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# FY 2006 ORA FIELD WORKPLAN



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





## Memorandum

Date September 12, 2005

From Director, Program Planning & Workforce Management Branch

Subject Final FY 2006 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 2006 ORA Field Workplan is based on the Center's compliance program forecasts and incorporates input of the Centers and the Field Committees during their review of the draft Workplanning Sheets. The Workplan is based on the FY 2006 FDA Appropriation Request submitted to Congress in February 2005. 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 2006 Program Forecasts.

The FY 2006 ORA Field Workplan is based on ORA's planning level of 1,933 Operational (3,328 Total) FTEs. This represents an overall reduction of 59 Operational FTEs from the FY 2005 Workplan. Only the Device program received an FTE increase for FY 2006. This increase is a result of a specific Congressional mandate for increased funding in the postmarket medical device program.

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. The result over time is a reduction in the level of FTEs that ORA can support. With a few exceptions, the current freeze on outside hiring will likely continue for the foreseeable future.

### **Foods and Cosmetics**

There are 1055 Operational FTEs for FY 2006. This is a reduction of 50 Operational FTEs from FY 2005. Significant changes include:

Import Acidified & LACF (03003/A): Field exams increased from 3,000 to 3,200 (Note: now planned as hours); sample collections and analyses increased from 1,300 to 1,400.

National Drug Residue Milk Compliance Program (03039): Program cancelled for FY 2006.

Import Foods (03819): Import Field Exams; Import Filer Evaluations, Follow-Up to refusal hours are now planned as investigations hours.

Domestic Fish and Fishery Products (03842): Inspections decreased from 3120 to 2480; sample collections and analyses reduced from 800 to 300.

Import Seafood Products (03844): Import Field Exams and Label Exams are now planned as investigation hours.

Contract Management (03R843): Title changed from “Food State Contract Audits.” Time for audits is planned under the “Contract Management” column.

Food Defense (03R845): Title changed from “Counter Terrorism Preparedness.” FTEs increased from 11.6 in FY 2005 to 38 in FY 2006.

Pesticides and Industrial Chemicals in Domestic and Import Foods (04004A, D): Domestic sample collections and analyses reduced from 2700 to 2400.

Field Assignments for Chemical Contaminants (04F800): Domestic samples for Perchlorate in Foods reduced from 750 to 100.

Mycotoxins (07001): Domestic sample collections and analyses reduced from 1875 to 1710, import sample collections and analyses reduced from 1280 to 1164.

Imported Foods – Food and Color Additives (09006A, B): Import sample collections and analyses increased from 1025 to 1175, Label reviews reduced from 790 to 520. No Research time planned for PPS 09.

Interstate Travel Program (18029): Investigational hours reduced from 1900 to 500 and time for food code standardization was eliminated.

Dietary Supplements (21008): Domestic sample collections/analyses reduced from 175 to 50.

Cosmetics (29001): Domestic sample collections reduced from 100 to 75, Investigation hours eliminated (reduced 350 hours), and 700 import label reviews combined into import entry review time.

## **Biologics**

There are 117 Operational FTEs for FY 2006. This is a reduction of 2 Operational FTEs from FY 2005. Significant changes include:

Source Plasma Establishments (42002): Inspections reduced from 193 to 164.

Examination of Biological Products Offered for Import (42007/42R833): Entry review hours reduced from 4,800 to 4,200.

Inspection of Medical Device Manufacturers (Biologics) (42845A,B,C): Inspections reduced from 45 to 35.

## **Human Drugs**

There are 390 Operational FTEs for FY 2006. This is a reduction of 18 Operational FTEs from FY 2005. Significant changes include:

NDA Inspections/Methods Validation – Domestic (46832): Inspections reduced from 140 to 129; methods validation time reduced by 2 FTE.

In Vivo Bioequivalence – Foreign (48001D): Resources for the President’s Emergency Plan for AIDS Relief (PEPFAR) are not planned separately. NDA PEPFAR resources are planned under 46832 and 48001A. ANDA PEPFAR resources are planned under 48001 and 52832.

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

Institutional Review Board (48809): Inspections reduced from 145 to 107.

The New Drugs Rx without Approved NDAs (old 52002) has been reassigned under 63002.

ANDA Inspections/Methods Validation – Domestic (52832): Inspections reduced from 176 to 137; methods validation time reduced by 2 FTE.

ANDA Inspections – Foreign (52832): Inspections increased from 46 to 62.

ORA/Center Directed Research (52R816) is planned under the 56R816 program.

Drug Process Inspections – Domestic (56002): Inspections increased from 1430 to 1504.

A new Project, “Unapproved and Misbranded Drugs – 63”, was created to include the consolidation of the following Human Drugs programs:

- The OTC Drug Monograph (61003) and Internet Drug Sales (63D012) are now under Internet, Health Fraud, and OTC Monographs (63001A).
- The New Drugs Rx without Approved NDAs (old 52002) is now PAC 63002.

## **Animal Drugs and Feeds**

There are 127 Operational FTEs for FY 2006. This is a reduction of 6 Operational FTEs from FY 2005. Significant changes include:

NADA Pre-Approval (68001): Domestic inspections reduced from 50 to 40.

Drug Process Inspections (71001): Domestic inspections reduced from 220 to 213; investigations reduced from 499 hours to 235 hours; sample collections reduced from 120 to 80; domestic sample analyses chem/micro reduced from 60 to 30, and 25 to 15.

Feed Contaminants (71003): Domestic sample collections and analyses increased from 760 to 805; heavy metals analysis was added to the program; dioxin inspections reduced from 60 to 15; import entry review and import field exams were cancelled and planned under the BSE program;

import sample collections increased from 175 to 220; import sample analyses chem/micro increased from 125 to 155, and 50 to 65 respectively.

Feed Manufacturing (71004): Inspections reduced from 258 to 243; Voluntary Self Inspection Program (VSIP) hours were added (250 hours); sample collections reduced from 65 to 55; micro sample analyses reduced from 15 to 5.

Illegal Residues in Meat and Poultry (71006): Inspections increased from 225 to 245; sample analyses reduced from 2,201 hours to 1,100 hours.

Ruminant Feed Ban/BSE Program (71009): Import entry review reduced from 14280 hours to 12900 hours; technical support hours were added (1500 hours); import field exams and filer evaluations were merged into import investigations (7900 hours).

Center Initiated Assignments (71V800): Investigations reduced from 3000 hours to 1000 hours.

### **Devices and Radiological Health**

There are 244 Operational FTEs for FY 2006. This is an increase of 17 Operational FTEs from FY 2005. There is an MDUFMA User Fee increase for the Medical Device Preapproval program. There are increases for the Medical Device Postmarket Approval program as a result of Congressional directives in the FY 2006 Appropriation. Significant changes include:

Monitoring Devices of Foreign Origin – Import (82008): Consolidation of Filer Evaluation Hours, Follow-up to Refusal Hours, and Import Field Exams into Import Investigational Hours; Entry Review Hours increased from 20,315 to 23,111.

Inspection of Medical Device Manufacturers: GMP program (82845): Level 1 Inspections increased from 714 to 800; Level 2 Inspections increased from 483 to 535; Accredited Persons Inspections decreased from 135 to 95; Foreign Inspections increased from 163 to 207.

BSE Assignment (82Z005): Inspections reduced from 48 to 23.

Medical Device Premarket Approval and Postmarket Inspections (83001): MDUFMA User Fee Inspections increased from 86 to 99.

Bioresearch Monitoring (83808-11): Consolidation of Inspection Operations: Good Laboratory Practices, Institutional Review Board, Sponsor/Monitor, and Clinical Investigator Inspections have been consolidated for planning purposes into columns for Domestic and Foreign inspections. A weighted average inspection module has been formulated in conjunction with these consolidated operations to facilitate flexible planning.

Mammography Facilities Inspection (85014): Follow-up Inspections reduced from 36 to 9.

Optical Electronic Products (86001): Inspections reduced from 133 to 99.

Imported Electronic Products (86007): Consolidation of Filer Evaluation Hours, Follow-up to Refusal Hours, and Import Field Exams into Import Investigational Hours; Entry Review Hours increased from 4,654 to 10,195.

X-Ray Surveillance Program (86004): Inspections reduced from 27 to 8.

## Workplan Changes between FY 2005 and FY 2006

There have been significant changes in the FY 2006 Workplan. Many of the changes are the result of recommendations from ORA's Workplanning Workgroup, which consists of 10 representatives from the Field and Headquarters and has been meeting regularly throughout 2005. Other changes are the result of analysis by DPEM or suggestions and comments from the Field, Centers, and ORA Headquarters. The goal of any change is to improve the Workplan. Significant changes include:

- Resources are not specifically planned for import field exams, filer evaluations, and follow-up to refused entries. Instead, time for these operations is planned in blocks of import investigations hours. Districts should use the planned hours to conduct these and other operations as needed to cover import program priorities. **There are no changes in the way operations are to be reported into the data systems. As in previous years, Districts are still expected to report time under the specific operations of import field exams, filer evaluations, follow-up to refusals, and label exams.** ORA is committed to meeting any Performance Goals for import activities.
- To assist the Districts in providing the planned types of samples to the laboratories, many sample collection columns will have "guidance" columns to indicate the specific numbers of types of samples (for example micro vs. chem) that should be collected. It is important for collecting Districts to follow the sample planning, because the laboratories are prepared to accept not only total numbers of samples, but specific types within the total number.
- Where possible, adjustments have been made to the Workplan to account for the on-board operational staff within a District or Regional Laboratory. DPEM is utilizing the on-board staffing information from FACTS to determine the number of investigators, microbiologists, chemists, and engineers within each office. It is very important that the Field maintain their FACTS information to ensure that the data indicates the correct number of operational staff available to perform Workplan operations. This is a short-term attempt to address some of the staffing inequities caused by the ongoing hiring freeze. Offices that are understaffed in relation to their FY 2006 ceilings will not "lose" positions as a result of the adjustments. Offices that are currently overstaffed will not "gain" positions. The staffing levels for each office are determined by the Table of Organization (T.O.) which will not be affected by the Workplan adjustments. The adjustments in the FY 2006 Workplan are just a short-term attempt to plan "to where the people are" in order to maximize ORA's ability to complete operational activities.
- The investigator FTE conversion factor for foods, drugs, and biologics has been increased to 950 hours. The conversion factor for devices was already at 950 hours. **The total number of operational hours expected from an investigator remains at 1,160.** The 950 hours represents the portion of the 1,160 hours that is specifically planned in the Workplan for the operations of inspections, investigations, field exams, and sample collections. The remaining 210 operational hours (1,160-950) are for any other operational activities, such as recalls, emergency response, or unplanned inspections and investigations.

- In the device BIMO program, inspections will not be planned separately for IRBs, GLPs, CIs, and sponsor/monitors. Instead, each District will see one number for the total amount of domestic BIMO assignments that CDRH plans to issue to your District during FY 2006. Since these assignments are driven by the premarket approval process, the specific types of inspectional assignments are not well known at the time the Workplan issues. The Workplan should be used by each District as a guide to anticipate the total number of device BIMO assignments for the upcoming year.

The “Reasons for Change” spreadsheets provide a listing of programs compared to the FY 2005 ORA Field Workplan, and will enable you to identify where specific resource shifts and programmatic cuts occurred.

The FY 2006 Servicing Laboratories Table continues to reflect the laboratory servicing changes consistent with ORA’s Laboratory capabilities determined by the Division of Field Science. **Please review this table carefully before shipping any samples and note the latest changes.**

The FY 2006 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](mailto: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 2006 WORKPLAN - REASONS FOR CHANGE

OCTOBER 1, 2005

PAC	PROGRAM	FTEs FY 2005	FTEs FY 2006	FTEs Differ- ence	Reason for Change
03003	Import Acidified and Low Acid Canned Foods	13.9	14.8	0.9	Budget/Reprogramming
03037	Domestic & Imported Cheese and Cheese Products	28.5	26.3	-2.2	Budget/Reprogramming
03039	National Drug Residue Milk Monitoring Program	3.6	Cancelled		Program Cancelled
03803A	Domestic Acidified and Low Acid Canned Food	14.9	14.7	-0.2	Budget/Reprogramming
03803B	Domestic Food Safety	94.9	88.6	-6.3	Budget/Reprogramming
03819	Import Foods	288.8	282.2	-6.6	Budget/Reprogramming
03842	Domestic Fish and Fishery Products	75.0	57.3	-17.7	Budget/Reprogramming
03844	Import Seafood Products	101.4	99.7	-1.7	Budget/Reprogramming
03847H	Juice HACCP Inspection Program (HACCP)	14.0	14.2	0.2	Budget/Reprogramming
03R233	Foreign Inspection/Assessments	7.5	7.3	-0.2	Budget/Reprogramming
03F098	Import & Domestic Micro Assignments	27.8	24.3	-3.5	Budget/Reprogramming
03R839	Emergency Response to Foodborne Outbreaks	7.0	7.0	0.0	
03R843	Contract Management	22.8	16.0	-6.8	Budget/Reprogramming
03R816	ORA/Center Directed Research Projects	12.0	12.5	0.5	Budget/Reprogramming
03R845	Food Defense	11.6	38.0	26.4	Budget/Reprogramming
<b>03</b>	<b>Food Safety</b>	<b>723.7</b>	<b>702.9</b>	<b>-20.8</b>	
04004A,D	Pesticides & Industrial Chemical - Domestic/Import	85.1	77.1	-8.0	Budget/Reprogramming
04018	Chemotherapeutics In Seafood	17.9	17.3	-0.6	Budget/Reprogramming
04019A,B,C	Toxic Elements Foods & Foodware (Dom. and Imp.)	23.7	21.8	-1.9	Budget/Reprogramming
04839	Total Diet Study	23.4	23.4	0.0	
04R816	ORA/Center Directed Research Projects	9.6	10.8	1.2	Budget/Reprogramming
04R838	Forensic Evaluation and Sample Analysis	10.8	10.8	0.0	Budget/Reprogramming
04F800	Field Assignments for Chemical Contaminants	14.9	12.8	-2.1	Budget/Reprogramming
<b>04</b>	<b>Pesticides and Industrial Contaminants</b>	<b>185.4</b>	<b>174.0</b>	<b>-11.4</b>	
07001	Mycotoxins Domestic and Imported	29.6	25.3	-4.3	Budget/Reprogramming
07R816	ORA/Center Directed Research Projects	6.5	4.6	-1.9	Budget/Reprogramming
<b>07</b>	<b>Molecular Biology and Natural Toxins</b>	<b>36.1</b>	<b>29.9</b>	<b>-6.2</b>	
09006A,B	Imported Foods - Food & Color Additives	10.0	11.6	1.6	Budget/Reprogramming
09R816	ORA/Center Directed Research Projects	1.1		-1.1	Cancelled
<b>09</b>	<b>Food and Color Additives</b>	<b>11.1</b>	<b>11.6</b>	<b>0.5</b>	
18002	Retail Food Protection - State Program	26.0	26.0	0.0	
18003	Milk Safety Program	26.0	26.0	0.0	
18004	Molluscan Shellfish Evaluation	14.0	14.0	0.0	
18029 A -E	Interstate Travel Program	27.8	23.3	-4.5	Budget/Reprogramming
<b>18</b>	<b>Technical Assistance</b>	<b>93.8</b>	<b>89.3</b>	<b>-4.5</b>	
21002	Medical Foods Import and Domestic	5.1	3.7	-1.4	Budget/Reprogramming
21005	NLEA, Nutrient Sample Analysis	9.4	9.3	-0.1	Budget/Reprogramming
21006	Infant Formula Import and Domestic	6.3	5.6	-0.7	Budget/Reprogramming
21008	Dietary Supplements	19.5	15.9	-3.6	Budget/Reprogramming
21839	Selected Nutrient in Foods survey - Total Diet	4.2	4.2	0.0	
21R816	ORA/Center Directed Research Projects	2.4	1.3	-1.1	Budget/Reprogramming
<b>21</b>	<b>Food Composition, Standards, Labeling &amp; Economics</b>	<b>46.9</b>	<b>40.0</b>	<b>-6.9</b>	
29001	Cosmetics - Domestic and Import	8.1	7.2	-0.9	Budget/Reprogramming
<b>29</b>	<b>Colors and Cosmetics Technology</b>	<b>8.1</b>	<b>7.2</b>	<b>-0.9</b>	
<b>TOTAL FOR PPS 03, 04, 07, 09, 18, 21, 29</b>		<b>1105.2</b>	<b>1055.0</b>	<b>-50.2</b>	

# CBER: FY 2006 Workplan - Reason For Change

<b>PAC</b>	<b>Program/Assignment</b>	<b>BASE FTEs FY 2005</b>	<b>BASE FTEs FY 2006</b>	<b>Differ- ence</b>	<b>Reason for Change</b>
41002	Tissue Establishments	15.5	15.5		
41808	Good Laboratory Practices	*	*		
41809	Institutional Review Board	*	*		
41810	Sponsors, CROs, Monitors	*	*		
41811	Clinical Investigators *	7.4	7.4		
<b>41</b>	<b>Human Cellular, Tissue &amp; Gene Therapies</b>	<b>22.9</b>	<b>22.9</b>		
42001F,G	Blood Bank Inspections	57.0	57.0		
	Foreign Blood Bank Inspections	1.0	1.0		
	Technical Assistance & Coordination	2.5	2.5		
42002,A	Source Plasma Establishments	11.4	10.4	<b>-1.0</b>	Budget Reduction
42007	Exam of Biological Products - Import	4.0	3.5	<b>-0.5</b>	Budget Reduction
42008,A	Licensed Viral Marker Test Kits	3.0	3.0		
42809	Institutional Review Board	*	*		
42810	Sponsors, CROs, Monitors	*	*		
42811	Clinical Investigators *	3.5	3.5		
42845A,B,C	Medical Device Manufacturers (Biol) (was PAC 42830)	2.5	2.0	<b>-0.5</b>	Budget Reduction
42848A,F,G	Plasma Derivatives of Human Origin (was PAC 42006)	3.0	3.0		
<b>42</b>	<b>Blood &amp; Blood Products</b>	<b>87.9</b>	<b>85.9</b>	<b>-2.0</b>	
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		
<b>45</b>	<b>Vaccines &amp; Allergenic Products</b>	<b>8.2</b>	<b>8.2</b>		
	<b>BIOLOGICS TOTALS</b>	<b>119.0</b>	<b>117.0</b>	<b>-2.0</b>	

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

## CDER: FY 2006 WORKPLAN - REASON FOR CHANGE

PAC	PROGRAM/ASSIGNMENTS	FTEs 2005	FTEs 2006	FTE DIFF	Reason for CHANGE
46832	NDA Pre-Approval/Meth Valid.(Domestic)	17.0	14.0	-3.0	<i>center/budget decrease</i>
46832	NDA Pre-Approval/Meth. Valid. (Foreign)	15.0	15.0	0.0	
46R845	<i>Counter-terrorism Initiative</i>				
46	<b>New Drug Evaluation</b>	<b>32.0</b>	<b>29.0</b>	<b>-3.0</b>	
48001	In Vivo Bioequivalence (Domestic)	5.4	5.4	0.0	
48001A	In Vivo Bioequivalence Foreign)	4.6	4.6	0.0	
48808	Good Laboratory Practices	5.5	4.2	-1.3	<i>budget decrease</i>
48809	Institutional Review Boards	9.1	6.9	-2.2	<i>budget decrease</i>
48810	Sponsors, Contract Research Orgs./Monitors	2.7	2.7	0.0	
48811	Clinical Investigators	27.0	26.5	-0.5	<i>budget decrease</i>
48	<b>Bioresearch Monitoring</b>	<b>54.3</b>	<b>50.3</b>	<b>-4.0</b>	
52002	New Drugs RX Without Approved NDAs	5.5	0.0	-5.5	<i>Reprogrammed under new PPS</i>
52832	ANDA Pre-Approval/Meth Valid (Domestic)	24.7	18.7	-6.0	<i>budget decrease</i>
52832	ANDA Pre-Approval/Meth Valid (Foreign)	12.1	11.1	-1.0	<i>budget decrease</i>
52R845	<i>Counter-terrorism Initiative</i>				
52R816	ORA/Center Directed Research Project	1.0	0.0		<i>Absorbed into 56R816</i>
52	<b>Generic Drug Evaluation</b>	<b>42.3</b>	<b>29.8</b>	<b>-12.5</b>	
53001A,B	Adverse Drg. Exp. Rpt. Regul.Domestic	6.3	8.3	2.0	<i>Reprogramming of Medical Errors</i>
53001A,B	Adverse Drg. Exp. Rpt. Regul.Foreign	1.7	1.7	0.0	
53001A,B	Medication Errors	2.0	0.0	-2.0	<i>Reprogramming</i>
53R845	<i>Counter-terrorism Initiative</i>				
53	<b>Postmarket Surv. &amp; Epidemiology</b>	<b>10.0</b>	<b>10.0</b>	<b>0.0</b>	
56002	Drug Process Inspections-Domestic non-gas	132.1	134.1	2.0	<i>Reprogramming</i>
56002E	Drug Process Inspections-Domestic-gas	5.0	5.0	0.0	
56002	Drug Process Inspections-Foreign Non-MRA	18.0	18.0	0.0	
56008A	Drug Prdt. Surveillance- Domestic Surveys	28.7	25.7	-3.0	<i>budget decrease</i>
56008H	Drug Product Surveillance- Import Drugs	41.1	41.1	0.0	
56021A/B	Drug Quality Reporting Systems-DQRS	5.0	4.0	-1.0	<i>budget decrease</i>
56022	Prescription Drug Marketing - Ctr Initiated	2.0	2.0	0.0	
56D015	Pharmacy Compounding Assignments	3.0	4.0	1.0	<i>Reprogramming</i>
56R816	ORA/Center Directed Research Project	3.0	3.6	0.6	<i>Reprogramming of 52R816</i>
56R838	Forensic Evaluation/Sample Analysis	9.0	9.0	0.0	
56	<b>Drug Quality Assurance</b>	<b>234.9</b>	<b>246.5</b>	<b>11.6</b>	
61003	OTC Drug Monographs	2.0	0.0	-2.0	<i>Reprogrammed under new PPS</i>
61	<b>OTC DRUG EVALUATION</b>	<b>2.0</b>	<b>0.0</b>	<b>-2.0</b>	
63001	Internet, Health Fraud, & OTC Monographs (NEW)	3.5	8.0	4.5	<i>Reprogramming</i>
63002	New Drugs RX Without Approved NDAs (NEW)	4.0	4.0	0.0	
63	<b>Unapproved and Misbranded Drugs</b>	<b>7.5</b>	<b>12.0</b>	<b>4.5</b>	
88---	Shelf Life Extension Projects	12.0	12.0	0.0	
88	<b>Interagency Cooperative Activities</b>	<b>12.0</b>	<b>12.0</b>	<b>0.0</b>	
<b>CDER Total Operational FTEs</b>		<b>395.0</b>	<b>389.6</b>	<b>-5.4</b>	

## CVM: FY 2006 Workplan - Reason For Change

PAC	Program/Assignment	FTEs FY 2005	FTEs FY 2006	FTEs Difference	Reason for Change
68001	NADA Preapproval Inspections	5.7	5.7	0.0	
	Foreign Inspections	(2.0)	(3.5)		
68808*	(Pre-Market) GLP	2.9	2.9	0.0	
68810*	Sponsors, Contract Research Org. (CROs), Monitors	*	*		
68811	(Pre-Market) Clinical Investigators	2.1	2.1	0.0	
<b>68</b>	<b>Pre-Approval Evaluation of Animal Drugs and Food Additives</b>	<b>10.7</b>	<b>10.7</b>	<b>0.0</b>	
71001/71R841	Drug Process Inspections	10.9	9.6	-1.3	Budget Reduction
71003A-H	Feed Contaminants	16.3	14.1	-2.2	Budget Reduction
71004/A	Feed Manufacturing	6.5	6.1	-0.4	Budget Reduction
71006	Illegal Tissue Residues in Meat & Poultry	12.0	12.0	0.0	
71009	Ruminant Feed Ban Rule (BSE) Program	66.8	66.8	0.0	
71R816	ORA/Center Directed Research Projects	6.0	5.8	-0.2	Reprogramming
71R831/71R838	Forensic Evaluation & Analysis	0.7	0.7	0.0	
71V800	Center Initiated Assignments	3.0	1.0	-2.0	Budget Reduction
<b>71</b>	<b>Monitoring of Marketed Animal Drugs, Feeds, and Devices</b>	<b>122.2</b>	<b>116.1</b>	<b>-6.1</b>	
<b>TOTAL Operational FTEs</b>		<b>132.9</b>	<b>126.8</b>	<b>-6.1</b>	

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

## CDRH: FY 2006 WORKPLAN - REASONS FOR CHANGE

PAC	PROGRAM/ASSIGNMENT	FTEs FY 2005	FTEs FY 2006	FTEs Differ- ence	REASON FOR CHANGE
81010	Med Dev Problem Reporting-MDR F/U	0.5	0.5	0.0	
<b>81</b>	<b>Postmarket Assurance: Devices</b>	<b>0.5</b>	<b>0.5</b>	<b>0.0</b>	
82008	Monitoring Device of Foreign Origin-Imports	25.0	28.1	3.1	Reprogramming Increase
82845 A,B,C,G,S	Inspection of Medical Dev Mfgs: GMP	73.8	87.3	13.5	Budget Increase
82845B	Foreign Inspection of Medical Dev Mfgs: GMP	11.1	14.2	3.1	Budget Increase
82845J,P	Auditing of Accredited Persons: MDUFMA	7.5	5.3	-2.2	Reprogramming Decrease
82Z002	Condom Assignment	5.0	4.3	-0.7	Reprogramming to Import programs
82Z003	Mfgs & Importers of Surgical/Exam Gloves	9.5	8.1	-1.4	Reprogramming to Import programs
82Z005	BSE Assignment	1.0	0.5	-0.5	Reprogramming to Import programs
82Z800	Center Initiated Assignments	2.0	1.5	-0.5	Reprogramming to Import programs
82R816	ORA/Center Directed Research Projects	0.9	2.0	1.1	Div of Field Science research increase
82R838	Forensic Analysis	0.3	0.3	0.0	
<b>82</b>	<b>Compliance: Devices</b>	<b>136.1</b>	<b>151.6</b>	<b>15.5</b>	
83001/A	Med Dev Premkt Approval & Postmkt Inspec	7.8	8.8	1.0	MDUFMA User Fee Budget Increase
83001/A	Foreign Med Dev Premkt Approval & Postmkt Insp	3.2	3.2	0.0	
83808-11	Bioresearch Monitoring	25.3	25.3	0.0	
<b>83</b>	<b>Project Evaluation: Devices</b>	<b>36.3</b>	<b>37.3</b>	<b>1.0</b>	
84Z002	Test Method Development & Evaluation	3.7	3.7	0.0	
84R816	ORA/Center Directed Research Projects	1.4	1.4	0.0	
<b>84</b>	<b>Science: Devices</b>	<b>5.1</b>	<b>5.1</b>	<b>0.0</b>	
85014 A,C,F	Mammography Facilities Inspection Program	15.5	14.8	-0.7	Reprogramming to Import programs
85014	Foreign Mammography Facilities Inspections	0.1	0.1	0.0	
<b>85</b>	<b>Mammography Quality Standards Act (MQSA)</b>	<b>15.6</b>	<b>14.9</b>	<b>-0.7</b>	
86001	Inspection of Mfgs of Laser Products	5.7	4.2	-1.5	Reprogramming to Import programs
86001	Foreign Inspection of Mfgs of Laser Products	0.2	0.2	0.0	
86002	Field Implementation of Sunlamp Products	0.8	0.3	-0.5	Reprogramming to Import programs
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	1.0	-1.0	Reprogramming to Import programs
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	10.2	4.7	Reprogramming Increase
86008	Med Dev & Rad Hlth Use Control & Pol Implem	4.6	3.6	-1.0	Reprogramming to Import programs
86009	Emergency Planning & Response Activities	2.0	2.0	0.0	
<b>86</b>	<b>Radiation Control &amp; Health Safety Act (RCHSA)</b>	<b>34.0</b>	<b>34.7</b>	<b>0.7</b>	
<b>Total Operational FTEs</b>		<b>227.6</b>	<b>244.1</b>	<b>16.5</b>	

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# FY 2006

## PART I - PLANNING GUIDANCE



**DEPT OF HEALTH & HUMAN SERVICES**



**FOOD & DRUG ADMINISTRATION**

**PROGRAM PLANNING & WORKFORCE**

**MANAGEMENT BRANCH**

**ORA/ORM/DPEM**

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# PART I - PLANNING GUIDANCE

## TABLE OF CONTENTS



<b>GENERAL PLANNING GUIDANCE</b>	<b>PAGE NO.</b>
<b>A. PLAN OVERVIEW</b> .....	<b>2</b>
1. Objective.....	2
2. An Overview of FDA's Program and Project Structure (PPS).....	2
3. Terms and Definitions.....	3
4. Resource Management.....	4
5. Work Assignment to Field Laboratories (Laboratory Specialization).....	6
6. Relation to Other Plans.....	6
a. Annual FDA Program Planning Process.....	6
b. Annual FDA Congressional Budget Request.....	6
<b>B. FY 2006 GUIDANCE</b> .....	<b>8</b>
1. Compliance Policy and Philosophy.....	8
2. ORA Contacts for Workplan-Related Problems.....	8
3. FY 2006 Resource Activities.....	9
4. Product Code.....	9
5. National Experts.....	9
6. Team Biologics.....	9
7. Emergencies.....	9
<b>C. REPORTING REQUIREMENTS</b> .....	<b>10</b>
1. Reporting of Operations.....	10
2. Projects with No Planned Field Resources.....	10
3. Data Reporting.....	10
4. Hard Copy Reporting.....	10
<b>D. REVISIONS TO THE FY 2006 FIELD WORKPLAN - PLANNING BULLETINS</b> .....	<b>11</b>
<b>E. OFFICIAL ESTABLISHMENT INVENTORY (OEI) DEVELOPMENT &amp; MAINTENANCE</b> .....	<b>11</b>
<b>APPENDIXES</b>	<b>PAGE NO.</b>
I. PROGRAM AND PROJECT STRUCTURE - FY 2006 PROJECT LIST.....	I-1
II. COMPARISON OF CHANGES FROM FY 2005 TO FY 2006 PROGRAM & PROJECT STRUCTURE.....	II-1
III. SERVICING LABORATORIES.....	III-1
IV. RESOURCES FOR PROGRAM OPERATIONS AND NON-PROGRAM ACTIVITIES.....	IV-1

# 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, 2005 to September 30, 2006.

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 2006, 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). <ul style="list-style-type: none"> <li>a. <b>General Guidance Programs:</b> 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.</li> <li>b. <b>Specific Action Programs, Assignments and/or Special Surveys:</b> <ul style="list-style-type: none"> <li>(1) <b>Industry and Product Regulatory Survey and Action Programs</b> - provide guidance and direction in approaching certain problems and an operational schedule with specific assignments to the field.</li> </ul> </li> </ul>	Import Foods - General Program
		Import and Domestic Micro Assignment

### 3. TERMS AND DEFINITIONS (Continued)

TERM	DEFINITION	EXAMPLE
	<p>(2) <b>Surveys</b> – provide guidance and direction to enable the field to perform surveys according to a specific operational schedule.</p> <p>In general, the compliance programs and assignments serve the following purposes:</p> <ul style="list-style-type: none"> <li>a. Recognize and deal with problem areas.</li> <li>b. Determine the degree of noncompliance with respect to recognized problems.</li> <li>c. Gather data for the promulgation of regulations or establishing administrative guidelines.</li> <li>d. Direct numbers/hours, and kinds of operations to be performed by field offices.</li> </ul>	Drug Product Surveillance-Center Initiated Surveys
Operations	The quantifiable activities to be done by field personnel.	Inspections, Sample Collections, Samples to be Analyzed, etc.

Appendix I lists all FY 2006 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. 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 2006 ORA Workplan reflects assignment of work in regional laboratories (Arkansas, Northeast, Pacific Northwest, Pacific Southwest, and Southeast); specialty laboratories (Forensic Chemistry Center (FCC), Philadelphia, San Juan, and Winchester Engineering and Analytical Center (WEAC)); or district laboratories (Denver, Detroit, Kansas City, San Francisco).

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

## 6. RELATION TO OTHER PLANS

The FY 2006 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 2006 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 2006 GUIDANCE**

This section provides guidance in relation to programmatic objectives and operational requirements related to the FY 2006 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 was replaced in FY 2005 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 2006 RESOURCE ACTIVITIES

The FY 2006 ORA Field Workplan is based on a FTE level of 3,328 FTEs which is a decrease of 157 FTEs from the FY 2005 ORA Field Workplan level of 3,485 FTEs. The FY 2006 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 2006 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 2006. 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 2006, 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 2006 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.

**PPS  
PROGRAM AND PROJECT STRUCTURE  
FY 2006 PROJECT LIST**

**FOOD AND COSMETICS**

**MICROBIOLOGICAL SAFETY OF FOODS**

- 03 Foodborne Biological Hazards
- 18 Technical Assistance: Food and Cosmetics

**CHEMICAL SAFETY OF FOODS**

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

**NUTRIENT QUALITY AND FOOD LABELING**

- 21 Food Composition, Standards, Labeling, and Economics

**COSMETICS SAFETY AND LABELING**

- 29 Colors and Cosmetics Technology

**BIOLOGICS**

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

**HUMAN DRUGS**

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

**ANIMAL DRUGS AND FEEDS**

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

**MEDICAL DEVICES & RADIOLOGICAL HEALTH**

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

**NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH**

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

**ORA PROJECTS FOR FIELD REPORTING PURPOSES ONLY**

- 88 ICA (Interagency Cooperative Activities)
- \*99 General

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\*No Resources Planned in FY 2006  
OCTOBER 1, 2005

**SCHEMATIC  
PROGRAM AND PROJECT STRUCTURE**

<u>FY 2006</u>	<u>FY 2005</u>
<u>NO.</u> <u>NAME</u>	<u>NO.</u> <u>NAME</u>
<b>FOOD AND COSMETICS</b>	
<b><u>Microbiological Safety of Foods</u></b>	
03    Foodborne Biological Hazards	
18    Technical Assistance: Food and Cosmetics	
<b><u>Chemical Safety of Foods</u></b>	
04    Pesticides and Chemical Contaminants	
07    Molecular Biology and Natural Toxins	
09    Food and Color Additive Petition Review and Policy Development	
	<    No Change
<b><u>Nutrient Quality &amp; Food Labeling</u></b>	
21    Food Composition, Standards, Labeling and Economics	
<b><u>Cosmetics Safety &amp; Labeling</u></b>	
29    Colors and Cosmetics Technology	

**SCHEMATIC  
PROGRAM AND PROJECT STRUCTURE**

<b><u>FY 2006</u></b>			<b><u>FY 2005</u></b>	
<b><u>NO.</u></b>	<b><u>NAME</u></b>		<b><u>NO.</u></b>	<b><u>NAME</u></b>
<b>BIOLOGICS</b>				
41	Human Cellular, Tissue and Gene Therapies	}		
42	Blood and Blood Products		<	No Change
45	Vaccines and Allergenic Products			
<b>HUMAN DRUGS</b>				
46	New Drug Evaluation	}		
48	Bioresearch Monitoring: Human Drugs			
52	Generic Drug Evaluation			
53	Postmarketing Surveillance and Epidemiology: Human Drugs		<	63 was previously called "Health Fraud: Human Drugs"
56	Drug Quality Assurance			
61	Over-the-Counter Drug Evaluation			
63	Unapproved and Misbranded Drugs			

**SCHEMATIC  
PROGRAM AND PROJECT STRUCTURE**

<b><u>FY 2006</u></b>		<b><u>FY 2005</u></b>	
<u>NO.</u>	<u>NAME</u>	<u>NO.</u>	<u>NAME</u>

**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	

**SCHEMATIC  
PROGRAM AND PROJECT STRUCTURE**

<u><b>FY 2006</b></u>		<u><b>FY 2005</b></u>	
<u>NO.</u>	<u>NAME</u>	<u>NO.</u>	<u>NAME</u>

**NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH**

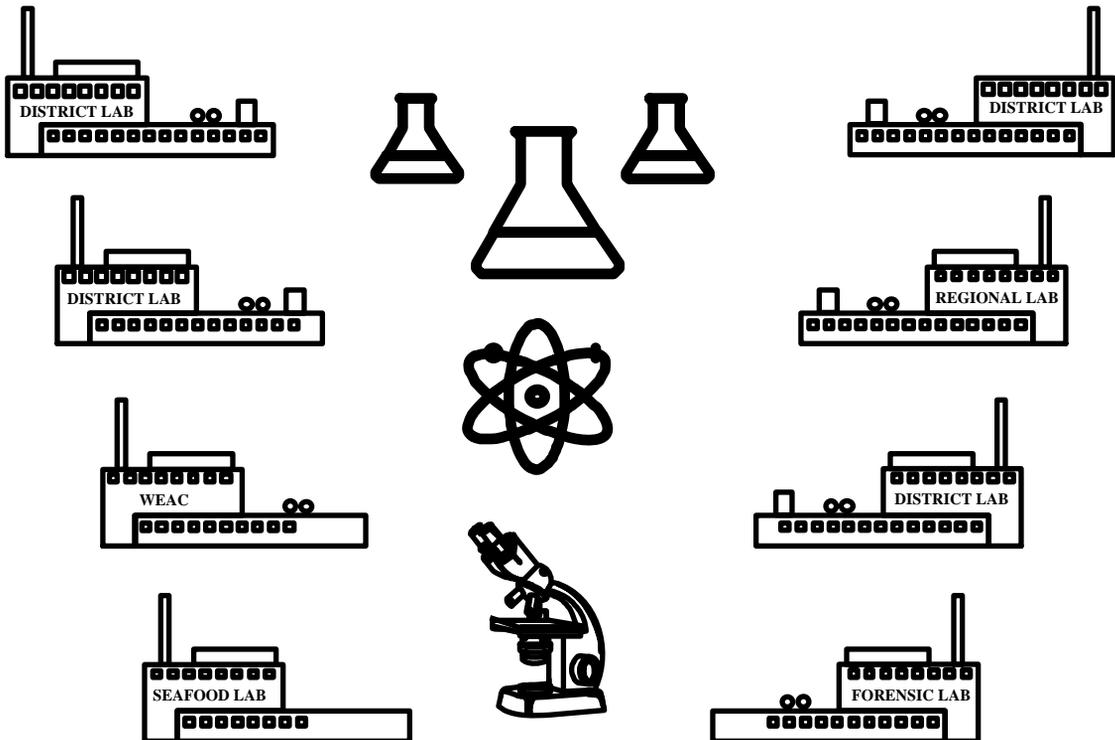
*34	Integrated Research for Health Protection: NCTR	}	< No Change
*35	Methods Development for Regulatory Needs: NCTR		

**ORA**

88	ICA (Interagency Cooperative Activities)	}	< No Change
*99	General		

**\* No Resources Planned in FY 2006**

# FY 2006 SERVICING LABORATORIES



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

**OCTOBER 2005**









# SERVICING LABORATORIES

\*\* FY 2006 \*\*

## MICROBIOLOGISTS

<i>REGIONS &gt;&gt;&gt;&gt;&gt;&gt;&gt;&gt;&gt;</i>		NORTHEAST		CENTRAL						SOUTHEAST				SOUTHWEST				PACIFIC				
		NWE	NYK	BLT	CHI	CIN	DET	MIN	NWJ	PHI	ATL	FLA	NOL	SJN	DAL	DEN	KAN	SWID	SWID	LOS	SAN	SEA
<i>COLLECTING DISTRICT &gt;&gt;&gt;&gt;&gt;</i>														TX&NM CA&AZ								
<i>ANIMAL DRUGS &amp; FEED</i>																						
<b>71 POST APPR MON ANIMAL DRUGS FDS</b>																						
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-
<b>MEDICAL DEV &amp; RAD HLTH</b>																						
<b>81 POSTMKT ASSURANCE:DEVICES</b>																						
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-
<b>82 COMPLIANCE: DEVICES</b>																						
MON DEV FOREIGN-STERILE	82008	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MED DEV MFG STERILITY	82845S	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MED DEV MFG BIOBURDEN	82845S	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MED MFG BIOINDICATOR	82845S	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS-DISINFEC	82845C	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	-DEN-	--	--	-DEN-	-DEN-	-DEN-
MFRS-ANTI-SERA	82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
MFRS-IN VITRO DIAG	82845C	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
CTR INIT ASSIGN-STER	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
CTR INIT ASGN-MEDIA TEST	82Z800	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-	-WEA-
<b>84 SCIENCE: DEVICES</b>																						
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.

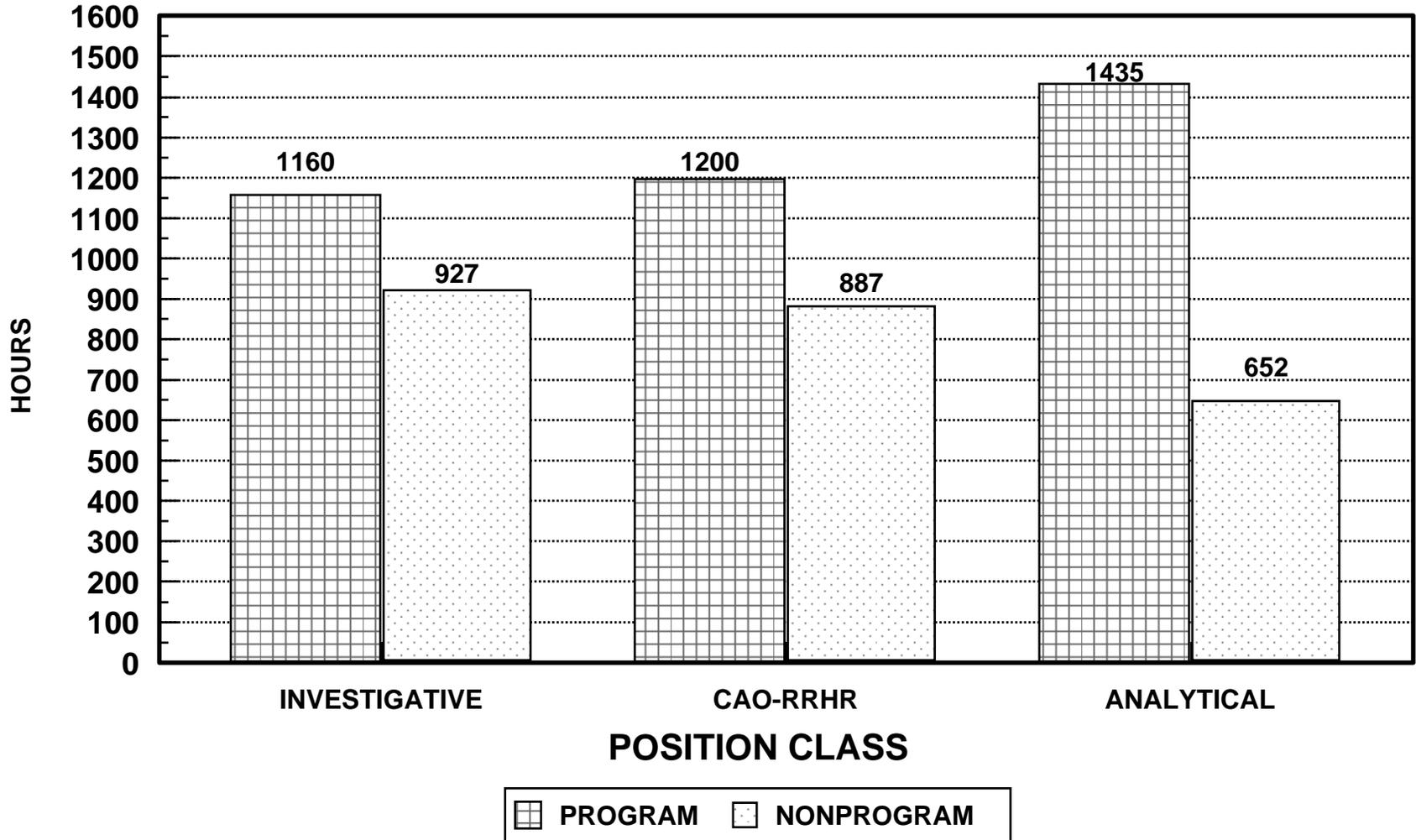
SWID - CA & AZ Column: Samples collected in CA or AZ will be analyzed by the Labs listed.



# ALL CENTERS - ALL PERSONNEL

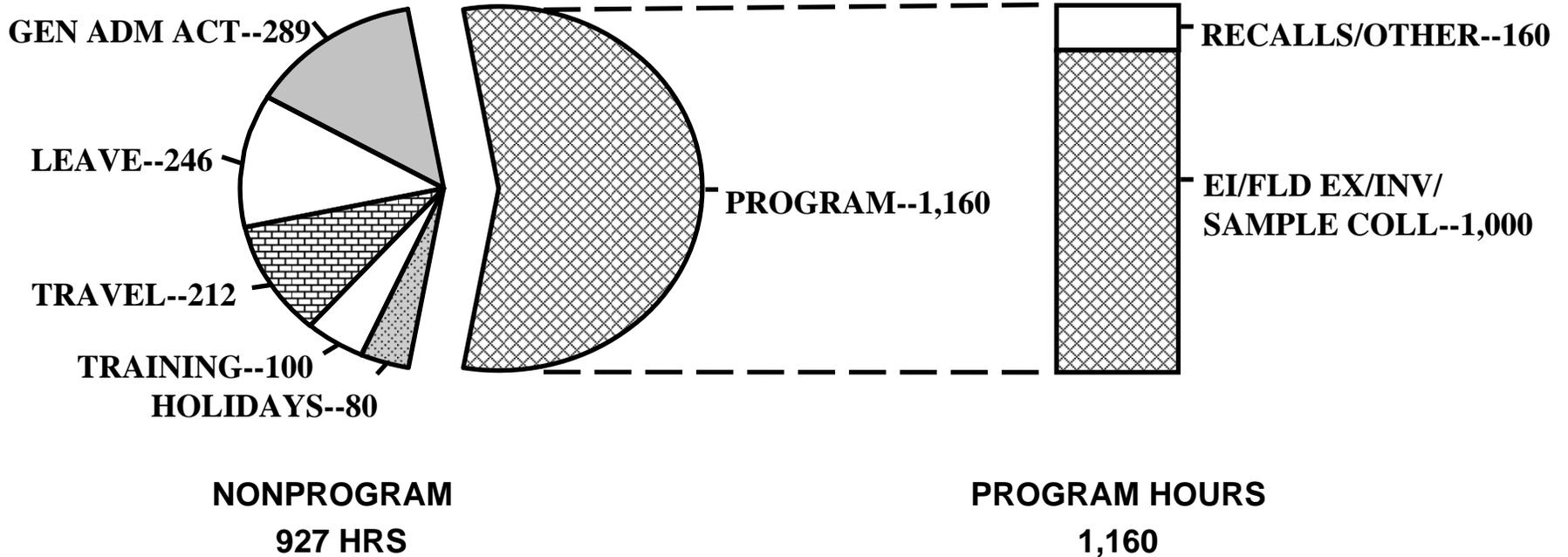
## FY 2006 PROGRAM/NONPROGRAM OPERATION TIME

### POSITION CLASS TOTALS - 2087 HOURS



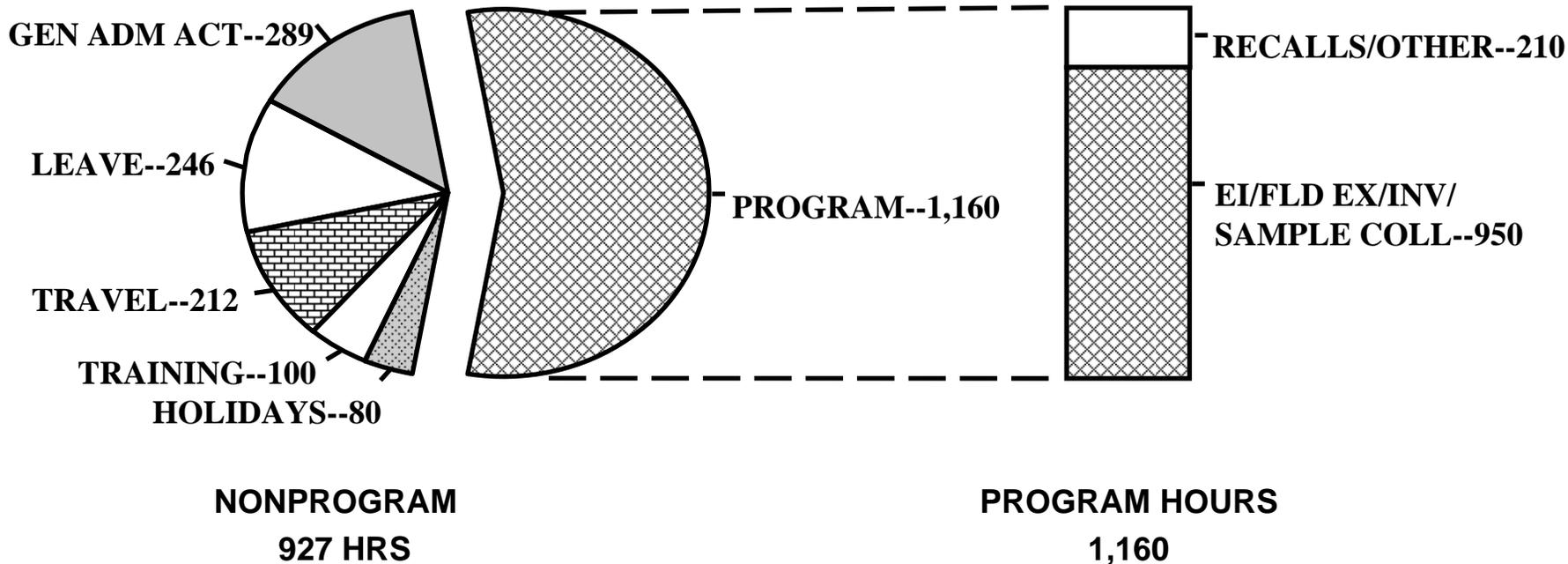
# CVM ONLY - INVESTIGATIVE/INSPECTIONAL FY 2006 PROGRAM/NONPROGRAM TIME

- 2,087 TOTAL HOURS -



# INVESTIGATIVE/INSPECTIONAL FY 2006 PROGRAM/NONPROGRAM TIME

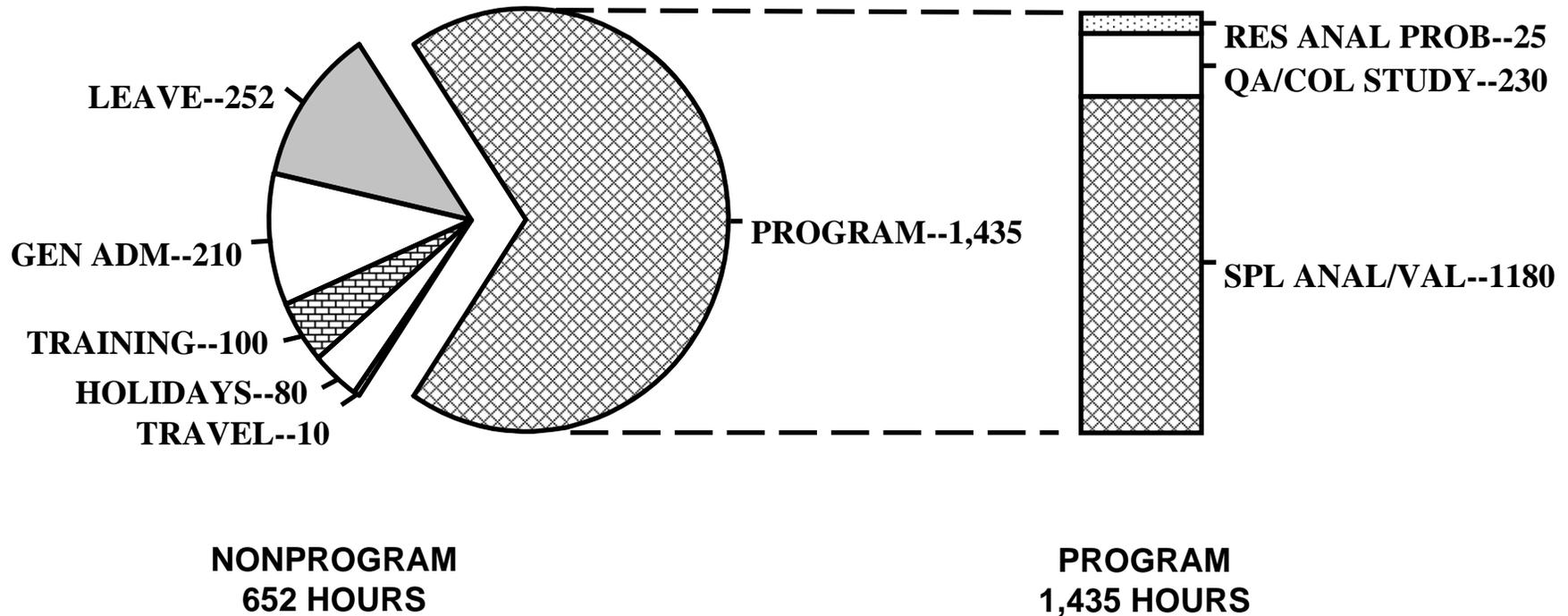
- 2,087 TOTAL HOURS -



# ALL CENTERS - ANALYTICAL

## FY 2006 PROGRAM/NONPROGRAM TIME

- 2087 TOTAL HOURS -



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# **FY 2006**

## **PART II - WORKPLAN SUMMARY OPERATIONS & POSITIONS**



**DEPT OF HEALTH & HUMAN SERVICES**



**FOOD & DRUG ADMINISTRATION**

**PROGRAM PLANNING & WORKFORCE**

**MANAGEMENT BRANCH**

**ORA/ORM/DPEM**

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# **PART II**

# **WORKPLAN SUMMARY**



## **POSITION CLASS**

**COMBINED ANALYTICAL & DISTRICT RESEARCH**















WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: NE REGN

FIELD	INVEST	DIST RES &	DIST REG &	DIST REG &	DISTRICT	RESEARCH	TOTALS	
		ANALYTICAL	ANALYTICAL	ANALYTICAL			OPR FTE'S	PERSNHR
		CHEM	MICRO	ENG/PHY	RESEARCH	CENTER		
TOTAL	219.28	67.26	48.58	12.16	0.00	1.41	348.69	372405.70
FOOD SAFETY/COS	119.92	42.82	41.72	0.00	0.00	0.00	204.46	221412.40
03	93.46	13.35	41.43	0.00	0.00	0.00	148.24	158417.50
04	6.00	21.57	0.00	0.00	0.00	0.00	27.57	31160.00
07	1.34	2.99	0.00	0.00	0.00	0.00	4.33	4812.00
09	1.00	3.35	0.00	0.00	0.00	0.00	4.35	4900.20
18	13.73	0.00	0.11	0.00	0.00	0.00	13.84	15773.50
21	3.38	0.00	0.00	0.00	0.00	0.00	3.38	3199.60
29	1.01	1.56	0.18	0.00	0.00	0.00	2.75	3149.60
BIOLOGICS	10.36	0.00	0.00	0.00	0.00	0.00	10.36	9997.30
41	2.24	0.00	0.00	0.00	0.00	0.00	2.24	2125.30
42	7.78	0.00	0.00	0.00	0.00	0.00	7.78	7551.60
45	0.34	0.00	0.00	0.00	0.00	0.00	0.34	320.40
HUMAN DRUGS	45.73	14.99	1.53	0.00	0.00	0.00	62.25	63214.50
46	2.14	2.76	0.09	0.00	0.00	0.00	4.99	5134.00
48	5.57	0.00	0.00	0.00	0.00	0.00	5.57	5288.40
52	2.58	5.85	0.00	0.00	0.00	0.00	8.43	9107.00
53	1.63	0.00	0.00	0.00	0.00	0.00	1.63	1548.00
56	32.21	6.31	1.44	0.00	0.00	0.00	39.96	40541.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.60	0.07	0.00	0.00	0.00	0.00	1.67	1596.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	13.84	4.18	0.44	0.00	0.00	0.00	18.46	20326.10
68	0.92	0.04	0.00	0.00	0.00	0.00	0.96	958.60
71	12.92	4.14	0.44	0.00	0.00	0.00	17.50	19367.50
DEVICES & RAD H	29.43	5.27	4.89	12.16	0.00	1.41	53.16	57455.40
81	0.16	0.03	0.02	0.03	0.00	0.00	0.24	238.90
82	19.43	5.24	4.19	3.99	0.00	0.00	32.85	35004.00
83	4.37	0.00	0.00	0.00	0.00	0.00	4.37	4143.00
84	0.00	0.00	0.68	3.04	0.00	1.41	5.13	6050.00
85	2.06	0.00	0.00	0.00	0.00	0.00	2.06	2389.00
86	3.41	0.00	0.00	5.10	0.00	0.00	8.51	9630.50



















WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: CE REGN

FIELD	INVEST	DIST RES &	DIST REG &	DIST REG &	DISTRICT	RESEARCH	TOTALS	
		ANALYTICAL	ANALYTICAL	ANALYTICAL			OPR FTE'S	PERSNHR
		CHEM	MICRO	ENG/PHY	RESEARCH	CENTER		
TOTAL	351.35	55.67	0.00	0.00	0.00	0.00	407.02	411579.80
FOOD SAFETY/COS	132.32	13.71	0.00	0.00	0.00	0.00	146.03	149769.10
03	92.78	0.94	0.00	0.00	0.00	0.00	93.72	92155.10
04	6.54	11.77	0.00	0.00	0.00	0.00	18.31	20401.20
07	2.74	0.00	0.00	0.00	0.00	0.00	2.74	2596.00
09	0.52	0.98	0.00	0.00	0.00	0.00	1.50	1645.80
18	22.88	0.00	0.00	0.00	0.00	0.00	22.88	26423.00
21	6.07	0.00	0.00	0.00	0.00	0.00	6.07	5760.60
29	0.79	0.02	0.00	0.00	0.00	0.00	0.81	787.40
BIOLOGICS	35.96	0.00	0.00	0.00	0.00	0.00	35.96	34343.40
41	7.85	0.00	0.00	0.00	0.00	0.00	7.85	7457.00
42	27.06	0.00	0.00	0.00	0.00	0.00	27.06	25895.20
45	1.05	0.00	0.00	0.00	0.00	0.00	1.05	991.20
HUMAN DRUGS	91.93	40.93	0.00	0.00	0.00	0.00	132.86	135124.40
46	7.32	3.86	0.00	0.00	0.00	0.00	11.18	11128.00
48	14.70	0.00	0.00	0.00	0.00	0.00	14.70	13953.70
52	5.44	4.38	0.00	0.00	0.00	0.00	9.82	10030.00
53	3.86	0.00	0.00	0.00	0.00	0.00	3.86	3666.00
56	58.25	23.49	0.00	0.00	0.00	0.00	81.74	83252.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.36	0.20	0.00	0.00	0.00	0.00	2.56	2474.00
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
ANIMAL D & F	33.34	0.73	0.00	0.00	0.00	0.00	34.07	34751.30
68	3.75	0.00	0.00	0.00	0.00	0.00	3.75	3747.60
71	29.59	0.73	0.00	0.00	0.00	0.00	30.32	31003.70
DEVICES & RAD H	57.80	0.30	0.00	0.00	0.00	0.00	58.10	57591.60
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	33.20
82	33.00	0.30	0.00	0.00	0.00	0.00	33.30	32232.10
83	12.00	0.00	0.00	0.00	0.00	0.00	12.00	11383.30
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.54	0.00	0.00	0.00	0.00	0.00	4.54	5274.00
86	8.22	0.00	0.00	0.00	0.00	0.00	8.22	8669.00







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







WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: SE REGN

FIELD	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHR
TOTAL	217.36	63.26	42.12	0.00	0.00	3.00	325.74	342090.20
FOOD SAFETY/COS	91.17	42.53	38.93	0.00	0.00	3.00	175.63	192170.60
03	64.36	9.58	36.56	0.00	0.00	0.00	110.50	118453.30
04	5.17	13.06	0.00	0.00	0.00	0.00	18.23	20318.50
07	1.41	6.22	0.00	0.00	0.00	3.00	10.63	12222.00
09	0.16	0.46	0.00	0.00	0.00	0.00	0.62	692.80
18	17.14	0.00	0.24	0.00	0.00	0.00	17.38	19610.00
21	2.44	12.97	1.60	0.00	0.00	0.00	17.01	19510.60
29	0.49	0.24	0.53	0.00	0.00	0.00	1.26	1363.40
BIOLOGICS	20.81	0.00	0.00	0.00	0.00	0.00	20.81	19977.60
41	4.31	0.00	0.00	0.00	0.00	0.00	4.31	4097.40
42	15.64	0.00	0.00	0.00	0.00	0.00	15.64	15065.80
45	0.86	0.00	0.00	0.00	0.00	0.00	0.86	814.40
HUMAN DRUGS	62.06	18.41	2.18	0.00	0.00	0.00	82.65	83088.10
46	3.69	1.10	0.00	0.00	0.00	0.00	4.79	4646.00
48	9.51	0.00	0.00	0.00	0.00	0.00	9.51	9025.00
52	3.88	1.14	0.00	0.00	0.00	0.00	5.02	4865.00
53	1.75	0.00	0.00	0.00	0.00	0.00	1.75	1662.00
56	40.90	13.01	2.18	0.00	0.00	0.00	56.09	56951.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.33	0.16	0.00	0.00	0.00	0.00	2.49	2399.00
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
ANIMAL D & F	10.19	2.32	1.01	0.00	0.00	0.00	13.52	14122.70
68	1.83	0.05	0.00	0.00	0.00	0.00	1.88	1879.20
71	8.36	2.27	1.01	0.00	0.00	0.00	11.64	12243.50
DEVICES & RAD H	33.13	0.00	0.00	0.00	0.00	0.00	33.13	32731.20
81	0.05	0.00	0.00	0.00	0.00	0.00	0.05	44.70
82	19.53	0.00	0.00	0.00	0.00	0.00	19.53	18930.60
83	6.43	0.00	0.00	0.00	0.00	0.00	6.43	6093.30
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.49	0.00	0.00	0.00	0.00	0.00	2.49	2888.00
86	4.63	0.00	0.00	0.00	0.00	0.00	4.63	4774.60













WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: SW REGN

FIELD	INVEST	DIST RES &	DIST REG &	DIST REG &	DISTRICT	RESEARCH	TOTALS	
		ANALYTICAL	ANALYTICAL	ANALYTICAL			OPR FTE'S	PERSNHRS
		CHEM	MICRO	ENG/PHY	RESEARCH	CENTER		
TOTAL	217.75	101.49	35.97	0.00	0.00	9.00	364.21	391359.40
FOOD SAFETY/COS	96.86	81.91	31.24	0.00	0.00	5.00	215.01	238350.30
03	67.17	8.35	30.74	0.00	0.00	0.00	106.26	113816.10
04	9.04	63.15	0.00	0.00	0.00	5.00	77.19	89051.20
07	2.02	4.56	0.00	0.00	0.00	0.00	6.58	7308.00
09	0.66	2.31	0.00	0.00	0.00	0.00	2.97	3355.40
18	13.99	0.00	0.13	0.00	0.00	0.00	14.12	16425.50
21	3.63	3.27	0.00	0.00	0.00	0.00	6.90	7314.90
29	0.35	0.27	0.37	0.00	0.00	0.00	0.99	1079.20
BIOLOGICS	18.46	0.00	0.00	0.00	0.00	0.00	18.46	17593.50
41	3.81	0.00	0.00	0.00	0.00	0.00	3.81	3628.40
42	14.00	0.00	0.00	0.00	0.00	0.00	14.00	13354.30
45	0.65	0.00	0.00	0.00	0.00	0.00	0.65	610.80
HUMAN DRUGS	38.06	8.40	0.97	0.00	0.00	0.00	47.43	46325.80
46	2.50	1.12	0.44	0.00	0.00	0.00	4.06	3956.00
48	9.28	0.00	0.00	0.00	0.00	0.00	9.28	8810.50
52	2.68	0.83	0.00	0.00	0.00	0.00	3.51	3378.00
53	0.79	0.00	0.00	0.00	0.00	0.00	0.79	750.00
56	21.66	6.33	0.53	0.00	0.00	0.00	28.52	28195.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.15	0.12	0.00	0.00	0.00	0.00	1.27	1236.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	21.50	11.18	2.87	0.00	0.00	4.00	39.55	42800.10
68	2.72	0.19	0.00	0.00	0.00	0.00	2.91	2908.10
71	18.78	10.99	2.87	0.00	0.00	4.00	36.64	39892.00
DEVICES & RAD H	42.87	0.00	0.89	0.00	0.00	0.00	43.76	46289.70
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	66.40
82	27.57	0.00	0.89	0.00	0.00	0.00	28.46	30000.80
83	4.87	0.00	0.00	0.00	0.00	0.00	4.87	4626.90
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.18	0.00	0.00	0.00	0.00	0.00	3.18	3696.00
86	7.17	0.00	0.00	0.00	0.00	0.00	7.17	7899.60









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





WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)  
 FY 2006

Output Reflects: OPR FTE'S

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	PERSNHR
TOTAL	296.05	64.56	58.36	0.00	0.00	7.00	425.97	447034.00
FOOD SAFETY/COS	166.78	48.12	57.05	0.00	0.00	6.00	277.95	299273.40
03	127.58	20.12	56.60	0.00	0.00	4.00	208.30	222830.50
04	9.25	23.40	0.00	0.00	0.00	0.00	32.65	36455.40
07	2.15	2.42	0.00	0.00	0.00	1.00	5.57	6078.00
09	0.55	1.66	0.00	0.00	0.00	0.00	2.21	2467.80
18	20.91	0.00	0.20	0.00	0.00	0.00	21.11	23300.00
21	5.69	0.00	0.00	0.00	0.00	1.00	6.69	6576.30
29	0.65	0.52	0.25	0.00	0.00	0.00	1.42	1565.40
BIOLOGICS	18.02	0.00	0.00	0.00	0.00	0.00	18.02	17352.60
41	4.71	0.00	0.00	0.00	0.00	0.00	4.71	4467.40
42	12.56	0.00	0.00	0.00	0.00	0.00	12.56	12187.60
45	0.75	0.00	0.00	0.00	0.00	0.00	0.75	697.60
HUMAN DRUGS	46.54	8.89	0.81	0.00	0.00	0.00	56.24	55307.60
46	1.89	1.09	0.00	0.00	0.00	0.00	2.98	2898.00
48	9.89	0.00	0.00	0.00	0.00	0.00	9.89	9381.90
52	1.61	0.97	0.00	0.00	0.00	0.00	2.58	2549.00
53	1.58	0.00	0.00	0.00	0.00	0.00	1.58	1500.00
56	28.00	6.37	0.81	0.00	0.00	0.00	35.18	35051.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	3.57	0.46	0.00	0.00	0.00	0.00	4.03	3927.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	15.87	3.46	0.50	0.00	0.00	1.00	20.83	22146.60
68	1.11	0.04	0.00	0.00	0.00	0.00	1.15	1142.30
71	14.76	3.42	0.50	0.00	0.00	1.00	19.68	21004.30
DEVICES & RAD H	48.84	4.09	0.00	0.00	0.00	0.00	52.93	52953.80
81	0.14	0.00	0.00	0.00	0.00	0.00	0.14	122.60
82	30.08	4.09	0.00	0.00	0.00	0.00	34.17	33910.40
83	9.70	0.00	0.00	0.00	0.00	0.00	9.70	9208.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.67	0.00	0.00	0.00	0.00	0.00	2.67	3091.00
86	6.25	0.00	0.00	0.00	0.00	0.00	6.25	6621.30

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)  
 FY 2006

Output Reflects: OPR FTE'S

TOTAL FIELD

FIELD	INVEST	DIST RES &	DIST REG &	DIST REG &	DISTRICT	RESEARCH	TOTALS	
		ANALYTICAL	ANALYTICAL	ANALYTICAL			OPR FTE'S	PERSNHR'S
		CHEM	MICRO	ENG/PHY	RESEARCH	CENTER		
TOTAL	1362.97	352.24	185.03	12.16	0.00	20.41	1932.81	2030524.50
FOOD SAFETY/COS	642.85	229.09	168.94	0.00	0.00	14.00	1054.88	1142903.80
03	481.15	52.34	165.33	0.00	0.00	4.00	702.82	747600.50
04	36.00	132.95	0.00	0.00	0.00	5.00	173.95	197386.30
07	9.66	16.19	0.00	0.00	0.00	4.00	29.85	33016.00
09	2.89	8.76	0.00	0.00	0.00	0.00	11.65	13062.00
18	88.65	0.00	0.68	0.00	0.00	0.00	89.33	101532.00
21	21.21	16.24	1.60	0.00	0.00	1.00	40.05	42362.00
29	3.29	2.61	1.33	0.00	0.00	0.00	7.23	7945.00
BIOLOGICS	117.11	0.00	0.00	0.00	0.00	0.00	117.11	112088.70
41	22.92	0.00	0.00	0.00	0.00	0.00	22.92	21775.50
42	85.93	0.00	0.00	0.00	0.00	0.00	85.93	82500.80
45	8.26	0.00	0.00	0.00	0.00	0.00	8.26	7812.40
HUMAN DRUGS	292.41	91.62	5.49	0.00	0.00	0.00	389.52	390750.20
46	18.52	9.93	0.53	0.00	0.00	0.00	28.98	28697.00
48	50.36	0.00	0.00	0.00	0.00	0.00	50.36	47802.70
52	16.63	13.17	0.00	0.00	0.00	0.00	29.80	30349.00
53	9.99	0.00	0.00	0.00	0.00	0.00	9.99	9486.00
56	185.90	55.51	4.96	0.00	0.00	0.00	246.37	248623.50
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	11.01	1.01	0.00	0.00	0.00	0.00	12.02	11632.00
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	95.19	21.87	4.82	0.00	0.00	5.00	126.88	134592.10
68	10.41	0.32	0.00	0.00	0.00	0.00	10.73	10711.10
71	84.78	21.55	4.82	0.00	0.00	5.00	116.15	123881.00
DEVICES & RAD H	215.41	9.66	5.78	12.16	0.00	1.41	244.42	250189.70
81	0.47	0.03	0.02	0.03	0.00	0.00	0.55	505.80
82	132.95	9.63	5.08	3.99	0.00	0.00	151.65	153245.90
83	37.37	0.00	0.00	0.00	0.00	0.00	37.37	35455.00
84	0.00	0.00	0.68	3.04	0.00	1.41	5.13	6050.00
85	14.94	0.00	0.00	0.00	0.00	0.00	14.94	17338.00
86	29.68	0.00	0.00	5.10	0.00	0.00	34.78	37595.00

# **PART II**

# **WORKPLAN SUMMARY**



**POSITION CLASS**  
**SEPARATE RESEARCH RESOURCES**







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









WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: NE REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	219.28	64.76	44.98	12.16	6.10	1.41	348.69	372405.70
FOOD SAFETY/COS	119.92	42.13	39.12	0.00	3.30	0.00	204.47	221412.40
03	93.46	13.35	38.83	0.00	2.60	0.00	148.24	158417.50
04	6.00	21.07	0.00	0.00	0.50	0.00	27.57	31160.00
07	1.34	2.80	0.00	0.00	0.20	0.00	4.34	4812.00
09	1.00	3.35	0.00	0.00	0.00	0.00	4.35	4900.20
18	13.73	0.00	0.11	0.00	0.00	0.00	13.84	15773.50
21	3.38	0.00	0.00	0.00	0.00	0.00	3.38	3199.60
29	1.01	1.56	0.18	0.00	0.00	0.00	2.75	3149.60
BIOLOGICS	10.36	0.00	0.00	0.00	0.00	0.00	10.36	9997.30
41	2.24	0.00	0.00	0.00	0.00	0.00	2.24	2125.30
42	7.78	0.00	0.00	0.00	0.00	0.00	7.78	7551.60
45	0.34	0.00	0.00	0.00	0.00	0.00	0.34	320.40
HUMAN DRUGS	45.73	14.28	1.53	0.00	0.70	0.00	62.24	63214.50
46	2.14	2.76	0.09	0.00	0.00	0.00	4.99	5134.00
48	5.57	0.00	0.00	0.00	0.00	0.00	5.57	5288.40
52	2.58	5.85	0.00	0.00	0.00	0.00	8.43	9107.00
53	1.63	0.00	0.00	0.00	0.00	0.00	1.63	1548.00
56	32.21	5.60	1.44	0.00	0.70	0.00	39.95	40541.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.60	0.07	0.00	0.00	0.00	0.00	1.67	1596.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	13.84	4.08	0.44	0.00	0.10	0.00	18.46	20326.10
68	0.92	0.04	0.00	0.00	0.00	0.00	0.96	958.60
71	12.92	4.04	0.44	0.00	0.10	0.00	17.50	19367.50
DEVICES & RAD H	29.43	4.27	3.89	12.16	2.00	1.41	53.16	57455.40
81	0.16	0.03	0.02	0.03	0.00	0.00	0.24	238.90
82	19.43	4.24	3.19	3.99	2.00	0.00	32.85	35004.00
83	4.37	0.00	0.00	0.00	0.00	0.00	4.37	4143.00
84	0.00	0.00	0.68	3.04	0.00	1.41	5.13	6050.00
85	2.06	0.00	0.00	0.00	0.00	0.00	2.06	2389.00
86	3.41	0.00	0.00	5.10	0.00	0.00	8.51	9630.50

















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



WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: CE REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	351.35	53.36	0.00	0.00	2.30	0.00	407.01	411579.80
FOOD SAFETY/COS	132.32	12.71	0.00	0.00	1.00	0.00	146.03	149769.10
03	92.78	0.94	0.00	0.00	0.00	0.00	93.72	92155.10
04	6.54	10.77	0.00	0.00	1.00	0.00	18.31	20401.20
07	2.74	0.00	0.00	0.00	0.00	0.00	2.74	2596.00
09	0.52	0.98	0.00	0.00	0.00	0.00	1.50	1645.80
18	22.88	0.00	0.00	0.00	0.00	0.00	22.88	26423.00
21	6.07	0.00	0.00	0.00	0.00	0.00	6.07	5760.60
29	0.79	0.02	0.00	0.00	0.00	0.00	0.81	787.40
BIOLOGICS	35.96	0.00	0.00	0.00	0.00	0.00	35.96	34343.40
41	7.85	0.00	0.00	0.00	0.00	0.00	7.85	7457.00
42	27.06	0.00	0.00	0.00	0.00	0.00	27.06	25895.20
45	1.05	0.00	0.00	0.00	0.00	0.00	1.05	991.20
HUMAN DRUGS	91.93	39.62	0.00	0.00	1.30	0.00	132.85	135124.40
46	7.32	3.86	0.00	0.00	0.00	0.00	11.18	11128.00
48	14.70	0.00	0.00	0.00	0.00	0.00	14.70	13953.70
52	5.44	4.38	0.00	0.00	0.00	0.00	9.82	10030.00
53	3.86	0.00	0.00	0.00	0.00	0.00	3.86	3666.00
56	58.25	22.18	0.00	0.00	1.30	0.00	81.73	83252.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.36	0.20	0.00	0.00	0.00	0.00	2.56	2474.00
88	0.00	9.00	0.00	0.00	0.00	0.00	9.00	10620.00
ANIMAL D & F	33.34	0.73	0.00	0.00	0.00	0.00	34.07	34751.30
68	3.75	0.00	0.00	0.00	0.00	0.00	3.75	3747.60
71	29.59	0.73	0.00	0.00	0.00	0.00	30.32	31003.70
DEVICES & RAD H	57.80	0.30	0.00	0.00	0.00	0.00	58.10	57591.60
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	33.20
82	33.00	0.30	0.00	0.00	0.00	0.00	33.30	32232.10
83	12.00	0.00	0.00	0.00	0.00	0.00	12.00	11383.30
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.54	0.00	0.00	0.00	0.00	0.00	4.54	5274.00
86	8.22	0.00	0.00	0.00	0.00	0.00	8.22	8669.00













WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: SE REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	217.36	61.87	41.02	0.00	2.50	3.00	325.75	342090.20
FOOD SAFETY/COS	91.17	42.03	37.83	0.00	1.60	3.00	175.63	192170.60
03	64.36	9.58	35.46	0.00	1.10	0.00	110.50	118453.30
04	5.17	13.06	0.00	0.00	0.00	0.00	18.23	20318.50
07	1.41	6.02	0.00	0.00	0.20	3.00	10.63	12222.00
09	0.16	0.46	0.00	0.00	0.00	0.00	0.62	692.80
18	17.14	0.00	0.24	0.00	0.00	0.00	17.38	19610.00
21	2.44	12.67	1.60	0.00	0.30	0.00	17.01	19510.60
29	0.49	0.24	0.53	0.00	0.00	0.00	1.26	1363.40
BIOLOGICS	20.81	0.00	0.00	0.00	0.00	0.00	20.81	19977.60
41	4.31	0.00	0.00	0.00	0.00	0.00	4.31	4097.40
42	15.64	0.00	0.00	0.00	0.00	0.00	15.64	15065.80
45	0.86	0.00	0.00	0.00	0.00	0.00	0.86	814.40
HUMAN DRUGS	62.06	17.62	2.18	0.00	0.80	0.00	82.66	83088.10
46	3.69	1.10	0.00	0.00	0.00	0.00	4.79	4646.00
48	9.51	0.00	0.00	0.00	0.00	0.00	9.51	9025.00
52	3.88	1.14	0.00	0.00	0.00	0.00	5.02	4865.00
53	1.75	0.00	0.00	0.00	0.00	0.00	1.75	1662.00
56	40.90	12.22	2.18	0.00	0.80	0.00	56.10	56951.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	2.33	0.16	0.00	0.00	0.00	0.00	2.49	2399.00
88	0.00	3.00	0.00	0.00	0.00	0.00	3.00	3540.00
ANIMAL D & F	10.19	2.22	1.01	0.00	0.10	0.00	13.52	14122.70
68	1.83	0.05	0.00	0.00	0.00	0.00	1.88	1879.20
71	8.36	2.17	1.01	0.00	0.10	0.00	11.64	12243.50
DEVICES & RAD H	33.13	0.00	0.00	0.00	0.00	0.00	33.13	32731.20
81	0.05	0.00	0.00	0.00	0.00	0.00	0.05	44.70
82	19.53	0.00	0.00	0.00	0.00	0.00	19.53	18930.60
83	6.43	0.00	0.00	0.00	0.00	0.00	6.43	6093.30
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.49	0.00	0.00	0.00	0.00	0.00	2.49	2888.00
86	4.63	0.00	0.00	0.00	0.00	0.00	4.63	4774.60













WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: SW REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	217.75	98.69	33.17	0.00	5.60	9.00	364.21	391359.40
FOOD SAFETY/COS	96.86	79.81	28.44	0.00	4.90	5.00	215.01	238350.30
03	67.17	8.35	27.94	0.00	2.80	0.00	106.26	113816.10
04	9.04	61.25	0.00	0.00	1.90	5.00	77.19	89051.20
07	2.02	4.36	0.00	0.00	0.20	0.00	6.58	7308.00
09	0.66	2.31	0.00	0.00	0.00	0.00	2.97	3355.40
18	13.99	0.00	0.13	0.00	0.00	0.00	14.12	16425.50
21	3.63	3.27	0.00	0.00	0.00	0.00	6.90	7314.90
29	0.35	0.27	0.37	0.00	0.00	0.00	0.99	1079.20
BIOLOGICS	18.46	0.00	0.00	0.00	0.00	0.00	18.46	17593.50
41	3.81	0.00	0.00	0.00	0.00	0.00	3.81	3628.40
42	14.00	0.00	0.00	0.00	0.00	0.00	14.00	13354.30
45	0.65	0.00	0.00	0.00	0.00	0.00	0.65	610.80
HUMAN DRUGS	38.06	8.10	0.97	0.00	0.30	0.00	47.43	46325.80
46	2.50	1.12	0.44	0.00	0.00	0.00	4.06	3956.00
48	9.28	0.00	0.00	0.00	0.00	0.00	9.28	8810.50
52	2.68	0.83	0.00	0.00	0.00	0.00	3.51	3378.00
53	0.79	0.00	0.00	0.00	0.00	0.00	0.79	750.00
56	21.66	6.03	0.53	0.00	0.30	0.00	28.52	28195.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.15	0.12	0.00	0.00	0.00	0.00	1.27	1236.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	21.50	10.78	2.87	0.00	0.40	4.00	39.55	42800.10
68	2.72	0.19	0.00	0.00	0.00	0.00	2.91	2908.10
71	18.78	10.59	2.87	0.00	0.40	4.00	36.64	39892.00
DEVICES & RAD H	42.87	0.00	0.89	0.00	0.00	0.00	43.76	46289.70
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	66.40
82	27.57	0.00	0.89	0.00	0.00	0.00	28.46	30000.80
83	4.87	0.00	0.00	0.00	0.00	0.00	4.87	4626.90
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.18	0.00	0.00	0.00	0.00	0.00	3.18	3696.00
86	7.17	0.00	0.00	0.00	0.00	0.00	7.17	7899.60













WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)  
 FY 2006

Output Reflects: OPR FTE'S

REGION: PA REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	296.05	61.46	56.36	0.00	5.10	7.00	425.97	447034.00
FOOD SAFETY/COS	166.78	45.72	55.05	0.00	4.40	6.00	277.95	299273.40
03	127.58	20.12	54.60	0.00	2.00	4.00	208.30	222830.50
04	9.25	21.00	0.00	0.00	2.40	0.00	32.65	36455.40
07	2.15	2.42	0.00	0.00	0.00	1.00	5.57	6078.00
09	0.55	1.66	0.00	0.00	0.00	0.00	2.21	2467.80
18	20.91	0.00	0.20	0.00	0.00	0.00	21.11	23300.00
21	5.69	0.00	0.00	0.00	0.00	1.00	6.69	6576.30
29	0.65	0.52	0.25	0.00	0.00	0.00	1.42	1565.40
BIOLOGICS	18.02	0.00	0.00	0.00	0.00	0.00	18.02	17352.60
41	4.71	0.00	0.00	0.00	0.00	0.00	4.71	4467.40
42	12.56	0.00	0.00	0.00	0.00	0.00	12.56	12187.60
45	0.75	0.00	0.00	0.00	0.00	0.00	0.75	697.60
HUMAN DRUGS	46.54	8.39	0.81	0.00	0.50	0.00	56.24	55307.60
46	1.89	1.09	0.00	0.00	0.00	0.00	2.98	2898.00
48	9.89	0.00	0.00	0.00	0.00	0.00	9.89	9381.90
52	1.61	0.97	0.00	0.00	0.00	0.00	2.58	2549.00
53	1.58	0.00	0.00	0.00	0.00	0.00	1.58	1500.00
56	28.00	5.87	0.81	0.00	0.50	0.00	35.18	35051.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	3.57	0.46	0.00	0.00	0.00	0.00	4.03	3927.00
88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	15.87	3.26	0.50	0.00	0.20	1.00	20.83	22146.60
68	1.11	0.04	0.00	0.00	0.00	0.00	1.15	1142.30
71	14.76	3.22	0.50	0.00	0.20	1.00	19.68	21004.30
DEVICES & RAD H	48.84	4.09	0.00	0.00	0.00	0.00	52.93	52953.80
81	0.14	0.00	0.00	0.00	0.00	0.00	0.14	122.60
82	30.08	4.09	0.00	0.00	0.00	0.00	34.17	33910.40
83	9.70	0.00	0.00	0.00	0.00	0.00	9.70	9208.50
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.67	0.00	0.00	0.00	0.00	0.00	2.67	3091.00
86	6.25	0.00	0.00	0.00	0.00	0.00	6.25	6621.30

WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)  
 FY 2006

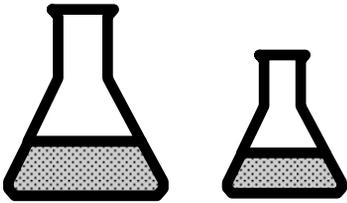
Output Reflects: OPR FTE'S

TOTAL FIELD

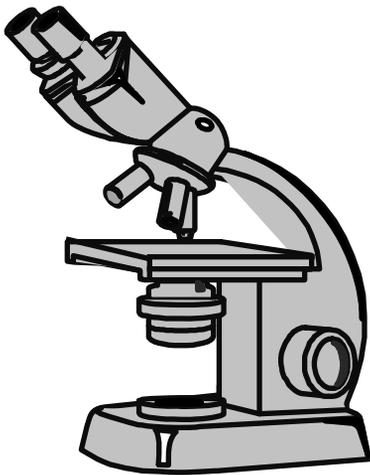
FIELD	INVEST	ANALYTICAL					TOTALS	
		CHEM	MICRO	ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	OPR FTE'S	PERSNHRS
TOTAL	1362.97	340.14	175.53	12.16	21.60	20.41	1932.81	2030524.50
FOOD SAFETY/COS	642.85	222.40	160.44	0.00	15.20	14.00	1054.89	1142903.80
03	481.15	52.34	156.83	0.00	8.50	4.00	702.82	747600.50
04	36.00	127.15	0.00	0.00	5.80	5.00	173.95	197386.30
07	9.66	15.60	0.00	0.00	0.60	4.00	29.86	33016.00
09	2.89	8.76	0.00	0.00	0.00	0.00	11.65	13062.00
18	88.65	0.00	0.68	0.00	0.00	0.00	89.33	101532.00
21	21.21	15.94	1.60	0.00	0.30	1.00	40.05	42362.00
29	3.29	2.61	1.33	0.00	0.00	0.00	7.23	7945.00
BIOLOGICS	117.11	0.00	0.00	0.00	0.00	0.00	117.11	112088.70
41	22.92	0.00	0.00	0.00	0.00	0.00	22.92	21775.50
42	85.93	0.00	0.00	0.00	0.00	0.00	85.93	82500.80
45	8.26	0.00	0.00	0.00	0.00	0.00	8.26	7812.40
HUMAN DRUGS	292.41	88.01	5.49	0.00	3.60	0.00	389.51	390750.20
46	18.52	9.93	0.53	0.00	0.00	0.00	28.98	28697.00
48	50.36	0.00	0.00	0.00	0.00	0.00	50.36	47802.70
52	16.63	13.17	0.00	0.00	0.00	0.00	29.80	30349.00
53	9.99	0.00	0.00	0.00	0.00	0.00	9.99	9486.00
56	185.90	51.90	4.96	0.00	3.60	0.00	246.36	248623.50
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	11.01	1.01	0.00	0.00	0.00	0.00	12.02	11632.00
88	0.00	12.00	0.00	0.00	0.00	0.00	12.00	14160.00
ANIMAL D & F	95.19	21.07	4.82	0.00	0.80	5.00	126.88	134592.10
68	10.41	0.32	0.00	0.00	0.00	0.00	10.73	10711.10
71	84.78	20.75	4.82	0.00	0.80	5.00	116.15	123881.00
DEVICES & RAD H	215.41	8.66	4.78	12.16	2.00	1.41	244.42	250189.70
81	0.47	0.03	0.02	0.03	0.00	0.00	0.55	505.80
82	132.95	8.63	4.08	3.99	2.00	0.00	151.65	153245.90
83	37.37	0.00	0.00	0.00	0.00	0.00	37.37	35455.00
84	0.00	0.00	0.68	3.04	0.00	1.41	5.13	6050.00
85	14.94	0.00	0.00	0.00	0.00	0.00	14.94	17338.00
86	29.68	0.00	0.00	5.10	0.00	0.00	34.78	37595.00

# PART II

## WORKPLAN SUMMARY



**OPERATIONS**

































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









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



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



WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 22  
 Date: 2-DEC-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	2792	86.10 *	171	83.21 *	1354	6.33 *	8068	18.30 *	712	0.70 *
FOOD SAFETY/COS	1587	29.07 *	171	54.51 *	966	4.41 *	7269	16.25 *	605	0.27 *
03	1265	25.10 *	171	50.93 *	296	1.49 *	4882	11.48 *	0	0.00 *
04	0	0.00 *	0	1.05 *	419	1.80 *	1438	3.13 *	17	0.01 *
07	0	0.00 *	0	0.00 *	140	0.60 *	357	0.75 *	0	0.00 *
09	0	0.00 *	0	0.40 *	0	0.00 *	408	0.60 *	0	0.00 *
18	277	3.06 *	0	0.09 *	16	0.07 *	0	0.00 *	0	0.00 *
21	32	0.69 *	0	1.49 *	85	0.39 *	59	0.10 *	588	0.26 *
29	13	0.22 *	0	0.55 *	10	0.06 *	125	0.19 *	0	0.00 *
BIOLOGICS	188	9.38 *	0	0.84 *	0	0.00 *	0	0.00 *	0	0.00 *
41	47	2.24 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	138	6.87 *	0	0.78 *	0	0.00 *	0	0.00 *	0	0.00 *
45	3	0.27 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	407	26.07 *	0	14.04 *	265	1.23 *	80	0.25 *	0	0.00 *
46	14	0.83 *	0	0.00 *	3	0.02 *	8	0.03 *	0	0.00 *
48	61	5.05 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	25	1.58 *	0	0.44 *	26	0.14 *	16	0.06 *	0	0.00 *
53	24	1.44 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	263	16.54 *	0	12.79 *	204	0.91 *	56	0.16 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	20	0.63 *	0	0.81 *	32	0.16 *	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	206	3.92 *	0	7.63 *	96	0.51 *	546	1.37 *	0	0.00 *
68	12	0.62 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	194	3.30 *	0	7.63 *	96	0.51 *	546	1.37 *	0	0.00 *
DEVICES & RAD H	404	17.66 *	0	6.19 *	27	0.18 *	173	0.43 *	107	0.43 *
81	9	0.12 *	0	0.04 *	0	0.00 *	0	0.00 *	0	0.00 *
82	260	13.02 *	0	3.81 *	26	0.18 *	173	0.43 *	0	0.00 *
83	58	3.78 *	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	57	0.41 *	0	1.07 *	0	0.00 *	0	0.00 *	0	0.00 *
86	20	0.33 *	0	1.27 *	1	0.00 *	0	0.00 *	107	0.43 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
FY 2006

Page: 23  
Date: 2-DEC-2005

REGION: NE REGN

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	1.22 *	1482	30.45 *	10149	85.30 *	607	28.28 *	150	8.82 *
FOOD SAFETY/COS	0	1.22 *	933	12.42 *	8557	68.51 *	606	17.26 *	18	0.57 *
03	0	1.22 *	303	5.34 *	5834	46.52 *	0	5.60 *	18	0.57 *
04	0	0.00 *	402	5.76 *	1854	15.31 *	0	0.50 *	0	0.00 *
07	0	0.00 *	202	1.03 *	298	1.77 *	0	0.20 *	0	0.00 *
09	0	0.00 *	0	0.00 *	450	3.35 *	0	0.00 *	0	0.00 *
18	0	0.00 *	16	0.11 *	0	0.00 *	279	10.51 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	327	0.45 *	0	0.00 *
29	0	0.00 *	10	0.18 *	121	1.56 *	0	0.00 *	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	0	0.00 *	236	10.07 *	238	5.64 *	1	0.79 *	66	4.17 *
46	0	0.00 *	9	1.48 *	50	1.27 *	1	0.09 *	22	1.27 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	8	0.52 *
52	0	0.00 *	40	2.54 *	155	3.31 *	0	0.00 *	6	0.38 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.19 *
56	0	0.00 *	183	5.98 *	33	1.06 *	0	0.70 *	27	1.81 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	4	0.07 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	108	0.92 *	554	3.61 *	0	0.17 *	5	0.34 *
68	0	0.00 *	0	0.04 *	0	0.00 *	0	0.00 *	4	0.30 *
71	0	0.00 *	108	0.88 *	554	3.61 *	0	0.17 *	1	0.04 *
DEVICES & RAD H	0	0.00 *	205	7.04 *	800	7.54 *	0	10.06 *	58	3.62 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	88	3.55 *	800	7.54 *	0	2.34 *	29	1.98 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.59 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	5.13 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.58 *	0	0.00 *
86	0	0.00 *	114	3.41 *	0	0.00 *	0	2.01 *	19	1.05 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 24  
 Date: 2-DEC-2005

REGION: NE REGN

TOTALS

FIELD	OPR FTE'S	PERSNHRS
TOTAL	348.71	372405.70
FOOD SAFETY/COS	204.49	221412.40
03	148.25	158417.50
04	27.56	31160.00
07	4.35	4812.00
09	4.35	4900.20
18	13.84	15773.50
21	3.38	3199.60
29	2.76	3149.60
BIOLOGICS	10.34	9997.30
41	2.24	2125.30
42	7.77	7551.60
45	0.33	320.40
HUMAN DRUGS	62.26	63214.50
46	4.99	5134.00
48	5.57	5288.40
52	8.45	9107.00
53	1.63	1548.00
56	39.95	40541.10
58	0.00	0.00
61	0.00	0.00
63	1.67	1596.00
88	0.00	0.00
ANIMAL D & F	18.47	20326.10
68	0.96	958.60
71	17.51	19367.50
DEVICES & RAD H	53.15	57455.40
81	0.24	238.90
82	32.85	35004.00
83	4.37	4143.00
84	5.13	6050.00
85	2.06	2389.00
86	8.50	9630.50





















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































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





WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 52  
 Date: 2-DEC-2005

REGION: CE REGN

FIELD	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	6856	201.72 *	124	67.36 *	4158	18.78 *	3874	9.00 *	1936	2.19 *
FOOD SAFETY/COS	2582	48.69 *	124	37.01 *	2555	11.14 *	3284	7.45 *	1524	0.67 *
03	2101	41.87 *	124	34.29 *	757	3.55 *	2018	4.73 *	0	0.00 *
04	0	0.00 *	0	0.60 *	989	4.04 *	809	1.87 *	50	0.02 *
07	0	0.00 *	0	0.00 *	554	2.34 *	190	0.40 *	0	0.00 *
09	0	0.00 *	0	0.19 *	0	0.00 *	212	0.32 *	0	0.00 *
18	344	3.90 *	0	0.11 *	20	0.09 *	0	0.00 *	0	0.00 *
21	103	2.36 *	0	1.77 *	209	0.97 *	43	0.12 *	1474	0.65 *
29	34	0.56 *	0	0.05 *	26	0.15 *	12	0.01 *	0	0.00 *
BIOLOGICS	609	31.02 *	0	2.03 *	0	0.00 *	0	0.00 *	0	0.00 *
41	148	7.85 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	452	22.36 *	0	1.82 *	0	0.00 *	0	0.00 *	0	0.00 *
45	9	0.81 *	0	0.21 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	965	62.78 *	0	14.45 *	795	3.62 *	97	0.33 *	0	0.00 *
46	60	3.52 *	0	0.00 *	15	0.09 *	17	0.07 *	0	0.00 *
48	158	13.40 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	44	2.79 *	0	0.99 *	45	0.25 *	52	0.17 *	0	0.00 *
53	58	3.48 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	611	38.50 *	0	12.43 *	685	3.03 *	28	0.09 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	34	1.09 *	0	1.03 *	50	0.25 *	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	1943	21.89 *	0	5.39 *	764	3.73 *	279	0.70 *	0	0.00 *
68	57	2.85 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	1886	19.04 *	0	5.39 *	764	3.73 *	279	0.70 *	0	0.00 *
DEVICES & RAD H	757	37.34 *	0	8.48 *	44	0.29 *	214	0.52 *	412	1.52 *
81	2	0.03 *	0	0.01 *	0	0.00 *	0	0.00 *	0	0.00 *
82	496	25.39 *	0	3.18 *	44	0.29 *	214	0.52 *	0	0.00 *
83	159	10.87 *	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	68	0.48 *	0	2.56 *	0	0.00 *	0	0.00 *	0	0.00 *
86	32	0.57 *	0	2.73 *	0	0.00 *	0	0.00 *	412	1.52 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
FY 2006

Page: 53  
Date: 2-DEC-2005

REGION: CE REGN

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	0.47 *	573	50.30 *	151	1.95 *	736	36.35 *	336	18.95 *
FOOD SAFETY/COS	0	0.47 *	0	10.19 *	134	1.40 *	736	27.11 *	60	1.89 *
03	0	0.47 *	0	0.40 *	0	0.40 *	0	6.12 *	60	1.89 *
04	0	0.00 *	0	9.79 *	0	0.00 *	0	1.98 *	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 *	131	0.98 *	0	0.00 *	0	0.00 *
18	0	0.00 *	0	0.00 *	0	0.00 *	580	18.79 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	156	0.22 *	0	0.00 *
29	0	0.00 *	0	0.00 *	3	0.02 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	9	0.36 *
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 *	9	0.36 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	0	0.00 *	573	39.08 *	17	0.55 *	0	1.30 *	172	10.82 *
46	0	0.00 *	36	3.86 *	0	0.00 *	0	0.00 *	63	3.64 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	20	1.31 *
52	0	0.00 *	67	4.38 *	0	0.00 *	0	0.00 *	20	1.28 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.38 *
56	0	0.00 *	458	21.64 *	17	0.55 *	0	1.30 *	63	4.21 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	12	0.20 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	9.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	0	0.73 *	0	0.00 *	0	0.59 *	17	1.11 *
68	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	12	0.91 *
71	0	0.00 *	0	0.73 *	0	0.00 *	0	0.59 *	5	0.20 *
DEVICES & RAD H	0	0.00 *	0	0.30 *	0	0.00 *	0	4.85 *	78	4.77 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	0	0.30 *	0	0.00 *	0	0.00 *	53	3.63 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	20	1.11 *
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	1.45 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	3.40 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 54  
 Date: 2-DEC-2005

REGION: CE REGN

TOTALS

	OPR FTE'S	PERSNHRS
FIELD		
TOTAL	407.07	411579.80
FOOD SAFETY/COS	146.02	149769.10
03	93.72	92155.10
04	18.30	20401.20
07	2.74	2596.00
09	1.49	1645.80
18	22.89	26423.00
21	6.09	5760.60
29	0.79	787.40
BIOLOGICS	35.91	34343.40
41	7.85	7457.00
42	27.04	25895.20
45	1.02	991.20
HUMAN DRUGS	132.93	135124.40
46	11.18	11128.00
48	14.71	13953.70
52	9.86	10030.00
53	3.86	3666.00
56	81.75	83252.70
58	0.00	0.00
61	0.00	0.00
63	2.57	2474.00
88	9.00	10620.00
ANIMAL D & F	34.14	34751.30
68	3.76	3747.60
71	30.38	31003.70
DEVICES & RAD H	58.07	57591.60
81	0.04	33.20
82	33.31	32232.10
83	11.98	11383.30
84	0.00	0.00
85	4.52	5274.00
86	8.22	8669.00





































WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 73  
 Date: 2-DEC-2005

REGION: SE REGN

FIELD	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	3379	112.73 *	81	52.76 *	2304	9.93 *	3899	9.63 *	1109	1.35 *
FOOD SAFETY/COS	1558	27.61 *	81	30.91 *	1586	6.56 *	3482	8.54 *	820	0.36 *
03	1093	21.88 *	81	29.57 *	380	1.70 *	2579	6.34 *	0	0.00 *
04	0	0.00 *	0	0.30 *	769	2.96 *	744	1.90 *	23	0.02 *
07	0	0.00 *	0	0.00 *	300	1.26 *	67	0.15 *	0	0.00 *
09	0	0.00 *	0	0.06 *	0	0.00 *	62	0.09 *	0	0.00 *
18	410	4.68 *	0	0.13 *	25	0.11 *	0	0.00 *	0	0.00 *
21	36	0.74 *	0	0.79 *	97	0.44 *	17	0.04 *	797	0.34 *
29	19	0.31 *	0	0.06 *	15	0.09 *	13	0.02 *	0	0.00 *
BIOLOGICS	388	19.13 *	0	1.56 *	0	0.00 *	0	0.00 *	0	0.00 *
41	90	4.31 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	290	14.09 *	0	1.44 *	0	0.00 *	0	0.00 *	0	0.00 *
45	8	0.73 *	0	0.12 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	615	39.68 *	0	13.63 *	448	2.04 *	88	0.25 *	0	0.00 *
46	27	1.59 *	0	0.00 *	6	0.04 *	11	0.03 *	0	0.00 *
48	100	8.72 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	33	2.10 *	0	0.68 *	34	0.17 *	33	0.10 *	0	0.00 *
53	26	1.56 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	398	24.73 *	0	11.82 *	361	1.61 *	44	0.12 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	31	0.98 *	0	1.13 *	47	0.22 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	396	5.96 *	0	1.82 *	241	1.14 *	16	0.04 *	0	0.00 *
68	23	1.08 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	373	4.88 *	0	1.82 *	241	1.14 *	16	0.04 *	0	0.00 *
DEVICES & RAD H	422	20.35 *	0	4.84 *	29	0.19 *	313	0.80 *	289	0.99 *
81	2	0.03 *	0	0.01 *	1	0.01 *	0	0.00 *	0	0.00 *
82	265	13.91 *	0	2.27 *	27	0.18 *	313	0.80 *	0	0.00 *
83	91	5.78 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	45	0.32 *	0	1.29 *	0	0.00 *	0	0.00 *	0	0.00 *
86	19	0.31 *	0	1.27 *	1	0.00 *	0	0.00 *	289	0.99 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
FY 2006

Page: 74  
Date: 2-DEC-2005

REGION: SE REGN

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	0.29 *	3854	54.91 *	5671	47.65 *	348	24.72 *	205	11.74 *
FOOD SAFETY/COS	0	0.29 *	2980	33.02 *	5602	46.51 *	348	20.43 *	44	1.39 *
03	0	0.29 *	754	12.70 *	4136	32.01 *	0	4.60 *	44	1.39 *
04	0	0.00 *	760	4.80 *	943	8.26 *	0	0.00 *	0	0.00 *
07	0	0.00 *	921	4.68 *	226	1.34 *	0	3.20 *	0	0.00 *
09	0	0.00 *	0	0.00 *	62	0.46 *	0	0.00 *	0	0.00 *
18	0	0.00 *	36	0.24 *	0	0.00 *	272	12.23 *	0	0.00 *
21	0	0.00 *	479	10.07 *	218	4.20 *	76	0.40 *	0	0.00 *
29	0	0.00 *	30	0.53 *	17	0.24 *	0	0.00 *	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	0	0.00 *	554	18.93 *	27	0.87 *	0	0.80 *	102	6.44 *
46	0	0.00 *	5	1.10 *	0	0.00 *	0	0.00 *	35	2.02 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	12	0.79 *
52	0	0.00 *	5	1.14 *	0	0.00 *	0	0.00 *	13	0.83 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.19 *
56	0	0.00 *	535	13.53 *	27	0.87 *	0	0.80 *	39	2.61 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	9	0.16 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	3.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	320	2.96 *	42	0.27 *	0	0.58 *	10	0.76 *
68	0	0.00 *	0	0.05 *	0	0.00 *	0	0.00 *	10	0.76 *
71	0	0.00 *	320	2.91 *	42	0.27 *	0	0.58 *	0	0.00 *
DEVICES & RAD H	0	0.00 *	0	0.00 *	0	0.00 *	0	2.91 *	46	3.03 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	35	2.40 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	11	0.63 *
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	0.87 *	0	0.00 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	2.04 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 75  
 Date: 2-DEC-2005

REGION: SE REGN

TOTALS

FIELD	OPR FTE'S	PERSNHRS
TOTAL	325.71	342090.20
FOOD SAFETY/COS	175.62	192170.60
03	110.48	118453.30
04	18.24	20318.50
07	10.63	12222.00
09	0.61	692.80
18	17.39	19610.00
21	17.02	19510.60
29	1.25	1363.40
BIOLOGICS	20.81	19977.60
41	4.31	4097.40
42	15.65	15065.80
45	0.85	814.40
HUMAN DRUGS	82.64	83088.10
46	4.78	4646.00
48	9.51	9025.00
52	5.02	4865.00
53	1.75	1662.00
56	56.09	56951.10
58	0.00	0.00
61	0.00	0.00
63	2.49	2399.00
88	3.00	3540.00
ANIMAL D & F	13.53	14122.70
68	1.89	1879.20
71	11.64	12243.50
DEVICES & RAD H	33.11	32731.20
81	0.05	44.70
82	19.56	18930.60
83	6.41	6093.30
84	0.00	0.00
85	2.48	2888.00
86	4.61	4774.60

























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













WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 94  
 Date: 2-DEC-2005

REGION: SW REGN

FIELD	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	3511	93.53 *	82	68.98 *	2369	10.31 *	7342	15.12 *	970	1.26 *
FOOD SAFETY/COS	906	17.00 *	82	42.24 *	1394	5.71 *	7044	14.36 *	705	0.32 *
03	685	13.80 *	82	40.16 *	279	1.28 *	2919	6.96 *	0	0.00 *
04	0	0.00 *	0	0.28 *	622	2.31 *	3583	6.45 *	0	0.00 *
07	0	0.00 *	0	0.00 *	367	1.54 *	226	0.48 *	0	0.00 *
09	0	0.00 *	0	0.26 *	0	0.00 *	271	0.40 *	0	0.00 *
18	155	1.90 *	0	0.05 *	10	0.04 *	0	0.00 *	0	0.00 *
21	53	1.09 *	0	1.44 *	106	0.49 *	33	0.05 *	705	0.32 *
29	13	0.21 *	0	0.05 *	10	0.05 *	12	0.02 *	0	0.00 *
BIOLOGICS	347	17.15 *	0	1.17 *	0	0.00 *	0	0.00 *	0	0.00 *
41	82	3.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	259	12.80 *	0	1.08 *	0	0.00 *	0	0.00 *	0	0.00 *
45	6	0.54 *	0	0.09 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	418	27.95 *	0	4.43 *	289	1.32 *	38	0.13 *	0	0.00 *
46	17	1.00 *	0	0.00 *	4	0.03 *	8	0.03 *	0	0.00 *
48	100	8.63 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	23	1.46 *	0	0.47 *	23	0.12 *	22	0.08 *	0	0.00 *
53	10	0.60 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	255	15.84 *	0	3.32 *	240	1.07 *	8	0.02 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	13	0.42 *	0	0.64 *	22	0.10 *	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	1385	14.96 *	0	1.78 *	666	3.14 *	37	0.09 *	0	0.00 *
68	32	1.52 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	1353	13.44 *	0	1.78 *	666	3.14 *	37	0.09 *	0	0.00 *
DEVICES & RAD H	455	16.47 *	0	19.36 *	20	0.14 *	223	0.54 *	265	0.94 *
81	4	0.06 *	0	0.02 *	0	0.00 *	0	0.00 *	0	0.00 *
82	206	10.67 *	0	14.06 *	20	0.14 *	223	0.54 *	0	0.00 *
83	61	4.27 *	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	167	1.16 *	0	1.23 *	0	0.00 *	0	0.00 *	0	0.00 *
86	17	0.31 *	0	4.05 *	0	0.00 *	0	0.00 *	265	0.94 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
FY 2006

Page: 95  
Date: 2-DEC-2005

REGION: SW REGN

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	0.37 *	6936	81.74 *	6217	48.58 *	487	34.77 *	172	9.67 *
FOOD SAFETY/COS	0	0.37 *	5663	60.87 *	5930	46.58 *	482	26.45 *	36	1.15 *
03	0	0.37 *	528	10.30 *	2749	25.20 *	0	7.09 *	36	1.15 *
04	0	0.00 *	3592	44.47 *	2510	16.77 *	0	6.90 *	0	0.00 *
07	0	0.00 *	459	2.33 *	342	2.03 *	0	0.20 *	0	0.00 *
09	0	0.00 *	0	0.00 *	310	2.31 *	0	0.00 *	0	0.00 *
18	0	0.00 *	19	0.13 *	0	0.00 *	277	12.00 *	0	0.00 *
21	0	0.00 *	1044	3.27 *	0	0.00 *	205	0.26 *	0	0.00 *
29	0	0.00 *	21	0.37 *	19	0.27 *	0	0.00 *	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	0	0.00 *	192	8.47 *	5	0.16 *	5	0.74 *	68	4.28 *
46	0	0.00 *	0	1.12 *	0	0.00 *	5	0.44 *	25	1.45 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.66 *
52	0	0.00 *	2	0.83 *	0	0.00 *	0	0.00 *	9	0.58 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.19 *
56	0	0.00 *	183	6.40 *	5	0.16 *	0	0.30 *	21	1.40 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	7	0.12 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	1064	11.51 *	282	1.84 *	0	4.94 *	18	1.29 *
68	0	0.00 *	0	0.19 *	0	0.00 *	0	0.00 *	16	1.21 *
71	0	0.00 *	1064	11.32 *	282	1.84 *	0	4.94 *	2	0.08 *
DEVICES & RAD H	0	0.00 *	17	0.89 *	0	0.00 *	0	2.64 *	47	2.83 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	17	0.89 *	0	0.00 *	0	0.00 *	32	2.19 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.61 *
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	0.75 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.89 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 96  
 Date: 2-DEC-2005

REGION: SW REGN

TOTALS

FIELD	OPR FTE'S	PERSNHRS
TOTAL	364.33	391359.40
FOOD SAFETY/COS	215.05	238350.30
03	106.31	113816.10
04	77.18	89051.20
07	6.58	7308.00
09	2.97	3355.40
18	14.12	16425.50
21	6.92	7314.90
29	0.97	1079.20
BIOLOGICS	18.44	17593.50
41	3.81	3628.40
42	14.00	13354.30
45	0.63	610.80
HUMAN DRUGS	47.48	46325.80
46	4.07	3956.00
48	9.29	8810.50
52	3.54	3378.00
53	0.79	750.00
56	28.51	28195.30
58	0.00	0.00
61	0.00	0.00
63	1.28	1236.00
88	0.00	0.00
ANIMAL D & F	39.55	42800.10
68	2.92	2908.10
71	36.63	39892.00
DEVICES & RAD H	43.81	46289.70
81	0.08	66.40
82	28.49	30000.80
83	4.88	4626.90
84	0.00	0.00
85	3.17	3696.00
86	7.19	7899.60









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



















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



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









WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 115  
 Date: 2-DEC-2005

REGION: PA REGN

FIELD	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	4656	134.47 *	242	92.63 *	3181	13.30 *	8703	20.86 *	1570	1.47 *
FOOD SAFETY/COS	2515	46.58 *	242	69.08 *	2590	10.39 *	7907	18.86 *	1346	0.59 *
03	1911	38.17 *	242	65.31 *	673	2.97 *	6002	14.39 *	0	0.00 *
04	0	0.00 *	0	0.98 *	1352	4.97 *	1255	3.29 *	10	0.00 *
07	0	0.00 *	0	0.00 *	349	1.47 *	324	0.68 *	0	0.00 *
09	0	0.00 *	0	0.22 *	0	0.00 *	222	0.33 *	0	0.00 *
18	514	6.67 *	0	0.15 *	29	0.12 *	0	0.00 *	0	0.00 *
21	69	1.40 *	0	2.25 *	173	0.78 *	66	0.11 *	1336	0.59 *
29	21	0.34 *	0	0.17 *	14	0.08 *	38	0.06 *	0	0.00 *
BIOLOGICS	327	16.39 *	0	1.49 *	0	0.00 *	0	0.00 *	0	0.00 *
41	94	4.71 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	226	11.05 *	0	1.40 *	0	0.00 *	0	0.00 *	0	0.00 *
45	7	0.63 *	0	0.09 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	447	30.10 *	0	10.25 *	275	1.26 *	37	0.13 *	0	0.00 *
46	11	0.65 *	0	0.00 *	2	0.02 *	6	0.03 *	0	0.00 *
48	101	8.90 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	12	0.76 *	0	0.29 *	12	0.06 *	17	0.06 *	0	0.00 *
53	20	1.20 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	275	17.70 *	0	7.54 *	199	0.91 *	14	0.04 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	28	0.89 *	0	2.42 *	62	0.27 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	687	8.88 *	0	4.53 *	273	1.38 *	242	0.61 *	0	0.00 *
68	17	0.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	670	8.07 *	0	4.53 *	273	1.38 *	242	0.61 *	0	0.00 *
DEVICES & RAD H	680	32.52 *	0	7.28 *	43	0.27 *	517	1.26 *	224	0.88 *
81	6	0.09 *	0	0.03 *	2	0.02 *	0	0.00 *	0	0.00 *
82	452	22.71 *	0	3.00 *	37	0.24 *	517	1.26 *	0	0.00 *
83	130	8.61 *	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	48	0.34 *	0	1.60 *	0	0.00 *	0	0.00 *	0	0.00 *
86	44	0.77 *	0	2.65 *	4	0.01 *	0	0.00 *	224	0.88 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 116  
 Date: 2-DEC-2005

REGION: PA REGN

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	1.00 *	2387	29.43 *	12538	87.42 *	625	34.92 *	187	10.42 *
FOOD SAFETY/COS	0	1.00 *	1925	19.58 *	11588	80.22 *	625	30.46 *	36	1.13 *
03	0	1.00 *	640	12.76 *	8506	61.00 *	0	11.55 *	36	1.13 *
04	0	0.00 *	1114	5.72 *	2522	15.27 *	0	2.40 *	0	0.00 *
07	0	0.00 *	128	0.65 *	298	1.77 *	0	1.00 *	0	0.00 *
09	0	0.00 *	0	0.00 *	222	1.66 *	0	0.00 *	0	0.00 *
18	0	0.00 *	29	0.20 *	0	0.00 *	244	13.95 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	381	1.56 *	0	0.00 *
29	0	0.00 *	14	0.25 *	40	0.52 *	0	0.00 *	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	0	0.00 *	184	7.67 *	68	1.53 *	0	0.50 *	76	4.85 *
46	0	0.00 *	3	1.09 *	0	0.00 *	0	0.00 *	21	1.22 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	15	0.99 *
52	0	0.00 *	5	0.97 *	0	0.00 *	0	0.00 *	7	0.45 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.38 *
56	0	0.00 *	149	5.15 *	68	1.53 *	0	0.50 *	27	1.81 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	27	0.46 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	278	2.18 *	242	1.58 *	0	1.33 *	5	0.34 *
68	0	0.00 *	0	0.04 *	0	0.00 *	0	0.00 *	4	0.30 *
71	0	0.00 *	278	2.14 *	242	1.58 *	0	1.33 *	1	0.04 *
DEVICES & RAD H	0	0.00 *	0	0.00 *	640	4.09 *	0	2.63 *	67	3.98 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	0	0.00 *	640	4.09 *	0	0.00 *	42	2.87 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	20	1.08 *
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	0.70 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.93 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 117  
 Date: 2-DEC-2005

REGION: PA REGN

TOTALS

FIELD	OPR FTE'S	PERSNHRS
TOTAL	425.92	447034.00
FOOD SAFETY/COS	277.89	299273.40
03	208.28	222830.50
04	32.63	36455.40
07	5.57	6078.00
09	2.21	2467.80
18	21.09	23300.00
21	6.69	6576.30
29	1.42	1565.40
BIOLOGICS	18.00	17352.60
41	4.71	4467.40
42	12.57	12187.60
45	0.72	697.60
HUMAN DRUGS	56.29	55307.60
46	3.01	2898.00
48	9.89	9381.90
52	2.59	2549.00
53	1.58	1500.00
56	35.18	35051.70
58	0.00	0.00
61	0.00	0.00
63	4.04	3927.00
88	0.00	0.00
ANIMAL D & F	20.83	22146.60
68	1.15	1142.30
71	19.68	21004.30
DEVICES & RAD H	52.91	52953.80
81	0.14	122.60
82	34.17	33910.40
83	9.69	9208.50
84	0.00	0.00
85	2.67	3091.00
86	6.24	6621.30

WORKPLAN SUMMARY / COMBINED OPERATIONS  
FY 2006

Page: 118  
Date: 2-DEC-2005

TOTAL FIELD

FIELD	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	21230	640.00 *	700	405.84 *	13366	58.65 *	31886	72.91 *	6297	6.97 *
FOOD SAFETY/COS	9148	168.95 *	700	269.33 *	9091	38.21 *	28986	65.46 *	5000	2.21 *
03	7055	140.82 *	700	255.84 *	2385	10.99 *	18400	43.90 *	0	0.00 *
04	0	0.00 *	0	3.21 *	4151	16.08 *	7829	16.64 *	100	0.05 *
07	0	0.00 *	0	0.00 *	1710	7.21 *	1164	2.46 *	0	0.00 *
09	0	0.00 *	0	1.13 *	0	0.00 *	1175	1.74 *	0	0.00 *
18	1700	20.21 *	0	0.53 *	100	0.43 *	0	0.00 *	0	0.00 *
21	293	6.28 *	0	7.74 *	670	3.07 *	218	0.42 *	4900	2.16 *
29	100	1.64 *	0	0.88 *	75	0.43 *	200	0.30 *	0	0.00 *
BIOLOGICS	1895	99.49 *	0	10.17 *	0	0.00 *	0	0.00 *	0	0.00 *
41	461	22.92 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	1387	70.61 *	0	9.60 *	0	0.00 *	0	0.00 *	0	0.00 *
45	47	5.96 *	0	0.57 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	2852	191.28 *	0	56.80 *	2072	9.47 *	340	1.09 *	0	0.00 *
46	129	7.59 *	0	0.00 *	30	0.20 *	50	0.19 *	0	0.00 *
48	520	45.73 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	137	8.69 *	0	2.87 *	140	0.74 *	140	0.47 *	0	0.00 *
53	138	8.28 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	1802	116.98 *	0	47.90 *	1689	7.53 *	150	0.43 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	126	4.01 *	0	6.03 *	213	1.00 *	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	4617	55.94 *	0	21.15 *	2040	9.90 *	1120	2.81 *	0	0.00 *
68	141	6.88 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	4476	49.06 *	0	21.15 *	2040	9.90 *	1120	2.81 *	0	0.00 *
DEVICES & RAD H	2718	124.34 *	0	48.39 *	163	1.07 *	1440	3.55 *	1297	4.76 *
81	23	0.33 *	0	0.11 *	3	0.03 *	0	0.00 *	0	0.00 *
82	1679	85.70 *	0	28.56 *	154	1.03 *	1440	3.55 *	0	0.00 *
83	499	33.31 *	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	385	2.71 *	0	7.75 *	0	0.00 *	0	0.00 *	0	0.00 *
86	132	2.29 *	0	11.97 *	6	0.01 *	0	0.00 *	1297	4.76 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
FY 2006

Page: 119  
Date: 2-DEC-2005

TOTAL FIELD

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	3.35 *	15232	246.83 *	34726	270.90 *	2803	159.07 *	1150	68.40 *
FOOD SAFETY/COS	0	3.35 *	11501	136.08 *	31811	243.22 *	2797	121.74 *	200	6.32 *
03	0	3.35 *	2225	41.50 *	21225	165.13 *	0	34.99 *	200	6.32 *
04	0	0.00 *	5868	70.54 *	7829	55.61 *	0	11.78 *	0	0.00 *
07	0	0.00 *	1710	8.69 *	1164	6.91 *	0	4.60 *	0	0.00 *
09	0	0.00 *	0	0.00 *	1175	8.76 *	0	0.00 *	0	0.00 *
18	0	0.00 *	100	0.68 *	0	0.00 *	1652	67.48 *	0	0.00 *
21	0	0.00 *	1523	13.34 *	218	4.20 *	1145	2.89 *	0	0.00 *
29	0	0.00 *	75	1.33 *	200	2.61 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	43	4.84 *
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 *	35	3.21 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	8	1.63 *
HUMAN DRUGS	0	0.00 *	1739	84.22 *	355	8.75 *	6	4.13 *	538	33.95 *
46	0	0.00 *	53	8.65 *	50	1.27 *	6	0.53 *	183	10.58 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	71	4.65 *
52	0	0.00 *	119	9.86 *	155	3.31 *	0	0.00 *	62	3.96 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	27	1.71 *
56	0	0.00 *	1508	52.70 *	150	4.17 *	0	3.60 *	195	13.05 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	59	1.01 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	12.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	1770	18.30 *	1120	7.30 *	0	7.61 *	57	3.96 *
68	0	0.00 *	0	0.32 *	0	0.00 *	0	0.00 *	47	3.56 *
71	0	0.00 *	1770	17.98 *	1120	7.30 *	0	7.61 *	10	0.40 *
DEVICES & RAD H	0	0.00 *	222	8.23 *	1440	11.63 *	0	23.09 *	312	19.33 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	105	4.74 *	1440	11.63 *	0	2.34 *	207	14.17 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	71	4.02 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	5.13 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	4.35 *	15	0.09 *
86	0	0.00 *	114	3.41 *	0	0.00 *	0	11.27 *	19	1.05 *

WORKPLAN SUMMARY / COMBINED OPERATIONS  
 FY 2006

Page: 120  
 Date: 2-DEC-2005

TOTAL FIELD

TOTALS

	OPR FTE'S	PERSNHRS
FIELD		
TOTAL	1932.92	2030524.50
FOOD SAFETY/COS	1054.87	1142903.80
03	702.84	747600.50
04	173.91	197386.30
07	29.87	33016.00
09	11.63	13062.00
18	89.33	101532.00
21	40.10	42362.00
29	7.19	7945.00
BIOLOGICS	117.00	112088.70
41	22.92	21775.50
42	85.92	82500.80
45	8.16	7812.40
HUMAN DRUGS	389.69	390750.20
46	29.01	28697.00
48	50.38	47802.70
52	29.90	30349.00
53	9.99	9486.00
56	246.36	248623.50
58	0.00	0.00
61	0.00	0.00
63	12.05	11632.00
88	12.00	14160.00
ANIMAL D & F	126.97	134592.10
68	10.76	10711.10
71	116.21	123881.00
DEVICES & RAD H	244.39	250189.70
81	0.55	505.80
82	151.72	153245.90
83	37.33	35455.00
84	5.13	6050.00
85	14.90	17338.00
86	34.76	37595.00

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# FY 2006

## PART III - PROGRAM FORECASTS



**DEPT OF HEALTH & HUMAN SERVICES**



**FOOD & DRUG ADMINISTRATION**

**PROGRAM PLANNING & WORKFORCE**

**MANAGEMENT BRANCH**

**ORA/ORM/DPEM**

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**PART III  
RESOURCE SUMMARY BY PROGRAM CATEGORY  
FY 2006**

	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
	DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
<b>TOTAL ALL PROGRAMS</b>	1174.7	671.9	85.8	1932.4	2020.2	1160.4	147.4	3328.0
<b>FOOD AND COSMETICS</b>	499.6	548.0	7.3	1054.9	856.7	947.7	12.6	1817.0
<b>BIOLOGICS</b>	108.6	3.5	4.9	117.0	186.6	6.0	8.4	201.0
<b>HUMAN DRUGS</b>	298.1	41.1	50.4	389.6	514.4	70.8	86.8	672.0
<b>ANIMAL DRUGS AND FEEDS</b>	94.2	28.7	3.9	126.8	162.7	49.6	6.7	219.0
<b>MEDICAL DEVICES AND RADIOLOGICAL HEALTH</b>	174.2	50.6	19.3	244.1	299.8	86.3	32.9	419.0

"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.

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
RESOURCE SUMMARY  
FY 2006**

October 1, 2005

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES	PROGRAM FTES			TOTAL PROGRAM FTES
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	499.6	548.0	7.3	1054.9	856.7	947.7	12.6	1817.0
03	FOODBORNE BIOLOGICAL HAZARDS	256.4	439.2	7.3	702.9	438.7	759.6	12.6	1210.9
04	PESTICIDES AND CHEMICAL CONTAMINANTS	99.6	74.4		174.0	170.8	128.8		299.6
07	MOLECULAR BIOLOGY AND NATURAL TOXINS	20.5	9.4		29.9	35.3	16.2		51.5
09	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		11.6		11.6		20.0		20.0
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	89.3			89.3	153.8			153.8
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	30.4	9.6		40.0	52.3	16.5		68.8
29	COLOR AND COSMETICS TECHNOLOGY	3.4	3.8		7.2	5.8	6.6		12.4

"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.



1. PROGRAM/ASSIGNMENT TITLE  
Import Acidified and Low-Acid Canned Foods, CP 7303.003  
FY 2006

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

3. PROGRAM TYPE:  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 was projected that in FY 05, foreign manufacturers will comprise approximately 86% of total number of registered firms. Therefore, in FY 06, the number of planned Import Field Exams will continue to increase in number to 3200 (from 3000 in FY 05) and the number of Import Sample Collections will increase to 1400 (from 1300 in FY 05).

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 and/or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements.

In FY 06, as in FY 05, 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)  
Refer to Compliance Program (7303.003)

d. INDUSTRY/PRODUCT CODE (S)  
03-04, 09, 12-18, 20-25, 27, 29, 30-31, 33-41

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

f. CHECK THE FOLLOWING ATTRIBUTES  
pH, water activity, salinity, soluble solids.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low Acid Canned Foods			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03003, 03003A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.8		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2	4	4	4	8	8	
			IMPORT FIELD EXAMS (Hours) *	IMPORT SAMPLE COLLECTION	IMPORT SAMPLE COLL MICRO GUIDANCE	IMPORT SAMPLE COLL CHEM GUIDANCE	IMPORT SAMPLES TO BE ANALYZED MICRO **	IMPORT SAMPLES TO BE ANALYZED CHEM **	
	<b>TOTAL FIELD</b>		<b>3200</b>	<b>1400</b>	<b>1230</b>	<b>170</b>		<b>1230</b>	<b>170</b>
	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								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION				1.8				7.0	10.0
TOTAL HOURS			3200	2520				8610	1700
CONVERSION FACTOR			950	950				1180	1180
TOTAL OPERATIONAL FTEs			3.37	2.65				7.30	1.44

**9. REMARKS**

\* Workload : Spreads for Field Exams and Import Sample Collections were determined by CFSAN using previous planned and accomplished data for each district and ORADSS line entry data for LACF, Acidified and aseptic foods. Field Exam hours are for field exams as required by the District to cover program priorities. Each field exam is estimated to take one hour.

Import Field Exams, are to routinely include: verification that the imported product is the same as declared (reconciliation exam); an assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, report the CT exam under the CT PAC (03R845, 04R845 etc.). See IOM Section 530.04 for additional information on Food & Cosmetic activities.

**\*\* 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 Domestic and Imported Cheese and Cheese Products 03037    FY 2006	2. PMS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM TYPE:       COMPLIANCE PROGRAM       PROGRAM CIRCULAR       ASSIGNMENT

4. OBJECTIVES

To conduct inspections of domestic soft cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered.

5. PROGRAM JUSTIFICATION

Cheese and cheese products have been demonstrated to contain pathogenic microorganisms and to cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.

6. FIELD OBLIGATIONS

The field is requested to conduct inspections of domestic cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings. The field is also requested to conduct sample collections and analyses of imported cheese focusing on soft cheese as high priority. Refer to the guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections.

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

DEN will perform Salmonella serotyping for isolates originating from the following labs: DEN, SAN, PRL-SW, PRL-NW.  
ARL will perform Salmonella serotyping for isolates originating from all labs: ARL, SRL, NRL

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

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) Hard and Soft Cheeses	d. INDUSTRY/PRODUCT CODE(S) 12
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e. EXAM TYPE:       CHEMICAL       MICROBIOLOGICAL       PHYSICAL       ENGINEERING

MICROANALYTICAL       OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

2006 ORA WORKPLAN

OCTOBER 1, 2005

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 <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 26.3			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)	2 INVESTI- GATIONS (Hours) (3)	3 DOMESTIC SAMPLE COLLECTION (2)	4 IMPORT SAMPLE COLL MICRO (5)	4 IMPORT SAMPLE COLL CHEM GUIDANCE	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	8 IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (7)	
	TOTAL FIELD	400	350	400	700	75	400	75	700	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)					
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	CE	REGIONAL STAFF								
		BALTIMORE								
		CHICAGO								
		CINCINNATI								
DETROIT										
MINNEAPOLIS										
NEW JERSEY										
PHILADELPHIA										
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION	17.0		4.0		2.0		17.0	6.1	16.0	
TOTAL HOURS	6800	350	1600		1400		6800	457.5	11200	
CONVERSION FACTOR	950	950	950		950		1180	1180	1180	
TOTAL OPERATIONAL FTEs	7.16	0.37	1.68		1.47		5.76	0.39	9.49	

9. REMARKS

(1) INSPECTIONS: BASED ON A 5/16/05 FACTS INVENTORY OF HIGH RISK FIRMS CONTAINING INDUSTRY CODE 12 (CHEESE) BUT NOT CONTAINING INDUSTRY CODE 16 (SEAFOOD). INSPECTIONS OF DOMESTIC FIRMS PRIORITIZES SOFT CHEESE (I.E. SOFT-FRESH, SEMI-SOFT, AND SOFT-RIPENED) MANUFACTURERS FIRST, HARD CHEESE MANUFACTURERS SECOND AND CHEESE PRODUCT MANUFACTURERS LAST.

PRIORITIZE INSPECTIONS TO LOOK AT SMALL MANUFACTURERS I.E. ARTISNAL AND FARMSTEAD CHEESE MANUFACTURERS PRODUCING HIGH RISK CHEESE WHICH DISTRIBUTE CHEESE IN INTERSTATE COMMERCE. HIGH RISK FIRMS WHOSE LAST INSPECTION WAS NAI MAY BE PLACED ON A 2 YEAR INSPECTION FREQUENCY.

(2) DOMESTIC SAMPLE COLLECTIONS: BASED ON INSPECTIONS. DISTRICTS MAY COLLECT BOTH COMPLIANCE AND SURVEILLANCE SAMPLES ACCORDING TO THE GUIDANCE IN THE COMPLIANCE PROGRAM TO FULFILL THEIR SAMPLING OBLIGATION. IF NO PROBLEMS ARE OBSERVED AT THE FIRM, THE DISTRICTS MAY ACCOMPLISH SAMPLING OBLIGATIONS BY COLLECTING SAMPLES DURING THE INSPECTION, OR BY COLLECTING SAMPLES AT THE WHOLESALE AND/OR RETAIL LEVEL.

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

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

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

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

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

(7) IMPORT SAMPLE ANALYSIS CHEM/MICRO: BASED ON IMPORT SAMPLE COLLECTIONS AND THE CURRENT SERVICING LABORATORIES CHART UNDER APPENDIX III OF THE ORA FIELD WORKPLAN.

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low-Acid Canned Foods, CP 7303.803A, FY 2006	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To determine if the firms comply with 21 <u>CFR</u> , Part 108, 113 and 114 and other requirements of the FD&C Act. To perform annual inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods.  A continued priority will remain with out- of- compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Firms who have been in compliance are on a 3-year inspection cycle. Please refer to the compliance program for guidance.	
5. PROGRAM JUSTIFICATION  <u>Low-Acid Canned Foods:</u> Inspections conducted in prior year's programs have demonstrated that the degree of compliance 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.  <u>Acidified Foods:</u> To improve the acidified food industry's degree of freedom from public health hazard and their degree of compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas, which need emphasis in future programs.	
6. FIELD OBLIGATIONS  Firms in compliance and that have not registered new products nor significantly changed a current process, may be inspected on a 3-year frequency. Special situation firms are to be inspected according to the guidance in the compliance program (see program). It is estimated that 400 FDA inspections are needed to fulfill program obligations FY 06. State contract inspections are to be used to increase firm coverage under this program.  State inspections may be conducted in addition to the number of inspections assigned per district. Resources include coverage of food security issues (see IOM) at domestic processors.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT (S) See Compliance Program	d. INDUSTRY/PRODUCT CODE(S) 16, 20-22, 24-25, 27, 35, 37, 38, 40-41
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program	

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low Acid Canned Food				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) 03803A (2)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.7		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1) (3)	3 INVESTI- GATIONS (HOURS) (1)	4 DOMESTIC SAMPLE COLLECTION (1) (5)	4 DOMESTIC SAMPLE COLLECTION MICRO GUIDANCE	4 DOMESTIC SAMPLE COLLECTION CHEM GUIDANCE	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 BETTER PROCESS- ING SCHOOL (Training Hours) (4)
	TOTAL FIELD	400	400	200	180	20	20	180	950
	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
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		25.0		5.0			8.0	10.0	
TOTAL HOURS		10000	400	1000			160	1800	950
CONVERSION FACTOR		950	950	950			1180	1180	950
TOTAL OPERATIONAL FTEs		10.53	0.42	1.05			0.14	1.53	1.00

9. REMARKS

- (1) Source of workload: Inspections, Investigation Hours and DSC's provided by CFSAN. Resource distribution based on CFSAN's LACF database as of 3/2005.
- (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) Attendance at Better Processing Schools (BPS).
- (5) Planned collections are for projected "for cause" sampling.

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety 03803 FY 2006		2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards – 03	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE	<input type="checkbox"/> PROGRAM <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. The top program priority for FY 2006 remains to inspect all high-risk firms annually. Coverage for allergens remains “for cause” only, until such time as new allergen inspection guidance is issued by CFSAN.  Ample resources have been provided to cover the full high-risk inventory covered by this program as well as to accomplish other program objectives (see compliance program). Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate district, will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. During FY 2006, FDA will continue to monitor chicken eggs for <i>Salmonella</i> 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. Currently, allergen surveillance inspections are on hold pending finalization of the Agency’s allergen enforcement strategy. The field may do “for cause” allergen inspections as needed, but only proceed with surveillance inspections when new allergen guidance is issued by CFSAN. <b>NOTE:</b> Confirmation tests for <i>Clostridium botulinum</i> , <i>Yersinia enterocolitica</i> will be split between SRL & Pacific Regional Laboratory-NW. SRL will be the confirmation servicing laboratory for NE, CE, & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) All Food Products (Except 12 & 16)		d. INDUSTRY/PRODUCT CODE (S) 02-11, 13-15, 17-41, 45-46, 50	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Filtration, 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 (2) (8)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 88.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS Including High Risk	1 NON- CLINICAL GLP INSPECTIONS	2 INVESTI- GATIONS (HOURS) INCL NATL EXPERTS	3 DOMESTIC SAMPLE COLL	3 DSC CERTIFIED COLOR SAMPLING ASSIGN	DOMESTIC SAMPLE COLLECTION MICRO GUIDANCE	DOMESTIC SAMPLE COLLECTION CHEM GUIDANCE	FOOD SAFETY METHOD VALIDATION MICRO	FOOD SAFETY METHOD VALIDATION CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	3400	5	7207	600	160	360	240	1500	1500	240	360
N E	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
N E	NEW ENGLAND	(b)(2) & (b)(7)(E)										
	NEW YORK	(b)(2) & (b)(7)(E)										
	REGIONAL LAB	(b)(2) & (b)(7)(E)										
	WEAC	(b)(2) & (b)(7)(E)										
C E	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	BALTIMORE	(b)(2) & (b)(7)(E)										
	CHICAGO	(b)(2) & (b)(7)(E)										
	CINCINNATI	(b)(2) & (b)(7)(E)										
	DETROIT	(b)(2) & (b)(7)(E)										
	MINNEAPOLIS	(b)(2) & (b)(7)(E)										
	NEW JERSEY	(b)(2) & (b)(7)(E)										
	PHILADELPHIA	(b)(2) & (b)(7)(E)										
S E	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	ATLANTA	(b)(2) & (b)(7)(E)										
	FLORIDA	(b)(2) & (b)(7)(E)										
	REGIONAL LAB	(b)(2) & (b)(7)(E)										
S W	NEW ORLEANS	(b)(2) & (b)(7)(E)										
	SAN JUAN	(b)(2) & (b)(7)(E)										
	REGIONAL LAB	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	DALLAS	(b)(2) & (b)(7)(E)										
P A	DENVER	(b)(2) & (b)(7)(E)										
	KANSAS CITY	(b)(2) & (b)(7)(E)										
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)										
	REGIONAL LAB	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	LOS ANGELES	(b)(2) & (b)(7)(E)										
P A	SAN FRANCISCO	(b)(2) & (b)(7)(E)										
	SEATTLE	(b)(2) & (b)(7)(E)										
	PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)										
	PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)										
HOURS PER OPERATION		18.5			5.2	2.0					15.0	15.0
TOTAL HOURS		62900		7207	3120	320			1500	1500	3600	5400
CONVERSION FACTOR		950		950	950	950			1180	1180	1180	1180
TOTAL OPERATIONAL FTES		66.21		7.59	3.28	0.34			1.27	1.27	3.05	4.58
9. REMARKS												
<p>(1) FY 2006 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 16, 2005. INCLUDES TIME FOR NATIONAL EXPERTS (4 FTES). RESOURCES HAVE BEEN ALLOCATED FOR 3500 TOTAL INSPECTIONS. HIGH RISK 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.</p> <p>(2) RESOURCES FOR 04803, 09803E, F ARE INCLUDED. RESOURCES FOR AUDITS ARE UNDER STATE CONTRACTS PROGRAM 03R843.</p> <p>(3) NO ALLERGEN INSPECTIONS ARE PLANNED AT THIS TIME IN FY 2006. DO NOT INITIATE SURVEILLANCE (ALLERGEN) INSPECTIONS UNTIL NEW ALLERGEN PROGRAM IS ISSUED. ALLERGEN INSPECTIONS MAY BE TAKEN FROM GENERAL INSPECTIONS. REPORT ALLERGEN INSPECTIONS UNDER PAC 03803E. "FOR CAUSE" ALLERGEN INSPECTIONS ARE TO BE CONDUCTED AS NEEDED.</p> <p>(4) NON-CLINICAL GOOD LABORATORY PRACTICE INSPECTIONS: CFSAN WILL CONTACT AFFECTED DISTRICTS TO ARRANGE INSPECTIONS DURING THE COURSE OF THE YEAR.</p> <p>(5) PER DFS THE ANALYTE FOR DSA ALLERGEN IS CLASSIFIED AS CHEM.</p> <p>(6) RESOURCES FOR SPECIAL CFSAN INSPECTIONAL ASSIGNMENTS FOR SPROUT PRODUCERS, EGG FARMS, AND GAME MEAT PROCESSORS, IF NEEDED IN FY 06, WILL BE TAKEN FROM THIS PROGRAM.</p> <p>(7) SALMONELLA SEROTYPING: SAMPLES GENERATED FROM NRL, SRL &amp; ARL GO TO ARL. SAMPLES GENERATED FROM OTHER LABS GO TO DENVER.</p> <p>(8) NON SEAFOOD INSPECTIONS FOR EU AND CHILEAN CERTIFICATIONS WILL BE HANDLED BY CFSAN ASSIGNMENT AND COUNTED AGAINST THE INSPECTIONAL OBLIGATIONS OF THIS PROGRAM.</p> <p>(9) FOOD SAFETY METHOD VALIDATION FOR CHEM AND MICRO: RESOURCES PRO RATED BASED ON THE CHEM AND MICRO LABS IN THE ORA FIELD WORKPLAN LAB SERVICING TABLE.</p> <p>(10) PER CFSAN, SAMPLES WILL BE ANALYZED BY THE OFFICE OF FOOD ADDITIVE SAFETY, COLOR CERTIFICATION GROUP.</p>												

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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 <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS N/A	
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	DSA MICRO SALMONELA SEROTYPING	FY 2006 STATE CONTRACTS PER DIVISION FEDERAL STATE RELATIONS (INFO ONLY)						
	TOTAL FIELD	1180	7847						
N E	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
C E	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
S E	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
S W	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
P A	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
P A	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 Import Foods – General 03819 FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.	
5. PROGRAM JUSTIFICATION  Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.	
6. FIELD OBLIGATIONS  To conduct activities directed by CFSAN, identified through program guidance, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth disease vector, or decomposition. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. <b>NOTE TO LABS: (see compliance program or contact DFS for additional details)</b> DEN will perform Salmonella antibiotic resistance testing. Salmonella Isolates from NRL, SRL and ARL will be serotyped in ARL. Salmonella Isolates from SAN, PRL-NW, PRL-SW and DEN will be serotyped in DEN.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:      NA <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      NA <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products (except seafood and cheese)	d. INDUSTRY/PRODUCT CODE(S) 02-09, 13-15, 17-41
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Microbiological Contamination, Filth, and Decomposition (See Compliance Program)	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.	

2006 ORA WORKPLAN

OCTOBER 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				
03R19A,B,C (03R833/99R833/R824) (1)			<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						282.2				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	4	4	8	8	8	8	
		IMPORT ENTRY REVIEW HRS	PRIOR NOTICE REVIEW HOURS	INVEST- IGATION HOURS	BSE ENTRY REVIEW & FOLLOW UP (HOURS)	IMPORT SAMPLE COLL PHYSICAL	IMPORT SAMPLE COLL CHEM (ACKEE SUBSET)	IMPORT SAMPLE COLL MICRO GUIDANCE	IMPORT SAMPLE COLL CHEM GUIDANCE	IMPORT SAMPLES TO BE ANALYZED MICRO	IMPORT SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED CHEM (ACKEE SUBSET)	IMPORT SAMPLES TO BE (HOURS) ANALYZED SALM RESIST
		OPER 14 03R833 (2)	03R833 (6)	(3)	(4)								
<b>TOTAL FIELD</b>		<b>92000</b>	<b>38000</b>	<b>86500</b>	<b>9000</b>	<b>8300</b>	<b>40</b>	<b>5730</b>	<b>2530</b>	<b>5730</b>	<b>2570</b>	<b>40</b>	<b>1180</b>
HEADQUARTERS (HQ PRIOR NOTICE CTR)		(b)(2) & (b)(7)(E)											
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)											
	NEW ENGLAND	(b)(2) & (b)(7)(E)											
	NEW YORK	(b)(2) & (b)(7)(E)											
	REGIONAL LAB	(b)(2) & (b)(7)(E)											
	WEAC	(b)(2) & (b)(7)(E)											
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)											
	BALTIMORE	(b)(2) & (b)(7)(E)											
	CHICAGO	(b)(2) & (b)(7)(E)											
	CINCINNATI	(b)(2) & (b)(7)(E)											
	DETROIT	(b)(2) & (b)(7)(E)											
	MINNEAPOLIS	(b)(2) & (b)(7)(E)											
	NEW JERSEY	(b)(2) & (b)(7)(E)											
	PHILADELPHIA	(b)(2) & (b)(7)(E)											
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)											
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)											
	ATLANTA	(b)(2) & (b)(7)(E)											
	FLORIDA	(b)(2) & (b)(7)(E)											
	NEW ORLEANS	(b)(2) & (b)(7)(E)											
	SAN JUAN	(b)(2) & (b)(7)(E)											
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)											
	REGIONAL STAFF	(b)(2) & (b)(7)(E)											
	DALLAS	(b)(2) & (b)(7)(E)											
	DENVER	(b)(2) & (b)(7)(E)											
	KANSAS CITY	(b)(2) & (b)(7)(E)											
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)											
	REGIONAL LAB	(b)(2) & (b)(7)(E)											
	REGIONAL STAFF	(b)(2) & (b)(7)(E)											
	LOS ANGELES	(b)(2) & (b)(7)(E)											
	SAN FRANCISCO	(b)(2) & (b)(7)(E)											
PA	SEATTLE	(b)(2) & (b)(7)(E)											
	PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)											
	PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)											
		(b)(2) & (b)(7)(E)											
HOURS PER OPERATION						2.2				8.2	7.0		
TOTAL HOURS		92000	38000	86500	9000	18260				46986	17990		1180
CONVERSION FACTOR		1200	1200	950	1200	950				1180	1180		1180
TOTAL OPERATIONAL FTEs		76.67	31.67	91.05	7.50	19.22				39.82	15.25		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) Investigation hours: resources are for Import Field Exams, Import Filer Evaluations, Follow-up to refusal hours (marking and tracking the disposition of detained lots) and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Note: Additional time for Import Field Exams under investigation hours is planned in the Import LACF, Import Seafood and Toxic Elements Program.

**ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:**

(a) VERIFICATION THAT THE IMPORTED PRODUCT IS THE SAME AS THAT WHICH WAS DECLARED (RECONCILIATION EXAM);

(b) AN ASSESSMENT OF SECURITY CONCERNS RELATED TO LABELING AND SOURCE COUNTRY (INCLUDING CONTAINER INTEGRITY, SIGNS OF INTENTIONAL ADULTERATION, ETC.);

(c) TRADITIONAL SAFETY CONCERNS.

**THESE ACTIVITIES ARE TO BE REPORTED AS A SINGLE IMPORT FIELD EXAM UNDER THIS COMPLIANCE PROGRAM AND PAC. ONLY ONE EXAM SHOULD BE REPORTED PER LINE ENTRY. ONLY IN THE EVENT OF A PRE-DETERMINED "FOR CAUSE" CT EXAM, OR IN THE EVENT CT SUSPICIONS ARE RAISED CONDUCTING ROUTINE FOLLOW-UP, SHOULD AN ADDITIONAL EXAM AND TIME BE REPORTED UNDER THE CT PAC (03R845, 04R845 ETC.). SEE IOM SECTION 530.04 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES.**

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

(5) Denver Laboratory: Salmonella Resistance

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

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

**FY 2006 WORKLOAD**

IMPORT ENTRY REVIEW HOURS OP 14: BASED ON ACS FDA REVIEW LINES BY INDUSTRY CODE (May 31, 2004 - May 31, 2005).

INVESTIGATION HOURS : BASED ON 100% ACS FDA REVIEW LINES (May 31, 2004 - May 31, 2005).

BSE ENTRY REVIEW AND FOLLOW-UP: BASED ON ACS FDA REVIEW LINES (May 31, 2004 - May 31, 2005).

ISC PHYSICAL: BASED ON 100% ACS FDA REVIEW LINES

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (03842) FY 2006	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the ACT.	
5. PROGRAM JUSTIFICATION  FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices, the Seafood HACCP Regulation, and the FD&C Act.	
6. FIELD OBLIGATIONS  Effective this fiscal year, HACCP verification samples are no longer to be routinely collected. Sample collections and analyses are to be made only for cause or as part of a CFSSAN issued assignment. It is important that products be analyzed for the health hazard as identified in the HACCP guide – i.e., raw scombroid fish should be analyzed for histamine not for parasites or micro; raw shrimp should be analyzed for undeclared sulfites, not for micro.  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: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Domestic Fish and Fishery Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) (PSP, ASP, Standards, Economic Deception, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

2006 ORA WORKPLAN

OCTOBER 1, 2005

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) 03842, B, C, D, H (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 57.3			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	STATE CONTRACTS IND 16 FY 2006 - INFO ONLY PER DIV FEDERAL STATE RELATIONS (5)	3	3	3	7	7	7	9	
		INSPECTIONS INCLUDING HIGH RISK (4)		DOMESTIC SAMPLES COLL (3)	DOMESTIC SAMPLES COLL MICRO GUIDANCE	DOMESTIC SAMPLES COLL CHEM GUIDANCE	DSAs ORGANO EXAMS (Hours) (2)	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	EU CERTIFICATION (HOURS) (6)	
TOTAL FIELD		2480	1037	300	225	75	400	75	225	1860	
HEADQUARTERS		(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
SW	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
PA	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
PA	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION		19.0		5.0			11.0	16.5			
TOTAL HOURS		47120		1500			400	825	1860		
CONVERSION FACTOR		950		950			1180	1180	950		
TOTAL OPERATIONAL FTEs		49.60		1.58			0.34	0.70	1.96		

9. REMARKS

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

(2) ORGANOLEPTIC NATIONAL EXPERT

(3) SEAFOOD COLLECTIONS ARE PLANNED "FOR CAUSE ONLY." FY 2006 HACCP VERIFICATION IS NO LONGER REQUIRED.

**SOURCE OF SEAFOOD WORKLOAD:**

(4) OEI OF SEAFOOD FIRMS FLAGGED IN FACTS AS HIGH RISK EXCLUDING FIRMS WITH INDUSTRY CODE 12 AS OF MAY 16, 2005.

INSPECTIONS, INVESTIGATION HOURS AND DSCs BASED ON OEI.

(5) DFRS IDENTIFIED STATE CONTRACTS AND ARE LISTED FOR INFORMATIONAL PURPOSES ONLY.

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

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program 03844 FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP Regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and Regulations promulgated under the Act	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety in conjunction with non-safety inspection for decomposition, filth, etc. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP regulation.	
6. FIELD OBLIGATIONS The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. It is equally important that products be analyzed for the health hazard as identified in the HACCP Guide – i.e. raw scombroid fish should be analyzed for histamine not for parasites or micro; raw shrimp should be analyzed for undeclared sulfites, not for micro.  During the fiscal year, CFSAN may issue one or more assignments calling for the collection of specific products from specific districts based on suspected problem areas. In that case, these collections assume priority over the compliance program guidelines and the samples will count against the district's sample 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. Inspectional priorities should be based on those listed in the current compliance program. NOTE: <i>Ciguatera toxin</i> confirmation which requires animals will be done at Pacific Regional Laboratory-NW. NOTE: Confirmation tests which require animals for <i>Clostridium botulinum</i> 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: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) (PSP, ASP, Standards, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES See the HACCP Guidance for hazards associated with each specific seafood product.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  See Compliance Program.	

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Products				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) 03844B, C, D, H; 07844: 09844E,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 99.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP * 03844H (1)	4 IMPORT SAMPLE COLL PHYSICAL (2) / (6)	4 IMPORT SAMPLE COLL MICRO GUIDANCE	4 IMPORT SAMPLE COLL CHEM GUIDANCE	9 INVESTIGATION HOURS (3)	8 ISAs ORGANO ANALYSES (Hours) (5)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (4) / (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (4) / (6)
	TOTAL FIELD	500	7500	5750	4500	960	1180	4500	5750
HEADQUARTERS (b)(2) & (b)(7)(E)									
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		13.0	2.4				5.3	10.6	
TOTAL HOURS		6500	18000			960	1180	23850	60950
CONVERSION FACTOR		950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs		6.84	18.95			1.01	1.00	20.21	51.65

9. REMARKS

(1) FY 2005 : IMPORTER INSPECTIONS: BASED ON OASIS CONSIGNEE DATA AS OF 6/23/05.  
 PER CFSAN, INSPECTIONS OF IMPORTERS ARE TO ASCERTAIN THAT THE IMPORTER HAS COMPLIED WITH SEAFOOD HACCP REGULATIONS (NOT TO PERFORM FILER INSPECTIONS).

(2) IMPORT SAMPLE COLLECTION: PER CFSAN BASED ON A TOTAL NUMBER OF LINE ENTRIES IN FY 04 WITH SPECIAL EMPHASIS TOWARDS THE OFFICE OF SEAFOOD'S TOP THREE PRIORITY PRODUCTS: READY TO EAT (RTE); MODIFIED ATMOSPHERE PACKAGING (MAP) AND HISTAMINE FORMING. CONSEQUENTLY, SEVERAL DISTRICTS WILL NOTE AN INCREASE IN THE SAMPLE COLLECTION TARGETS BECAUSE THEY HAVE A HIGH PERCENTAGE OF RTE, MAP AND HISTAMINE LINE ENTRIES. ALL DISTRICTS SHOULD CONCENTRATE ON COLLECTIONS AS PER THE PRIORITIES SET IN THE IMPORT SEAFOOD COMPLIANCE PROGRAM. WHEN PHYSICAL SAMPLES ARE COLLECTED FOR ANALYSIS, THE GUIDANCE IN THE COMPLIANCE PROGRAM SHOULD BE FOLLOWED IN DETERMINING WHAT THE PRODUCT SHOULD BE ANALYZED FOR. SPECIFICALLY, RAW SCROMBROTOXIC FISH SHOULD BE ANALYZED FOR HISTAMINE NOT FOR MICRO; RAW SHRIMP SHOULD BE ANALYZED FOR UNDECLARED SULFITE (AND/OR CHEMOTHERAPEUTICS) NOT FOR MICRO.

(3) IMPORT INVESTIGATION HOURS ARE FOR FIELD EXAMS, LABEL EXAMS AND OTHER OPERATIONS AS REQUIRED BY THE DISTRICT TO COVER PROGRAM PRIORITIES. DISTRICTS SHOULD REPORT TIME UNDER THE APPROPRIATE OPERATION AND PAC FOR THE ACTIVITIES PERFORMED.

ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:

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

THESE ACTIVITIES ARE TO BE REPORTED AS A SINGLE IMPORT FIELD EXAM UNDER THIS COMPLIANCE PROGRAM AND PAC. ONLY ONE EXAM SHOULD BE REPORTED PER LINE ENTRY. ONLY IN THE EVENT OF A PRE-DETERMINED "FOR CAUSE" CT EXAM, OR IN THE EVENT CT SUSPICIONS ARE RAISED CONDUCTING ROUTINE FOLLOW-UP, SHOULD AN ADDITIONAL EXAM AND TIME BE REPORTED UNDER THE CT PAC (03R845, 04R845 ETC.). SEE IOM SECTION 530.04 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES.

(4) MULTIPLE ANALYSES (I.E., CHEM AND MICRO) WILL BE RUN ON NUMEROUS SAMPLES, THEREFORE, ANALYSES OUTNUMBER COLLECTIONS.

(5) ORGANOLEPTIC NATIONAL EXPERT

(6) WEAC MICRO & CHEM: PER DFS AN INTERNAL AGREEMENT FOR FY 2006 (CARRIED OVER FROM FY 2005) 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 Juice HACCP Inspection Program 03847, 03847H FY 2006	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To 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 <p>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.</p> <p>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.</p>	
6. FIELD OBLIGATIONS <p>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. Juice importers are also to be inspected under the program.</p> <p>Resources have been provided for "for cause" samples.</p> <p>State inspections may be conducted in addition to the number of inspections assigned per district. Resources have also been added to cover food security issues (see IOM) at domestic processors.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT (S) Juice Products	d. INDUSTRY/PRODUCT CODE (S) 20-22, 24, 25
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )      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 Juice HACCP Inspection Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03847H, 03847 (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.2		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS	4 DOMESTIC SAMPLE COLLECTION	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	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	(2)	(3)	60	165	60	165	(4)	
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		18.5	6.2			11.0	15.0	13.0	
TOTAL HOURS		6938	1395			660	2475	2600	
CONVERSION FACTOR		950	950			1180	1180	950	
TOTAL OPERATIONAL FTEs		7.30	1.47			0.56	2.10	2.74	

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) Per CFSAN, Domestic Inspections based on OEI juice processor data as of 4/19/05. State inspections may be conducted in addition to the number of inspections assigned per district.

Resources added to cover food security issues at all domestic processor inspections.

(3) Per CFSAN, DSC resources based on OEI juice processor data as of 4/19/05.

Resources have been provided for anticipated "for cause" samples.

(4) Importer inspections based on FDA review lines (5/31/04- 5/31/05) of juice products and adjusted to account for physical locations of importers. Inspections assigned to SWID will be shared with DAL-DO as necessary.

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments 03F098 (Domestic), 03F100 (Import) FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To collect and analyze selected food commodities of domestic and foreign origin for pathogenic microorganisms as needed and directed by CFSAN assignments.	
5. PROGRAM JUSTIFICATION  The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it.	
6. FIELD OBLIGATIONS  To collect samples and perform analyses as specified in the assignments issued by CFSAN.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:      NA <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      NA <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh fruits and vegetables as specified in the assignments	d. INDUSTRY/PRODUCT CODE(S) 20-22, 24-25
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03				
3. PROGRAM/ASSIGNMENT CODE(S) 03F098 (Import) 03F100 (Domestic)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 24.3		
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLLECTION	4 IMPORT SAMPLE 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							
SE	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION	3.0	3.0	25.0	25.0			
	TOTAL HOURS	1500	1500	12500	12500			
	CONVERSION FACTOR	950	950	1180	1180			
	TOTAL OPERATIONAL FTEs	1.58	1.58	10.59	10.59			

9. REMARKS  
 Assignments will be issued by CFSAN for the collection of cantaloupe, green onions, tomatoes, loose-leaf lettuce, spinach, cilantro, basil, parsley and snow peas.  
 Note: SWID samples collected for TX & NM are sent to ARL. SWID samples collected for CA & AZ are sent to DEN.  
 RESOURCE DISTRIBUTION PER CFSAN.  
  
 Domestic and Import Sample Analysis based on Domestic and Import Sample collection(s) and Laboratory Servicing Table.

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments 03R233 FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, 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). <b>PAC REPORTING INSTRUCTIONS:</b> All CFSAN foreign inspection time is planned under PAC 03R233. Report accomplishments against PAC 03R233, using the Foreign Inspection Operation Code 11.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection outbreaks, infant formulas, seafood, cheese, etc.	d. INDUSTRY/PRODUCT CODE(S) 02-50, 54
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
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 Foreign Inspections/Assessments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R233	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	2 INVESTIG- ATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) *					9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>200</b>		<b>950</b>					
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL 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		950					
	CONVERSION FACTOR	950		950					
	TOTAL OPERATIONAL FTEs	6.32		1.00					

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





1. PROGRAM/ASSIGNMENT TITLE Emergency Response to Foodborne Outbreaks and Illnesses 03R839 – FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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. When the source of outbreaks are determined, conduct inspections, investigations, and/or visits to attempt to determine conditions leading up to the outbreak.	
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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH
b. INSPECTION TYPE:	NA <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) To be directed by assignment	d. INDUSTRY/PRODUCT CODE(S) All human food codes
e. EXAM TYPE:	<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES As directed by assignment	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by assignment.	

1. PROGRAM/ASSIGNMENT TITLE Emergency Response to Foodborne Outbreaks and Illnesses			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03R839 *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2 INVESTI- GATIONS (Hours)	2 MICRO- BIOLOGIST ON INVESTIGATION (Hours)				9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>		<b>5700</b>	<b>950</b>				
	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							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
PA	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
PA	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION							
	TOTAL HOURS		5700	950				
	CONVERSION FACTOR		950	950				
	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 Investigations, & Inspections, and will usually be directed by the Office of Crisis Management and/or CFSAN's Emergency Coordination and Response Staff.

REPORTING: Emergency Response Activities are planned under 03R839, expanded time should be reported against the appropriate CFSAN PACs 04R839, 07R839, 09R839 and 21R839.

Workload: Per CFSAN, based on data outlining the origin of foods that could cause an outbreak.

1. PROGRAM/ASSIGNMENT TITLE Contract Management 03R843                      FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT By DFSR	
4. OBJECTIVES To conduct an effective state contract inspection program, augmenting regulatory inspections conducted by Agency investigators. To perform audits of inspections by states that are under contract to FDA to conduct food inspections.	
5. PROGRAM JUSTIFICATION Over 9,000 food inspections are anticipated to be contracted out in FY 06 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.	
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the district. To perform audits of approximately 7% of state contract inspections in FY 06. Guidance for conducting an audit investigation is to be provided by the Division of Federal State Relations. Resources are also provided for district management of state contracts. <b>Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.</b>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED Audits	
c. PRODUCT(S) All Food Products	d. INDUSTRY/PRODUCT CODE(S) 02-41, 45-46, 50
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )     Audits of State Contract Food Inspections.	
f. CHECK THE FOLLOWING ATTRIBUTES Follow DFSR guidance.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

2006 ORA WORKPLAN

OCTOBER 1, 2005

1. PROGRAM/ASSIGNMENT TITLE Contract Management	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R843	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INFO ONLY	2006 DOMESTIC	2006 DOMESTIC	2006 TOTAL	7 DSAs	7 DOMESTIC	7 DOMESTIC	9 CONTRACT
		NUMBER OF FOOD STATE CONTRACT AUDITS (1)	FOOD STATE CONTRACTS LESS SEAFOOD (3)	SEAFOOD STATE CONTRACTS IND 16 (3)	STATE CONTRACTS (3)	(Hours)	SAMPLES TO BE ANALYZED CHEM	SAMPLES TO BE ANALYZED MICRO	MANAGE- MENT HOURS (2)
	<b>TOTAL FIELD</b>	612	7847	1037	8884				15200
	HEADQUARTERS	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	NEW ENGLAND	(b)(2) & (b)(7)(E)							
	NEW YORK	(b)(2) & (b)(7)(E)							
	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	WEAC	(b)(2) & (b)(7)(E)							
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	BALTIMORE	(b)(2) & (b)(7)(E)							
	CHICAGO	(b)(2) & (b)(7)(E)							
	CINCINNATI	(b)(2) & (b)(7)(E)							
	DETROIT	(b)(2) & (b)(7)(E)							
	MINNEAPOLIS	(b)(2) & (b)(7)(E)							
	NEW JERSEY	(b)(2) & (b)(7)(E)							
	PHILADELPHIA	(b)(2) & (b)(7)(E)							
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)							
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	ATLANTA	(b)(2) & (b)(7)(E)							
	FLORIDA	(b)(2) & (b)(7)(E)							
	NEW ORLEANS	(b)(2) & (b)(7)(E)							
	SAN JUAN	(b)(2) & (b)(7)(E)							
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	DALLAS	(b)(2) & (b)(7)(E)							
	DENVER	(b)(2) & (b)(7)(E)							
	KANSAS CITY	(b)(2) & (b)(7)(E)							
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	LOS ANGELES	(b)(2) & (b)(7)(E)							
	SAN FRANCISCO	(b)(2) & (b)(7)(E)							
	SEATTLE	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	HOURS PER OPERATION								
	TOTAL HOURS								15200
	CONVERSION FACTOR								950
	TOTAL OPERATIONAL FTEs								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 provided by Division Federal-State Relations: For information purposes and guidance. Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.

(2) Time planned for contract management includes resources to conduct audits.

(3) Food State Contract inventory per Division of Federal State Relations.

1. PROGRAM/ASSIGNMENT TITLE Food Defense 03R845      FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards
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3. PROGRAM TYPE: NA  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES

To conduct food defense activities and to enhance food defense preparedness by means of:

- special CFSAN/ORA field assignments,
- incorporating food defense activities into compliance programs and planned food safety 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, as well as enhance food industry food defense awareness .

6. FIELD OBLIGATIONS

The field is to maintain food defense readiness and conduct special assignments. CFSAN will be issuing guidance and directives to incorporate food defense activities into existing programs and planned assignments. 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.
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e. EXAM TYPE:  CHEMICAL  MICROBIOLOGICAL  PHYSICAL  ENGINEERING

MICROANALYTICAL  OTHERS (*Specify*) All food security examinations

f. CHECK THE FOLLOWING ATTRIBUTES

To be directed by assignment and protocols jointly developed by CFSAN and ORA.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

To be directed by assignment and protocols jointly developed by CFSAN and ORA.





1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES  To 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 typically high dioxin levels are found.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH
b. INSPECTION TYPE: NA		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT(S) All human foods.		d. INDUSTRY/PRODUCT CODE(S) All human food codes	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )
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 Pesticides and Industrial Chemicals in Domestic and Imported Foods				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04						
3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 77.1 (38.2)			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs		DSCs DIOXINS *	DSAs DIOXINS	DSAs DIOXINS **	DSCs SEAFOOD	DSAs SEAFOOD
	<b>TOTAL FIELD</b>	<b>1100</b>	<b>2400</b>	<b>2400</b>		<b>750</b>	<b>750</b>	<b>232</b>	<b>100</b>	<b>100</b>
N E	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)				
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
C E	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
S E	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
S W	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
P A	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
P A	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW									
HOURS PER OPERATION			3.0	5.2		4.0	20.0	11.6	3.0	5.2
TOTAL HOURS		1100	7200	12480		3000	15000	2691	300	520
CONVERSION FACTOR		950	950	1180		950	1180	1180	950	1180
TOTAL OPERATIONAL FTEs		1.16	7.58	10.58		3.16	12.71	2.28	0.32	0.44

7. REMARKS  
 Report Counter Terrorism work performed only under 04R845  
 \*Includes 232 Total Diet Study samples . CFSAN will issue Quarterly Dioxin Schedule.  
 DSC Seafoods: See compliance program for collection details.  
 \*\*Samples for KAN-DO lab will come from the Quarterly Dioxin Schedule.

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1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To sample and analyze selected import and domestic aquacultured seafood products. To determine the presence of unapproved chemical compounds such as drugs or anti-fungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.	
5. PROGRAM JUSTIFICATION  Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. With the advent of this trend, there will be incentives to protect investments and/or gain a competitive edge through the use of chemotherapeutic agents. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the U.S. and do not have adequate regulatory controls to prevent their export to the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.	
6. FIELD OBLIGATIONS  Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 06 Collection Schedule.  One analysis (chemotherapeutic agent) will be run per sample. Please refer to the FY 06 Collection Schedule (when issued) for species to collect and assigned servicing laboratories.  Individual subsample analyses will only be required for samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining sample will be composite of 12 sub samples. Please refer to the FY 06 Collection Schedule for additional collection instructions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )      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	

Chemotherapeutics in Seafood	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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3. PROGRAM/ASSIGNMENT CODE(S) 04018	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 17.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSCs	DSAs	DSAs IND SUBS	DSAs COMPOSITES	ISCs	ISAs	ISAs IND SUBS	ISAs COMPOSITES
	<b>TOTAL FIELD</b>	<b>200</b>	<b>200</b>	<b>60</b>	<b>140</b>	<b>750</b>	<b>750</b>	<b>240</b>	<b>510</b>
	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	4.0	17.5			3.0	17.5		
	TOTAL HOURS	800	3500			2250	13125		
	CONVERSION FACTOR	950	1180			950	1180		
	TOTAL OPERATIONAL FTEs	0.84	2.97			2.37	11.12		

7. REMARKS

CFSAN spread the number of sample collections per district based on ORADSS line entry data and domestic OEI data. DFS spreads the laboratory analyses. Individual sub sample analyses will be for Chloramphenicol and Nitrofurans samples. All remaining residue analyses will be a composite of 12 subsamples. The analytical module is a field wide average based on number of total samples planned for individual subsample analysis and for composite analysis. Refer to the FY 06 Collection Schedule for specific commodities to collect (when issued). Domestic samples can be collected as D/I samples if district cannot meet sample obligations with OEI firms or if samples are being collected fresh.

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Food , Foodware and Radionuclides in Foods (Import and Domestic)		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants – 04	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
<input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine the incidence and levels of lead-cadmium, mercury and other toxic elements of significance and radionuclides in domestic imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in foodware.  To take regulatory action against any food or foodware found to contain levels of toxic-elements or radionuclides of regulatory significance.			
5. PROGRAM JUSTIFICATION Historical evidence mandates the continued monitoring of domestic and imported food (including seafood) and foodware for the presence of toxic elements (i.e. lead, cadmium and mercury).  The continuing monitoring of radionuclides in foods is necessary to guard against any dangerous level of radiochemical contamination of domestic and imported foods. Also, this monitoring will provide continuing background data to identify any upward trend in tritium, gamma-ray emitters and Sr levels.			
6. FIELD OBLIGATIONS Raw agricultural products and their processed derivatives and seafood are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" program and assignments (to be issued). Planned assignments include mercury in tuna and other seafood species. CFSAN issued collections schedules and directed other FY 06 food work. Sample collections, analyses and other activities relating to domestic and imported foodware will continue as directed by the "Toxic Element" program and related field assignments. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclide.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER
		<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED
		<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All humans food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) 02 – 41, 52A	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES Lead, cadmium, mercury and other toxic elements as directed. Domestic – tritium, 90 Sr & gamma ray emitters; <b>IMPORTS; 134 Cs, 137 Cs, 90 Sr</b>			
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 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 <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 21.8 (8.8)					
R E G I O N	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
	<b>TOTAL FIELD</b>		<b>100</b>	<b>180</b>	<b>100</b>	<b>180</b>	<b>100</b>	<b>100</b>	<b>200</b>	<b>200</b>	<b>170</b>
	HEADQUARTERS		(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
SW	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
PA	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
SAN FRANCISCO											
SEATTLE											
PACIFIC REGIONAL LABORTORY - SW											
PACIFIC REGIONAL LABORTORY - NW											
HOURS PER OPERATION			3.5	1.8	12.0	12.0	4.5	12.0	4.5	12.0	4.5
TOTAL HOURS			350	324	1200	2160	450	1200	900	2400	765
CONVERSION FACTOR			950	950	1180	1180	950	1180	950	1180	950
TOTAL OPERATIONAL FTEs			0.37	0.34	1.02	1.83	0.47	1.02	0.95	2.03	0.81
7. REMARKS Both Seafood and non-seafood domestic and import collection: CFSAN will issue collection schedule.											

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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 <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (7.8)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISA SEAFOOD	DISC MERCURY IN TUNA ***	DISA MERCURY IN TUNA ***		DISC MERCURY IN SEAFOOD ***	DISA MERCURY IN SEAFOOD ***		
	<b>TOTAL FIELD</b>	170	150	150		270	270		
	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	NEW ENGLAND	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	NEW YORK	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	REGIONAL LAB	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	WEAC	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	BALTIMORE	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	CHICAGO	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	CINCINNATI	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	DETROIT	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	MINNEAPOLIS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	NEW JERSEY	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	PHILADELPHIA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)				
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	ATLANTA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	FLORIDA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	NEW ORLEANS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	SAN JUAN	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	DALLAS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	DENVER	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	KANSAS CITY	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	REGIONAL LAB	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	LOS ANGELES	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	SAN FRANCISCO	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	SEATTLE	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	PACIFIC REGIONAL LABORTORY - SW	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	PACIFIC REGIONAL LABORTORY - NW	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	HOURS PER OPERATION	12.0	3.5	12.0		4.5	12.0		
	TOTAL HOURS	2040	525	1800		1215	3240		
	CONVERSION FACTOR	1180	950	1180		950	1180		
	TOTAL OPERATIONAL FTEs	1.73	0.55	1.53		1.28	2.75		
7. REMARKS *** TO BE ISSUED AS CFSAN FIELD ASSIGNMENT.									

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foodware (Domestic and Import)			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04														
3. PROGRAM/ASSIGNMENT CODE(S) 04019B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (4.5)										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		3 DSCs (Houseware)	4 ISCs (Houseware)	5 DOMESTIC FIELD EXAMS	6 IMPORT INV HOURS *	7 DSAs	8 ISAs									
	<b>TOTAL FIELD</b>		<b>25</b>	<b>200</b>	<b>100</b>	<b>1925</b>	<b>25</b>	<b>200</b>									
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)														
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
SW	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
PA	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORTORY-SW																
	PACIFIC REGIONAL LABORTORY-NW																
	HOURS PER OPERATION									3.5	1.8	0.7		10.0	10.0		
	TOTAL HOURS									88	360	70.0	1925	250	2000		
	CONVERSION FACTOR									950	950	950	950	1180	1180		
	TOTAL OPERATIONAL FTEs									0.09	0.38	0.07	2.03	0.21	1.69		

7. REMARKS

\*IMPORT INV Hours are for field exams and any other import operations as required by the District to cover import priorities. District should report time under the appropriate operation and PAC for the activities performed.

Import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

1. PROGRAM/ASSIGNMENT TITLE Radionuclides in Foods (Domestic and Import)				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) 04019C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (0.7)			
R E G I O N	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)
	<b>TOTAL FIELD</b>			<b>16</b>	<b>84</b>			<b>16</b>	<b>84</b>	
NE	HEADQUARTERS			(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION				2.5	1.7			13.0	4.2	
TOTAL HOURS				40	143			208	353	
CONVERSION FACTOR				950	950			1180	1180	
TOTAL OPERATIONAL FTEs				0.04	0.15			0.18	0.30	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex groups through analyses of table-ready foods. In addition, to observe differences or trends in the intake of these chemicals and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.	
5. PROGRAM JUSTIFICATION  The continuing study has provided valuable information on dietary intakes of residues and nutrients and has 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 which each consisting of three separate samplings of 286 food items to be collected from three locales in a 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: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) .Various Human Foods	d. INDUSTRY/PRODUCT CODE(S) All Human Food Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )      Radiochemical Analysis	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04					
3. PROGRAM/ASSIGNMENT CODE(S) 04839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 23.4			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DSCs (TOTAL) (DIET)  *	2 DOMESTIC SAMPLE TO BE ANALYZED  **	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES)  ***					
	<b>TOTAL FIELD</b>	<b>60</b>	<b>1144</b>	<b>1</b>					
	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								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORTORY-SW								
	PACIFIC REGIONAL LABORTORY-NW								
	HOURS PER OPERATION	26.0	20.0	2800.0					
	TOTAL HOURS	1560	22880	2800					
	CONVERSION FACTOR	950	1180	1180					
	TOTAL OPERATIONAL FTEs	1.64	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.

CFSAN will issue an FY 06 TDS sample collection schedule.

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

3. PROGRAM TYPE:       COMPLIANCE PROGRAM       PROGRAM CIRCULAR       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 chloramphenicol in selected foods and general pesticide and toxic element analysis in dietary supplements. Total Diet Study(TDS) program will supply samples for perchlorate, acrylamide and furan analysis.

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 monitoring data available to the Agency for these products.

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

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) Selected human foods and dietary supplements	d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignments
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e. EXAM TYPE:       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 Field Assignments for Chemical Contaminants					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04				
3. PROGRAM/ASSIGNMENT CODE(S) 04F800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 12.8 (9.54)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSC PERCHLORATE IN FOODS *	DSA PERCHLORATE IN FOODS **** (HOURS)	DSAs ACRYLAMIDE *****	ISC CONTAMINANTS IN HONEY *****	ISA CONTAMINANTS IN HONEY *****	DISC PES & TE DIETARY SUPPL. **	DISA PES & TE DIETARY SUPPL. ***	
	<b>TOTAL FIELD</b>	<b>100</b>	<b>3000</b>	<b>100</b>	<b>200</b>	<b>200</b>	<b>200</b>	<b>200</b>	
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY- SW								
	PACIFIC REGIONAL LABORATORY- NW								
HOURS PER OPERATION		3.0		3.0	3.0	6.5	3.0	24.0	
TOTAL HOURS		300	3000	300	600	1300	600	4800	
CONVERSION FACTOR		950	1180	1180	950	1180	950	1180	
TOTAL OPERATIONAL FTEs		0.32	2.54	0.25	0.63	1.10	0.63	4.07	

7. REMARKS

\*Collection time for approximately 100 samples for Perchlorate in Foods F/U as directed by CFSAN.

\*\*Collection of samples for both Pesticides and Toxic Elements analysis. Samples may be collected as domestic samples if specified in CFSAN assignment.

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

\*\*\*\*Time to analyze 800-900 TDS samples for Perchlorate collected under TDS program and time for analyses of approximately 100 additional F/U samples as directed by CFSAN.

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

\*\*\*\*\* Resources are for continued coverage of CAP in imported honey (Import Bulletin #36-B03) unless superseded by CFSAN assignment.

\*\*\*\*\*Samples collected under the Total Diet Study

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1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04			
3. PROGRAM/ASSIGNMENT CODE(S) 04F800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (3.23)	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY			ISC CAP N' DRIED MILK *	ISA CAP N' DRIED MILK *	DSC FURAN IN FOODS	DSA FURAN IN FOODS ***
	<b>TOTAL FIELD</b>			<b>25</b>	<b>25</b>	<b>100</b>	<b>500</b>
NE	HEADQUARTERS			(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
SE	PHILADELPHIA						
	FORENSIC CHEM. CTR						
	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
SW	NEW ORLEANS						
	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF						
PA	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
LOS ANGELES							
SAN FRANCISCO							
SEATTLE							
PACIFIC REGIONAL LABORATORY- SW							
PACIFIC REGIONAL LABORATORY- NW							
HOURS PER OPERATION				3.0	4.0	3.0	6.5
TOTAL HOURS				75	100	300	3250
CONVERSION FACTOR				950	1180	950	1180
TOTAL OPERATIONAL FTEs				0.08	0.08	0.32	2.75

7. REMARKS  
 \* Resources are allocated for either an Import Bulletin or a CFSAN initiated assignment for Chloramphenicol in Dried Milk .  
 CFSAN initiated assignment for coverage of Nitrofurans in honey (domestic to be collected at manufacturers).  
 \*\*\* include 400 TDS samples.

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM TYPE:	N/A	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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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 A	<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	N/A A	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
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e. EXAM TYPE:	N/A	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS <i>(Specify)</i>		

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 DISTRICT RESEARCH (CHEM)	9 RESEARCH CENTER (CHEM)							
	<b>TOTAL FIELD</b>	<b>6990</b>	<b>5900</b>							
	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									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY - SW										
PACIFIC REGIONAL LABORATORY - NW										
HOURS PER OPERATION										
TOTAL HOURS		6990	5900							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		5.80	5.00							

7. REMARKS:

<p>1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis</p>	<p>2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04</p>
<p>3. PROGRAM TYPE:                    N/A                    <input type="checkbox"/> COMPLIANCE PROGRAM                    <input type="checkbox"/> PROGRAM CIRCULAR                    <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations.</p> <p>This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&amp;C and related acts so that the findings are suitable to be presented as technical evidence in a court of law.</p> <p>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.</p>	
<p>5. PROGRAM JUSTIFICATION</p> <p>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.</p>	
<p>6. FIELD OBLIGATIONS</p> <p>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.</p> <p>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.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:                    N/A                    <input type="checkbox"/> BY DISTRICT OFFICE                    <input type="checkbox"/> BY CENTER                    <input type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE:                    N/A                    <input type="checkbox"/> COMPREHENSIVE                    <input type="checkbox"/> ABBREVIATED                    <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S)</p>	<p>d. INDUSTRY/PRODUCT CODE(S)</p>
<p>e. EXAM TYPE:                    N/A                    <input type="checkbox"/> CHEMICAL                    <input type="checkbox"/> MICROBIOLOGICAL                    <input type="checkbox"/> PHYSICAL                    <input type="checkbox"/> ENGINEERING</p> <p style="margin-left: 100px;"><input type="checkbox"/> MICROANALYTICAL                    <input type="checkbox"/> OTHERS <span style="margin-left: 100px;"><i>(Specify)</i></span></p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.8
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	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION							
	<b>TOTAL FIELD</b>	<b>1180</b>	<b>11800</b>							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SW	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - 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.



1. PROGRAM/ASSIGNMENT TITLE  
Mycotoxins in Domestic and Import Foods  
PAC 07001

2. PPS PROJECT NAME/NUMBER  
Molecular Biology and Natural Toxins - 07

3. PROGRAM TYPE:  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 food 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. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established.

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.  
Fumonisin B<sub>1</sub> and B<sub>2</sub> are naturally occurring toxic metabolites produced mainly by the fungus, *Fusarium verticilloides*, which are found ubiquitously on corn from around the world. Because of their potential carcinogenicity and frequent occurrence in corn-based feeds and foods, their presence should be monitored, especially for incidence data.  
Deoxynivalenol (DON) is a trichothecene mycotoxin produced by several strains of *Fusarium*, which under certain climate conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated gastrointestinal illnesses in China and India. FDA has issued an advisory level of 1ppm for DON in finished wheat products. There is a need for continuous monitoring of this toxin.  
Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera *Aspergillus* and *Penicillium*. It is mainly a contaminant in cereal grains and is carcinogenic in mice and rats. There is a need for current information on the incidence and levels of this toxin in the U.S. food supply.  
Patulin is a mold metabolite produced by several species of mold fungi including *Penicillium expansum*, the casual organism of apple rot. Apple juice prepared from rotten apples is a possible source of patulin in the human diet. Patulin is regulated in at least 10 countries so far. There is a need for more exposure data to further review the international standards for patulin. The current action level for patulin in apple juice and apple juice components is 50 ppb.

6. FIELD OBLIGATIONS  
The Field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic products as directly by the Compliance Program.  
Mycotoxins in Domestic Foods (07001) and Mycotoxins in Import (07002) compliance programs were combined into one program in FY05, Mycotoxins in Domestic and Import Foods, under a single program assignment code, PAC 07001.

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

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
See Attachment "A" C.O. 7307.001 for list of Products.

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

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

f. CHECK THE FOLLOWING ATTRIBUTES  
Aflatoxins, Fumonisin B<sub>1</sub> and B<sub>2</sub>, Deoxynivalenol (DON), Ochratoxin A, and Patulin.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  
See Compliance Program (C.O.) 7307.001



1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 2	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DSA, ISCs)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.5
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REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	7 DSAs OCHRA TOXIIN	7 DSAs PATULIN	4 ISCs AFLA TOXIN	4 ISCs PEANUT BUTTER *	4 ISCs FUMON- ISON	4 ISCs DON	4 ISCs OCHRA TOXIN	4 ISCs PATUIN	4 ISCs SPECIAL SURVEY
	<b>TOTAL FIELD</b>	<b>100</b>	<b>240</b>	<b>500</b>	<b>(105)</b>	<b>160</b>	<b>160</b>	<b>64</b>	<b>240</b>	<b>39</b>

	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION			2.0		2.0	2.0	2.0	2.0	2.0
	TOTAL HOURS			1000		320	320	128	480	78
	CONVERSION FACTOR			950		950	950	950	950	950
	TOTAL OPERATION FTEs			1.05		0.34	0.34	0.13	0.51	0.08

7. REMARKS

\* Peanut Butter ISCs were spread by CFSAN  
 Surveillance of imported peanut butter for aflatoxins was increased due to observations from previous recalls and market information.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 3				2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07						
3. PROGRAM/ASSIGNMENT CODE(S) 07001 (ISAs)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.9				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8 ALL IMPORT SAMPLE ANALYSES	8 ISAs AFLA TOXIN	8 ISAs FUMON- ISON	8 ISAs DON	8 ISAs OCHRA TOXIN	8 ISAs PATULIN	8 ISAs SPECIAL SURVEY	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERAT- IONS (HOURS)
	<b>TOTAL FIELD</b>	<b>1164</b>	<b>500</b>	<b>160</b>	<b>160</b>	<b>64</b>	<b>240</b>	<b>40</b>		
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	7.0								
	TOTAL HOURS	8148								
	CONVERSION FACTOR	1180								
	TOTAL OPERATION FTEs	6.91								

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE  
ORA/Center Directed Research Projects  
PAC 07R816

2. PPS PROJECT NAME/NUMBER  
Molecular Biology and Natural Toxins - 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 refereed 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*) Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH (CHEM)	DISTRICT RESEARCH (MICRO)	CENTER RESEARCH (CHEM)	CENTER RESEARCH (MICRO)				9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	720		4130	590				
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION									
TOTAL HOURS		720		4130	590				
CONVERSION FACTOR		1205		1180	1180				
OPERATIONAL FTEs		0.60		3.50	0.50				

7. REMARKS

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



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Imported Foods - Food and Color Additives PAC 09006A,B	<b>2. PPS PROJECT NAME/NUMBER</b> Food & Color Additive Petition Review & Policy Development - 09
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To direct coverage of imported food products to determine their compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and its regulations promulgated under the Act with respect to food and color additives.	
<b>5. PROGRAM JUSTIFICATION</b>  Imported products must comply with the provisions of the Act and its 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.	
<b>6. FIELD OBLIGATIONS</b>  Districts should conduct label reviews, collect and analyze imported foods for known potential food and color additive violations and take appropriate regulatory actions when violations are found.  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 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All human foods	<b>d. INDUSTRY/PRODUCT CODE(S)</b> All food codes
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) Label Reviews	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>  Food and Color Additives	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives	2. PPS PROJECT NAME/NUMBER Food & Color Additives Petition Review & Policy Development - 09
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3. PROGRAM/ASSIGNMENT CODE(S) 09006A (Foods), 09006B (Colors)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 ISCs FOOD ADDITIVES	8 ISAs FOOD ADDITIVES	4 ISCs COLOR ADDITIVES	8 ISAs COLOR ADDITIVES	9 IMPORT INVESTIGATIONS (HOURS) *	OTHER OPERATIONS (Hours)
	TOTAL FIELD	310	310	865	865	1087	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		1.4	11.0	1.4	8.0		
TOTAL HOURS		434	3410	1211	6920	1087	
CONVERSION FACTOR		950	1180	950	1180	950	
OPERATIONAL FTEs		0.46	2.89	1.27	5.86	1.14	

7. REMARKS

Note: Resources for Entry Review and Filer Evaluation are planned under the Import Foods - General Program (PAC 03819). For FY05 and beyond all Import Field Exams are to routinely include: verification that the imported products are the same as that which were declared (Reconciliation Exams), an assessment of security concerns related to labeling and source country (including container integrity signs of intentional adulteration, etc.), and traditional safety concerns. These activities are to be reported as a single Import Field Exam under this compliance program and PAC. Only one exam should be reported per line entry.

Only in the event of: Pre-Determined "for cause" CT Exam, or CT suspicions raised while conducting routine work requiring follow-up should additional time be reported under a CT PAC (03R845, 04R845, etc.).

See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

\* Import Investigation Hours are for import field exams and label reviews of Food and Color Additives as required by the District to cover program priorities.



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

**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 06 this program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, National Food Safety needs at retail level, CFSAN directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.

**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.

**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 uniform retail program standard. Provide training on the provisions of FDA Food Code, HACCP, Facility Plan Review, the Egg Rule, and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events impacting retail food safety. Participate in the FDA Retail Food Steering Committee, the National Conference for Food Protection committees, and other conferences and industry events to share information and present FDA's position on issues concerning retail food protection. Specialists will participate in the National Team Workgroups. These workgroups will address issues which include 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       BY BOTH

b. INSPECTION TYPE:      /A       COMPREHENSIVE                       ABBREVIATED       DIRECTED

c. PRODUCT(S) Human Foods	d. INDUSTRY/PRODUCT CODE(S) Inspections: 51 NY
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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 Retail Food Protection - State Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18						
3. PROGRAM/ASSIGNMENT CODE(S) 18002		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 26.0 (23.0)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL FOOD PROGRAM STANDARDS (1)	STANDARD- IZATION (ITP CDC IHS, STATE AND LOCAL) (2)	RE-STANDARD- IZATION (ITP, STATE AND LOCAL) (3)	NATL CFSAN DIRECTED PROJECTS SECURITY (4)	TEAM LEADERS SC/NATIONAL (5)	NATL TEAM WORK GROUP (6)	REGIONAL SEMINARS (7)	TRAINING WORKSHOPS (8)	TECHNICAL ASSISTANCE (9)
	<b>TOTAL FIELD</b>	<b>7800</b>	<b>35</b>	<b>74</b>	<b>624</b>	<b>1200</b>	<b>2080</b>	<b>1300</b>	<b>1690</b>	<b>8896</b>
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	NEW ENGLAND	(b)(2) & (b)(7)(E)								
	NEW YORK	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
CE	WEAC	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE	(b)(2) & (b)(7)(E)								
	CHICAGO	(b)(2) & (b)(7)(E)								
	CINCINNATI	(b)(2) & (b)(7)(E)								
	DETROIT	(b)(2) & (b)(7)(E)								
	MINNEAPOLIS	(b)(2) & (b)(7)(E)								
	NEW JERSEY	(b)(2) & (b)(7)(E)								
SE	PHILADELPHIA	(b)(2) & (b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	ATLANTA	(b)(2) & (b)(7)(E)								
	FLORIDA	(b)(2) & (b)(7)(E)								
SW	NEW ORLEANS	(b)(2) & (b)(7)(E)								
	SAN JUAN	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	DALLAS	(b)(2) & (b)(7)(E)								
PA	DENVER	(b)(2) & (b)(7)(E)								
	KANSAS CITY	(b)(2) & (b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
LOS ANGELES	(b)(2) & (b)(7)(E)									
SAN FRANCISCO	(b)(2) & (b)(7)(E)									
SEATTLE	(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LAB - SW	(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)									
HOURS PER OPERATION			48.0	32.0						
TOTAL HOURS		7800	1680	2368	624	1200	2080	1300	1690	8896
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		6.50	1.40	1.97	0.52	1.00	1.73	1.08	1.41	7.41
7. REMARKS: Report Counter Terrorism work performed only under 18R845. (1) Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards. (2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code. (3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code. (4) Time allocated to accommodate CFSAN priority assignments in response to National food safety needs. (5) Time allocated for team leaders of the National Retail Food Team Steering Committee for retail food program planning, development, coordination. (6) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards, and initiatives of national importance. (7) Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the annual Regional Retail Food Seminars. (8) Includes training workshops not limited to Food Code courses, pre-standardization workshops, HACCP workshops, and other identified training topics. (9) Includes technical assistance and consultation to enrolled state and local jurisdictions performing self-assessments and developing strategic plans using the Program Standards as the foundation for enhancing the effectiveness of their retail food programs. Also includes interpretations and consultations on the Food Code and other food safety issues. Also includes planning and field activities related to food safety and security events working in conjunction with other federal agencies.										

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1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18							
3. PROGRAM/ASSIGNMENT CODE(S) 18002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (3.0)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CFP National Meeting & FDA Pre- Meeting (10)	CFP position Papers (CFSAN) (10)	CFP Committee Work (10)	Food Defense (11)						
	<b>TOTAL FIELD</b>	<b>1664</b>	<b>624</b>	<b>624</b>	<b>650</b>						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
SE	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
SW	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
LOS ANGELES											
SAN FRANCISCO											
SEATTLE											
PACIFIC REGIONAL LAB - SW											
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION											
TOTAL HOURS		1664	624	624	650						
CONVERSION FACTOR		1200	1200	1200	1200						
TOTAL OPERATIONAL FTEs		1.39	0.52	0.52	0.54						
7. REMARKS:											
(10) Time allocated for the participation as members of the Conference committees charged with the responsibility for developing consensus recommendations on significant retail food safety issues, such as the Food Code3, and National Retail Food Regulatory Program Standards and certification. The CFC will hold its biennial meeting in 2006.											
(11) Time allocated for the presentation and distribution of FDA materials related to food defense, such as guidance document, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures ", to state and local regulatory agencies and industry. Also includes counter-terrorism presentations at seminars, meetings, conferences, etc.											

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

4. OBJECTIVES

To implement FDA's responsibility under the Public Health Service Act, 42 USC 214; 42 USC 243; and 42 USC 246a and the Memorandum of Understanding between FDA and the National Conference on Interstate Milk Shipments. This responsibility includes all Grade "A" dairy products processing plants, and all dairy farms supplying raw milk to these plants.

5. PROGRAM JUSTIFICATION

This program will promote a uniform, safe, and wholesome supply of Grade "A" Milk and Milk products throughout the U.S. This program enables FDA to exert influence on the application of Uniform Sanitary Standards for Grade "A" Milk produced in the U.S. This program provides a mechanism for reciprocity between states, thereby eliminating the need for costly *duplicative inspection* across jurisdictional lines. Without this program, FDA would have direct responsibility for inspecting all Grade "A" Milk products moving in Interstate commerce. This program also provides a mechanism for promoting greater sanitation uniformity of all dairy products. Due to the increasing consumer interest in chemical contaminants in the food supply, the perception and the potential for animal drug residues in milk and dairy products has become an important issue. This program will place additional emphasis toward continuous vigilance in maintaining a safe wholesome milk supply that is free of illegal animal drug residues.

6. FIELD OBLIGATIONS

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       BY BOTH

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S)  
Grade "A" Milk and Milk Products, (Cheese, Butter, Dry Milk and Frozen Dessert – when produced in IMS Plants)

d. INDUSTRY/PRODUCT CODE(S)  
09, 13 & 14

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

f. CHECK THE FOLLOWING ATTRIBUTES  
Listeria, Yersinia, Salmonella, Coliform and animal drug residues in milk and milk products.

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

1. PROGRAM/ASSIGNMENT TITLE Milk Safety Program					2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18					
3. PROGRAM/ASSIGNMENT CODE(S) 18003			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 26.0 (24.2)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANT <sup>1</sup>	CHECK RATINGS TRANSFER AND RECEIVING <sup>1</sup>	CHECK RATING BTU <sup>1</sup>	SINGLE SERVICE AUDITS <sup>1</sup>	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICATION <sup>2</sup>	TECHNICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION <sup>3</sup>	STATE MILK SAMPLING SURVEILLANCE OFFICER INITIAL CONT <sup>1</sup>	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER <sup>4</sup>
	TOTAL FIELD	219	63	370	83	36	51	17	53	24
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		24.0	12.0	20.0	8.0	40.0	150.0	160.0	24.0	80.0
TOTAL HOURS		5256	756	7400	664	1440	7650	2720	1272	1920
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		4.38	0.63	6.17	0.55	1.20	6.38	2.27	1.06	1.60

7. REMARKS:

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

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

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

4/ Activities Include the National Steering Team Meetings and conference calls and time for team leader activities.

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1. PROGRAM/ASSIGNMENT TITLE Milk Safety Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18			
3. PROGRAM/ASSIGNMENT CODE(S) 18003			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			OPERATIONAL FTE POSITIONS (1.8)	
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	RMS STANDARD- IZATION <sup>5</sup>	Food Defense <sup>7</sup>	TRAINING GIVEN <sup>6</sup>			
	TOTAL FIELD	6	18	18			
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
WEAC							
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
REGIONAL LAB							
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
REGIONAL LAB							
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		50.0	25.0	80.0			
TOTAL HOURS		300	450	1440			
CONVERSION FACTOR		1200	1200	1200			
TOTAL OPERATIONAL FTEs		0.25	0.38	1.20			

<sup>5/</sup> Activities include the Initial and Re-standardization (Group Field Exercise) of RMSs

<sup>6/</sup> Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops

<sup>7/</sup> Includes time for presentation and distribution of the food defense preventive measures guidance document for dairy products to the state regulatory agencies during check ratings routine field work and state program assessments. Presentations may be made at regional seminars or local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of food defense activities and field activities related to food defense.

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

b. INSPECTION TYPE:      N/A       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) Fresh and fresh frozen molluscan shellfish	d. INDUSTRY/PRODUCT CODE(S) 16, 52 B,Y
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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 <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 14.0 (11.7)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION (1)	PATROL EVALUATION (2)	VIBRIO SPECIES MANAGE- MENT (HOURS) (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	TRAINING WORKSHOPS (7)	PLANT EVALUATION (8)	STANDARD- IZATION & RE-STAN- IZATION (9)
	TOTAL FIELD	184	16	500	2918	5	2	20	287	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									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
HOURS PER OPERATION		20.0	80.0			200.0	400.0	50.0	8.0	40.0
TOTAL HOURS		3680	1280	500	2918	1000	800	1000	2296	600
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3.07	1.07	0.42	2.43	0.83	0.67	0.83	1.91	0.50
7. REMARKS:										
(1) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity to the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO).										
(2) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity to the requirements of the NSSP MO. Illnesses and outbreaks have been attributed to the illegal harvest of shellfish from closed waters.										
(3) Activities include technical assistance, education, and evaluation of state shellfish programs <i>Vibrio vulnificus</i> and <i>vibrio parahaemolyticus</i> education and management programs.										
(4) Includes interpretations and consultation on NSSP MO requirements related to program administration, risk management, laboratory, shellfish growing areas, shellstock relaying, shellfish aquaculture, shellfish wet storage and depuration, patrol, shellfish harvest and transportation, HACCP, and general sanitation in processing plants.										
(5) Activities include planning, field evaluations, file reviews, and report writing for countries with MOUs with the FDA. Current MOU countries include Canada, Chile, South Korea Mexico, and New Zealand.										
(6) Includes time for shellfish program planning, development and coordination responsibilities assigned to two specialists selected as team representatives of the Regional Shellfish Specialists' team.										
(7) Includes training workshops coordinated and delivered by the specialists, including but not limited to basic shellfish plant and program courses applied concepts for shellfish growing areas courses and HACCP workshops.										
(8) Includes time for planning, field evaluations of processing plants, file reviews, and final report writing to determine state conformity with the NSSP MO. Plant evaluations include a full evaluation of HACCP, including plan implementation and adherence to the sanitation requirements of the NSSP MO.										
(9) Standardization conducted every 5 years for all FDA and state standardization officers. Restandardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs										

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1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18							
3. PROGRAM/ASSIGNMENT CODE(S) 18004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/>			5. OPERATIONAL FTE POSITIONS (2.3)				
R E G I O N	6	DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM MEETING (10)	CENTER INITIA- TIVES (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE (HOURS (13)	ISSC COMMITTEE (14)			
	TOTAL FIELD		14	14	14	350	14			
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	NEW ENGLAND	(b)(2) & (b)(7)(E)								
	NEW YORK	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	WEAC	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE	(b)(2) & (b)(7)(E)								
	CHICAGO	(b)(2) & (b)(7)(E)								
	CINCINNATI	(b)(2) & (b)(7)(E)								
DETROIT	(b)(2) & (b)(7)(E)									
MINNEAPOLIS	(b)(2) & (b)(7)(E)									
NEW JERSEY	(b)(2) & (b)(7)(E)									
PHILADELPHIA	(b)(2) & (b)(7)(E)									
FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)									
REGIONAL STAFF	(b)(2) & (b)(7)(E)									
ATLANTA	(b)(2) & (b)(7)(E)									
FLORIDA	(b)(2) & (b)(7)(E)									
NEW ORLEANS	(b)(2) & (b)(7)(E)									
SAN JUAN	(b)(2) & (b)(7)(E)									
REGIONAL LAB	(b)(2) & (b)(7)(E)									
REGIONAL STAFF	(b)(2) & (b)(7)(E)									
DALLAS	(b)(2) & (b)(7)(E)									
DENVER	(b)(2) & (b)(7)(E)									
KANSAS CITY	(b)(2) & (b)(7)(E)									
SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)									
REGIONAL LAB	(b)(2) & (b)(7)(E)									
REGIONAL STAFF	(b)(2) & (b)(7)(E)									
LOS ANGELES	(b)(2) & (b)(7)(E)									
SAN FRANCISCO	(b)(2) & (b)(7)(E)									
SEATTLE	(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LAB - SW	(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)									
HOURS PER OPERATION			30.0	80.0	40.0		20.0			
TOTAL HOURS			420	1120	560	350	280			
CONVERSION FACTOR			1200	1200	1200	1200	1200			
TOTAL OPERATIONAL FTE			0.35	0.93	0.47	0.29	0.23			

- (10) Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, and initiatives of national importance. Includes discussions of FDA issues for the ISSC agency program priorities, etc.
- (11) Time allocated for CFSAN priority assignments in response to national shellfish safety. Time is also allocated for the specialists to assist the FDA Laboratory Evaluation Officer (LEO) in the planning and evaluation activities of state shellfish program labs.
- (12) Includes time for the Regional Shellfish Specialists to attend regional shellfish conferences.
- (13) Time allocated for presentation and distribution of the Food Producers, Processors, and Transporter: Food Security Preventive Measures Guidance to the state regulatory agencies and industries during field work and state program evaluations. Presentations may be made at regional seminars or local meetings and presentations may also be included in training sessions for all segments of the regulatory and industry community.
- (14) Time allocated for the specialists to work on current and new ISSC proposals.

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To 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 to ensure conformance with the public health principles 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 technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication with CFSAN and ORA Headquarters regarding significant program issues and activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Environmental Conditions, Human Food, Water and Wastes	d. INDUSTRY/PRODUCT CODE(S) Inspections/Investigations: Industry 51 All food codes, including water 29W (Y30).
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
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 Interstate Travel Program - Conveyances and Support Facilities			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18																
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 23.3 (22.9)												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	CONVEY UNDER CONSTRUCTION HOURS (*)	WATERING POINTS INSP (A)	CATERING POINTS INSP (B) (**)	VESSELS INSP (C)	DSCs	DSAs MICRO	INV (HOURS)	ITP SPECIALIST TIME (HOURS) (****)									
	TOTAL FIELD	1700	1360	(710)	(380)	(300)	100	100	500	950									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB																			
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
REGIONAL LAB																			
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LAB - SW																		
PACIFIC REGIONAL LAB - NW																			
HOURS PER OPERATION											10.5					4.0	8.0		
TOTAL HOURS											17850	1360				400	800	500	950
CONVERSION FACTOR											950	950				950	1180	950	950
TOTAL OPERATIONAL FTEs											18.79	1.43				0.42	0.68	0.53	1.00

7. REMARKS:

Inspections in Columns A-C are included in Column 1. Columns will not add across since other firms may be covered under this program.  
 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 randomly collected from on-board conveyances water systems outlets 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.  
 \*\*\*\*ITP Specialist-475 hours provided to each of districts (SAN and SEA) for specialized inspections of aircraft constructions, cruise ship constructions and their galley components.

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1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18					
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (.4)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	STEERING COMMITTEE (HOURS)  (****)					
	<b>TOTAL FIELD</b>	400					
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
	REGIONAL LAB						
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
	HOURS PER OPERATION						
	TOTAL HOURS	400					
	CONVERSION FACTOR	950					
	TOTAL OPERATIONAL FTEs	0.42					

7. REMARKS:

\*\*\*\*\*Steering Committee - time provided to each of the districts (NWE,CIN,FLA,DAL and SAN) for updating handbooks.



1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To 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 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 for medical foods firms. Inspections of foreign manufacturers of medical foods are planned under PAC 03R233. 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: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Medical Foods	d. INDUSTRY/PRODUCT CODE(S) 41G[ ] [ ] Use appropriate product identification number
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )      Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , and Aerobic Plate Count (APC).	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program	

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.7			
R E G I O N	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
	<b>TOTAL FIELD</b>	<b>19</b>	<b>38</b>	<b>21</b>	<b>17</b>	<b>8</b>	<b>17</b>	<b>21</b>	<b>8</b>	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	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		570	198			40	510	2100	800	
CONVERSION FACTOR		950	950			950	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.60	0.21			0.04	0.43	1.78	0.68	

7. REMARKS

CFSAN spreads inspections and DSCs.  
 ORA spreads import operations.  
 Time to investigate import entries for admissibility is planned under the Imports Foods General Program (7303.819)  
 \*Includes samples resulting from import entry review as well as samples collected during foreign inspections.  
 \*\*May be used for microbiological analysis.

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis And General Food Labeling Program	2. PPS PROJECT NAME/NUMBER Food Composition Standards Labeling and Economics - 21
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3. PROGRAM TYPE:       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 appear on 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). Beginning January 2006, CFSAN anticipates adding coverage for Trans fat and additional allergen labeling. CFSAN will issue guidance in this regard. 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 all import field exams, see note under “ Remarks “ section for the program 21005

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

b. INSPECTION TYPE: NA       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) All food Products (except vitamins/minerals)	d. INDUSTRY/PRODUCT CODE(S) 02-41
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e. EXAM TYPE:       CHEMICAL       MICROBIOLOGICAL       PHYSICAL       ENGINEERING

MICROANALYTICAL       OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

Label review and nutrient analyses as appropriate

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

1. PROGRAM/ASSIGNMENT TITLE Infant Formula Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21006	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>5.6 (4.5)</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	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 **
	<b>TOTAL FIELD</b>	<b>24</b>		<b>32</b>	<b>21</b>	<b>11</b>	<b>21</b>	<b>11</b>	<b>15</b>	<b>15</b>
NE	HEADQUARTERS	(b)(2) &		(b)(2) & (b)(7)(E)						
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	<b>HOURS PER OPERATION</b>	<b>37.0</b>		<b>5.3</b>			<b>100.0</b>	<b>30.0</b>	<b>5.0</b>	<b>100.0</b>
	<b>TOTAL HOURS</b>	<b>888</b>		<b>170</b>			<b>2100</b>	<b>330</b>	<b>75</b>	<b>1500</b>
	<b>CONVERSION FACTOR</b>	<b>950</b>		<b>950</b>			<b>1180</b>	<b>1180</b>	<b>950</b>	<b>1180</b>
	<b>TOTAL OPERATIONAL FTEs</b>	<b>0.93</b>		<b>0.18</b>			<b>1.78</b>	<b>0.28</b>	<b>0.08</b>	<b>1.27</b>

7. REMARKS

ORA spreads import operations  
 \* Includes samples resulting from import entry review as well as samples collected during foreign inspections.  
 Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819)  
 \*\* May also be used for microbiological analysis.  
 Numbers that are shaded are included in Domestic Sample Collections

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1. PROGRAM/ASSIGNMENT TITLE Infant Formula Program				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) 21006		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS <b>(1.1)</b>			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INVEST- GATION (Hours)	2 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE ANALYZED	3	3	7	4	8
	<b>TOTAL FIELD</b>	<b>200</b>	<b>10</b>	<b>10</b>					
	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-S								
	PACIFIC REGIONAL LABORTORY-N								
	HOURS PER OPERATION		5.3	100.0					
	TOTAL HOURS	200	53	1000					
	CONVERSION FACTOR	950	950	1180					
	TOTAL OPERATIONAL FTEs	0.21	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.

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements – Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure compliance with the Dietary Supplement Health and Education Act and regulations promulgated there under by inspections of dietary supplement manufacturers and import label exams. Dietary supplements of both domestic and import origin will be collected and analyzed for nutrient content vs. label declarations. All non-exempt dietary supplement must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these requirements will be determined by domestic and import field exams and documentary sample collections.	
5. PROGRAM JUSTIFICATION Dietary supplements are a special class of products consisting of such dietary ingredients as vitamins, minerals, amino acids, glandulars, herbs and other botanicals. These products are subject to specific safety and labeling requirements. This program provides guidance to FDA district offices regarding inspections, import investigations, sample collection and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994.  The Center has set aside resources for special headquarters initiated assignments to address emerging issues. Investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on their labels and supplements being marketed with claims to treat diseases. 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Dietary supplements	d. INDUSTRY/PRODUCT CODE(S) 54
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )      Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Analyze selected nutrients and compare with levels declared on product label. Review labels as directed in Part III of C.P. 7321.008	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.	

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements			2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21								
3. PROGRAM/ASSIGNMENT CODE(S) 21008, 21R829 (Health Fraud)			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 15.9 (13.0)			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		INSPEC-TIONS	DOMESTIC FIELD EXAMS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED	HQ INIT DOMESTIC SAMPLE COLL	HQ INIT DOMESTIC SAMPLE ANALYZED CHEM			INV HOURS
	TOTAL FIELD		250	900	200	100	50	50			4000
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF		(b)(2) & (b)(7)(E)								
	NEW ENGLAND		(b)(2) & (b)(7)(E)								
	NEW YORK		(b)(2) & (b)(7)(E)								
	REGIONAL LAB		(b)(2) & (b)(7)(E)								
CE	WEAC		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF		(b)(2) & (b)(7)(E)								
	BALTIMORE		(b)(2) & (b)(7)(E)								
	CHICAGO		(b)(2) & (b)(7)(E)								
	CINCINNATI		(b)(2) & (b)(7)(E)								
	DETROIT		(b)(2) & (b)(7)(E)								
	MINNEAPOLIS		(b)(2) & (b)(7)(E)								
	NEW JERSEY		(b)(2) & (b)(7)(E)								
SE	PHILADELPHIA		(b)(2) & (b)(7)(E)								
	FORENSIC CHEM. CTR		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF		(b)(2) & (b)(7)(E)								
	ATLANTA		(b)(2) & (b)(7)(E)								
	FLORIDA		(b)(2) & (b)(7)(E)								
SW	NEW ORLEANS		(b)(2) & (b)(7)(E)								
	SAN JUAN		(b)(2) & (b)(7)(E)								
	REGIONAL LAB		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF		(b)(2) & (b)(7)(E)								
	DALLAS		(b)(2) & (b)(7)(E)								
PA	DENVER		(b)(2) & (b)(7)(E)								
	KANSAS CITY		(b)(2) & (b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT		(b)(2) & (b)(7)(E)								
	REGIONAL LAB		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF		(b)(2) & (b)(7)(E)								
LOS ANGELES		(b)(2) & (b)(7)(E)									
SAN FRANCISCO		(b)(2) & (b)(7)(E)									
SEATTLE		(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LABORTORY-SW		(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LABORTORY-NW		(b)(2) & (b)(7)(E)									
HOURS PER OPERATION			18.0	0.5	4.2	20.0	4.2	20.0			
TOTAL HOURS			4500	450	840	2000	210	1000		4000	
CONVERSION FACTOR			950	950	950	1180	950	1180		950	
TOTAL OPERATIONAL FTEs			4.74	0.47	0.88	1.69	0.22	0.85		4.21	

7. REMARKS

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

Additional resources have been planned in the Domestic Pesticide Program (7304.004) for a pesticide contaminant assignments for select supplement products.

Investigational hours are planned primarily for CFSAN directed assignments

Import resources planned in page 2.

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

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1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements					2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21												
3. PROGRAM/ASSIGNMENT CODE(S) 21008, 21R829 (Health Fraud)			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (2.9)											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISC PAPER OASIS #41	ISC PHYSICAL ***	IMPORT INV HOURS	ISA PHYSICAL CHEM												
	TOTAL FIELD	360	70	900	70												
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
SAN FRANCISCO																	
SEATTLE																	
PACIFIC REGIONAL LABORATORY-SW																	
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										1.6	1.6		20.0				
TOTAL HOURS										576	112	900	1400				
CONVERSION FACTOR										950	950	950	1180				
TOTAL OPERATIONAL FTEs										0.61	0.12	0.95	1.19				

7. REMARKS

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrient in Foods Survey - Total Diet				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 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
NE	HEADQUARTERS							(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL 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 ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 21
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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

ORA/Center Directed Research Projects

2. PPS PROJECT NAME/NUMBER

Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)

21R816

4. WORK ALLOCATION PLANNED BY

ORA  CENTER

5. OPERATIONAL FTE POSITIONS

1.3

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH (CHEM)	DISTRICT CENTER (MICRO)	RESEARCH CENTER (CHEM)						
	TOTAL FIELD	360		1180						
NE	HEADQUARTERS	(b)(2) &		(b)(2) &						
	REGIONAL STAFF	(b)(7)(E)		(b)(7)(E)						
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY- NW									
HOURS PER OPERATION										
TOTAL HOURS		360		1180						
CONVERSION FACTOR		1205		1180						
TOTAL OPERATIONAL FTEs		0.30		1.00						

7. REMARKS

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



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

4. OBJECTIVES

To determine by inspection, sample collection, and label exam, if 1) cosmetic manufacturers or repackers, 2) 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 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.

6. FIELD OBLIGATIONS

Districts will conduct inspections, perform import field exams, collect and analyze samples for non-permitted ingredients, perform microbiological analyses and 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                     BY CENTER                     BY BOTH

b. INSPECTION TYPE:                     COMPREHENSIVE                     ABBREVIATED                     DIRECTED

c. PRODUCT(S) Cosmetic Products	d. INDUSTRY/PRODUCT CODE(S) 53
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e. EXAM TYPE:                     CHEMICAL                     MICROBIOLOGICAL                     PHYSICAL                     ENGINEERING

MICROANALYTICAL                     OTHERS (*Specify*)    Label Reviews

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 <b>Cosmetics: Domestic and Imports</b>	2. PPS PROJECT NAME/NUMBER <b>Colors and Cosmetics Technology - 29</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833,	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECT- IONS	2 DOMESTIC INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT ENTRY REVIEW (HOURS) *		4 IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	8 IMPORT SAMPLE ANALYSIS (CHEM)	8 IMPORT SAMPLE ANALYSIS (MICRO)
	TOTAL FIELD	100		75	75	1050		200	100	100
	HEADQUARTERS	(b)(2) &		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									

HOURS PER OPERATION	15.6		5.5	20.7			1.5	10.0	20.7
TOTAL HOURS	1560		413	1553	1050		300	1000	2070
CONVERSION FACTOR	950		950	1180	1200		950	1180	1180
OPERATIONAL FTEs	1.64		0.43	1.32	0.88		0.32	0.85	1.75

7. REMARKS

\* Import Entry Review Hours include time for Filer Evaluation (PAC 99R833) and Follow Up to Refusal (PAC 29R824) and **700 Import Label Reviews.**

For FY06 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 event of a Pre-Determined "for cause" CT exam, or in the event that CT suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC 29R845.  
See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

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

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2006**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>108.6</b>	<b>3.5</b>	<b>4.9</b>	<b>117.0</b>	<b>186.6</b>	<b>6.0</b>	<b>8.4</b>	<b>201.0</b>
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	22.9			22.9	39.3			39.3
42	BLOOD AND BLOOD PRODUCTS	79.1	3.5	3.3	85.9	136.0	6.0	5.6	147.6
45	VACCINES AND ALLERGENIC PRODUCTS	6.6		1.6	8.2	11.3		2.8	14.1

"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.



1. PROGRAM/ASSIGNMENT TITLE  
Tissue Establishments

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

3. PROGRAM TYPE:  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:  
 BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Biologics

d. INDUSTRY/PRODUCT CODE(S)  
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 Tissue Establishments	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41002B, C, D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L	4 I M P O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours)	
	<b>TOTAL FIELD</b>	<b>385</b>									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
REGIONAL LAB											
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB											
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION		38.3									
TOTAL HOURS		14746									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTES		15.52									

9. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE <b>GLPs (Nonclin. Lab), IRBs, Spon./Mon., Clin. Investigators (PDUFA)</b>	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM TYPE:     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 there under, 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                       BY CENTER                       BY BOTH

b. INSPECTION TYPE:     COMPREHENSIVE                       ABBREVIATED                       DIRECTED

c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products n.e.c.
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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 GLPs, IRBs, Sponsor-Monitors, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue & Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41808-GLP, 41809-IRB, 41810-Spon./ Monitor, 41811 Clinical Investigator *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	76								
NE	HEADQUARTERS	(b)(2) &								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	92.5								
	TOTAL HOURS	7030								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	7.40								

9. REMARKS

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

Personnel Types Required: Investigator



1. PROGRAM/ASSIGNMENT TITLE  
Inspection of Licensed and Unlicensed Blood Banks

2. PPS PROJECT NAME/NUMBER  
Blood and Blood Products - 42

3. PROGRAM TYPE:  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:  
 BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Blood and Blood Products

d. INDUSTRY/PRODUCT CODE(S)  
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 Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign) *				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42						
3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G 42R825			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 60.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSPEC- TIONS	1	2 DOMESTIC INVESTI- GATIONS (Hours) **	1 FOREIGN BLOOD BANK INSPEC- TIONS ***	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDIN- ATION (Hours)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>1131</b>		<b>2926</b>	<b>24</b>			<b>2375</b>		
NE	HEADQUARTERS	(b)(2) & (b)		(b)(2) & (b)(7)(E)				(b)(2) & (b)		
	REGIONAL STAFF	(7)(E)						(7)(E)		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		45.3			39.6					
TOTAL HOURS		51234		2926	950			2375		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		53.93		3.08	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 for PPS 41, 42, 45 and Field Investigation Hours are not planned separately. Use above resources for these as needed, at district discretion.

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

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

\*\*\* Foreign Blood Bank Inspections spread by DFI.

Personnel Types Required: Investigator, National Experts

1. PROGRAM/ASSIGNMENT TITLE  
Inspection of Source Plasma Establishments

2. PPS PROJECT NAME/NUMBER  
Blood and Blood Products - 42

3. PROGRAM TYPE:  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:  
 BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Source Plasma

d. INDUSTRY/PRODUCT CODE(S)  
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 Inspection of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours) *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>164</b>	<b>2271</b>							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	46.4								
	TOTAL HOURS	7610	2271							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATION FTEs	8.01	2.39							

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 Examination of Biological Products Offered for Import	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM TYPE:     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 of unlicensed blood products 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 procedures for the importation of blood products and ensure consistent handling of imported blood products by the field.

In 2005 new regulations for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) became effective. Because the new regulations at 21 CFR 1271 include new import provisions, there is a need for a compliance program to clarify the procedures for the importation of HCT/Ps.

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.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE                       BY CENTER                       BY BOTH

b. INSPECTION TYPE:                       COMPREHENSIVE                       ABBREVIATED                       DIRECTED

c. PRODUCT(S) Biological Products	d. INDUSTRY/PRODUCT CODE(S) 57
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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 Examination of Biological Products Offered for Import	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42007, 42R833, 42R824, 99R833 41R824, 45R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.5
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R E G I O N	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)	
	<b>TOTAL FIELD</b>		<b>4200</b>								
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - NW										
	PACIFIC REGIONAL LAB - SW										
HOURS PER OPERATION											
TOTAL HOURS			4200								
CONVERSION FACTOR			1200								
TOTAL OPERATION FTES			3.50								

9. REMARKS

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

note: New guidance has been issued for importation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE  
Inspections of Licensed Viral Marker Test Kits  
(Inspections of In Vitro Diagnostic Product Manufacturers)

2. PPS PROJECT NAME/NUMBER  
Blood and Blood Products - 42

3. PROGRAM TYPE:  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:  
 BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
In Vitro Diagnostic Products accordance with the stated objective.

d. INDUSTRY/PRODUCT CODE(S)  
55, 57, 65 & 81 (Device Categories)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING



1. PROGRAM/ASSIGNMENT TITLE  
IRBs, Spon./Mon./ CROs, Clinical Investigators  
(PDUFA)

2. PPS PROJECT NAME/NUMBER  
Blood and Blood Products - 42

3. PROGRAM TYPE:  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 there under, 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  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Biologics

d. INDUSTRY/PRODUCT CODE(S)  
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 GLPs, IRBs, Sponsor-Monitors, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42809-IRB, 42810-Spon./Monitor, 42811 Clinical Investigator *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>38</b>								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION		87.5								
TOTAL HOURS		3325								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		3.50								

9. REMARKS

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

Personnel Types Required: Investigator

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspection of Medical Device Manufacturers (Biologics) <b>PACs 42845A,B,C</b>	<b>2. PPS PROJECT NAME/NUMBER</b> Blood and Blood Products - 42
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  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.	
<b>5. PROGRAM JUSTIFICATION</b>  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.	
<b>6. FIELD OBLIGATIONS</b>  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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All devices in the product categories transferred to CBER	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 65 & 81 (Device Categories)
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )                      Device Specific	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42							
3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C *		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.0					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	<b>35</b>									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
REGIONAL LAB											
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB											
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION		54.3									
TOTAL HOURS		1901									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTEs		2.00									

7. REMARKS

No Investigation Hours or Foreign Inspections are planned, use above resources if needed.  
 The module used reflects the time needed for a comprehensive inspection.

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

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE  
Inspections of Plasma Derivatives of Human Origin  
PACs 42848A,F,G

2. PPS PROJECT NAME/NUMBER  
Blood and Blood Products - 42

3. PROGRAM TYPE:  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:  
 BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Fractionation Products

d. INDUSTRY/PRODUCT CODE(S)  
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 Inspection of Plasma Derivatives of Human Origin	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42848A, F, G; 41848A, F, G Domestic & Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPECT- IONS	1 FOREIGN LICENSED INSPECT- IONS	3 DOMESTIC SAMPLE COLL	2 DOMESTIC INVESTI- GATIONS (Hours)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	8	7							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)								
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LAB - SW		(b)(2) & (b)(7)(E)								
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		207.0	170.0							
TOTAL HOURS		1656	1190							
CONVERSION FACTOR		950	950							
OPERATIONAL FTEs		1.74	1.25							

7. REMARKS

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

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

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



1. PROGRAM/ASSIGNMENT TITLE IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  <b>IRBs:</b> 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).  <b>Spon./Mon./CROs:</b> To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.  <b>Clin. Investigators:</b> 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  <b>IRBs:</b> 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.  <b>Spon./Mon./CROs:</b> 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.  <b>Clin. Investigators:</b> The Kefauver Harris amendment to the Act and the regulations promulgated there under, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.	
6. FIELD OBLIGATIONS  <b>IRBs:</b> 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. <b>Spon./Mon./CROs:</b> Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office. <b>Clin. Investigators:</b> Conducts inspections as assigned by CBER and forward the reports including recommendations for compliance follow-up as needed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99    99 is used for products n.e.c.
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsors-Monitors, Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45					
3. PROGRAM/ASSIGNMENT CODE(S) 45809 IRBs, 45810 Spon/Mon, 45811 Clin. Invest.			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.0				
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	SPECIALIZED									
	<b>TOTAL FIELD</b>	<b>33</b>								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION		86.8								
TOTAL HOURS		2864								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		3.01								

7. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE  
Inspection of Licensed Allergenic Products  
PACs 45848A,F,G

2. PPS PROJECT NAME/NUMBER  
Vaccines and Allergenic Products - 45

3. PROGRAM TYPE:  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:  
 BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Biologics

d. INDUSTRY/PRODUCT CODE(S)  
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 Inspection of Licensed Allergenic Products (Post-Market & Pre-License)					2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45					
3. PROGRAM/ASSIGNMENT CODE(S) 45848A,F,G Domestic/Foreign *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 1.2			
R E G I O N	6.	1 *	1 *	2	3	4	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	DOMESTIC INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
<b>TOTAL FIELD</b>		7	2							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		104.0	202.0							
TOTAL HOURS		728	404							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.77	0.43							

7. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products PACs 45848B,C,D	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To ensure the safety and effectiveness of 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, <b>comprehensive inspections</b> that assess the adequacy of all significant processes and systems. These should be performed on <b>at least a Biennial Basis</b> . 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: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic/Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP CTIONS	1 FOREIGN INSP CTIONS	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	7	6	570						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		300.0	191.0							
TOTAL HOURS		2100	1146	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		2.21	1.21	0.60						

7. REMARKS

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

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

**CENTER FOR DRUG EVALUATION AND RESEARCH  
 RESOURCE SUMMARY  
 FY 2006 ORA WORKPLAN  
 October 1, 2005**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES	PROGRAM FTES			TOTAL PROGRAM FTES
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	298.1	41.1	50.4	389.6	514.4	70.8	86.8	672.0
46	NEW DRUG EVALUATION	14.0		15.0	29.0	24.1		25.9	50.0
48	BIORESEARCH MONITORING HUMAN DRUGS	45.7		4.6	50.3	78.8		7.9	86.7
52	GENERIC DRUG EVALUATION	18.7		11.1	29.8	32.2		19.1	51.3
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	8.3		1.7	10.0	14.3		2.9	17.2
56	DRUG QUALITY ASSURANCE	187.4	41.1	18.0	246.5	323.4	70.8	31.0	425.2
63	UNAPPROVED AND MISBRANDED DRUGS	12.0			12.0	20.8			20.8
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0	20.8			20.8

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

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

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



## FY 2006

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

**FY 2006**

1. PROGRAM/ASSIGNMENT TITLE NDA Methods Validations	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Inv. Methods Validation-Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46832M <input checked="" type="checkbox"/>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	5	7	7	7	7
		NDA TO INSPECT (Domestic)	CHEMIST INSPECT (HOURS) (Domestic) *	INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) **	DSAs METH. VALID. (MICRO) ***		DSAs (METH.) (VALID) CHEM ****
	<b>TOTAL FIELD</b>	<b>129</b>	<b>2275</b>		<b>30</b>		<b>30</b>	<b>6</b>		<b>23</b>
	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	7224	2275		150		1500	630		2415
	CONVERSION FACTOR	950	950		950		1180	1180		1180
	TOTAL OPERATIONAL FTES	7.60	2.39		0.16		1.27	0.53		2.05

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 2006**

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

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations (Methods Validation) - Foreign (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46832D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS ++ FOREIGN	1 CHEMIST INSPS (Hours) 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	183	2788	50			50	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)	
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		55.0		3.0			30.0	
TOTAL HOURS		10065	2788	150			1500	
CONVERSION FACTOR		950	950	950			1180	
TOTAL OPERATIONAL FTEs		10.59	2.93	0.16			1.27	

7. REMARKS

\* **Report as follows: Insp./Chem on Insp. under foreign operation code 11 Pac Code 46832;**  
M. Valid.-46832; Profile ISCs & ISAs -46832B; Biotest ISCs & ISAs (not planned) if collected -46832C.  
\*\* Includes microbiologists on inspections. \*\*\* 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).



1. PROGRAM/ASSIGNMENT TITLE  
In Vivo Bioequivalence  
(PDUFA)

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

3. PROGRAM TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES  
Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.

5. PROGRAM JUSTIFICATION  
Bioequivalence studies are conducted mainly by private and university affiliated contract laboratories. Previous inspections noted deviations from protocols, poor recordkeeping, inadequate controls over test subjects, poor analytical procedures and fraud. Results of bioequivalence inspections have a direct relationship to approvability of NDA and ANDA applications.

6. FIELD OBLIGATIONS  
Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.

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

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)  
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 <b>In Vivo Bioequivalence (Pre-Approval)</b>	2. PPS PROJECT NAME/NUMBER <b>Bioresearch Monitoring: Human Drugs - 48</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSP EC T I O N S  DOMESTIC	1 48001A NDA INSP EC T I O N S (PDUFA) DOMESTIC	2 IMPORT INVESTIGATION HOURS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	<b>36</b>	<b>37</b>								
	HEADQUARTERS	(b)(2) & (b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
SEATTLE											
PACIFIC REGIONAL LAB (SW)											
PACIFIC REGIONAL LAB (NW)											
HOURS PER OPERATION		64.1	76.3								
TOTAL HOURS		2308	2823								
CONVERSION FACTOR		950	950								
TOTAL OPERATIONAL FTEs		2.43	2.97								

7. REMARKS

Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification.

An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 45%, PDUFA 48001A (NDA) 55%.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To determine through audit procedures whether: (a) bioequivalence data, (b) non-clinical laboratory study data, and (c) clinical data are substantiated by on-site documentation, are valid, scientifically accurate and the studies were conducted according to appropriate regulations.  GLP inspections in foreign laboratories may also provide an assessment of the effectiveness of an existing Memorandum of Understanding with that named nation.	
5. PROGRAM JUSTIFICATION  An increasing number of bioequivalence studies are conducted by contract laboratories, private and university affiliated, located in Canada and Europe. In addition, large numbers of animal studies (GLP) and clinical studies are conducted in Europe and other foreign countries. Serious problems associated with lack of adherence to protocols, lack of and inadequate record keeping, inadequate and inaccurate analytical procedures, and fraud have been documented in such studies. These studies are required for drug approval in the United States.  The President's Emergency Plan for AIDS Relief (PEPFAR) requires inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs. Data audit under PEPFAR will be verified by on site inspections.	
6. FIELD OBLIGATIONS  Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.  The audit of data from bioequivalence manufacturers and clinical studies will be verified.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:  <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60 , 61
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)				2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48811; 48001D,E; 48811D NDA &, ANDA *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSP EC- TIONS (PDUFA)	1 FOREIGN 48001 ANDA INSP EC- TIONS (PRE-APPR)	2 IMPORT INVESTIGATION HOURS	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	41	30							
	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										
SW	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
PA	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	60.7	62.7							
	TOTAL HOURS	2489	1881							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	2.62	1.98							
7. REMARKS  * Planned inspections include: 48001,A In Vivo Bioequivalence, 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): 48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator. NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001. We are not planning separate PEPFAR work.  Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs. Data audit under PEPFAR will be verified by on site inspections.  Personnel Types Required: Investigator, National Expert										

1. PROGRAM/ASSIGNMENT TITLE  
Good Laboratory Practice  
(Nonclinical Laboratory)

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

3. PROGRAM TYPE:  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  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)  
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 Good Laboratory Practices (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48808	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 NAT'L EXPERT INVESTI- GATIONS (Hours)	2 IMPORT INVESTIGATION HOURS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>38</b>	<b>646</b>							
	HEADQUARTERS	( b & ( ) b ( ) 2								
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	3344	646							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	3.52	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 Institutional Review Board (IRB); Radioactive Drug Research Committee (RDRC)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  IRB: To assure compliance and integrity of institutional review boards (21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.  RDRC: To assure the quality and integrity of Radioactive Drug Research Committees and assure they are operating in compliance with (21 CFR 361.1).	
5. PROGRAM JUSTIFICATION  IRB: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected. The inspectional program assures that IRBs protect the safety and welfare of clinical trial subjects and ensures that the informed consent form and the process of obtaining informed consent comply with current regulations.  RDRC: The Nuclear Regulatory Commission and the FDA have decided that certain protocols involving radioactive drugs do not need an IND, but must be reviewed by an institutional RDRC. These protocols are those intended for basic research purposes, not those protocols intended to determine the safety and efficacy of the drug in humans. The RDRC assures that the radiation doses and pharmacological doses are within specified limits. The Division of Scientific Investigations, Office of Compliance, CDER, issues assignments to the districts, reviews all complete EIRs and their classification, and issues letters as needed to RDRCs after such review.	
6. FIELD OBLIGATIONS  IRB: Conduct inspections of IRBs which are involved in the review of clinical trials of human drug studies and forward the reports to the Division of Scientific Investigations, CDER.  Assist in presentation of IRB workshops.  RDRC: Conduct inspections of RDRCs and forward the EIRs to the Division of Scientific Investigations, CDER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60 , 61
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	



1. PROGRAM/ASSIGNMENT TITLE  
Sponsors, Contract Research Organizations, & Monitors

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

3. PROGRAM TYPE:  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  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)  
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  
Clinical Investigators

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

3. PROGRAM TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES  
To assess through audit procedures whether data submitted to FDA in a specific study are substantiated by source documents and whether clinical investigators have complied with regulations (21 CFR 312).

5. PROGRAM JUSTIFICATION  
Clinical data are submitted to FDA in support of a marketing permit (IND, NDA). The clinical studies that generated the data are evaluated for accuracy, completeness, and regulatory compliance.

6. FIELD OBLIGATIONS  
Conduct inspections and forward EIRs directly to the Division of Scientific Investigations, CDER.  
District may make classification and recommend compliance actions.

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

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)  
60 , 61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING





## FY 2006

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

## FY 2006

1. PROGRAM/ASSIGNMENT TITLE ANDA - Methods Validation (DESI and Post 1962)	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To 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: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Validate methods, potency, purity, and other requirements	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Inv. Methods Validation - Domestic	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 18.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	3	7	7	7	9
		ANDAs TO INSPECT Domestic	CHEMIST INSPECT. (Hours) *	DOMESTIC INVEST (Hours)	DOMESTIC SAMPLE COLL **	PROFILE/ PORTION OF DSCs FOR DDA **	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	BIOTEST (Chem) ***	DSAs (METH) (VALID) (Chem) (Hours)	MISC. HOURS
	<b>TOTAL FIELD</b>	<b>137</b>	<b>1931</b>	<b>1593</b>	<b>140</b>	<b>(50)</b>	<b>45</b>	<b>45</b>	<b>29</b>	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	NEW ENGLAND	(b)(2) & (b)(7)(E)								
	NEW YORK	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	WEAC	(b)(2) & (b)(7)(E)								
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE	(b)(2) & (b)(7)(E)								
	CHICAGO	(b)(2) & (b)(7)(E)								
	CINCINNATI	(b)(2) & (b)(7)(E)								
	DETROIT	(b)(2) & (b)(7)(E)								
	MINNEAPOLIS	(b)(2) & (b)(7)(E)								
	NEW JERSEY	(b)(2) & (b)(7)(E)								
	PHILADELPHIA	(b)(2) & (b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	ATLANTA	(b)(2) & (b)(7)(E)								
	FLORIDA	(b)(2) & (b)(7)(E)								
	NEW ORLEANS	(b)(2) & (b)(7)(E)								
SW	SAN JUAN	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	DALLAS	(b)(2) & (b)(7)(E)								
	DENVER	(b)(2) & (b)(7)(E)								
PA	KANSAS CITY	(b)(2) & (b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
PA	LOS ANGELES	(b)(2) & (b)(7)(E)								
	SAN FRANCISCO	(b)(2) & (b)(7)(E)								
	SEATTLE	(b)(2) & (b)(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2) & (b)(7)(E)								
	PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)								
	HOURS PER OPERATION	60.0			5.0		50.0	30.0	105.0	
	TOTAL HOURS	8220	1931	1593	700		2250	1350	3045	
	CONVERSION FACTOR	950	950	950	950		1180	1180	1180	
	TOTAL OPERATIONAL FTEs	8.65	2.03	1.68	0.74		1.91	1.14	2.58	

7. REMARKS

\*Includes microbiologists on inspections. \*\* DSCs for profile/biotest analyses. Includes 50 Profile DSCs to be analyzed by Division of Drug Analysis (HFD-920). \*\*\* NRL-analyzes profile/biotest DSCs collected in NE & SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.  
Use CT PAC 52R845 only when specific CT work is performed.

## FY 2006

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

ANDA Pre - Approval Inspections/Investigations (Methods Validation) - Foreign	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B ,52832C, 52832E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS * (Foreign) **	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS		5 IMPORT SAMPLE COLL ***	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST '(Chem) ****	8 IMPORT SAMPLE ANALYSES METH. VALID. ****
	<b>TOTAL FIELD</b>	<b>62</b>	<b>2095</b>	<b>1125</b>		<b>140</b>		<b>70</b>	<b>70</b>	<b>15</b>
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	DALLAS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	DENVER									
	KANSAS CITY									
	Southwest Import District									
	REGIONAL LAB									
	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
HOURS PER OPERATION										
TOTAL HOURS										
CONVERSION FACTOR										
TOTAL OPERATIONAL FTEs										

7. REMARKS

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

Meth. Valid. under PAC 52832; Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C.  
 \*\* Includes microbiologists on inspections \*\*\* Samples are collected at foreign manufacturers.  
 \*\*\*\* NRL analyzes all Profile/Biotest ISCs and methods Validation ISAs.  
 Use CT PAC 52R845 only when specific CT work is performed.



## FY 2006

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

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN	2 INVESTI- GATION	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	138	27								
	HEADQUARTERS	(b)(2) & (b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - NW										
	PACIFIC REGIONAL LAB - SW										
	HOURS PER OPERATION	57.0	60.0								
	TOTAL HOURS	7866	1620								
	CONVERSION FACTOR	950	950								
	TOTAL OPERATIONAL FTEs	8.28	1.71								

7. REMARKS

\*Report both Domestic and Foreign inspections 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. Foreign Inspections are spread by ORA/DFI.



## FY 2006

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

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832, 56R359, 56002M*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 134.1
--	---	---------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	3	7	7	7	9	9	
		INSPECTIONS	INSPECTIONS (Hours) *	CHEMIST INSPECTIONS (Hours)	MICRO INSP CTIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	CERTIFICATION HOURS For Audits	MISC HOURS For Team Biologics Therapeutics INV hours
	<b>TOTAL FIELD</b>	<b>1504</b>	<b>2810</b>	<b>7574</b>	<b>1538</b>	<b>450</b>	<b>229</b>	<b>40</b>	<b>229</b>	<b>40</b>	<b>4800</b>	<b>2730</b>
	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF											
NE	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
	REGIONAL STAFF											
CE	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
	REGIONAL STAFF											
SE	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
	REGIONAL LAB											
SW	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
PA	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW											
	PACIFIC REGIONAL LAB - NW											
	HOURS PER OPERATION	65.0				5.0		38.0	28.0			
	TOTAL HOURS	97760	2810	7574	1538	2250		8702	1120	4800	2730	
	CONVERSION FACTOR	950	950	950	950	950		1180	1180	950	950	
	TOTAL OPERATIONAL FTEs	102.90	2.96	7.97	1.62	2.37		7.37	0.95	5.05	2.87	

7. REMARKS

\* Inspections hours are for additional drug inspections or investigations as needed.

Any new registrants in the high risk categories should be inspected during the first 6 months after registration.

Investigational resources include 3 FTEs for transfer of therapeutics from Biologics planned as headquarters positions.

Gas firms are under a separate worksheet 56-4 . \*\* DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.

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

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

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1. PROGRAM/ASSIGNMENT TITLE <b>DRUG Process Inspections- Domestic</b> (Gas Manufacturer)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS ( 5.0 )
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R E G I O N	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
	<b>TOTAL FIELD</b>	<b>157</b>								
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL-SW									
PACIFIC REGIONAL-NW										
	HOURS PER OPERATION	30.0								
	TOTAL HOURS	4710								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	4.96								

9. REMARKS  
 \* Total number of planned gas inspections in the Program for 2006.  
 (b)(2) & (b)(7)(E)

## FY 2006

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

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002,A,B,C,D,E,F 56832	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 18.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **						
	<b>TOTAL FIELD</b>	<b>195</b>	<b>4670</b>						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
	HOURS PER OPERATION	63.7							
	TOTAL HOURS	12422	4670						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	13.08	4.92						

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 2006

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

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56						
3. PROGRAM/ASSIGNMENT CODE(S) 56008A, C				4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 25.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 CHEMIST ON INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTIONS	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	3 DOMESTIC SAMPLE COLLECTIONS (API)	7 DOMESTIC SAMPLES ANALYZED (CHEM)	7 DOMESTIC SAMPLES ANALYZED (MICRO)	7 DOMESTIC SAMPLES ANALYZED (API) (Chem)
	TOTAL FIELD	310	998	955	827	128	220	827	128	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									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION				4.0			4.0	19.0	22.0	19.5
TOTAL HOURS		310	998	3820			880	15713	2816	4290
CONVERSION FACTOR		950	950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.33	1.05	4.02			0.93	13.32	2.39	3.64
9. REMARKS										
*DSAs are assigned by Division of Field Science, ORO per lab expertise for specific Drugs.										
<div style="background-color: #cccccc; width: 20px; height: 10px; display: inline-block; vertical-align: middle;"></div> The shaded area breaks out the sample collections and is only a guideline for Districts.										

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## FY 2006

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

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	8 IMPORT SAMPLES TO BE ANALYZED	9
		<b>TOTAL FIELD</b>	<b>100</b>	<b>300</b>	<b>30</b>				<b>30</b>	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)						(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION		25.0		4.0				35.0		
TOTAL HOURS		2500	300	120				1050		
CONVERSION FACTOR		950	950	950				1180		
TOTAL OPERATIONAL FTEs		2.63	0.32	0.13				0.89		

7. REMARKS

**FY 2006**

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

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56				
3. PROGRAM/ASSIGNMENT CODE(S) 56022, 56022A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	8 IMPORT SAMPLES TO BE ANALYZED
	TOTAL FIELD	41	950	34				34	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)						(b)(2) & (b)(7)(E)	
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		15.0		2.0				11.0	
TOTAL HOURS		615	950	68				374	
CONVERSION FACTOR		950	950	950				1180	
TOTAL OPERATIONAL FTEs		0.65	1.00	0.07				0.32	
7. REMARKS									

## FY 2006

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

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56D015 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)	
	<b>TOTAL FIELD</b>		<b>3800</b>								
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)								
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
SW	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION										
	TOTAL HOURS		3800								
	CONVERSION FACTOR		950								
	TOTAL OPERATIONAL FTEs		4.00								

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

## FY 2006

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 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: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R816, 52R816*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS								
	<b>TOTAL FIELD</b>	<b>4335</b>								
NE	HEADQUARTERS	(b)(2) & (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	4335								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	3.60								

7.REMARKS

\* Resources for 52R816 are planned under 56R816.

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

## FY 2006

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56			
3. PROGRAM TYPE:                    N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT					
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.					
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.					
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic activities PAC 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:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATE	<input type="checkbox"/> DIRECTED	
c. PRODUCT(S)		d. INDUSTRY/PRODUCT CODE(S)			
e. EXAM TYPE:    N/A		<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS <i>(Specify)</i>		
f. CHECK THE FOLLOWING ATTRIBUTES					
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING					

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R838, 56R831	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION								
	<b>TOTAL FIELD</b>	<b>10820</b>								
NE	HEADQUARTERS	(b)(2) & (b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL 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.



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

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs 	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012	4. WORK ALLOCATION PLANNED BY <div style="text-align: center;"> <input checked="" type="checkbox"/> ORA      <input type="checkbox"/> CENTER                 </div>	5. OPERATIONAL FTE POSITIONS <div style="text-align: center;">8.0</div>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVEST- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL. *	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED Chem	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	<b>TOTAL FIELD</b>	47	4775	118				59		
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)						(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	30.0		4.0				20.0		
	TOTAL HOURS	1410	4775	472				1180		
	CONVERSION FACTOR	950	950	950				1180		
	TOTAL OPERATIONAL FTEs	1.48	5.03	0.50				1.00		

7. REMARKS

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

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

## FY 2006

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

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Without Approved NDAs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	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)
	<b>TOTAL FIELD</b>	79	950	95						
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	30.0		5.0						
	TOTAL HOURS	2370	950	475						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	2.49	1.00	0.50						

7. REMARKS

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

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

**CENTER FOR VETERINARY MEDICINE  
RESOURCE SUMMARY  
FY 2006**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	94.2	28.7	3.9	126.8	162.7	49.6	6.7	219.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	7.2		3.5	10.7	12.5		6.0	18.5
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	87.0	28.7	0.4	116.1	150.2	49.6	0.7	200.5

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

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

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



1. PROGRAM/ASSIGNMENT TITLE  
NADA Pre-Approval Inspections

2. PPS PROJECT NAME/NUMBER  
Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE:  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  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Animal Drugs, Type A Medicated Feed Articles

d. INDUSTRY/PRODUCT CODE(S)  
56, 67, 68

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

f. CHECK THE FOLLOWING ATTRIBUTES  
Petition validation work.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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3. PROGRAM/ASSIGNMENT CODE(S) 68001	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	1 CHEMIST ON INSP **	1 INSPEC- TIONS (Foreign) ***	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)					
	<b>TOTAL FIELD</b>	40	310	47								
	HEADQUARTERS	(b)(2) & (b)(7)(E)										
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
FORENSIC CHEM. CTR												
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
PA	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW											
PACIFIC REGIONAL LABORATORY-NW												
	HOURS PER OPERATION	46.4		75.3								
	TOTAL HOURS	1856	310	3539								
	CONVERSION FACTOR	1000	1000	1000								
	TOTAL OPERATIONAL FTEs	1.86	0.31	3.54								

7. REMARKS

\*\* Analyst will participate on inspections as necessary.

Districts and Laboratories should collect and analyze samples as needed by the program, time for these operations is planned under inspections and chemist on inspections.

\*\*\* Foreign inspections spread by DFI. Use Operation Code 11 to report foreign inspections.

Workload Source: FACTS database (registered firms in IND 56, 67, and 68; Workload Obligation is "Yes" and Status is "Operational".)

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-clinical Laboratory)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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3. PROGRAM TYPE:  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       BY CENTER       BY BOTH

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S)  
Animal Drugs

d. INDUSTRY/PRODUCT CODE(S)  
67, 68, or 69

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To assure the adherence of sponsors, contract research organizations and monitors to the clinical monitoring regulations 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: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 67, 68, or 69
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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3. PROGRAM/ASSIGNMENT CODE(S) 68808, 68810, 68811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 68808 INSPEC- TIONS (GLPs) (SPON/MON)	1 68811 INSPEC- TIONS (CLINICAL INVEST)						
	<b>TOTAL FIELD</b>	50	51						
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	NEW ENGLAND	(b)(2) & (b)(7)(E)							
	NEW YORK	(b)(2) & (b)(7)(E)							
	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	WEAC	(b)(2) & (b)(7)(E)							
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	BALTIMORE	(b)(2) & (b)(7)(E)							
	CHICAGO	(b)(2) & (b)(7)(E)							
	CINCINNATI	(b)(2) & (b)(7)(E)							
	DETROIT	(b)(2) & (b)(7)(E)							
	MINNEAPOLIS	(b)(2) & (b)(7)(E)							
	NEW JERSEY	(b)(2) & (b)(7)(E)							
	PHILADELPHIA	(b)(2) & (b)(7)(E)							
FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)								
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	ATLANTA	(b)(2) & (b)(7)(E)							
	FLORIDA	(b)(2) & (b)(7)(E)							
	NEW ORLEANS	(b)(2) & (b)(7)(E)							
	SAN JUAN	(b)(2) & (b)(7)(E)							
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	DALLAS	(b)(2) & (b)(7)(E)							
	DENVER	(b)(2) & (b)(7)(E)							
	KANSAS CITY	(b)(2) & (b)(7)(E)							
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)							
	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	LOS ANGELES	(b)(2) & (b)(7)(E)							
	SAN FRANCISCO	(b)(2) & (b)(7)(E)							
	SEATTLE	(b)(2) & (b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)							
	HOURS PER OPERATION	58.3	41.0						
	TOTAL HOURS	2915	2091						
	CONVERSION FACTOR	1000	1000						
	TOTAL OPERATIONAL FTEs	2.92	2.09						

7. REMARKS

\* Resources for 68808 and 68810 are planned under 68808. Report inspections under the appropriate PAC. Inspections are to be conducted only when assignments are received from CVM.

Workload Source: FACTS database (BIMO firms in IND 67, 68, and 69 with Status of "Operational"; 3-year inspectional data from OPAS (PAC 68811).



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Drug Process and New Animal Drug Inspections / Type A Medicated Articles	<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21 CFR 211 for dosage form products and 21 CFR 226 for Type A Medicated Articles. To obtain accurate listing and labeling information for veterinary drug establishments. To check and verify the existence and scope of stability testing programs, protocols and commitments, and the validity of storage conditions, testing criteria and methodology together with reporting of results in the Drug Experience Report (DER) as specified in the approval New Animal Drug Application (NADA).	
<b>5. PROGRAM JUSTIFICATION</b>  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.	
<b>6. FIELD OBLIGATIONS</b>  The field will conduct CGMP inspections of registered animal drug establishments. Top priority will be given to establishments which manufacture sterile products.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 56, 60-66, 67-69
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Sterility, purity, identify, potency, decomposition	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> N/A	

1. PROGRAM/ASSIGNMENT TITLE Drug Process and New Animal Drug Inspections / Type A Medicated Articles	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71001 /A /B, 71005 /A, 71R841	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2	3			7	7
		INSP CTIONS	NAT'L EXPERTS ON INSP (Hours)	CHEM ON INSP (Hours)	INSP CTIONS (Foreign)	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	DOMESTIC SAMPLE COLL (Micro)	DOMESTIC SAMPLES TO BE ANALYZED (Chem)	DOMESTIC SAMPLES TO BE ANALYZED (Micro)
	<b>TOTAL FIELD</b>	213	210	500	10	235	80	30	15	30	15
	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
NE	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
CE	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	33.0			40.0		5.5			18.4	21.1
	TOTAL HOURS	7029	210	500	400	235	440			552	317
	CONVERSION FACTOR	1000	1000	1000	1000	1000	1000			1180	1180
	TOTAL OPERATIONAL FTEs	7.03	0.21	0.50	0.40	0.24	0.44			0.47	0.27

9. REMARKS

Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples. Investigational or official samples should be collected as appropriate.  
 Type A Medicated Articles program (71005 / A is now under 71001); continue to report work to PAC 71005 / A.

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

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

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To monitor domestic and imported animal feed and feed ingredients to prevent widespread contamination of the nation's food supply.  Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION  The use of contaminated feed ingredients has resulted in adulterated animal feeds and in economic losses to producers and processors when food-producing animals consume adulterated feeds. A hazard to human health may result from subsequent deposition of residues in meat, poultry, eggs, fish and dairy products. These foods constitute a significant portion of the human diet and fraud.  Outcome: Prevention or containment of potential human or animal health hazard.	
6. FIELD OBLIGATIONS  To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis.  Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Complete animal feeds and feed ingredients.	d. INDUSTRY/PRODUCT CODE(S) 69-72
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
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
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3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-J	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS TOTAL 14.1 DOMESTIC 11.9 IMPORT 2.2
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	3	3	3	3	7	7	7	7	7
		INSPEC- TIONS (Dioxin) *	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL Metals	DOMESTIC SAMPLE COLL Myco	DOMESTIC SAMPLE COLL Micro	DOMESTIC SAMPLE COLL Chem	DOMESTIC SAMPLE COLL Dioxin	DOMESTIC SAMPLE ANALYSIS Metals	DOMESTIC SAMPLE ANALYSIS Myco	DOMESTIC SAMPLE ANALYSIS Micro	DOMESTIC SAMPLE ANALYSIS Chem	DOMESTIC SAMPLE ANALYSIS Dioxin
				71003B	71003C	71003E	71003A	71003G	71003B	71003C	71003E	71003A	71003G
	<b>TOTAL FIELD</b>	15	805	20	250	200	200	135	20	250	200	200	135

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

HOURS PER OPERATION	20.0	4.2							12.0	7.7	19.4	5.5	19.0
TOTAL HOURS	300	3381							240	1925	3880	1100	2565
CONVERSION FACTOR	1000	1000							1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs	0.30	3.38							0.20	1.63	3.29	0.93	2.17

9. REMARKS

\* Inspections performed as F/U to violative dioxin samples

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

Workload Source: FACTS database; firms in IND 69-72 with Workload Obligation of "YES" and Firm Status of "OPERATIONAL".  
NOTE: Continued on Page 71-7

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1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-5	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices -71
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3. PROGRAM/ASSIGNMENT CODE(S)  71003 A-J	4. WORK ALLOCATION PLANNED BY  <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS  2.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL	4 IMPORT SAMPLE COLL Chem	4 IMPORT SAMPLE COLL Micro	4 IMPORT SAMPLE ANALYSIS Chem	8 IMPORT SAMPLE ANALYSIS Micro				
	TOTAL FIELD	220	155	65	155	65				
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	2.5			7.5	12.0				
	TOTAL HOURS	550			1163	780				
	CONVERSION FACTOR	1000			1180	1180				
	TOTAL OPERATIONAL FTEs	0.55			0.99	0.66				

9. REMARKS

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

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

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

Workload Source: FACTS and OASIS databases.

1. PROGRAM/ASSIGNMENT TITLE  
Feed Manufacturing

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

3. PROGRAM TYPE:  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  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Medicated Feeds

d. INDUSTRY/PRODUCT CODE(S)  
69

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

f. CHECK THE FOLLOWING ATTRIBUTES  
Drug analysis (potency) and drug contamination

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71004 / A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FEED ESTABS	1 INSPEC- TIONS NATIONAL EXPERTS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	DOMESTIC SAMPLE COLL (Micro)	7 DOMESTIC SAMPLES ANALYZED (Chem)	7 DOMESTIC SAMPLES ANALYZED (Micro)	1 VSIP INSPEC- TIONS (Hours) *	
	<b>TOTAL FIELD</b>	243	120	55	15	5	15	5	250	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
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		6.6			44.0	44.0		
	TOTAL HOURS	4617	120	363			660	220	250	
	CONVERSION FACTOR	1000	1000	1000			1180	1180	1000	
	TOTAL OPERATIONAL FTEs	4.62	0.12	0.36			0.56	0.19	0.25	

9. REMARKS

Non-potency feed sample analysis should be charged to 71003 A/E.  
 There are 348 State Contract inspections.  
 The 120 hours of inspections by National Experts equals to 6 Medicated Feed Inspections.

\* Resources are for the Voluntary Self Inspection Program (VSIP)

Shaded area serves as a **guideline** for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis. The remaining 35 collected samples are available for documentary sample collection.

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

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

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71006	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	7	7	9									
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES ANALYZED Chem (Hours)	DOMESTIC SAMPLES ANALYZED Micro (Hours)	METHODS VALID (Hours) *									
	<b>TOTAL FIELD</b>	245	1000	200	600	500	360									
	HEADQUARTERS	(b)(2) & (b)(7)(E)														
NE	REGIONAL STAFF															
	NEW ENGLAND															
	NEW YORK															
	REGIONAL LAB															
	WEAC															
CE	REGIONAL STAFF															
	BALTIMORE															
	CHICAGO															
	CINCINNATI															
	DETROIT															
	MINNEAPOLIS															
	NEW JERSEY															
	PHILADELPHIA															
FORENSIC CHEM. CTR																
SE	REGIONAL STAFF															
	ATLANTA															
	FLORIDA															
	NEW ORLEANS															
	SAN JUAN															
SW	REGIONAL LAB															
	REGIONAL STAFF															
	DALLAS															
	DENVER															
	KANSAS CITY															
PA	SOUTHWEST IMPORT DISTRICT															
	REGIONAL LAB															
	REGIONAL STAFF															
	LOS ANGELES															
	SAN FRANCISCO															
	SEATTLE															
	PACIFIC REGIONAL LABORATORY-SW															
	PACIFIC REGIONAL LABORATORY-NW															
	HOURS PER OPERATION	35.0		6.0												
	TOTAL HOURS	8575	1000	1200	600	500	360									
	CONVERSION FACTOR	1000	1000	1000	1180	1180	1180									
	TOTAL OPERATIONAL FTEs	8.58	1.00	1.20	0.51	0.42	0.31									

9. REMARKS

Planned analytical time may be converted to methods development per CVM's concurrence. Methods development work will be assigned by CVM.

Sample collections represent FSIS repeat violator samples involving C/R's, no sample analysis.

\* Additional time for method validation studies.

Feed and Animal Drug samples are analyzed by Denver Laboratory.

Workload Source: Inspections and investigation hours are assigned by Center.

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

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71				
3. PROGRAM/ASSIGNMENT CODE(S) 71009, 71R844 (99R833, 71R833, 71R824)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS Domestic      40.3      66.8 Import      26.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSPECTIONS *	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INVESTIGATION HOURS **	3 DOMESTIC SAMPLE COLLECTIONS	4 IMPORT SAMPLES COLLECTIONS	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES ANALYZED	9 TECHNICAL SUPPORT (HOURS) ***
	<b>TOTAL FIELD</b>	<b>3760</b>	<b>12900</b>	<b>7900</b>	<b>900</b>	<b>900</b>	<b>900</b>	<b>900</b>	<b>1500</b>
(b)(2) & (b)(7)(E)									
HEADQUARTERS									
REGIONAL STAFF									
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		7.5			5.0	2.5	8.0	7.4	
TOTAL HOURS		28200	12900	7900	4500	2250	7200	6660	1500
CONVERSION FACTOR		1000	1200	1000	1000	1000	1180	1180	1000
TOTAL OPERATIONAL FTEs		28.20	10.75	7.90	4.50	2.25	6.10	5.64	1.50

9. REMARKS

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

BSE inspections are allocated based on a weighted inventory of: 1) Renderers, Feed Mills, Protein Blenders who manufacture or process products using prohibited materials requiring annual BSE inspections, Operational, Seasonal, Workload Obligation Yes or No; 2) Renderers, Feed Mills, Protein Blenders, Operational, Seasonal, who only distribute prohibited material or do not handle prohibited material, Workload Obligation Yes or No; 3) All other firms, Workload Obligation Yes, Operational, Seasonal, that handle prohibited material, only distribute prohibited material, or do not handle prohibited material requiring an annual BSE inspection.

\*\* Import investigation hours are for field exams, filer evaluations, follow-up to refusals, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

\*\*\* Technical support hours includes supporting state activities under the Ruminant Feed Ban Regulation.

**Reporting Guidance:** Import Entry Review (Electronic and Manual--operation code 14, PAC 71R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refused Import Entries (PAC 71R824).

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program

2. PPS PROJECT NAME/NUMBER

Monitoring of Marketed Animal Drugs Feeds and Devices - 71

**Inspection Priorities.**

21 CFR §589.2000 pertains to a variety of firms and animal production operations that involve the manufacture, distribution, transportation, and feeding of animal feeds. While the intent of the rule is to ensure that specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources should be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with the regulations be encountered. Certain higher risk firm types, such as renderers, protein blenders, and feed mills, generally require regular re-inspections, even if the firm did not manufacture with prohibited material at their last inspection. Efforts should also be placed on regulatory agencies in identifying additional firms to be inspected under this program. In the identification, planning, and prioritization of inspections conducted under this program, the following firm / industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- 'For Cause' inspections
- Firms that have a violative history
- Renderers, Protein Blenders, and Feed Mills manufacturing with prohibited materials (Performance Goal Firms)
- Rendering operations (involving any product)
- Protein Blenders (involving any product)
- Commercial feed mills (ruminant feeds involved)
- Commercial feed mills (non-ruminant feeds involved)
- Animal feed distributors/retailers (ruminant feed or feed ingredients involved)
- Pet food/animal feed salvage operations
- Commercial feed mills (pet food manufacturing ONLY)
- Haulers/transporters of animal feeds (ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (non-ruminant feed or feed ingredients involved)
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Mobile feed mixers
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feed or feed ingredients involved)
- Haulers/transporters of animal feeds (no ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (pet foods ONLY involved)
- On-farm feed mixers (ONLY ruminant OR no ruminant animals on farm premises)

Inspection planning should generally be based on the priority of firms as listed above. Information should be collected on whether a firm has been documented as receiving, processing or distributing prohibited material. This information can be obtained directly through FACTS database, and through the BSE District Coordinator. A listing of these firms can also be found through the CVM website (<http://www.fda.gov/cvm/RuminantFeedInspections.htm>).

1. PROGRAM/ASSIGNMENT TITLE  
ORA/Center Directed Research Projects

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

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  
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  
Forensic Evaluation and Sample Analyses

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

3. PROGRAM TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

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

5. PROGRAM JUSTIFICATION

6. FIELD OBLIGATIONS

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

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING



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



**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
RESOURCE SUMMARY  
FY 2006**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>174.2</b>	<b>50.6</b>	<b>19.3</b>	<b>244.1</b>	<b>299.8</b>	<b>86.3</b>	<b>32.9</b>	<b>419.0</b>
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	97.0	40.4	14.2	151.6	165.6	68.9	24.2	258.7
83	PRODUCT EVALUATION: DEVICES	33.3		4.0	37.3	56.8		6.8	63.6
84	SCIENCE: DEVICES	5.1			5.1	8.7			8.7
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.8		0.1	14.9	27.7		0.2	27.9
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	23.5	10.2	1.0	34.7	40.1	17.4	1.7	59.2

"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.



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device Problem Reporting – MDR Follow-up	<b>2. PPS PROJECT NAME/NUMBER</b> Postmarket Assurance: Devices - 81
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> On assignment, follow up on MDR reports either at the medical facility or manufacturer.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Medical Devices	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 73-91
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Sterility Performance	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
---	--

3. PROGRAM/ASSIGNMENT CODE(S) 81010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S  (1)	2 INVE ST I G A T I O N S (Hours) (2)	3 DOMESTIC SAMPLE COLL ENG	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL STER	7 DOMESTIC SAMPLES TO BE ANALYZED ENG (3)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (4)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (5)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	23	100	1	1	1	1	1	1	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									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	12.1		11.5	11.5	11.5	37.0	36.0	20.0	
	TOTAL HOURS	278	100	12	12	12	37	36	20	
	CONVERSION FACTOR	950	950	950	950	950	1180	1180	1180	
	TOTAL OPERATIONAL FTEs	0.29	0.11	0.01	0.01	0.01	0.03	0.03	0.02	

9. REMARKS

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

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

(3) MDR samples to confirm reported defects.

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

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

# PROJECT SUMMARY SHEET

FY 2006

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			
	<b>TOTAL</b>		<b>97.0</b>	<b>40.4</b>	<b>14.2</b>	<b>151.6</b>	<b>258.7</b>	
1	Monitoring Devices of Foreign Origin - Import	82008 *		28.1		28.1	47.9	2-3
2	Inspection of Medical Device Manufacturers:		92.6		14.2	106.8	182.3	4-9
	GMP Inspections	82845ABCGS	(87.3)		(14.2)	(101.5)	(173.3)	
	Accredited Persons Audit Investigations	82845J	(0.3)			(0.3)	(0.5)	
	Accredited Persons Audit Inspections	82845P	(5.0)			(5.0)	(8.5)	
3	Condom Assignment	82Z002		4.3		4.3	7.3	10-11
4	Manufacturers and Importers of Surgical/ Examination Gloves	82Z003	0.1	8.0		8.1	13.9	12-13
5	BSE Assignment	82Z005	0.5			0.5	0.8	14-15
6	Center Initiated Assignments	82Z800	1.5			1.5	2.6	14-17
7	ORA/Center Directed Research Projects	82R816	2.0			2.0	3.4	18-19
8	Forensic Evaluation & Sample Analysis	82R838	0.3			0.3	0.5	20-21
	* In addition to PAC 82008, includes reporting PACs 82R824, 82R833, and 99R833.							

CENTER PROJECT MANAGER/TELEPHONE  
Tim Ulatowski 301-594-4692

ORA PLANNER/TELEPHONE  
John Aydinian 301-827-1634

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

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 28.1					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1 INSPEC- TIONS	2 ENTRY REVIEW (Hours)	2 IMPORT INV HOURS *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (Physical) ENG	4 IMPORT SAMPLE COLL (Physical) MICRO **	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>			23111	5663		60	60	60	60	
	HEADQUARTERS			(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)				
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION						2.2	2.2	25.5	25.5		
TOTAL HOURS			23111	5663		132	132	1530	1530		
CONVERSION FACTOR			1200	950		950	950	1180	1180		
TOTAL OPERATIONAL FTEs			19.26	5.96		0.14	0.14	1.30	1.30		

9. REMARKS

\* Import investigation hours are for field exams, filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 106.8 [101.7]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS LEVEL I DOMESTIC	1 INSPEC- TIONS LEVEL II DOMESTIC	1 INSPEC- TIONS LEVEL III COMPLIANCE DOMESTIC	1 INSPEC- TIONS FOREIGN	1 INSPEC- TIONS FOR CAUSE DOMESTIC	1 INSPEC- TIONS ACCREDITED PERSONS DOMESTIC	2 INVESTI- GATIONS (Hours)	2 INVESTI- GATIONS (Hours) A.P. AUDITS MDUFMA	
		82845A	82845B	82845C	82845B	82845G	82845P	82845B	82845J	
	<b>TOTAL FIELD</b>	<b>800</b>	<b>535</b>	<b>107</b>	<b>207</b>	<b>95</b>	<b>95</b>	<b>2602</b>	<b>255</b>	

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

HOURS PER OPERATION	34.0	60.0	89.0	65.0	71.0	50.1			
TOTAL HOURS	27200	32100	9523	13455	6745	4760	2602	255	
CONVERSION FACTOR	950	950	950	950	950	950	950	950	
TOTAL OPERATIONAL FTEs	28.63	33.79	10.02	14.16	7.10	5.01	2.74	0.27	

9. REMARKS

Quality Systems Inspection Technique (QSIT) Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause " inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Reprogram any unused resources into Level 1 and 2 inspections.

Inspectional modules include time for 82845S (sterilization), MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections. Investigational Hours resources have also been planned for National Experts (HQ line) and State Contract Monitoring (DAL-DO line).

Foreign inspections include resources for Level I, II, III, and For Cause-related inspections. For planning purposes Foreign inspections will be planned under the Level II inspection PAC (82845B); use the appropriate reporting PAC to record accomplishments associated with these Foreign inspections.

Accredited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program. Accredited Person Audits are conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO.

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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 106.8 [4.5]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	3	3	7	7	7		
	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED	DOMESTIC SAMPLES TO BE ANALYZED	DOMESTIC SAMPLES TO BE ANALYZED		
	82845C	82845C	82845C	82845C	82845C	ENG 82845C	MICRO 82845C	CHEM 82845C		
	<b>TOTAL FIELD</b>	<b>96</b>	<b>18</b>	<b>43</b>	<b>18</b>	<b>18</b>	<b>43</b>	<b>18</b>		

	HEADQUARTERS	(b)(2) & (b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	6.0				72.0	62.0	32.5			
	TOTAL HOURS	576				1296	2666				
	CONVERSION FACTOR	950				1180	1180	1180			
	TOTAL OPERATIONAL FTEs	0.61				1.10	2.26	0.50			

9. REMARKS

NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

MICRO Sample Analyses: Antisera and Products Media Testing to support GMP observations at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.

CHEM Sample Analyses: Test Kit or Reagent Testing to support GMP observations at WEAC.

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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 106.8    [0.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR 82845S	3 DOMESTIC SAMPLE COLL STERILITY 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82845S	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	44	11	6	11	6				
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	6.0			25.0	25.0				
	TOTAL HOURS	264			275	150				
	CONVERSION FACTOR	950			1180	1180				
	TOTAL OPERATIONAL FTEs	0.27			0.23	0.13				

9. REMARKS

NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.3				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL CHEM	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	3		2	320			2	320	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.8		3.0	2.5			12.0	12.7	
TOTAL HOURS		26		6	800			24	4064	
CONVERSION FACTOR		950		950	950			1180	1180	
TOTAL OPERATIONAL FTEs		0.03		0.01	0.84			0.02	3.44	

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

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 8.1			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	1 INSPEC-TIONS	3 DOMESTIC SAMPLE COLL ENG	3 DOMESTIC SAMPLE COLL CHEM	4 IMPORT SAMPLE COLL ENG (PHYSICAL)	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	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)
	<b>TOTAL FIELD</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>222</b>	<b>778</b>	<b>1</b>	<b>1</b>	<b>222</b>	<b>778</b>
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	NEW ENGLAND	(b)(2) & (b)(7)(E)								
	NEW YORK	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	WEAC	(b)(2) & (b)(7)(E)								
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE	(b)(2) & (b)(7)(E)								
	CHICAGO	(b)(2) & (b)(7)(E)								
	CINCINNATI	(b)(2) & (b)(7)(E)								
	DETROIT	(b)(2) & (b)(7)(E)								
	MINNEAPOLIS	(b)(2) & (b)(7)(E)								
	NEW JERSEY	(b)(2) & (b)(7)(E)								
	PHILADELPHIA	(b)(2) & (b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)								
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	ATLANTA	(b)(2) & (b)(7)(E)								
	FLORIDA	(b)(2) & (b)(7)(E)								
	NEW ORLEANS	(b)(2) & (b)(7)(E)								
	SAN JUAN	(b)(2) & (b)(7)(E)								
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	DALLAS	(b)(2) & (b)(7)(E)								
	DENVER	(b)(2) & (b)(7)(E)								
	KANSAS CITY	(b)(2) & (b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)								
PA	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	LOS ANGELES	(b)(2) & (b)(7)(E)								
	SAN FRANCISCO	(b)(2) & (b)(7)(E)								
	SEATTLE	(b)(2) & (b)(7)(E)								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)								
HOURS PER OPERATION		8.0	6.0	6.0	2.3	2.3	20.0	13.0	6.6	6.6
TOTAL HOURS		16	6	6	511	1789	20	13	1465	5135
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.02	0.01	0.01	0.54	1.88	0.02	0.01	1.24	4.35

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 <b>BSE Assignment/Center Initiated Assignments</b>	2. PPS PROJECT NAME/NUMBER <b>Compliance: Devices - 82</b>
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b>BSE: To enhance FDA's uniformity in inspection and compliance of BSE firms subject to the regulation and to determine compliance with the BSE regulation.</b>  <b>Center Initiated Assignments: Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.</b>	
5. PROGRAM JUSTIFICATION <b>BSE: FDA seeks to protect the public through the development of a comprehensive strategy of education, inspection and enforcement action on industry. These activities were initiated to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) regulations.</b>  <b>Center Initiated Assignments: A number of potential or emerging problems which cannot be predicted must be handled rapidly. This workplan activity provides resources for Center assignments which can rapidly address potential or emerging problems.</b>	
6. FIELD OBLIGATIONS <b>BSE: Districts will, upon assignment, conduct inspections of firms whose devices may contain or be exposed to BSE risk material to implement the objectives of this assignment.</b>  <b>Center Initiated Assignments: Conduct inspections and investigations as directed by Center assignments.</b>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) <b>Center Initiated Assignments: All Devices</b>	d. INDUSTRY/PRODUCT CODE(S) <b>Center Initiated</b>
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES <b>Center Initiated Assignments: Sterility/Performance</b>	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE BSE Assignment, Center Initiated Assignments				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82Z005, 82Z800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.0 [1.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS BSE (1) 82Z005	1 INSP CTIONS CENT ER- INIT IATED 82Z800	2 INVEST IGATIONS (Hours) 82Z800	3 DOMEST IC SAMPLE COLL (2) 82Z800	3 DOMEST IC SAMPLE COLL STER ILITY 82Z800	3 DOMEST IC SAMPLE COLL MICRO 82Z800	3 DOMEST IC SAMPLE COLL CHEM 82Z800	7 DOMEST IC SAMPLE TO BE ANALYZ ED STERIL ITY (3) 82Z800	7 DOMEST IC SAMPLE TO BE ANALYZ ED MICRO (4) 82Z800
	<b>TOTAL FIELD</b>	<b>23</b>	<b>19</b>	<b>300</b>	<b>10</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>2</b>
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	NEW ENGLAND	(b)(2) & (b)(7)(E)								
	NEW YORK	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	WEAC	(b)(2) & (b)(7)(E)								
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE	(b)(2) & (b)(7)(E)								
	CHICAGO	(b)(2) & (b)(7)(E)								
	CINCINNATI	(b)(2) & (b)(7)(E)								
	DETROIT	(b)(2) & (b)(7)(E)								
	MINNEAPOLIS	(b)(2) & (b)(7)(E)								
	NEW JERSEY	(b)(2) & (b)(7)(E)								
	PHILADELPHIA	(b)(2) & (b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)								
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	ATLANTA	(b)(2) & (b)(7)(E)								
	FLORIDA	(b)(2) & (b)(7)(E)								
	NEW ORLEANS	(b)(2) & (b)(7)(E)								
	SAN JUAN	(b)(2) & (b)(7)(E)								
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	DALLAS	(b)(2) & (b)(7)(E)								
	DENVER	(b)(2) & (b)(7)(E)								
	KANSAS CITY	(b)(2) & (b)(7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	LOS ANGELES	(b)(2) & (b)(7)(E)								
	SAN FRANCISCO	(b)(2) & (b)(7)(E)								
SEATTLE	(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)									
PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)									
HOURS PER OPERATION		20.0	30.0		10.0				50.0	50.0
TOTAL HOURS		460	570	300	100				100	100
CONVERSION FACTOR		950	950	950	950				1180	1180
TOTAL OPERATIONAL FTEs		0.48	0.60	0.32	0.11				0.08	0.08

9. REMARKS

(1) BSE Inspections (82Z005):Districts will, upon assignment, conduct inspections of firms whose devices may contain, or be exposed to, BSE risk material.

(2) Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

(3) WEAC--Sterility samples.

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

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1. PROGRAM/ASSIGNMENT TITLE BSE Assignment, Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z005, 82Z800	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0    [0.3]
---	--	--

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (5) 82Z800	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) METH DEV ENG (6) 82Z800
	<b>TOTAL FIELD</b>							1		400
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION							15.0		
	TOTAL HOURS							15		400
	CONVERSION FACTOR							1180		1180
	TOTAL OPERATIONAL FTEs							0.01		0.34

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE  
ORA/Center Directed Research Projects

2. PPS PROJECT NAME/NUMBER  
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 ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	DISTRICT RESEARCH CHEM (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)				
	<b>TOTAL FIELD</b>	<b>1205</b>		<b>1205</b>					
	HEADQUARTERS	(b)(2) &		(b)(2) &					
	REGIONAL STAFF	(b)(7)(E)		(b)(7)(E)					
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS	1205		1205					
	CONVERSION FACTOR	1205		1205					
	TOTAL OPERATIONAL FTEs	1.00		1.00					

9. REMARKS

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

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

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE <b>Medical Device Premarket Approval and Postmarket Inspections/510(k) Premarket Approval Inspections</b>	2. PPS PROJECT NAME/NUMBER <b>Product Evaluation: Devices - 83</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p><b>Medical Device Premarket Approval and Postmarket Inspections:</b> 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.</p> <p><b>510(k) Premarket Approval Inspections:</b> 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.</p>	
5. PROGRAM JUSTIFICATION <p><b>Medical Device Premarket Approval and Postmarket Inspections:</b> 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.</p> <p><b>510(k) Premarket Approval Inspections:</b> 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.</p>	
6. FIELD OBLIGATIONS <p><b>Medical Device Premarket Approval and Postmarket Inspections:</b> 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 post-approval inspections to occur approximately 8 months following approval of the PMA. 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. <b>510(k) Inspections:</b> 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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) <b>All Medical Devices</b>	d. INDUSTRY/PRODUCT CODE(S) <b>73-91</b>
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections					2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83					
3. PROGRAM/ASSIGNMENT CODE(S) 83001, A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 12.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	6	7	8	9
	<b>TOTAL FIELD</b>	INSPEC- TIONS PRE- APPROVAL 83001	INSPEC- TIONS POST- APPROVAL 83001A	FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	FOREIGN INSPEC- TIONS POST- APPROVAL 83001A	INSPEC- TIONS MDUFMA USER FEE 83001 (1)	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>33</b>	<b>67</b>	<b>34</b>	<b>27</b>	<b>99</b>					
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NEW ENGLAND	NEW ENGLAND									
	NEW YORK									
REGIONAL LAB	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
CHICAGO	CHICAGO									
	CINCINNATI									
DETROIT	DETROIT									
	MINNEAPOLIS									
NEW JERSEY	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
NEW ORLEANS	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
KANSAS CITY	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE	SEATTLE									
	PACIFIC REGIONAL LABORATORY-S									
PACIFIC REGIONAL LABORATORY-N	PACIFIC REGIONAL LABORATORY-N									
	HOURS PER OPERATION	48.2	30.0	50.7	49.4	48.2				
TOTAL HOURS	1591	2010	1724	1334	4772					
CONVERSION FACTOR	950	950	950	950	950					
TOTAL OPERATIONAL FTEs	1.67	2.12	1.81	1.40	5.02					
9. REMARKS Report all time used for evaluating compliance with <u>domestic pre-market</u> requirements in PAC 83001, OP CODE 12; report all time used for <u>domestic post-market</u> requirements in PAC 83001A, OP CODE 12.  Report all time used for evaluating compliance with <u>foreign pre-market</u> requirements in PAC 83001, OP CODE 11; report all time used for <u>foreign post-market</u> requirements in PAC 83001A, OP CODE 11.  1) 1 additional FTE in FY 2006 has been planned for Medical Device User Fee and Modernization Act (MDUFMA).										

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

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	<b>300</b>	<b>10</b>								
	HEADQUARTERS	(b)(2) & (b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	77.5	77.5								
	TOTAL HOURS	23250	775								
	CONVERSION FACTOR	950	950								
	TOTAL OPERATIONAL FTEs	24.47	0.82								

9. REMARKS

New for FY 2006: GLP, IRB, Sponsor/Monitor, and Clinical Investigator Inspections have been consolidated for planning purposes, with a column for Domestic and Foreign inspections. Continue to report time against PACs 83808 (GLP), 83809 (IRB), 83810 (Sponsor/Monitor), and 83811 (Clinical Investigator), depending on the type of inspection.

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

Please contact Matthew Tarosky at (240) 276-0243 with any questions.



1. PROGRAM/ASSIGNMENT TITLE  
Test Method Development and Evaluation

2. PPS PROJECT NAME/NUMBER  
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  BY CENTER  BY BOTH

b. INSPECTION TYPE: N/A  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
To be assigned

d. INDUSTRY/PRODUCT CODE(S)  
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 Test Method Development and Evaluation					2. PPS PROJECT NAME/NUMBER Science: Devices - 84						
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.7				
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	9 OTHER OPERATIONS (Hours)	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	<b>TOTAL FIELD</b>									<b>800</b>	<b>3590</b>
	HEADQUARTERS								(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
PACIFIC REGIONAL LABORATORY-SW											
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION											
TOTAL HOURS									800	3590	
CONVERSION FACTOR									1180	1180	
TOTAL OPERATIONAL FTEs									0.68	3.04	

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

1. PROGRAM/ASSIGNMENT TITLE  
ORA/Center Directed Research Projects

2. PPS PROJECT NAME/NUMBER  
Science: Devices - 84

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

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

5. PROGRAM JUSTIFICATION  
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 ORA/Center Directed Research Projects					2. PPS PROJECT NAME/NUMBER Science: Devices - 84				
3. PROGRAM/ASSIGNMENT CODE(S) 84R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 1.4			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)			
	<b>TOTAL FIELD</b>					<b>1660</b>			
NE	HEADQUARTERS					(b)(2) & (b)(7)(E)			
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
LOS ANGELES									
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS						1660			
CONVERSION FACTOR						1180			
TOTAL OPERATIONAL FTEs						1.41			

9. REMARKS



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

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.9 [10.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	2										
		INSP CTIONS  85014 (1)	INSP CTIONS FOREIGN 85014 (2)	INSP CTIONS  85014 (3)	INSP CTIONS  85014 (4)	INSP CTIONS  85014F (5)	INSP CTIONS  85014F (6)	INVESTI GATIONS (Hours) 85014A (7)	INVESTI GATIONS (Hours) 85014F (8)										
	<b>TOTAL FIELD</b>	<b>216</b>	<b>15</b>	<b>119</b>	<b>32</b>	<b>9</b>	<b>9</b>	<b>2365</b>	<b>6629</b>										
	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	8.0	8.0	8.0	11.0	11.0			
	TOTAL HOURS										1728	120	952	256	99	99	2365	6629	
	CONVERSION FACTOR										1160	1160	1160	1160	1160	1160	1160	1160	
	TOTAL OPERATIONAL FTEs										1.49	0.10	0.82	0.22	0.09	0.09	2.04	5.71	

9. REMARKS

**RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS**

1) Inspection of Certified Mammography Facilities not covered by the states.  
 2) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries.  
 3) Federal Facility Inspections (does not include VHA Facility inspections).  
 4) VHA Facility Inspections.  
 5) Follow-up Inspections.  
 6) Follow-up Inspection after Warning Letter.  
 7) Audit Investigations.  
 8) Inspection Follow-Up Activities (Non-Warning Letter).

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1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program							2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85				
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.9 [4.3]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	9 OTHER OPERATIONS (Hours) 85014 (9)	9 OTHER OPERATIONS (Hours) 85014 (10)	9 OTHER OPERATIONS (Hours) 85014C (11)
	<b>TOTAL FIELD</b>								1200	3831	59
	HEADQUARTERS								(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
PACIFIC REGIONAL LABORATORY-SW											
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION											
TOTAL HOURS								1200	3831	59	
CONVERSION FACTOR								1200	1160	1160	
TOTAL OPERATIONAL FTEs								1.00	3.30	0.05	
9. REMARKS <b>RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE &amp; COORDINATION HOURS</b>  9) Technical Assistance and Coordination Activities: RRHRs. 10) Technical Assistance and Coordination Activities. 11) Compliance Activities.											

# PROJECT SUMMARY SHEET

FY 2006

<b>1. PROGRAM CATEGORY</b> Medical Devices and Radiological Health			<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	<b>TOTAL</b>		<b>23.5</b>	<b>10.2</b>	<b>1.0</b>	<b>34.7</b>	<b>59.2</b>	
1	Optical Electronic Products:		4.5		0.2	4.7	8.0	2-3
	Inspection of Manufacturers of Laser Products	86001	(4.2)		(0.2)	(4.4)	(7.5)	
	Field Implementation of the Sunlamp & Sunlamp Products Performance Standard as Amended	86002	(0.3)			(0.3)	(0.5)	
2	X-Ray Surveillance Programs:		10.0			10.0	17.1	4-11
	Field Compliance Testing of Diagnostic X-Ray Equipment	86003	(9.0)			(9.0)	(15.4)	
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	(1.0)			(1.0)	(1.7)	
3	Compliance Testing of Electronic Products at WEAC	86006, A, B, D, E	3.4		0.8	4.2	7.2	12-13
4	Imported Electronic Products	86007 *		10.2		10.2	17.4	14-15
5	Radiological Health Control Activities:		5.6			5.6	9.5	16-19
	Medical Device and Radiological Health Use Control and Policy Implementation	86008	(3.6)			(3.6)	(6.1)	
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	(3.4)	
	* In addition to PAC 86007, includes reporting PACs 86R824, 86R833, and 99R833.							

**CENTER PROJECT MANAGER/TELEPHONE**  
Lynne L. Rice 301-443-2845

**ORA PLANNER/TELEPHONE**  
John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b>Inspection of Manufacturers of Laser Products:</b> To determine if laser products are in compliance with the radiation safety emissions and other requirements of the "laser performance standard."  <b>Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:</b> 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 <b>Inspection of Manufacturers of Laser Products:</b> 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. <b>Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:</b> 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 <b>Inspection of Manufacturers of Laser Products:</b> 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/ORR inspections when such inspections are scheduled by the Center. <b>Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:</b> 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: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Lasers and laser products Sunlamp, suntanning booths, and sunlamp products.	d. INDUSTRY/PRODUCT CODE(S) 95LS-99 95 US-11
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES <b>Sunlamp Products:</b> 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 <i>Caution:</i> laser product <i>may</i> be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.	

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS 86001 (1)	1 INSP CTIONS FOREIGN 86001 (2)	1 INSP CTIONS 86002 (3)	2 INVEST IGATIONS (Hours) 86001 (4)	3 DOMESTIC SAMPLE COLL 86001	5 FIELD EXAMS/ TESTS 86001 (5)	5 FIELD EXAMS/ TESTS 86002 (6)	9 OTHER OPERATIONS (Hours) 86001 (7)	9 OTHER OPERATIONS (Hours) 86002
	<b>TOTAL FIELD</b>	<b>99</b>	<b>5</b>	<b>7</b>	<b>639</b>	<b>6</b>	<b>73</b>	<b>27</b>	<b>1216</b>	<b>75</b>

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

	HOURS PER OPERATION	17.5	52.4	13.8		3.0	5.0	4.3		
	TOTAL HOURS	1733	262	97	639	18	365	116	1216	75
	CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	1.82	0.22	0.10	0.67	0.02	0.38	0.12	1.28	0.08

9. Remarks

**Inspection of Manufacturers of Laser Products:**

- 1) Comprehensive Inspections can only be claimed for manufacturers of radiation-emitting products on a recurring basis.
- 2) Number of inspections for Engineering Analyst.
- 4) Investigation Hours--refer to Compliance Program for reporting information.
- 5) Will include laser products located at a user facility and laser light shows.
- 7) To include all other activities such as technical assistance, coordination, and training.

**Sunlamps and Sunlamp Products:**

- 3) Inspectional figures are only for biennial inspections of manufacturers of sunlamp products ( to include sunlamps, booth beds, etc.). Inspections are to be conducted in conjunction with a GMP inspection. Examination of booth beds at tanning parlors, athletic clubs, etc. should be reported as field exams and not inspections.
- 6) The field test of each sunlamp product should be counted as a separate operation.

NOTE: RRRH's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b>Field Compliance Testing of Diagnostic X-Ray Equipment:</b> 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.  <b>Field Compliance Testing of Cabinet X-Ray Equipment:</b> To determine compliance with the performance standard for cabinet x-ray equipment with respect to radiation emissions under conditions of use.	
5. PROGRAM JUSTIFICATION <b>Field Compliance Testing of Diagnostic X-Ray Equipment:</b> 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.  <b>Field Compliance Testing of Cabinet X-Ray Equipment:</b> 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 <b>Diagnostic X-Rays:</b> 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. <b>Cabinet X-Rays:</b> 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: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Diagnostic X-Ray Equipment Cabinet x-ray and baggage x-ray	d. INDUSTRY/PRODUCT CODE(S) 94DS--- 94 IS-11 94 IS-21
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING <b>Diagnostic X-Rays:</b> 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 X-Ray Surveillance Programs			2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86							
3. PROGRAM/ASSIGNMENT CODE(S) 86003, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 10.0			
R E G I O N	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
	<b>TOTAL FIELD</b>	<b>18</b>	<b>8</b>	<b>1007</b>	<b>40</b>	<b>952</b>	<b>163</b>	<b>82</b>		<b>4081</b>
	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		16.0	8.0			3.0	5.2	4.0		
TOTAL HOURS		288	64	1007	40	2856	848	328		4081
CONVERSION FACTOR		950	950	950	950	950	950	950		950
TOTAL OPERATIONAL FTEs		0.30	0.07	1.06	0.04	3.01	0.89	0.35		4.30

9. REMARKS

\* CSO trained for surveying X-Ray equipment. Inspections to be performed during first quarter of fiscal year.

**Planning guidance:**

**1st quarter:** Contact all X-Ray manufacturers in the District, and conduct an onsite inspection of 50% of the manufacturers (rather than phone contact only).

**2nd quarter:** Complete one-third of field tests.

**3rd quarter:** Complete two-thirds of field tests.

**4th quarter:** Complete remaining field tests.

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

**Diagnostic X-Rays (86003):**

1) Inspections are spread based on the number of x-ray assemblers. (b)(2) & (b)(7)(E)

2) Investigation hours are for review of assembler reports.

3) Field Tests and Audits are obtained from Attachment A, and are provided by CDRH's Compliance X-Ray Products Branch, HFZ 300.

Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor to verify both Federal and State data.

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  
2006 WORKPLAN FOR FIELD COMPLIANCE TESTING  
OF DIAGNOSTIC X-RAY SYSTEMS  
(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2006)**

**NEW ENGLAND DISTRICT**

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

**NEW YORK DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
NY	(b)(2) & (b)(7)(E)				

**BALTIMORE DISTRICT**

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

**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					
<b>Total</b>					

**ATLANTA DISTRICT**

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

**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					
<b>Total</b>					

**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					
<b>Total</b>					

**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					
<b>Total</b>					

**SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
IA	(b)(2) & (b)(7)(E)				
KS					
NE					
MO					
<b>Total</b>					

**LOS ANGELES DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
AZ	(b)(2) & (b)(7)(E)				
CA					
<b>Total</b>					

**SAN FRANCISCO DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
CA	(b)(2) & (b)(7)(E)				
HI					
NV					
<b>Total</b>					

**SEATTLE DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
AK	(b)(2) & (b)(7)(E)				
ID					
MT					
OR					
WA					
<b>Total</b>					

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Microwaves, TV Receivers, Diagnostic X-Ray Equipment, Mercury Vapor/Sunlamp, Ultrasonic Therapy Equipment	d. INDUSTRY/PRODUCT CODE(S) 96MS, 94VS, 94DS, 95US, 97US
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
--	---

3. PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.2
--	--	-------------------------------------

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS (PL 90-602 STANDARD)	7 DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	7 DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY SOURCE	7 DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	14	70	23	4	1	16			
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		70.0	25.0	43.0	245.0	120.0	11.2			
TOTAL HOURS		980	1750	989	980	120	179			
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs		0.83	1.48	0.84	0.83	0.10	0.15			

9. REMARKS

All samples to be shipped by distributors/manufacturers to WEAC.

-Diagnostic X-Ray

Whole - For analysis of entire diagnostic X-Ray systems for compliance;

Source - Leakage test of diagnostic source assembly only.

Foreign Inspections--PL 90-602 Standard Inspections:

Report accomplishments in PAC 86006;

To ensure conformance to Rad Health Standards; to be conducted by Engineering Analyst.

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 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: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All electronic products or devices that emit radiation.	d. INDUSTRY/PRODUCT CODE(S) 94-97
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 10.2			
R E G I O N	6.	1	2	2	3	4	5	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	ENTRY REVIEW (Hours)	IMPORT INV HOURS *	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
<b>TOTAL FIELD</b>			<b>10195</b>	<b>1620</b>						
	HEADQUARTERS		(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS			10195	1620						
CONVERSION FACTOR			1200	950						
TOTAL OPERATIONAL FTEs			8.50	1.71						

9. REMARKS

\* Import investigation hours are for field exams, filer evaluations, follow-up to refusals, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

**Reporting Guidance:**

- Import Entry Reviews (Electronic and Manual--operation code 14, PAC 86R833);
- Filer Evaluations (operation code 95, PAC 99R833); and
- Follow-up to Refusals (PAC 86R824).

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b>Use Control:</b> 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.  <b>Emergency Planning &amp; Response Activities:</b> To act as a focal point for emergency readiness response planning by States.	
5. PROGRAM JUSTIFICATION <b>Medical Device and Radiological Health Use Control and Policy Implementation:</b> 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.  <b>Emergency Planning &amp; Response Activities:</b> 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 <b>Use Control:</b> 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.  <b>Emergency Planning &amp; Response Activities:</b> Provide consultation to states and attend regional emergency planning meetings.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <b>Emergency Planning &amp; Response Activities</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) <b>Emergency Planning &amp; Response Activities:</b> 94YN-99
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.6		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	9 TECHNICAL ASSISTANCE (Hours) RRHR	9 MISC (Hours) DENT	9 MISC (Hours) RRHR	
	TOTAL FIELD					2400	750	3600	
NE	HEADQUARTERS					(b)(2) & (b)(7)(E)	(b)(2) & (b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
PA	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS						2400	750	3600	
CONVERSION FACTOR						1200	1180	1200	
TOTAL OPERATIONAL FTEs						2.00	0.64	3.00	

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

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

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.**

**FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):**

Technical Assistance hours will be performed by RRHRs.

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



FY 2006

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56, and 60-66
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Environmental chambers used to stress drug products.	

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

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