			390	660	660	
	CONVERSION FACTOR	1000	1000			1000	1180	1180	
	TOTAL OPERATIONAL FTEs	4.90	0.14			0.39	0.55	0.55	

9. REMARKS

Some inspection time may be used as investigation time where appropriate.
Non-potency feed sample analysis should be charged to 71003 A/E. Some samples collected are documentary.
There are 359 State Contract inspections and 25 FDA contract audit inspections.
The 139 hours of inspections by National Experts equals to 7 Medicated Feed Inspections.

Workload Source: FACTS database (registered firms in IND 69); Workload Obligation is "YES", Firm Status is "Operational" .

FY 2005

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 be partners with FSIS/HACCP on the environment, educational initiatives, and, as necessary, regulatory actions.

5. PROGRAM JUSTIFICATION

FDA is charged with the responsibility to ensure that food is free of adulterants which may render it injurious to health. FDA conducts investigations as a follow-up to USDA residue findings in meat and poultry to identify the source of adulteration and take corrective action to prevent it from re-occurring. This 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 between FDA, USDA and EPA. See CPG 7155a.19. 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	17, 67, 68, and 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, including confirmation on USDA CAST samples.

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 INSPECTIONS	2 INVEST-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL			7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)	9 TECHNICAL SUPPORT (HOURS) **	METHODS VALID (HOURS) *
	TOTAL FIELD	**225**	**1000**	**200**			**1201**	**1000**		**360**
	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	35.0		5.0						
	TOTAL HOURS	7875	1000	1000			1201	1000		360
	CONVERSION FACTOR	1000	1000	1000			1180	1180		1180
	TOTAL OPERATIONAL FTEs	7.88	1.00	1.00			1.02	0.85		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 FSIS repeat violator samples involving C/R's, no sample analysis.
* Additional time for method validation studies.

Workload Source: Inspections are planned by Center; State contracts.

FY 2005

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 and investigations and sample collections/analysis 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	X ORA X CENTER	Domestic 39.7 Import 27.1 66.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSPECT-IONS *		3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES ANALYZED Chem	4 IMPORT SAMPLES COLL	8 IMPORT SAMPLES ANALYZED Chem	2 IMPORT ENTRY REVIEW Hours	2 FILER EVAL Hours	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**3760**		**900**	**900**	**900**	**900**	**14280**	**5100**	
	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									
	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	7.5		6.0	8.0	5.0	7.4			
	TOTAL HOURS	28200		5400	7200	4500	6660	14280	5100	
	CONVERSION FACTOR	1000		1000	1180	1000	1180	1200	1000	
	TOTAL OPERATIONAL FTEs	28.20		5.40	6.10	4.50	5.64	11.90	5.10	

9. Remarks

* Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills will 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 allocated based on the inventory of: 1) All BSE firms with a Workload Obligation of "YES" in FACTS; and 2) Renderers feed mills, and protein blenders with a status of "Operational" or "Seasonal" and a Workload Obligation of "NO". Districts should review their inventory of Operational / Seasonal renderers, feed mills, and protein blenders to determine if firms marked with a Workload Obligation of "NO" are properly coded in FACTS.

Planned inspections have been adjusted for state contracts and performance goal coverage.

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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 continually expanding the inventory of firms that are potentially subject to this regulation. Districts should work closely with state and other 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 ingreditents 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/index/bse/RuminantFeedInspections.htm).

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

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

Research

6. FIELD OBLIGATIONS

All research will be distributed in-house and/or published in the referred scientific literature.

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
ORA/Center Directed Research Projects	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	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEM (Hours)						
	TOTAL FIELD	**1200**		**5877**						
	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									
	TOTAL HOURS	1200		5877						
	CONVERSION FACTOR	1205		1180						
	TOTAL OPERATIONAL FTEs	1.00		4.98						

9. Remarks

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

FY 2005

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: N/A [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

To analyze domestic and imported animal feed and feed ingredients in support of criminal investigations. Prevent widespread abuses by nation's food suppliers.

5. PROGRAM JUSTIFICATION

6. FIELD OBLIGATIONS

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
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	0.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	**875**								
	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	875								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.73								

9. Remarks

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

FY 2005

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	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: N/A [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All veterinary products	54, 56, 67-72

e. EXAM TYPE: N/A [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	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71V800	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI-GATIONS (Hours)								
	TOTAL FIELD	**3000**								
	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	3000								
	CONVERSION FACTOR	1000								
	TOTAL OPERATIONAL FTEs	3.00								

9. Remarks

These resources include time for a Center-directed assignment to inspect pharmacies compounding animal drug products.

Workload Source: Based on pro-rated inventory in Feed Manufacturing, Feed Contaminants and Pre-Approval programs.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2005

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	166.3	44.9	16.4	227.6	285.7	77.5	30.8	394.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	85.6	39.4	11.1	136.1	145.4	68.0	21.6	235.0
83	PRODUCT EVALUATION: DEVICES	32.1		4.2	36.3	55.4		7.3	62.7
84	SCIENCE: DEVICES	5.1			5.1	8.8			8.8
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	15.5		0.1	15.6	27.7		0.2	27.9
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	27.5	5.5	1.0	34.0	47.5	9.5	1.7	58.7

"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 2005

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 (3)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED ENG (4)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (6)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**25**	**100**	**3**			**1**	**1**	**1**	
	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	11.5		5.8			37.0	36.0	20.0	
	TOTAL HOURS	288	100	17			37	36	20	
	CONVERSION FACTOR	950	950	950			1180	1180	1180	
	TOTAL OPERATIONAL FTEs	0.30	0.11	0.02			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) Includes Documentary samples.

(4) MDR samples to confirm reported defects.

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

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

PROJECT SUMMARY SHEET

FY 2005

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		**85.6**	**39.4**	**11.1**	**136.1**	**235.0**	
1	Monitoring Devices of Foreign Origin - Import	82008 *		25.0		25.0	43.2	2-3
2	Inspection of Medical Device Manufacturers:		81.3		11.1	92.4	159.7	4-7
	GMP Inspections	82845ABCGS	(73.8)		(11.1)	(84.9)	(147.0)	
	Accredited Persons Audit Investigations	82845J	(0.3)			(0.3)	(0.5)	
	Accredited Persons Audit Inspections	82845P	(7.2)			(7.2)	(12.2)	
3	Condom Assignment	82Z002		5.0		5.0	8.6	8-9
4	Manufacturers and Importers of Surgical/	82Z003	0.1	9.4		9.5	16.4	10-11
	Examination Gloves							
5	BSE Assignment	82Z005	1.0			1.0	1.7	12-13
6	Center Initiated Assignments	82Z800	2.0			2.0	3.4	14-15
7	ORA/Center Directed Research Projects	82R816	0.9			0.9	1.5	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 examinations of Form 701 import records 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	25.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI-GATIONS (Hours)	4 IMPORT FIELD EXAMS *	4 IMPORT SAMPLE COLL (Physical) **	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 IMPORT LABEL EXAM
	TOTAL FIELD		**20315**	**3400**		**1835**	**120**	**60**	**60**	**1475**
	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					0.6	2.2	25.5	25.5	0.3
	TOTAL HOURS		20315	3400		1101	264	1530	1530	443
	CONVERSION FACTOR		1200	950		950	950	1180	1180	950
	TOTAL OPERATIONAL FTEs		16.93	3.58		1.16	0.28	1.30	1.30	0.47

9. REMARKS

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).

NOTE: Determination of failure to register or list is included in the Entry Review operation.
Planning Guidance: Any unused resources for Filer Evaluations should be used, if necessary, towards Entry Reviews.
Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.

* Import Field Exams to implement performance standard for lead wires and cables.

** 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.

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	92.4 [87.3]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS LEVEL I 82845A	1 INSPECTIONS LEVEL II 82845B	1 INSPECTIONS LEVEL III COMPLIANCE FOLLOWUP 82845C	1 INSPECTIONS FOREIGN	1 INSPECTIONS FOR CAUSE 82845G	1 INSPECTIONS ACCREDITED PERSONS 82845P (1)	2 INVESTIGATIONS (Hours) DOMESTIC 82845J (2)	2 INVESTIGATIONS (Hours)	2 INVESTIGATIONS (Hours)
	TOTAL FIELD	**714**	**483**	**100**	**163**	**75**	**135**	**255**		**2042**
	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	34.0	51.0	89.0	65.0	72.0	50.8			
	TOTAL HOURS	24276	24633	8900	10595	5400	6858	255		2042
	CONVERSION FACTOR	950	950	950	950	950	950	950		950
	TOTAL OPERATIONAL FTEs	25.55	25.93	9.37	11.15	5.68	7.22	0.27		2.15

9. REMARKS

QUALITY SYSTEMS INSPECTION PLANNING

The workplan reflects the number of operations to be performed in FY 2005 for each district. 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. Any unused resources in those two areas should be reprogrammed into Level 1 and Level 2 inspections.
The hours per operation, or inspectional modules, reflect the most recent historical data. Time for 82845S (sterilization) is included in the inspectional modules. Time spent on the QSIT satellites: MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing is averaged into the inspectional module for Level 2 inspections. For additional information regarding inspection strategies refer to the latest Compliance Program. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections.
(1) 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. (2) Accredited Person Audits conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO. For informational purposes: 30 inspections under State Contract will be conducted in DAL-DO; 20 inspections under State Contract will be conducted in DEN-DO for FY 2005.

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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	92.4 [5.1]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR	3 DOMESTIC SAMPLE COLL MICRO STERILITY	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (1)	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (2)	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN BIOINDICATOR	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO STERILITY	7 DOMESTIC SAMPLES TO BE ANALYZED ENG	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**89**	**37**	**10**	**18**	**43**	**14**	**6**	**18**	
	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	5.5	5.5	5.5	32.1	62.0	25.0	25.0	72.0	
	TOTAL HOURS	490	204	55	578	2666	350	150	1296	
	CONVERSION FACTOR	950	950	950	1180	1180	1180	1180	1180	
	TOTAL OPERATIONAL FTEs	0.52	0.21	0.06	0.49	2.26	0.30	0.13	1.10	

9. REMARKS

(1) Test Kit or Reagant Testing to support GMP observations (CHEM) at WEAC.

(2) Antisera and Products Media Testing to support GMP observations (MICRO) at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.

Note: Domestic Sample Collections for Contract Sterilizers and/or Bioburden, Bioindicator 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	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**3**		**2**	**354**			**2**	**354**	
	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	8.8		3.0	2.5			12.0	13.5	
	TOTAL HOURS	26		6	885			24	4779	
	CONVERSION FACTOR	950		950	950			1180	1180	
	TOTAL OPERATIONAL FTEs	0.03		0.01	0.93			0.02	4.05	

9. REMARKS

Domestic Samples should only be collected on a for cause basis; 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	9.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (PHYSICAL)	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED ENG	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
	TOTAL FIELD	**2**		**2**	**1000**		**1**	**1**	**222**	**778**
	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	8.0		6.0	3.0		20.0	13.0	7.4	7.4
	TOTAL HOURS	16		12	3000		20	13	1643	5757
	CONVERSION FACTOR	950		950	950		1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.02		0.01	3.16		0.02	0.01	1.39	4.88

9. REMARKS

Domestic Samples should only be collected on a for cause basis. 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	Compliance: Devices - 82

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

4. OBJECTIVES

To enhance FDA's uniformity in inspection and compliance of BSE firms subject to the regulation and to determine compliance with the BSE regulation.

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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.

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)

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
BSE Assignment	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z005	X ORA X CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INSPEC-TIONS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**48**								
	HEADQUARTERS	(b)(2)&b (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	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								
	TOTAL HOURS	960								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	1.01								

9. REMARKS

Districts will, upon assignment, conduct inspections of firms whose devices may contain, or be exposed to, BSE risk material.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	Compliance: Devices - 82

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 rapidly. This workplan activity provides resources for Center assignments which can rapidly address potential or emerging problems.

6. FIELD OBLIGATIONS

Conduct inspections and investigations as directed by Center assignments.

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

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

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z800	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (3)	9 OTHER OPERATIONS (Hours) METH DEV ENG (4)
	TOTAL FIELD	**25**		**350**	**12**		**2**	**2**	**2**	**500**
	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	34.0			10.0		50.0	15.0	50.0	
	TOTAL HOURS	850		350	120		100	30	100	500
	CONVERSION FACTOR	950		950	950		1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.89		0.37	0.13		0.08	0.03	0.08	0.42

9. REMARKS

NOTE: User Reporting Inspections are discontinued for this program; resources transferred to Inspections.

(1) WEAC--Ad Hoc testing of media.

(2) WEAC--Ad Hoc testing of test kits or reagents.

(3) WEAC--Sterility samples.

(4) WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Compliance: Devices - 82

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

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects. All research will be distributed in-house and/or published in the referred scientific literature.

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
ORA/Center Directed Research Projects	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82R816	[X] ORA [ ] CENTER	0.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	DISTRICT RESEARCH CHEM (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)					
	TOTAL FIELD			**400**	**700**					
	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			400	700					
	CONVERSION FACTOR			1205	1180					
	TOTAL OPERATIONAL FTEs			0.33	0.59					

9. REMARKS

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 spend 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)								
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	360								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.30								

9. REMARKS

PROJECT SUMMARY SHEET

FY 2005

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 DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
	TOTAL		**32.1**		**4.2**	**36.3**	**62.7**	
1	Medical Device Premarket Approval and		7.8		3.2	11.0	19.1	2-3
	Postmarket Inspections:							
	MDUFMA User Fee	83001	(4.0)			(4.0)	(6.9)	
	PreMarket Approval Inspections	83001	(1.7)		(1.8)	(3.5)	(6.2)	
	Postmarket Approval Inspections	83001A	(2.1)		(1.4)	(3.5)	(6.0)	
2	Bioresearch Monitoring:		24.3		1.0	25.3	43.6	4-5
	Good Laboratory Practices	83808	(3.0)			(3.0)	(5.2)	
	Institutional Review Board Program	83809	(1.6)			(1.6)	(2.7)	
	Sponsors, Contract Research Organizations &	83810	(5.8)		(0.1)	(5.9)	(10.2)	
	Monitors							
	Clinical Investigators	83811	(13.9)		(0.9)	(14.8)	(25.5)	

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Daniel Schultz 301-594-2022	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Premarket Approval and Postmarket Inspections/510(k) Premarket Approval Inspections	Product Evaluation: Devices - 83

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

4. OBJECTIVES

Medical Device Premarket Approval and Postmarket Inspections: 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.

510(k) Premarket Approval Inspections: To assure, prior to approval of the 510(k) for selected devices, that the manufacturer is in compliance with the requirements of the device GMP regulation. To verify that the manufacturer has procedures in place and adequate documentation to support their premarket submission Declarations of Conformity to Standards, and/or their declaration of compliance with design controls.

5. PROGRAM JUSTIFICATION

Medical Device Premarket Approval and Postmarket Inspections: 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.

510(k) Premarket Approval Inspections: The General Counsel has ruled that compliance with the GMP regulation is one of the elements of device safety which must be considered when reviewing a 510(k) application. This policy is being initially applied to all 510(k)s for preamendment Class III devices. In November 1997, the Federal Food, Drug, and Cosmetic Act (FFDCA) was modified by the FDA Modernization Act (FDAMA) to include Section 205, Device Standards. This section requires FDA to "recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization." After FDA recognizes a standard through publication in the Federal Register, "a person may submit a declaration of conformity in order to meet a premarket submission or other requirement under the FFDCA to which such standard is applicable." The use of standards is applicable to all types of pre-market submissions. These changes became effective on February 20, 1998.

6. FIELD OBLIGATIONS

Medical Device Premarket Approval and Postmarket Inspections: 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) [redacted] 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. **510(k) Inspections**: On assignment from CDRH, conduct a comprehensive GMP inspection as instructed in the compliance program. Regarding Conformance Standards inspections, conduct inspections based on assignments by the Field Programs Branch: 100% of assignments issued should be completed as high priority. Class II or III devices in the applicable declaration will be covered.

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	11.0

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 (1)	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**36**	**67**	**34**	**27**	**86**				
	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	44.0	30.0	50.7	49.4	44.0				
	TOTAL HOURS	1584	2010	1724	1334	3784				
	CONVERSION FACTOR	950	950	950	950	950				
	TOTAL OPERATIONAL FTEs	1.67	2.12	1.81	1.40	3.98				

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) 1 additional FTE in FY 2005 has been planned for Medical Device User Fee and Modernization Act (MDUFMA).

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 INSPEC-TIONS (GLPs)	1 INSPEC-TIONS (IRBs)	1 INSPEC-TIONS (SPON/MON)	1 INSPEC-TIONS (CLINICAL INVEST) (1)	1 INSPEC-TIONS (SPON/MON) FOREIGN	1 INSPEC-TIONS (CLINICAL INVEST) FOREIGN	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**35**	**30**	**63**	**168**	**2**	**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									
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	82.0	52.0	87.0	79.0	35.0	68.0			
	TOTAL HOURS	2870	1560	5481	13272	70	816			
	CONVERSION FACTOR	950	950	950	950	950	950			
	TOTAL OPERATIONAL FTEs	3.02	1.64	5.77	13.97	0.07	0.86			

9. REMARKS

1) 2 FTE are planned to provide for the FY 2005 Congressional Budget Medical Device Review FTE increase. The additional resources will enable FDA to conduct pre-approval inspections for device manufacturers and to thereby meet premarket performance goals committed to under the Medical Device User Fee and Modernization Act (MDUFMA) legislation.

PROJECT SUMMARY SHEET

FY 2005

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		**5.1**			**5.1**	**8.8**	
1	Test Method Development and Evaluation	84Z002	3.7			3.7	6.4	2-3
2	ORA/Center Directed Research Projects	84R816	1.4			1.4	2.4	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								**775**	**3540**
	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								775	3540
	CONVERSION FACTOR								1180	1180
	TOTAL OPERATIONAL FTEs								0.66	3.00

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
ORA/Center Directed Research Projects	Science: Devices - 84

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

Accomplishment of goals of the individual research projects. All research will be distributed in-house and/or published in the referred scientific literature.

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
ORA/Center Directed Research Projects	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84R816	[X] ORA [ ] CENTER	1.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)					
	TOTAL FIELD				**1660**					
	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				1660					
	CONVERSION FACTOR				1180					
	TOTAL OPERATIONAL FTEs				1.41					

9. REMARKS

PROJECT SUMMARY SHEET

FY 2005

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		**15.5**		**0.1**	**15.6**	**27.9**	
1	Mammography Facilities Inspection Program	85014 A,C,F	15.5		0.1	15.6	27.9	2-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Lireka P. Joseph 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	15.6 [7.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 85014 (1)	1 INSPEC-TIONS 85014F (2)	1 INSPEC-TIONS 85014 (3)	1 INSPEC-TIONS 85014 (4)	1 INSPEC-TIONS FOREIGN 85014 (5)	2 INVESTI-GATIONS (Hours) 85014A (6)	2 INVESTI-GATIONS (Hours) 85014 (7)	9 OTHER OPERATIONS (Hours) 85014C (8)	9 OTHER OPERATIONS (Hours) 85014 (9)
	TOTAL FIELD	**216**	**36**	**122**	**33**	**15**	**2266**	**50**	**468**	**2900**
	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	8.0	11.0	8.0	8.0	8.0				
	TOTAL HOURS	1728	396	976	264	120	2266	50	468	2900
	CONVERSION FACTOR	1160	1160	1160	1160	1160	1160	1160	1160	1160
	TOTAL OPERATIONAL FTEs	1.49	0.34	0.84	0.23	0.10	1.95	0.04	0.40	2.50

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

1) Inspection of Certified Mammography Facilities not covered by the states.
2) Follow-up Inspections.
3) Federal Facility Inspections (does not include VHA Facility inspections).
4) VHA Facility Inspections.
5) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries.
6) Audit Investigations.
7) Investigations of Uncertified Mammography Facilities.
8) Compliance Activities.
9) Technical Assistance and Coordination Activities.

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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	15.6 [7.7]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 85014F (10)	2 INVESTI-GATIONS (Hours) 85014F (11)	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) 85014 (12)
	TOTAL FIELD	**72**	**6965**							**1200**
	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	11.0								
	TOTAL HOURS	792	6965							1200
	CONVERSION FACTOR	1160	1160							1200
	TOTAL OPERATIONAL FTEs	0.68	6.00							1.00

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

10) Follow-up Inspection after warning letter

11) Inspection Follow-Up Activities (Non-Warning Letter).

12) Technical Assistance and Coordination Activities: RRHRs.

PROJECT SUMMARY SHEET

FY 2005

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		**27.5**	**5.5**	**1.0**	**34.0**	**58.7**	
1	Optical Electronic Products:		6.5		0.2	6.7	11.5	2-5
	Inspection of Manufacturers of Laser Products	86001	(5.7)		(0.2)	(5.9)	(10.1)	
	Field Implementation of the Sunlamp & Sunlamp	86002	(0.8)			(0.8)	(1.4)	
	Products Peformance Standard as Amended							
2	X-Ray Surveillance Programs:		11.0			11.0	19.0	6-13
	Field Compliance Testing of Diagnostic X-Ray	86003	(9.0)			(9.0)	(15.6)	
	Equipment							
	Field Compliance Testing of Cabinet X-Ray	86004	(2.0)			(2.0)	(3.4)	
	Equipment							
3	Compliance Testing of Electronic Products	86006, A, B,	3.4		0.8	4.2	7.3	14-15
	at WEAC	D, E						
4	Imported Electronic Products	86007 *		5.5		5.5	9.5	16-17
5	Radiological Health Control Activities:		6.6			6.6	11.4	18-21
	Medical Device and Radiological Health Use	86008	(4.6)			(4.6)	(7.9)	
	Control and Policy Implementation							
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	(3.5)	
	* In addition to PAC 86007, includes reporting							
	PACs 86R824, 86R833, and 99R833.							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Tim Ulatowski 301-594-4692	John Aydinian 301-827-1634

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 safety emissions and other requirements 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 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 and other skin cancers.

6. FIELD OBLIGATIONS

Inspection of Manufacturers of Laser Products: Field personnel will initiate and schedule their own inspections of laser manufacturers listed in the compliance program. In addition, they 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 products in 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	95LS-99
Sunlamp, suntanning booths, and sunlamp products.	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	6.7 [5.2]

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)	2 INVESTI-GATIONS (Hours) 86002	3 DOMESTIC SAMPLE COLL 86001	3 DOMESTIC SAMPLE COLL 86002	5 FIELD EXAMS/ TESTS 86001 (5)	5 FIELD EXAMS/ TESTS 86002 (6)
	TOTAL FIELD	**133**	**5**	**7**	**1147**	**90**	**6**	**3**	**97**	**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	18.4	52.4	13.8			3.0	8.0	6.2	3.2
	TOTAL HOURS	2447	262	97	1147	90	18	24	601	320
	CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	2.58	0.22	0.10	1.21	0.09	0.02	0.03	0.63	0.34

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).

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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	6.7 [1.5]

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	7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) 86001 (7)	9 OTHER OPERATIONS (Hours) 86002
	TOTAL FIELD								**1215**	**220**
	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								1215	220
	CONVERSION FACTOR								950	950
	TOTAL OPERATIONAL FTEs								1.28	0.23

Inspection of Manufacturers of Laser Products:

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

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	11.0

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**	**27**	**1029**	**227**	**916**	**285**	**88**		**4121**
	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	19.0	10.0			3.0	4.9	4.0		
	TOTAL HOURS	342	270	1029	227	2748	1397	352		4121
	CONVERSION FACTOR	950	950	950	950	950	950	950		950
	TOTAL OPERATIONAL FTEs	0.36	0.28	1.08	0.24	2.89	1.47	0.37		4.34

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 (Henry Knox). 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.

4) Other Operations includes Coordination/Technical Assistance resources for Field Test Review.

Sources of Diag. X-Ray Workloads: Inspections are based on the OEI of Diag. X-Ray Assemblers;Investigation Hours are based on reviewing 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
2005 WORKPLAN FOR FIELD COMPLIANCE TESTING OF DIAGNOSTIC X-RAY SYSTEMS
(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2005)

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	4.2

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	9 OTHER OPERATIONS (Hours)		
	TOTAL FIELD	**12**	**60**	**26**	**4**	**1**	**18**			
	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	80.0	28.0	43.0	240.0	105.0	8.0			
	TOTAL HOURS	960	1680	1118	960	105	144			
	CONVERSION FACTOR	1180	1180	1180	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	0.81	1.42	0.95	0.81	0.09	0.12			

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	5.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI-GATIONS (Hours)	2 ENTRY REVIEW (Hours)	4 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		**4654**	**1420**			**200**			
	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						0.60			
	TOTAL HOURS		4654	1420			120			
	CONVERSION FACTOR		1200	950			950			
	TOTAL OPERATIONAL FTEs		3.88	1.49			0.13			

9. REMARKS

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).

Investigation Hours Based On:

- Import Entry Review Hours (Electronic and Paper):

- MAY 1, 2003 - APRIL 30, 2004 Electronic Entry Review Hours Reported Under 86R833;
- MAY 1, 2003 - APRIL 30, 2004 Entry Review Investigation Hours (Operation 14) Reported Under 86007.

- Import Filer Evaluation Hours:

- MAY 1, 2003 - APRIL 30, 2004 Total Hours Reported in PODS; These hours are multiplied by 6.7% (Rad Health's Percentage of the Total PODS Hours).

Note-Import Follow-Up To Refusal Hours:

- Not To Be Planned; Reporting PACS To Be Sent To Field.

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	6.6

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 TECHNICAL ASSISTANCE (Hours) CSO 86009	9 MISC (Hours) DENT * 86008	9 MISC (Hours) RRHR ** 86008
	TOTAL FIELD						**1200**	**925**	**750**	**4800**
	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						1200	925	750	4800
	CONVERSION FACTOR						1200	950	1180	1200
	TOTAL OPERATIONAL FTEs						1.00	0.97	0.64	4.00

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

9. 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 are performed by either RRHRs or CSOs trained in radiological and technological hazards.

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.