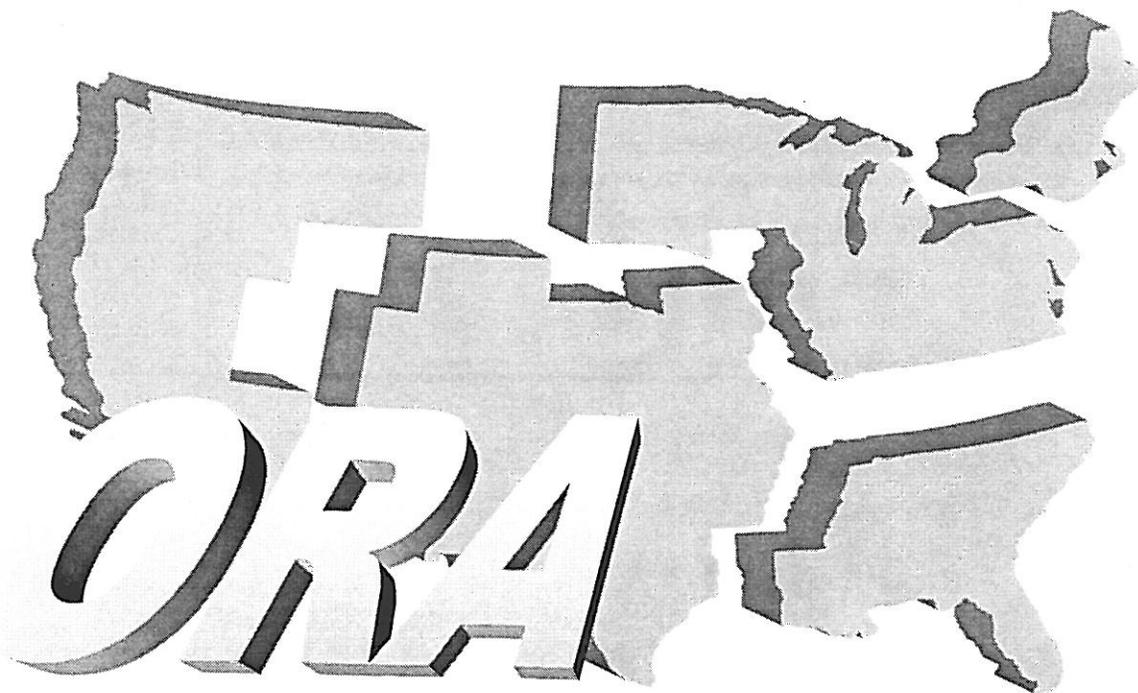

FY 2007

PART III - PROGRAM FORECASTS



DEPT OF HEALTH & HUMAN SERVICES



FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE

MANAGEMENT BRANCH

ORA/ORM/DPEM

**PART III
RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2007**

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

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

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

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2007**

October 1, 2006

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low-Acid Canned Foods, CP 7303.003, FY 07		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 detain Acidified and Low-Acid Canned Foods which are packed in food canning establishments not in compliance with 21 <u>CFR</u> 108, 113 and 114. According to recent AF and LACF violation rates, products from the following countries should be considered high priority: Bangladesh, Brazil, Bulgaria, Ecuador, Jordan, Pakistan, China, Taiwan, Ukraine and Vietnam.			
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 <u>CFR</u> Parts 108, 113 and 114. The number of foreign AF/LACF firms submitting registrations has been increasing significantly each year. As in FY 06, the number of planned hours for Import Field Exams will remain at 3200 and the number of Import Sample Collections will remain at 1400.			
6. FIELD OBLIGATIONS The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements. All import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		NA <input type="checkbox"/>	BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH <input type="checkbox"/>
b. INSPECTION TYPE:		NA <input type="checkbox"/>	COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED <input type="checkbox"/>
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: <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 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 IMPORT FIELD EXAMS (Hours) *	4 IMPORT SAMPLE COLLECTION	4 IMPORT SAMPLE COLL MICRO GUIDANCE	4 IMPORT SAMPLE COLL CHEM GUIDANCE	8 IMPORT SAMPLES TO BE ANALYZED MICRO **	8 IMPORT SAMPLES TO BE ANALYZED CHEM **
NE	HEADQUARTERS						
	REGIONAL STAFF						
	NEW ENGLAND	250	110	97	13		
	NEW YORK	850	372	326	46		
	REGIONAL LAB					442	62
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE	150	66	58	8		
	CHICAGO	60	26	23	3		
	CINCINNATI	40	18	16	2		
	DETROIT	170	74	65	9		
	MINNEAPOLIS	20	9	8	1		
	NEW JERSEY						
	PHILADELPHIA	50	22	19	3		
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA	40	18	16	2		
	FLORIDA	140	60	53	7		
	NEW ORLEANS	20	9	8	1		
	SAN JUAN	50	22	19	3		
SW	REGIONAL LAB					170	23
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT	300	131	115	16		
	REGIONAL LAB					154	21
	REGIONAL STAFF						
	LOS ANGELES	550	240	211	29		
	SAN FRANCISCO	300	131	115	16	115	16
PA	SEATTLE	210	92	81	11		
	PACIFIC REGIONAL LABORATORY-SW					268	37
	PACIFIC REGIONAL LABORATORY-NW					81	11
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.

According to recent AF and LACF violation rates, products from the following countries should be considered high priority: Bangladesh, Brazil, Bulgaria, Ecuador, Jordan, Pakistan, China, Taiwan, Ukraine and Vietnam.

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

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

1. PROGRAM/ASSIGNMENT TITLE Domestic and Imported Cheese and Cheese Products 03037 FY 2007	2. PMS 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 conduct inspections of domestic soft cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered.	
5. PROGRAM JUSTIFICATION Cheese and cheese products have been demonstrated to contain pathogenic microorganisms and to cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.	
6. FIELD OBLIGATIONS The field is requested to conduct inspections of domestic cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings. The field is also requested to conduct sample collections and analyses of imported cheese focusing on soft cheese as high priority. Refer to the guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections. New for FY 07: High Risk firms whose last inspection was NAI may be placed on a 3-year inspection frequency. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. NOTE: (For specialized micro testing below, see compliance program or contact DFS for additional details) DEN will perform Salmonella serotyping for isolates originating from the following labs: DEN, SAN, PRL-SW, PRL-NW. ARL will perform Salmonella serotyping for isolates originating from all labs: ARL, SRL, NRL	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Hard and Soft Cheeses	d. INDUSTRY/PRODUCT CODE(S) 12
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES <u>Salmonella</u> , <u>Listeria</u> , <u>E. coli</u> , <u>Enterotoxigenic E. Coli (ETEC)</u> , <u>Enterohemorrhagic E. Coli EHEC 0157:H7</u> - <u>S. Aureus</u> , And Phosphatase and Filth	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.	

1. PROGRAM/ASSIGNMENT TITLE Domestic 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 22.7			
6 R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	4	7	8	8
		INSP EC T I O N S (1)	INVEST I G A T I O N S (Hours) (3)	DOMESTIC SAMPLE COLLECTION (2)	IMPORT SAMPLE COLL MICRO (5)	IMPORT SAMPLE COLL CHEM GUIDANCE	DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (6)	IMPORT SAMPLES TO BE ANALYZED MICRO (7)
TOTAL FIELD		300	350	300	700	75	300	75	700
HEADQUARTERS									
REGIONAL STAFF									
NE	NEW ENGLAND	30	70	30	35	4			
	NEW YORK	27	70	27	400	43			
	REGIONAL LAB						27	43	500
	WEAC								
REGIONAL STAFF									
CE	BALTIMORE	3	70	3	10	1			
	CHICAGO	8		8	20	2			
	CINCINNATI	5		5					
	DETROIT	10		10					
	MINNEAPOLIS	95		95					
	NEW JERSEY	12	70	12					
	PHILADELPHIA	15	70	15					
	FORENSIC CHEM. CTR								
REGIONAL STAFF									
SE	ATLANTA	2		2					
	FLORIDA	5		5	75	8			
	NEW ORLEANS	1		1					
	SAN JUAN	5		5					
REGIONAL LAB						78	13	120	
REGIONAL STAFF									
SW	DALLAS	8		8					
	DENVER	3		3			30		
	KANSAS CITY	19		19					
	SOUTHWEST IMPORT DISTRICT				100	11			
REGIONAL LAB						113	7	20	
REGIONAL STAFF									
PA	LOS ANGELES	17		17	30	3			
	SAN FRANCISCO	22		22	30	3	22	3	30
	SEATTLE	13		13					
	PACIFIC REGIONAL LABORATORY-SW						17	3	30
	PACIFIC REGIONAL LABORATORY-NW						13	6	
HOURS PER OPERATION		17.0		4.0	2.0		17.0	6.1	16.0
TOTAL HOURS		5100	350	1200	1400		5100	458	11200
CONVERSION FACTOR		950	950	950	950		1180	1180	1180
TOTAL OPERATIONAL FTEs		5.37	0.37	1.26	1.47		4.32	0.39	9.49

9 REMARKS

(1) INSPECTIONS: DISTRIBUTED BY CFSAN.
 INSPECTIONS OF DOMESTIC FIRMS PRIORITIZES SOFT CHEESE (I.E. SOFT-FRESH, SEMI-SOFT, AND SOFT-RIPENED) MANUFACTURERS FIRST, HARD CHEESE MANUFACTURERS SECOND AND CHEESE PRODUCT MANUFACTURERS LAST.
 PRIORITIZE INSPECTIONS TO LOOK AT SMALL MANUFACTURERS I.E. ARTISANAL AND FARMSTEAD CHEESE MANUFACTURERS PRODUCING HIGH RISK CHEESE WHICH DISTRIBUTE CHEESE IN INTERSTATE COMMERCE. HIGH RISK FIRMS WHOSE LAST INSPECTION WAS NAI MAY BE PLACED ON A 3 YEAR INSPECTION FREQUENCY.

(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. 350 OF THE ISCS WERE BASED ON THE PRIORITY COUNTRIES, ARMENIA, BOLIVIA, DOMINICAN REPUBLIC, HONDURAS, MEXICO, NICARAGUA, AND VENEZUELA. THE ADDITIONAL ISCS WERE PRORATED BASED ON VOLUME.
 SAMPLING OF FRENCH CHEESES SHOULD BE REDUCED TO NO MORE THAN 200 SOFT CHEESE SAMPLES. THE REMAINDER OF SAMPLES SHOULD BE REFOCUSSED TO PROBLEM AREAS IN SOUTH AND CENTRAL AMERICA, EASTERN EUROPEAN COUNTRIES AND THE MIDDLE EAST.

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

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

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

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

4. OBJECTIVES

To determine if the firms comply with 21 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act.
To perform annual inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods.

A continued priority will remain with out-of-compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Firms who have been in compliance are on a 3-year inspection cycle. Please refer to the compliance program for guidance.

5. PROGRAM JUSTIFICATION

Low-Acid Canned Foods: Inspections conducted in prior year's programs have demonstrated that the degree of compliance of Low-acid canned food regulations relate directly to the degree of freedom from hazard to consumers found in the food produced. High risk industry segments, identified under previous programs, as well as re-inspection of the remaining portions of the industry is needed to establish and maintain compliance with the low-acid canned food regulations.

Acidified Foods: To improve the acidified food industry's degree of freedom from public health hazard and their degree of compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas, which need emphasis in future programs.

6. FIELD OBLIGATIONS

Firms in compliance and that have not registered new products nor significantly changed a current process, may be inspected on a 3-year frequency. Special situation firms are to be inspected according to the guidance in the compliance program (see program). It is estimated that 400 FDA inspections are needed to fulfill program obligations FY 07. State contract inspections are to be used to increase firm coverage under this program.

State inspections may be conducted in addition to the number of inspections assigned per district. Resources include coverage of food security issues (see IOM) at domestic processors.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT (S) See Compliance Program	d. INDUSTRY/PRODUCT CODE(S) 16, 20-22, 24-25, 27, 35, 37, 38, 40-41
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8. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

9. 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)
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	11	11	6	5	1			50
	NEW YORK	27	27	13	12	1			50
	REGIONAL LAB						3	30	
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE	26	26	13	12	1			50
	CHICAGO	11	11	6	5	1			50
	CINCINNATI	18	18	9	8	1			50
	DETROIT	15	15	8	7	1			50
	MINNEAPOLIS	34	34	17	15	2			50
	NEW JERSEY	10	10	5	5				50
	PHILADELPHIA	19	19	9	8	1			50
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA	25	25	12	11	1			50
	FLORIDA	5	5	3	3				50
	NEW ORLEANS	19	19	9	8	1			50
	SAN JUAN	3	3	2	2				50
REGIONAL LAB						4	44		
SW	REGIONAL STAFF								
	DALLAS	40	40	20	18	2			50
	DENVER	19	19	9	8	1	4	33	50
	KANSAS CITY	15	15	8	7	1	1		50
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB						3	27		
PA	REGIONAL STAFF								
	LOS ANGELES	41	41	20	18	2			50
	SAN FRANCISCO	14	14	7	6	1	1	6	50
	SEATTLE	48	48	24	22	2			50
	PACIFIC REGIONAL LABORATORY-SW						2	18	
PACIFIC REGIONAL LABORATORY-NW						2	22		
HOURS PER OPERATION		25.0		5.0			8.0	10.0	
TOTAL HOURS		10000	400	1000			160	1800	950
CONVERSION FACTOR		950	950	950			1180	1180	950
TOTAL OPERATIONAL FTEs		10.53	0.42	1.05			0.14	1.53	1.00

9 REMARKS

(1) Source of workload: Inspections, Investigation Hours and DSC's provided by CFSAN. Resource distribution based on CFSAN's LACF database as of 3/2006.

(2) Report all resources expended for NLEA under PAC 21005.

(3) Inspect NAI firms on 3-year inspection cycle. State inspections may be conducted in addition to the number of inspections assigned per district.

(4) Attendance at Better Processing Schools (BPS).

(5) Planned collections are for projected "for cause" sampling.

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety 03803 FY 2007		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE	<input type="checkbox"/> PROGRAM <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. The top program priority for FY 2007 remains to inspect all high-risk firms annually. Ample resources have been provided to cover the full high-risk inventory covered by this program as well as to accomplish other program objectives (see compliance program). Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate district, will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. Resources from this program may be directed to monitor chicken eggs for <i>Salmonella</i> Enteritidis and for follow-up Assignments. Also, resources needed for inspections of domestic firms for FDA E.U. certification will be taken from this program. Food security issues are to be covered during all inspections (See IOM).			
5. PROGRAM JUSTIFICATION Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibilities of assuring that manufacturers produce these products under current Good Manufacturing Practices.			
6. FIELD OBLIGATIONS To conduct domestic inspections, focusing on high-risk firms and allergen firms, and with additional program resources to provide coverage with the priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk, allergen, and other firms. Sample collections will typically be "for cause," i.e., no surveillance sampling is to be conducted. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations. Only those "for cause" collections needed to support regulatory inspections are to be conducted. Currently, allergen surveillance inspections are on hold pending finalization of the Agency's allergen enforcement strategy. The field may do "for cause" allergen inspections as needed, but only proceed with surveillance inspections when new allergen guidance is issued by CFSAN. NOTE: Confirmation tests for <i>Clostridium botulinum</i> , <i>Yersinia enterocolitica</i> will be split between SRL & Pacific Regional Laboratory-NW. SRL will be the confirmation servicing laboratory for NE, CE, & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions. Surveillance activities planned under this program may be pro-rated by enforcement initiatives agreed upon by ORA & CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) All Food Products (Except 12 & 16)		d. INDUSTRY/PRODUCT CODE (S) 02-11, 13-15, 17-41, 45-46, 50	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES 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) (5) (8)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 96.1				
R E G I O N	6.	1	1	4	3							
	DISTRICT/ SPECIALIZED LABORATORY	INSP CTIONS INCLUDING HIGH RISK (1) (3) (6)	NON CLINICAL GLP INSP CTIONS (4)	INVEST GATIONS (HOURS) INCLUDES NAT'L EXPERTS (1)	DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL MICRO GUIDANCE	DOMESTIC SAMPLE COLL MICRO GUIDANCE	DSAs MICRO SALMONELLA SEROTYPING (HOURS) (6)	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	FOOD SAFETY METHOD VALIDATION MICRO (7)	FOOD SAFETY METHOD VALIDATION CHEM (7)
	TOTAL FIELD	4000	10	13860	400	240	160	1180	240	160	1500	1500
NE	HEADQUARTERS			2850								
	REGIONAL STAFF											
	NEW ENGLAND	373		889	32	19	13					
	NEW YORK	317		873	32	19	13					
	REGIONAL LAB								38	40	215	167
CE	WEAC											
	REGIONAL STAFF											
	BALTIMORE	177	2	488	18	11	7					
	CHICAGO	91	2	319	12	7	5					
	CINCINNATI	105		358	13	8	5					
	DETROIT	159		439	16	10	6					166
	MINNEAPOLIS	332		914	33	20	13					
	NEW JERSEY	119		327	12	7	5					
	PHILADELPHIA	232		638	23	14	9					
	FORENSIC CHEM. CTR											
SE	REGIONAL STAFF											
	ATLANTA	154	4	423	15	9	6					
	FLORIDA	92		321	12	7	5					
	NEW ORLEANS	139		382	14	8	6					
	SAN JUAN	120		331	12	7	5					
SW	REGIONAL LAB								71	34	215	167
	REGIONAL STAFF											
	DALLAS	211		580	21	13	8					
	DENVER	100		345	13	8	5	590	27	5	214	167
	KANSAS CITY	107	2	294	11	6	5			13		166
	SOUTHWEST IMPORT DISTRICT											
PA	REGIONAL LAB							590	37	24	214	167
	REGIONAL STAFF											
	LOS ANGELES	491		1351	48	29	19					
	SAN FRANCISCO	384		920	33	20	13		20	13	214	166
	SEATTLE	297		818	30	18	12					
PACIFIC REGIONAL LAB - SW								29	19	214	167	
PACIFIC REGIONAL LAB - NW								18	12	214	167	
HOURS PER OPERATION		17.0			5.6				12.0	12.0		
TOTAL HOURS		68000		13860	2240			1180	2880	1920	1500	1500
CONVERSION FACTOR		950		950	950			1180	1180	1180	1180	1180
OPERATIONAL FTEs		71.58		14.59	2.36			1.00	2.44	1.63	1.27	1.27

7. REMARKS

- (1) FY 2007 100% INSP, DSC, and Investigations based on: OEI of firms flagged as High Risk in FACTS less firms with only industry code 12, 16, or 51 as of February 28, 2006. Includes time for National Experts (3 FTEs). Resources have been allocated for 4000 total inspections. High Risk and GLP firms are included in this total number. Some of the inspectional & analytical resources planned may be directed for Allergen Work, once an Allergen Program or Assignment is issued by CFSAN.
- (2) Resources for 04803 and 09803E,F are included. Resources for audits are under State Contracts Program, 03R843.
- (3) Allergen Inspections may be assigned upon the issuance of an Allergen Program for FY07.
 * Do Not Initiate Surveillance (Allergen) Inspections until a New Allergen Program is issued.
 * Report Allergen inspections under PAC 03803E. "For Cause" Allergen Inspections are to be conducted as needed.
- (4) Non-Clinical Good Laboratory Practice Inspections: CFSAN will contact affected Districts to arrange inspections during the course of the year.
- (5) Assignments for sprout producers and egg farms, if needed in FY 07, will be taken from this Program.
- (6) Salmonella Serotyping: Samples generated from NRL, SRL & ARL go to ARL; Samples generated from other labs go to Denver.
- (7) Food Safety Method Validation for CHEM and MICRO: Resources are Pro-Rated based on the CHEM and MICRO Labs in the ORA Field Workplan Lab Servicing Table.
- (8) Non Seafood Inspections for EU and Chilean Certification will be handled by CFSAN Assignment and counted against the inspectional obligations of this program.

1. PROGRAM/ASSIGNMENT TITLE Import Foods - General 03819 FY 2007	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 examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.	
6. FIELD OBLIGATIONS To conduct activities directed by CFSAN, identified through program guidance, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth disease vector, or decomposition. Districts should emphasize priority products from the compliance program. The Compliance Program prioritizes high risk products (raw produce, RTE foods, ice cream products, dried milk products, tahini, sesame seed and halva candy, bush meat, baked goods, custard or cream-filled (egg containing), and BSE at-risk products), imported foods of regional significance, foods with a high frequency of contamination with filth which presents a public health hazard, and foods subject to decomposition which presents a public health hazard. Districts should deemphasize coverage of products that are not consistent with the Compliance Program priorities. Districts should also consider deemphasizing the following product/country pairs due to a low violation rate: bakery products from Thailand, whole grains, bakery products, macaroni products, and snack food items from Korea, and bakery products from Canada. Also, small value entries of packaged foods (< -\$2,000) should be de-emphasized for microscopic filth, unless a public health concern is present (i.e., likely to contain vectors of disease). See full program for additional details. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.	
NOTE TO LABS: (see compliance program or contact DFS for additional details) DEN will perform Salmonella antibiotic resistance testing. Salmonella Isolates from NRL, SRL and ARL will be serotyped in ARL. Salmonella Isolates from SAN, PRL-NW, PRL-SW and DEN will be serotyped in DEN.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> 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.	

1. PROGRAM/ASSIGNMENT TITLE Import Foods General				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03									
3. PROGRAM/ASSIGNMENT CODE(S) 03R19A,B,C (03R833/99R/833/03R824)(1)				4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 277.1					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	2	4	4	4	4	8	8	8	8
		IMPORT ENTRY REVIEW HRS OPR 14 03R833 (2)	PRIOR NOTICE REVIEW HOURS OPER 14 03R833 (6)	INVESTI- GATION HOURS	BSE ENTRY REVIEW & FOLLOW UP (4)	IMPORT SAMPLE COLL PHYSICAL	IMPORT SAMPLE COLL CHEM (ACKEE SUBSET) (7)	IMPORT SAMPLE COLL MICRO GUIDANCE	IMPORT SAMPLE COLL CHEM GUIDANCE	IMPORT SAMPLES TO BE ANALYZED MICRO	IMPORT SAMPLES TO BE ANALYZED CHEM (7)	IMPORT SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED SALM RESIST (5)
	TOTAL FIELD	92000	42000	82380	9000	7750	40	5080	2630	5080	40	2670	1180
NE	HEADQUARTERS PRIOR NOTICE		42000										
	REGIONAL STAFF												
	NEW ENGLAND	4791		4340	330	349		230	119				
	NEW YORK	12687		11905	2648	1578	20	1026	532				
	REGIONAL LAB WEAC									1336		692	
CE	REGIONAL STAFF												
	BALTIMORE	3295		2932	202	187		123	64				
	CHICAGO	1077		1027	174	214		141	73				
	CINCINNATI	720		594	33	20		13	7				
	DETROIT	3292		3103	882	401		264	137				
	MINNEAPOLIS	2638		2238	95	121		80	41				
	NEW JERSEY												
	PHILADELPHIA	1138		1050	94	121		80	41				
SE	FORENSIC CHEM. CTR												
	REGIONAL STAFF												
	ATLANTA	1976		1787	109	88		58	30				
	FLORIDA	6229		5578	373	357	20	222	115				
	NEW ORLEANS	3354		1861	58	49		32	17				
SW	SAN JUAN	1378		1215	46	100		66	34				
	REGIONAL LAB									514	40	307	
	REGIONAL STAFF												
	DALLAS												
	DENVER									485			1180
PA	KANSAS CITY												
	SOUTHWEST IMPORT DISTRICT	17971		17110	2040	1916		1263	653				
	REGIONAL LAB									632		578	
	REGIONAL STAFF												
	LOS ANGELES	15696		13822	886	979		645	334				
PA	SAN FRANCISCO	7490		6551	382	687		453	234	453		234	
	SEATTLE	8268		7267	648	583		384	199				
	PACIFIC REGIONAL LAB - SW									645		660	
	PACIFIC REGIONAL LAB - NW									1015		199	
HOURS PER OPERATION						2.2				8.2		7.5	
TOTAL HOURS		92000	42000	82380	9000	17050				41656		20025	1180
CONVERSION FACTOR		1200	1200	950	1200	950				1180		1180	1180
OPERATIONAL FTEs		76.67	35.00	86.72	7.50	17.95				35.30		16.97	1.00

7. REMARKS

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

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

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

ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:

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

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

(c) TRADITIONAL SAFETY CONCERNS.

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

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

(5) Denver Laboratory: Salmonella Resistance

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

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

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

NOTE: ADJUSTMENTS IN IMPORT INVESTIGATIONAL RESOURCES HAVE BEEN MADE TO ACCOUNT FOR ON-BOARD IMPORT STAFFING IN SOME DISTRICTS. SA CHEM AND ISA MICRO BASED ON ISC AND LAB SERVICING TABLE

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (03842) FY 07		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 Starting in FY07 High Risk Potential Products (HRPP) processors whose last two inspections were NAI, can be considered for a 2-year inspection cycle. An exception would be if the firm added a new High Risk seafood product to their line since the last inspection. HACCP verification samples are not to be routinely collected. Sample collections and analyses are to be made only for cause or as part of a CFSAN issued assignment. It is important that products be analyzed for the health hazard as identified in the HACCP guide - i.e., raw scombroid fish should be analyzed for histamine not for parasites or micro; raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw Seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw There are obligations to provide the states with standards and instructions for sampling/analyzing for PSP/ASP in seafood. Note: Animal confirmation tests for PSP, NSP, ciguatera toxin and botulinum toxins will be done at ARL for all regions. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.					
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<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					

2007 ORA WORKPLAN

OCTOBER 1, 2006

1 PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER									
Domestic Fish and Fishery Products Inspection Program		Foodborne Biological Hazards - 03									
3 PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY					5. OPERATIONAL FTE POSITIONS			
03842, B, C, D, H (1)			ORA <input type="checkbox"/> CENTER <input checked="" type="checkbox"/>					69.7			
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS INCLUDING HIGH RISK (4) (5)	3 DOMESTIC SAMPLES COLL VIBRIO ASSIGNMENT (7)	3 DOMESTIC SAMPLES COLL (3) (5)	3 DOMESTIC SAMPLES COLL MICRO GUIDANCE	3 DOMESTIC SAMPLES COLL CHEM GUIDANCE	7 DSA VIBRIO ASSIGNMENT (7)	7 DSAs ORGANO EXAMS (Hours) (2)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 EU CERTIFICATION (HOURS) (6)
	HEADQUARTERS										
	REGIONAL STAFF										
NE	NEW ENGLAND	268		32	24	8					897
	NEW YORK	129		16	12	4					64
	REGIONAL LAB						54	300	18	56	
	WEAC										
	REGIONAL STAFF										
CE	BALTIMORE	123		15	11	4					38
	CHICAGO	65		8	6	2					
	CINCINNATI	35		4	3	1					
	DETROIT	41		6	4	2					
	MINNEAPOLIS	106		13	10	3					8
	NEW JERSEY	114		13	10	3					91
	PHILADELPHIA	113		13	10	3					8
	FORENSIC CHEM. CTR										
REGIONAL STAFF											
SE	ATLANTA	171		20	15	5					
	FLORIDA	158	36	19	14	5					102
	NEW ORLEANS	161		20	15	5					
	SAN JUAN	11		2	2						
	REGIONAL LAB						54		20	60	
REGIONAL STAFF											
SW	DALLAS	65		8	6	2					
	DENVER	41		5	4	1				12	
	KANSAS CITY	26		3	2	1					
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB								11	20	
REGIONAL STAFF											
PA	LOS ANGELES	204		24	18	6					68
	SAN FRANCISCO	205		24	18	6			6	18	110
	SEATTLE	294		35	26	9					474
	PACIFIC REGIONAL LABORATORY-SW						54		6	18	
	PACIFIC REGIONAL LABORATORY-NW						54	100	9	26	
HOURS PER OPERATION		22.0	5.0	5.0			45.0		11.0	16.5	
TOTAL HOURS		51260	180	1400			9720	400	770	3465	1860
CONVERSION FACTOR		950	950	950			1180	1180	1180	1180	950
TOTAL OPERATIONAL FTEs		53.96	0.19	1.47			8.24	0.34	0.65	2.94	1.96

9. REMARKS

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

(2) ORGANOLEPTIC NATIONAL EXPERT

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

(4) STARTING IN FY 07 HIGH RISK POTENTIAL PRODUCTS (HRPP) PROCESSORS WHOSE LAST TWO INSPECTIONS WERE NAI, CAN BE CONSIDERED FOR A 2-YEAR INSPECTION CYCLE UNLESS THE FIRM HAS ADDED A NEW HIGH RISK SEAFOOD PRODUCT TO THEIR LINE.

SOURCE OF SEAFOOD WORKLOAD:

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

INSPECTIONS AND DSCs BASED ON OEI.

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

(7) THE MAJORITY OF THE SAMPLES FOR THE SPECIAL VIBRIO ASSIGNMENT WILL BE COLLECTED BY AND PAID FOR BY STATE REPRESENTATIVES OF ISSC. THERE WILL BE 324 SAMPLES COLLECTED/ANALYZED BUT 1/3 OF THE ANALYSIS WILL BE DONE BY THE GULF COAST SEAFOOD LABORATORY.

DFS ASSIGNED THE LABORATORY DISTRIBUTION.

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program 03844 FY 2007		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 a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP Regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and Regulations promulgated under the Act			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety in conjunction with non-safety inspection for decomposition, filth, etc. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP regulation.			
6. FIELD OBLIGATIONS The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. It is equally important that products be analyzed for the health hazard as identified in the HACCP Guide - i.e. raw scombroid fish should be analyzed for histamine not for parasites or micro; raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw. HACCP trained investigators, will review importers' written verification procedures, product specifications and affirmative step documents, which demonstrate that the foreign processors' product was produced under HACCP, food safety hazards prevention program. Inspectional priorities should be based on those listed in the current compliance program. Surveillance activities planned under this program may be pre-empted by enforcement initiatives or other special assignments agreed Upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. NOTE: Animal confirmation tests for PSP, NSP, ciguatera toxin and botulinum toxins will be done at ARL for all regions. NOTE: <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 80.3			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP * 03844H (1)	4 IMPORT SAMPLE COLL PHYSICAL (2) / (5)	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)
	HEADQUARTERS								
	REGIONAL STAFF								
NE	NEW ENGLAND	49	680	476	324	88			
	NEW YORK	64	855	598	407	158			
	REGIONAL LAB						885	617	1005
	WEAC							119	76
	REGIONAL STAFF								
CE	BALTIMORE	14	340	238	162	34			
	CHICAGO	18	70	49	33	14			
	CINCINNATI	8	10	7	5				
	DETROIT	18	85	60	41	42			
	MINNEAPOLIS	12	10	7	5				
	NEW JERSEY	22							
	PHILADELPHIA	11	10	7	5	4			
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA	16	40	28	10	8			
	FLORIDA	41	1220	854	581	150			
	NEW ORLEANS	7	110	77	52	10			
	SAN JUAN	5	10	7	5	4			
	REGIONAL LAB							824	1211
SW	REGIONAL STAFF								
	DALLAS	4							
	DENVER	10							
	KANSAS CITY	8							
	SOUTHWEST IMPORT DISTRICT	20	280	196	133	44			
PA	REGIONAL LAB							145	215
	REGIONAL STAFF								
	LOS ANGELES	59	1785	1249	851	250			
	SAN FRANCISCO	66	425	298	203	62		203	298
	SEATTLE	48	470	329	224	82			
	PACIFIC REGIONAL LABORATORY-SW							918	1346
PACIFIC REGIONAL LABORATORY-NW							295	329	
HOURS PER OPERATION		13.0	2.6					5.3	10.6
TOTAL HOURS		6500	16640			950	1180	16185	47488
CONVERSION FACTOR		950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs		6.84	17.52			1.00	1.00	13.70	40.24

9 REMARKS

(1) FY 2007 : IMPORTER INSPECTIONS: BASED ON OASIS CONSIGNEE DATA.
PER CFSAN, INSPECTIONS OF IMPORTERS ARE TO ASCERTAIN THAT THE IMPORTER HAS COMPLIED WITH SEAFOOD HACCP REGULATIONS (NOT TO PERFORM FILER INSPECTIONS).

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

(3) IMPORT INVESTIGATION HOURS WERE DISTRIBUTED BY CFSAN. RESOURCES ARE FOR FIELD EXAMS, LABEL EXAMS AND OTHER OPERATIONS AS REQUIRED BY THE DISTRICT TO COVER PROGRAM PRIORITIES. DISTRICTS SHOULD REPORT TIME UNDER THE APPROPRIATE OPERATION AND PAC FOR THE ACTIVITIES PERFORMED. ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:

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

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

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

(5) ORGANOLEPTIC NATIONAL EXPERT

(6) WEAC MICRO & CHEM: PER DFS AN INTERNAL AGREEMENT (BASED ON 2007 WORKPLAN) BETWEEN THE WEAC LAB DIRECTOR AND THE NEW ENGLAND IB DIRECTOR TO HAVE 119 CHEM AND 76 MICRO SAMPLES SENT TO WEAC.

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

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program 03847, 03847H FY 2007		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 The Juice HACCP regulation was adopted to ensure safe and sanitary processing of fruit and vegetable juices after reports of many outbreaks of foodborne illnesses, some of which directly affected children. FDA is responsible for assuring that juice processing firms establish and implement the principles of HACCP. HACCP plans must include a minimum five-log pathogen reduction process control (or performance standard) for juices that are not shelf-stable according to the regulation. The collection of verification samples will be implemented this fiscal year to help further validate firms' HACCP plans.					
6. FIELD OBLIGATIONS Inspectional priority should be the following: Firms associated with recent outbreaks, unpasteurized juice firms whose previous inspections were OAI, and followed by firms that have not been inspected. HACCP-trained investigators will also review importers' verification procedures and product specifications, which demonstrate that the foreign processor's product was produced according to HACCP principles. Resources have been provided for "for cause" samples and "verification" samples (pending issuance of revised compliance program). State inspections may be conducted in addition to the number of inspections assigned per district. Resources have also been added to cover food security issues (see IOM) at domestic processors. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.					
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<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 10.0			
6 R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1	4	DOMESTIC	DOMESTIC	7		7	1	9
		DOMESTIC INSPECTIONS (2)	DOMESTIC SAMPLE COLLECTION (3)	DOMESTIC SAMPLE COLLECTION CHEM. GUIDE ONLY	DOMESTIC SAMPLE COLLECTION MICRO GUIDE ONLY	DOMESTIC SAMPLES ANALYZED CHEM		DOMESTIC SAMPLES ANALYZED MICRO	IMPORTER INSPECTIONS (4)	OTHER OPERATIONS (Hours)
TOTAL FIELD		300	150	37	113	37		113	100	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	24	12	2	10				3	
	NEW YORK	21	11	3	8				21	
	REGIONAL LAB					5		18		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	12	6	2	4				3	
	CHICAGO	10	5	1	4				5	
	CINCINNATI	17	8	2	6					
	DETROIT	22	11	3	8				2	
	MINNEAPOLIS	18	9	2	7					
	NEW JERSEY	9	5	1	4				11	
	PHILADELPHIA	31	16	4	12					
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	10	5	1	4				3	
	FLORIDA	17	8	2	6				10	
	NEW ORLEANS	5	2	1	1					
	SAN JUAN	4	2	1	1				2	
SW	REGIONAL LAB					20		57		
	REGIONAL STAFF									
	DALLAS	18	9	2	7				6	
	DENVER	8	4	1	3			15		
	KANSAS CITY	11	6	1	5					
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB					4				
	REGIONAL STAFF									
	LOS ANGELES	20	10	3	7				20	
	SAN FRANCISCO	19	9	2	7	2		7	11	
	SEATTLE	24	12	3	9				3	
PACIFIC REGIONAL LABORATORY-SW						3		7		
PACIFIC REGIONAL LABORATORY-NW						3		9		
HOURS PER OPERATION		18.5	6.2			11.0		15.0	13.0	
TOTAL HOURS		5550	930			407		1695	1300	
CONVERSION FACTOR		950	950			1180		1180	950	
TOTAL OPERATIONAL FTEs		5.84	0.98			0.34		1.44	1.37	

9. REMARKS

- (1) Additional related PAC's: 03847, 04847H, 07847H, 09847H, 21847H. 03847 would be used for general sanitation issues (non-HACCP) and the "H" PACs for HACCP verification samples and the HACCP component of inspection. Non "H" PACs would be used for "For Cause" samples and filth/sanitation component of inspection.
- (2) Per CFSAN, Domestic Inspections based on OEI juice processor data as of 3/24/06. State inspections may be conducted in addition to the number of inspections assigned per district (PAC 03S004). Resources have been added to cover food security issues at all domestic processor inspections. Inspectional priority is as follows: firms associated with recent outbreaks, unpasteurized juice firms, firms whose previous inspections were OAI, and firms that have not yet been inspected. OEI inventory will be provided to each district prior to the beginning of each year.
- (3) Per CFSAN, DSC resources have been provided for anticipated "for cause" and "verification" samples (pending issuance of revised compliance program).
- (4) Per CFSAN, Importer inspections based on ORADSS data as of April 2006 (physical location of juice importers).
- (5) Please refer to the list of juice importers distributed by the program monitor and follow the same inspectional priority as above.
- (6) Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments 03F098 (Domestic), 03F100 (Import) FY 2007	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected food commodities of domestic and foreign origin for pathogenic microorganisms as needed and directed by CFSAN assignments.	
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it.	
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the FY 07 produce assignments issued by CFSAN.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: NA <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh fruits and vegetables as specified in the assignment.	d. INDUSTRY/PRODUCT CODE(S) 20-22, 24-25
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

2007 ORA WORKPLAN

OCTOBER 1, 2006

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 type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 21.9		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLLECTION	DOMESTIC SAMPLE COLLECTION	IMPORT SAMPLE ANALYSIS MICRO	DOMESTIC SAMPLE ANALYSIS MICRO				9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		450	450	450	450			
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK	116							
	REGIONAL LAB			111					
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE		52						
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY			72					
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA		83						
	FLORIDA	126	19						
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB			135	226				
	REGIONAL STAFF								
	DALLAS		20						
	DENVER			99	20				
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT	208							
	REGIONAL LAB			101					
	REGIONAL STAFF								
	LOS ANGELES		105						
PA	SAN FRANCISCO		99	4	99				
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW				105				
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		3.0	3.0	25.0	25.0				
TOTAL HOURS		1350	1350	11250	11250				
CONVERSION FACTOR		950	950	1180	1180				
TOTAL OPERATIONAL FTEs		1.42	1.42	9.53	9.53				

9. REMARKS
 Assignments will be issued by CFSAN for the collection of cantaloupe, green onions, tomatoes, loose-leaf lettuce, spinach, cilantro, basil, parsley.
 Note: SWID samples collected from TX & NM are sent to ARL. SWID samples collected from CA & AZ are sent to DEN.
 RESOURCE DISTRIBUTION PER CFSAN.

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

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments 03R233 FY 2007	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, will take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety.	
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to food borne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. To the best of our knowledge, approximately half of the foods that have been associated with food borne illness have been imported. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. An important aspect of this new initiative is to increase our knowledge of the conditions under which a variety of foods are manufactured in foreign countries.	
6. FIELD OBLIGATIONS ORA/DFI shall assist CFSAN by reviewing imported food entry and compliance data to assist in determining the countries and firms whose inspections would be of greatest value to the Agency. ORA/DFI shall plan inspections of foreign firms recommended by CFSAN in so far as contacting the firms and foreign governments and working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN review and classification. The Investigator shall prepare and, after obtaining any CFSAN team member concurrence, submit the entire original EIR to the Imports Branch no later than 30 days following the trip. Submit individual EIRs as they are completed. Don't delay until all EIRs from a particular trip are completed; rather submit each EIR individually as they are completed due to workflow issues. Prioritize submission of EIRs based on classification (i.e., OAI and VAI before NAI). In FY 07, 100 foreign inspections of food firms are planned. On a "for cause" basis as needed, additional inspections may be requested by CFSAN, such as those needed to follow-up on food borne outbreaks. PAC REPORTING INSTRUCTIONS: All CFSAN foreign inspection time is planned under PAC 03R233. Report accomplishments against PAC 03R233, using the Foreign Inspection Operation Code 11.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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					
3. PROGRAM/ASSIGNMENT CODE(S) 03R233			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input 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 F O R E I G N	2 I N V E S T I G A T I O N S (H O U R S)	9 F O R E I G N A S S E S S M E N T T E C H N I C A S S I S T A N C E (H O U R S) [*]				9 O T H E R O P E R A T I O N S (H O U R S)
	TOTAL FIELD		100		950			
NE	HEADQUARTERS	3		28				
	REGIONAL STAFF							
	NEW ENGLAND	6		56				
	NEW YORK	3		28				
	REGIONAL LAB WEAC							
CE	REGIONAL STAFF							
	BALTIMORE	6		56				
	CHICAGO	3		28				
	CINCINNATI	3		29				
	DETROIT	3		29				
	MINNEAPOLIS	6		56				
	NEW JERSEY	3		29				
	PHILADELPHIA FORENSIC CHEM. CTR	3		29				
SE	REGIONAL STAFF	3		29				
	ATLANTA	6		57				
	FLORIDA	6		57				
	NEW ORLEANS	5		48				
	SAN JUAN	3		29				
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS	6		57				
	DENVER	3		29				
	KANSAS CITY	6		57				
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	2		19				
PA	REGIONAL STAFF	3		29				
	LOS ANGELES	6		57				
	SAN FRANCISCO	6		57				
	SEATTLE	6		57				
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW							
HOURS PER OPERATION		30.0						
TOTAL HOURS		3000		950				
CONVERSION FACTOR		950		950				
TOTAL OPERATIONAL FTEs		3.16		1.00				

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

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

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program 03R816 FY 2007	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM TYPE:	N/A	<input type="checkbox"/>	COMPLIANCE PROGRAM	<input type="checkbox"/>	PROGRAM CIRCULAR	<input checked="" type="checkbox"/>	ASSIGNMENT
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4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	N/A	<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	<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 Methods Validation/Development Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) 03R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 12.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV MICRO (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)						
	TOTAL FIELD	10245	4720						
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB	1800							
	WEAC	1205							
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	600							
	REGIONAL STAFF								
	DALLAS								
	DENVER	840							
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB	850							
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO	1205							
PA	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW	2540							
	PACIFIC REGIONAL LABORATORY-NW	1205	4720						
HOURS PER OPERATION									
TOTAL HOURS		10245	4720						
CONVERSION FACTOR		1205	1180						
TOTAL OPERATIONAL FTEs		8.50	4.00						

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Contract Management 03R843		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03 FY 2007	
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 8000 food inspections are anticipated to be contracted out in FY 07 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.			
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the district. Inspections should be planned by the field. Report under Operation Code 13 (Domestic Investigation). Audits are not considered inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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			

1. PROGRAM/ASSIGNMENT TITLE Contract Management			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03R843			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		INFO ONLY	2007	2007	2007			9
			NUMBER OF FOOD STATE CONTRACT AUDITS (1)	DOMESTIC FOOD STATE CONTRACTS LESS SEAFOOD (3)	DOMESTIC SEAFOOD STATE CONTRACTS IND 16 (3)	TOTAL STATE CONTRACTS (3)			
TOTAL FIELD			629	8111	879	8990			13300
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND		34	364	116	480			710
	NEW YORK		27	378		378			559
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE		50	616	99	715			1058
	CHICAGO		27	390		390			577
	CINCINNATI		43	601	20	621			919
	DETROIT		21	300		300			444
	MINNEAPOLIS		35	480	20	500			740
	NEW JERSEY		29	361	50	411			608
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA		27	391		391			578
	FLORIDA		32	320	130	450			666
SW	NEW ORLEANS		45	540	100	640			947
	SAN JUAN		6	90		90			133
	REGIONAL LAB								
	REGIONAL STAFF								
PA	DALLAS		62	825	60	885			1309
	DENVER		17	230	12	242			358
	KANSAS CITY		48	690		690			1021
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
PA	SEATTLE		126	1535	272	1807			2673
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS									13300
CONVERSION FACTOR									950
TOTAL OPERATIONAL FTEs									14.00

9 REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Food Defense 03R845 FY 2007	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards
3. PROGRAM TYPE: NA <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENTS & Preparedness Activities	
4. OBJECTIVES To maintain food defense preparedness by means of joint CFSAN/ORA field assignments, FDA collection and analysis of proficiency samples for the Food Emergency Response Network, providing resources for general laboratory preparedness activities including instrument, reagent, and standards maintenance, and related activities. Maintain and expand food defense alertness to the food industry.	
5. PROGRAM JUSTIFICATION A secure food supply is considered part of the nation's infrastructure. FDA, along with other federal Agencies, is responsible for responding to threats to the security of the food supply. The resources and activities planned under this program will help the Agency maintain a necessary state of readiness to respond to threats and activities planned for periods of heightened alert, as well as initiate and/or maintain food defense alertness to expanding industry groups.	
6. FIELD OBLIGATIONS Actual emergency and code-red alert status activities, when needed, will be directed jointly by CFSAN and ORA, and the Field will be instructed on planned work that will be halted. Food defense assignments, cleared by CFSAN and ORA, are to be carried out expeditiously.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All food products.	d. INDUSTRY/PRODUCT CODE(S) All food industry/product codes.
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) 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.	

2007 ORA WORKPLAN

OCTOBER 1, 2006

1. PROGRAM/ASSIGNMENT TITLE Food Defense	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 38.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	8	8			CHEM	MICRO	
		CSO DOMESTIC HOURS	CSO IMPORT HOURS	IMPORT CHEM HOURS	IMPORT MICRO HOURS	DOMESTIC CHEM HOURS	DOMESTIC MICRO HOURS	HOURS FD METHOD VALIDATION	HOURS FD METHOD VALIDATION	* INFO ONLY
	TOTAL FIELD	15960	6840	2830	2128	6610	4956	2500	1750	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1240	264							
	NEW YORK	782	2071							
	REGIONAL LAB			283	304	661	708	250	250	
	WEAC			283		661		250		
CE	REGIONAL STAFF									
	BALTIMORE	618	154							
	CHICAGO	593	135							
	CINCINNATI	700	20							
	DETROIT	745	750							
	MINNEAPOLIS	849	72							
	NEW JERSEY	490								
	PHILADELPHIA	587	67							
	FORENSIC CHEM. CTR			283		661		250		
SE	REGIONAL STAFF									
	ATLANTA	759	79							
	FLORIDA	594	293							
	NEW ORLEANS	779	56							
	SAN JUAN	257	38							
	REGIONAL LAB			283	304	661	708	250	250	
SW	REGIONAL STAFF									
	DALLAS	1275								
	DENVER	485		283	304	661	708	250	250	
	KANSAS CITY	591		283		661		250		
	SOUTHWEST IMPORT DISTRICT		1421							
	REGIONAL LAB			283	304	661	708	250	250	
PA	REGIONAL STAFF									
	LOS ANGELES	1197	661							
	SAN FRANCISCO	1151	295	283	304	661	708	250	250	
	SEATTLE	2268	464							
	PACIFIC REGIONAL LABORATORY-SW			283	304	661	708	250	250	
	PACIFIC REGIONAL LABORATORY-NW			283	304	661	708	250	250	
HOURS PER OPERATION										
TOTAL HOURS		15960	6840	2830	2128	6610	4956			
CONVERSION FACTOR		950	950	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs		16.80	7.20	2.40	1.80	5.60	4.20			

9. REMARKS
Reporting: Food Defense activities are reported under 03R845, expanded time should be reported under 04R845, 07R845, 09R845, 21R845.
 Planned resources are for all special food defense related activities, over and above resources for food defense activities that are incorporated into routine safety monitoring activities (i.e., food defense coverage during routine food safety inspection and import and domestic food defense reconciliation exams). Resources for food defense coverage during routine operations are included in the parent programs.
 Resources are to be used for CFSAN food defense assignments for inspections, sample collections and analyses, including those to support the FERN. Resources for lead FERN Lab (FCC, NRL, WEAC) activities are funded separately. Total lab time may be used for maintaining general food defense capabilities.
 * Resources for food defense method validation are a subset of the total Chemist and Microbiologist resources planned.
 Note: SWID samples collected from TX & NM are sent to ARL. SWID samples collected from CA & AZ are sent to PRS.
 CSO DOMESTIC HOURS BASED ON TOTAL FOODS M/R OEI INCLUDING IND CODE 02-51 DATED 2/28/06
 CSO IMPORT HOURS BASED ON TOTAL FOODS ACS FDA REVIEW LINES
 LAB RESOURCES PRE-PLANNED BY ORA
 LABORATORY RESOURCES PLANNED BY DFS.

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

The food supply requires monitoring for both pesticides and industrial chemicals to protect the public health and enforce legal residue limits.

Findings are also used to estimate dietary exposure for risk assessments performed by FDA, EPA, and other national and international organizations.

6. FIELD OBLIGATIONS

Emphasis on pesticide/commodity combinations with high exposure potentials in planning sampling for pesticides. Emphasis should also be given on foods eaten by infants and children. Designation of portion of each district's total resources may be devoted to special assignments (e.g., Center-directed surveys and district-initiated surveys). The field is to collect and analyze general pesticide samples, seafood samples, and dioxin samples as directed in the compliance program. Dioxin collections will be handled by bi-annual collection schedules issued by CFSAN. Dioxin investigation assignments and follow-up sampling may be issued by CFSAN under this program when typically high dioxin levels are found.

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
All human foods.

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

e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES
Pesticides and industrial chemicals as directed by compliance program.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
See compliance program, PAM, IOM, etc.

1. PROGRAM/ASSIGNMENT TITLE 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
	TOTAL FIELD	1100	2400	2400		750	750	232	100	100
N E	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	12	27			40			10	
	NEW YORK	55	119			60			10	
	REGIONAL LAB WEAC			146						20
C E	REGIONAL STAFF									
	BALTIMORE	22	49			60			10	
	CHICAGO	34	75			30				
	CINCINNATI	24	52			30				
	DETROIT	48	105			30				
	MINNEAPOLIS	121	265							
	NEW JERSEY	14	30			30				
	PHILADELPHIA	14	30			30				
	FORENSIC CHEM. CTR									
S E	REGIONAL STAFF									
	ATLANTA	30	66			60			10	
	FLORIDA	92	200			60			10	
	NEW ORLEANS	22	49			60			10	
	SAN JUAN REGIONAL LAB	3 480	4							40
W	REGIONAL STAFF									
	DALLAS	36	79			60			10	
	DENVER	31	67			30				
	KANSAS CITY	104	227	373		30		232		10
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB			445			750			
P A	REGIONAL STAFF									
	LOS ANGELES	63	137			60			10	
	SAN FRANCISCO	169	369			50			10	
	SEATTLE	206	450			30			10	
	PACIFIC REGIONAL LABORATORY- SW PACIFIC REGIONAL LABORATORY- NW			506 450						20 10
HOURS PER OPERATION			3.0	5.2		4.0	20.0	11.6	3.0	5.2
TOTAL HOURS		1100	7200	12480		3000	15000	2691	300	520
CONVERSION FACTOR		950	950	1180		950	1180	1180	950	1180
TOTAL OPERATIONAL FTEs		1.16	7.58	10.58		3.16	12.71	2.28	0.32	0.44

7. REMARKS

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

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1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (38.9)
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	6. DISTRICT/ SPECIALIZED LABORATORY				ISCs	ISAs		ISCs SEAFOOD	ISAs SEAFOOD	
	TOTAL FIELD				5300	5300		300	300	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND				113			30		
	NEW YORK				690			30		
	REGIONAL LAB					803			60	
MA	WEAC									
	REGIONAL STAFF									
	BALTIMORE				14			20		
	CHICAGO				12			10		
	CINCINNATI									
	DETROIT				250			10		
	MINNEAPOLIS				9					
	NEW JERSEY									
SE	PHILADELPHIA				104					
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA				5					
	FLORIDA				218			40		
	NEW ORLEANS				13			20		
PA	SAN JUAN				30					
	REGIONAL LAB					384			80	
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				3483			40		
REGIONAL LAB								40		
PA	REGIONAL STAFF									
	LOS ANGELES				124			50		
	SAN FRANCISCO				24			30		
	SEATTLE				211			20		
	PACIFIC REGIONAL LABORATORY- SW					2238			100	
PACIFIC REGIONAL LABORATORY- NW					211			20		
	HOURS PER OPERATION				1.6	6.2		1.6	6.2	
	TOTAL HOURS				8480	32860		480	1860	
	CONVERSION FACTOR				950	1180		950	1180	
	TOTAL OPERATIONAL FTEs				8.93	27.85		0.51	1.58	

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

1. PROGRAM/ASSIGNMENT TITLE 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 anit-fungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.	
5. PROGRAM JUSTIFICATION Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. With the advent of this trend, there will be incentives to protect investments and/or gain a competitive edge through the use of chemotherapeutic agents. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the U.S. and do not have adequate regulatory controls to prevent their export to the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.	
6. FIELD OBLIGATIONS Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 07 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or additional validated methods are ready to implement. As a budget relief, two agent analyses may be run per sample provided the second agent is one of interest for that product. Please refer to the FY 07 Collection Schedule and Compliance Program (both when issued) for species to collect, assigned servicing laboratories, and agents of interest. Individual subsample analyses will only be required for samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining samples will be a composite of 12 sub-samples. Please refer to the FY 07 Collection Schedule for additional collection instructions when issued. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved drugs per the Compliance Program	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

Chemotherapeutics in Seafood				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04						
3. PROGRAM/ASSIGNMENT CODE(S) 04018			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		DSCs	DSAs	DSAs IND SUBS	DSAs COMPOSITES	ISCs	ISAs	ISAs IND SUBS	ISAs COMPOSITES
			TOTAL FIELD	150	150	45	105	1150	1175	445
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		20				130			
	NEW YORK						190			
	REGIONAL LAB			25	10	15		360	175	185
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		10				60			
	CHICAGO						40			
	CINCINNATI									
	DETROIT						20			
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		15				75			
	FLORIDA		20				230			
	NEW ORLEANS		35				25			
	SAN JUAN									
SW	REGIONAL LAB			60		60		245		245
	REGIONAL STAFF									
	DALLAS		30							
	DENVER			60	30	30		415	115	300
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT						65			
PA	REGIONAL LAB			5	5			80	80	
	REGIONAL STAFF									
	LOS ANGELES		5				220			
	SAN FRANCISCO						35			
	SEATTLE		15				60			
PACIFIC REGIONAL LABORATORY- SW										
PACIFIC REGIONAL LABORATORY- NW								75	75	
HOURS PER OPERATION			4.0	19.0			3.0	18.6		
TOTAL HOURS			600	2850			3450	21855		
CONVERSION FACTOR			950	1180			950	1180		
TOTAL OPERATIONAL FTEs			0.63	2.42			3.63	18.52		

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

1. PROGRAM/ASSIGNMENT TITLE 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 Imported agricultural products and their processed derivatives, candy, chocolate/cocoa, and seafood are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" program and assignments (to be issued). Planned assignments include mercury in specific seafood species. CFSAN will issue collection schedules and directed other FY 07 food work. Import field exams should be focused upon foodware products coming from China, Mexico, France, Italy, Thailand, and UK. Sample collections and analyses of domestic and imported foodware will continue as directed by the "Toxic Element" program. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclide. The program should be maintained to keep expertise and proficiency in this area. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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 human food products. Ceramic foodware.	d. INDUSTRY/PRODUCT CODE(S) 02-41, 52A
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Lead, cadmium, mercury and other toxic elements as directed. Domestic - tritium, 90 Sr & gamma ray emitters; IMPORTS; 134 Cs, 137 Cs, 90 Sr	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Radiochemical analysis capability. (Available only at WEAC). Graphite furnace atomic absorption with Zeeman background correction.	

1. PROGRAM/ASSIGNMENT TITLE 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 type="checkbox"/> X ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 17.7 (8.5)				
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
	TOTAL FIELD	100	280	100	280	100	100	100	100	170
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	10				10		10		10
	NEW YORK	10	20			10		10		20
	REGIONAL LAB			20	20		20		20	
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		10			10				
	CHICAGO		10							
	CINCINNATI									
	DETROIT	10								
	MINNEAPOLIS	10								
	NEW JERSEY					10		10		20
	PHILADELPHIA		10							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	10								
	FLORIDA	10	20			10		20		20
	NEW ORLEANS					10		10		10
	REGIONAL LAB			20	40		40		40	
SW	REGIONAL STAFF									
	DALLAS	10				10		10		
	DENVER									
	KANSAS CITY			30	130		10		10	
	REGIONAL LAB		120							30
PA	REGIONAL STAFF									
	LOS ANGELES	10	50			10		10		30
	SAN FRANCISCO	10	20	30	90	10	30	10	30	20
	SEATTLE	10	20			10		10		10
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION		3.5	1.8	12.0	12.0	4.5	12.0	4.5	12.0	4.5
TOTAL HOURS		350	504	1200	3360	450	1200	450	1200	765
CONVERSION FACTOR		950	950	1180	1180	950	1180	950	1180	950
TOTAL OPERATIONAL FTEs		0.37	0.53	1.02	2.85	0.47	1.02	0.47	1.02	0.81

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

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1. PROGRAM/ASSIGNMENT TITLE 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 (4.8)														
R E G I O N	6 D I S T R I C T / S P E C I A L I Z E D / L A B O R A T O R Y	I S A S E A F O O D	D I S C M E R C U R Y I N T U N A *	D I S A M E R C U R Y I N T U N A *			D I S C M E R C U R Y I N S E A F O O D *	D I S A M E R C U R Y I N S E A F O O D *												
											TOTAL FIELD	170	75	75			135	135		
NE	HEADQUARTERS																			
	REGIONAL STAFF																			
	NEW ENGLAND																			
	NEW YORK			10			10													
	REGIONAL LAB	30			10															
WEAC																				
CE	REGIONAL STAFF																			
	BALTIMORE			5			10													
	CHICAGO			10																
	CINCINNATI																			
	DETROIT																			
	MINNEAPOLIS																			
	NEW JERSEY												10							
	PHILADELPHIA												5							
FORENSIC CHEM. CTR																				
SE	REGIONAL STAFF																			
	ATLANTA																			
	FLORIDA			10			10													
	NEW ORLEANS						10													
	REGIONAL LAB	50			15															
SW	REGIONAL STAFF																			
	DALLAS			10																
	DENVER																			
	KANSAS CITY	30			20															
	SOUTHWEST IMPORT DISTRICT												40							
REGIONAL LAB																				
PA	REGIONAL STAFF																			
	LOS ANGELES			10			20													
	SAN FRANCISCO	60		10	30		10	40												
	SEATTLE			10			10													
	PACIFIC REGIONAL LABORTORY - SW																			
PACIFIC REGIONAL LABORTORY - NW																				
HOURS PER OPERATION		12.0	3.5	12.0			4.5	12.0												
TOTAL HOURS		2040	263	900			608	1620												
CONVERSION FACTOR		1180	950	1180			950	1180												
TOTAL OPERATIONAL FTEs		1.73	0.28	0.76			0.64	1.37												
7 REMARKS * To be issued as CFSAN Field Assignment.																				

1. PROGRAM/ASSIGNMENT TITLE
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
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
(3.7)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		3	4	5	6	7	8		
			DSCs (Houseware)	ISCs (Houseware)	DOMESTIC FIELD EXAMS	IMPORT INV HOURS	DSAs	ISAs		
	TOTAL FIELD		10	200	25	1400	10	200		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		4	5	10	28				
	NEW YORK			80		622				
	REGIONAL LAB						4	85		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE			10		77				
	CHICAGO			5		42				
	CINCINNATI			5		14				
	DETROIT			5		21				
	MINNEAPOLIS					11				
	NEW JERSEY									
	PHILADELPHIA			5		39				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA			10		46				
	FLORIDA			10		14				
	NEW ORLEANS			5		32				
	SAN JUAN					7				
	REGIONAL LAB							45		
SW	REGIONAL STAFF									
	DALLAS									
	DENVER		3		7					
	KANSAS CITY						3	30		
	SOUTHWEST IMPORT DISTRICT			20		91				
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			20		209				
	SAN FRANCISCO		3	10	8	70	3	20		
	SEATTLE			10		77				
	PACIFIC REGIONAL LABORTORY-SW							20		
PACIFIC REGIONAL LABORTORY-NW										
HOURS PER OPERATION			3.5	1.8	0.7		10.0	10.0		
TOTAL HOURS			35	360	18	1400	100	2000		
CONVERSION FACTOR			950	950	950	950	1180	1180		
TOTAL OPERATIONAL FTEs			0.04	0.38	0.02	1.47	0.08	1.69		

7. REMARKS

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

Import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) For districts that are not provided domestic field exam and sample collection resources, district should still collect samples, if necessary.

1. PROGRAM/ASSIGNMENT TITLE 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)
	TOTAL FIELD				16	84			16	84
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND				3					
	NEW YORK			4	25					
	REGIONAL LAB									
	WEAC							16	84	
CE	REGIONAL STAFF									
	BALTIMORE			4	3					
	CHICAGO			4	3					
	CINCINNATI									
	DETROIT				8					
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA				5					
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				19					
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			4	8					
PA	SAN FRANCISCO				4					
	SEATTLE				6					
	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 dioxins under the pesticide program.	
6. FIELD OBLIGATIONS The collection and analysis of four market baskets which each consisting of three separate samplings of 284 food items to be collected from three locales in the region over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, and toxic elements. WEAC will analyze all foods from one market basket for radionuclides.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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) (1)	2 DOMESTIC SAMPLE TO BE ANALYZED (2)	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) (3)		
	TOTAL FIELD	60	1136	1		
NE	HEADQUARTERS					
	REGIONAL STAFF					
	NEW ENGLAND	5				
	NEW YORK					
	REGIONAL LAB					
CE	WEAC			1		
	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO	5				
	CINCINNATI					
	DETROIT	5				
	MINNEAPOLIS					
	NEW JERSEY	5				
	PHILADELPHIA	5				
FORENSIC CHEM. CTR						
SE	REGIONAL STAFF					
	ATLANTA	5				
	FLORIDA	5				
	NEW ORLEANS	5				
	SAN JUAN					
SW	REGIONAL LAB					
	REGIONAL STAFF					
	DALLAS					
	DENVER	5				
	KANSAS CITY	5	1136			
PA	SOUTHWEST IMPORT DISTRICT					
	REGIONAL LAB					
	REGIONAL STAFF					
	LOS ANGELES	5				
	SAN FRANCISCO					
	SEATTLE	5				
	PACIFIC REGIONAL LABORTORY-SW					
	PACIFIC REGIONAL LABORTORY-NW					
HOURS PER OPERATION		26.0	20.1	2800.0		
TOTAL HOURS		1560	22834	2800		
CONVERSION FACTOR		950	1180	1180		
TOTAL OPERATIONAL FTEs		1.64	19.35	2.37		

7. REMARKS

- (1) Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over five week period and involves 3 separate districts. Four market baskets are planned annually.
- (2) Represents the total number of food items analyzed for various attributes.
- (3) All TDS food items from one market basket analyzed by WEAC for selected radionuclides.

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04						
3. PROGRAM/ASSIGNMENT CODE(S) 04F800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.7		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSC PERCHLORATE IN FOODS	DSA PERCHLORATE IN FOODS			ISC CONTAMINANTS IN HONEY	ISA CONTAMINANTS IN HONEY	ISC/DISC PES & TE DIETARY SUPPL.	ISA/DISA PES & TE DIETARY SUPPL. **
	TOTAL FIELD	200	200			100	100	200	200
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	10							
	NEW YORK	20				10		40	
	REGIONAL LAB								40
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	10						10	
	CHICAGO	10				10		10	
	CINCINNATI								
	DETROIT	10						10	
	MINNEAPOLIS	10							
	NEW JERSEY								
	PHILADELPHIA	10						10	
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	10							
	FLORIDA	10				10		10	
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB		200						30
	REGIONAL STAFF								
	DALLAS	20						10	
	DENVER							10	
	KANSAS CITY	10							
	SOUTHWEST IMPORT DISTRICT					30		30	
PA	REGIONAL LAB						70		55
	REGIONAL STAFF								
	LOS ANGELES	30				20		30	
	SAN FRANCISCO	30						20	
	SEATTLE	10				20		10	
	PACIFIC REGIONAL LABORATORY- SW								65
PACIFIC REGIONAL LABORATORY- NW								10	
	HOURS PER OPERATION	3.0	3.0			3.0	6.5	3.0	24.0
	TOTAL HOURS	600	600			300	650	600	4800
	CONVERSION FACTOR	950	1180			950	1180	950	1180
	TOTAL OPERATIONAL FTEs	0.63	0.51			0.32	0.55	0.63	4.07

7. REMARKS
 *Collection of samples for both Pesticides and Toxic Elements analysis.
 ** The Analytical module includes resources for both Pesticides and Toxic Elements
 Collections for Perchlorate and Dietary Supplements will be directed by CFSAN field assignments.
 Contaminants in honey include chloroamphenicol (See Import Bulletin) and CFSAN assignment.

1. PROGRAM/ASSIGNMENT TITLE
Methods Validation/Development Program

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE: 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 Methods Validation/Development Program	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 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)						
	TOTAL FIELD	6025	5900						
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB	500							
	WEAC	300							
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR	900							
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB	600							
SW	REGIONAL STAFF								
	DALLAS								
	DENVER	500							
	KANSAS CITY	820	5900						
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB	600							
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO	1205							
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW	300							
PACIFIC REGIONAL LABORATORY-NW	300								
HOURS PER OPERATION									
TOTAL HOURS		6025	5900						
CONVERSION FACTOR		1205	1180						
TOTAL OPERATIONAL FTEs		5.00	5.00						

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) 04R838			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9	9						
		FORENSIC SAMPLE ANALYSIS (CHEM)	FORENSIC EVALUATION						
TOTAL FIELD		1205	13255						
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR	1205	13255							
SW	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
HOURS PER OPERATION									
TOTAL HOURS		1205	13255						
CONVERSION FACTOR		1205	1205						
TOTAL OPERATIONAL FTEs		1.00	11.00						

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

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods PAC 07001	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze domestic and import samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin. To remove from interstate commerce, or to detain upon entry, those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established. Data from current monitoring will be used to establish enforcement levels.	
5. PROGRAM JUSTIFICATION 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 ₁ and B ₂ are naturally occurring toxic metabolites produced mainly by the fungus, <i>Fusarium verticilloides</i> , which are found ubiquitously on corn from around the world. Because of their potential carcinogenicity and frequent occurrence in corn-based feeds and foods, their presence should be monitored, especially for incidence data. Deoxynivalenol (DON) is a trichothecene mycotoxin produced by several strains of <i>Fusarium</i> , which under certain climate conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated gastrointestinal illnesses in China and India. FDA has issued an advisory level of 1ppm for DON in finished wheat products. There is a need for continuous monitoring of this toxin. Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera <i>Aspergillus</i> and <i>Penicillium</i> . It is mainly a contaminant in cereal grains and is carcinogenic in mice and rats. There is a need for current information on the incidence and levels of this toxin in the U.S. food supply. Patulin is a mold metabolite produced by several species of mold fungi including <i>Penicillium expansum</i> , the casual organism of apple rot. Apple juice prepared from rotten apples is a possible source of patulin in the human diet. Patulin is regulated in at least 10 countries so far. There is a need for more exposure data to further review the international standards for patulin. The current action level for patulin in apple juice and apple juice components is 50 ppb.	
6. FIELD OBLIGATIONS The Field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic products as directly by the Compliance Program. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited, to the Program PAC unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) See Attachment "A" C.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: <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 Aflatoxins, Fumonisin B ₁ and B ₂ , Deoxynivalenol (DON), Ochratoxin A, and Patulin.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program (C.O.) 7307.001	

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods				2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07						
3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DOMESTIC)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS Total (25.3) 15.9			
R E G I O N	6.	3	3	3	3	3	7	7	7	7
	DISTRICT/ SPECIALIZED LABORATORY	DSCs AFLA- TOXIN	DSCs FUMON- ISON	DSCs DON	DSCs OCHRA TOXIN	DSCs PATULIN	ALL DOMESTIC SAMPLE ANALYSES	DSAs AFLA- TOXIN	DSAs FUMON- ISON	DSAs DON
	TOTAL FIELD	800	320	250	100	240	1710	800	320	250
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	24	10		3	44				
	NEW YORK	25	13	18	6	25				
	REGIONAL LAB						205			62
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	26	7	13	2	9				
	CHICAGO	81	46	6	11	11				
	CINCINNATI	75	25	18	10	7				
	DETROIT	40	17	13	3	20				
	MINNEAPOLIS	30	8	12	4	11				
	NEW JERSEY	21	8	5	2	12				
PHILADELPHIA	14	7	8	3	20					
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	79	22	13	6	2				
	FLORIDA	20	7	5	2	9				
	NEW ORLEANS	49	23	13	9	5				
	SAN JUAN	3	1	6	1					
SW	REGIONAL LAB						926	800		68
	REGIONAL STAFF									
	DALLAS	105	46	18	12	6				
	DENVER	12	4	13	2	2				
	KANSAS CITY	60	26	32	6	13	460		320	63
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	54	32	5	8	9				
	SAN FRANCISCO	30	1	15	1	4				
	SEATTLE	52	17	37	9	31				
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW						119			57	
HOURS PER OPERATION		4.0	4.0	4.0	4.0	4.0	6.0			
TOTAL HOURS		3200	1280	1000	400	960	10260			
CONVERSION FACTOR		950	950	950	950	950	1180			
TOTAL OPERATION FTEs		3.37	1.35	1.05	0.42	1.01	8.69			

7. REMARKS

Report all Domestic and Import operations under PAC 07001.

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods				2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07							
3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DSA, ISCs)				4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	7 DSA's OCHRA TOXIN	7 DSA's PATULIN	4 ISCs AFLA TOXIN	4 ISCs PEANUT BUTTER	4 ISCs FUMON- ISON	4 ISCs DON	4 ISCs OCHRA TOXIN	4 ISCs PATULIN	4 ISCs SPECIAL SURVEY	
	TOTAL FIELD	100	240	500	(105)	160	160	64	240	40	
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND			4		1		1	7		
	NEW YORK			148	(35)	62	6	20	91	19	
	REGIONAL LAB	26	117								
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE			16	(4)	1	8	3	5	1	
	CHICAGO			13		1			13	1	
	CINCINNATI			5							
	DETROIT			66	(27)	15	14	8	25	3	
	MINNEAPOLIS			5		1	1	1	1		
	NEW JERSEY										
	PHILADELPHIA						6		3		
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA			8	(3)	1	6	1	3	1	
	FLORIDA			20		17	3	7	13	4	
	NEW ORLEANS			2							
	SAN JUAN			2		1		1	2	1	
SW	REGIONAL LAB		58								
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY	56	21								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB			75	(3)	44	87	5	33	1	
PA	REGIONAL STAFF										
	LOS ANGELES			49	(6)	7	11	3	13	4	
	SAN FRANCISCO			30		3	2	6	2	3	
	SEATTLE			57	(27)	6	16	8	29	2	
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW	18	44								
HOURS PER OPERATION				2.0		2.0	2.0	2.0	2.0	2.0	
TOTAL HOURS				1000		320	320	128	480	80	
CONVERSION FACTOR				950		950	950	950	950	950	
TOTAL OPERATION FTEs				1.05		0.34	0.34	0.13	0.51	0.08	

7. REMARKS

* Peanut Butter ISCs were spread by CFSAN

1. PROGRAM/ASSIGNMENT TITLE 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"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.9			
R E G I O N	6.	8	8	8	8	8	8	8	8	9
	DISTRICT/ SPECIALIZED LABORATORY	ALL IMPORT SAMPLE ANALYSES	ISAs AFLA TOXIN	ISAs FUMON- ISON	ISAs DON	ISAs OCHRA TOXIN	ISAs PATULIN	ISAs SPECIAL SURVEY	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERAT- IONS (HOURS)
	TOTAL FIELD	1164	500	160	160	64	240	40		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	302	152		20	24	106			
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB	269	137		24	11	57	40		
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY	367	75	160	87	12	33			
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW	226	136		29	17	44			
	HOURS PER OPERATION	7.0								
	TOTAL HOURS	8148								
	CONVERSION FACTOR	1180								
	TOTAL OPERATION FTEs	6.91								

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE
Methods Validation/Development Program

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
Validated analytical methods are essential to support enforcement activities.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives	2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09
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3. PROGRAM/ASSIGNMENT CODE(S) 09006A (Foods), 09006B (Colors)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 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	IMPORT INVESTIGATIONS (HOURS) *	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	310	310	865	865	1087	
	HEADQUARTERS						
NE	REGIONAL STAFF						
	NEW ENGLAND				20	25	
	NEW YORK	95			270	341	
	REGIONAL LAB		114				
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE		7		18	23	
	CHICAGO		6		17	22	
	CINCINNATI		1		3	4	
	DETROIT		31	31	86	86	108
	MINNEAPOLIS		4		10	12	
	NEW JERSEY						
	PHILADELPHIA		4		10	13	
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA		4		11	14	
	FLORIDA		8		23	29	
	NEW ORLEANS		2		5	7	
	SAN JUAN		2		5	10	6
	REGIONAL LAB			16		34	
SW	REGIONAL STAFF						
	DALLAS						
	DENVER					219	
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT		78			219	273
	REGIONAL LAB			10			27
PA	REGIONAL STAFF						
	LOS ANGELES		27		75	94	
	SAN FRANCISCO		13	61	35	168	44
	SEATTLE		21		58	72	
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		1.4	11.0	1.4	8.0		
TOTAL HOURS		434	3410	1211	6920	1087	
CONVERSION FACTOR		950	1180	950	1180	950	
OPERATIONAL FTEs		0.46	2.89	1.27	5.86	1.14	

7. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide guidance, support, and assistance to the federal, state, tribal, and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in foodborne illnesses. This program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, National Food Safety needs at retail level, CFSAN directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.	
5. PROGRAM JUSTIFICATION There are more than 3,000 federal, tribal, state, and local regulatory food control agencies which together represent the regulatory resource through which federal food policy is implemented at the retail level. This segment totals more than one million commercial and institutional food establishments, locations, and operations. Each year the Centers for Disease Control and Prevention's Annual Report shows that a major percentage of foodborne outbreaks, where mishandling of food is implicated, occur in retail food establishments. Therefore, an important part of FDA's mission is to provide assistance to federal, tribal, state, and local regulatory agencies with control over this segment of the food industry.	
6. FIELD OBLIGATIONS Provide technical assistance to federal, tribal, state, and local regulatory food agencies. Provide technical assistance to CFSAN and Headquarters in the preparation of position papers. Conduct periodic baseline and follow-up studies to measure trends on the occurrence of foodborne illness risk factors nationwide in selected food service and retail food establishment. Promote the adoption of retail program standards. Provide training on the provisions of FDA Food Code, HACCP, Facility Plan Review, the Egg Rule, and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events impacting retail food safety. Participate in the FDA Retail Food Steering Committee, the National Conference for Food Protection committees, and other conferences and industry events to share information and present FDA's position on issues concerning retail food protection. Specialists will participate in the National Team Workgroups. These workgroups will address issues which include Voluntary National Retail Food Regulatory Program Standards, standardization procedures, prestandardization workshops, HACCP, and Retail Specialist certification, etc. Maintain a cadre of trained FDA Food Specialists.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Foods	d. INDUSTRY/PRODUCT CODE(S) Inspections: 51 NY
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>) 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 23.0 (22.0)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL/FOOD PROGRAM STANDARDS BASELINE SUPPORT (1)	STANDARD- IZATION (ITP CDC IHS, STATE AND LOCAL) (2)	RE-STANDARD- IZATION (ITP, STATE AND LOCAL) (3)	FOOD DEVELOP- MENT (4)	TEAM LEADERS SC/NATIONAL (5)	NATL TEAM WORK GROUP (6)	REGIONAL SEMINARS (7)	TRAINING WORKSHOPS PRE-STANDARD- IZATION TRAINING (8)	TECHNICAL ASSISTANCE (9)
	TOTAL FIELD		8412	1926	1788	460	1200	2760	1380	2070
NE	HEADQUARTERS									
	REGIONAL STAFF	1485	240	316	80		480	240	360	1399
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF	1555	480	320	80	600	480	240	360	485
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	1412	480	256	80	600	480	240	360	692
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF	1500	288	416	100		600	300	450	2096
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF	2460	438	480	120		720	360	540	1782
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION										
TOTAL HOURS		8412	1926	1788	460	1200	2760	1380	2070	6454
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		7.01	1.61	1.49	0.38	1.00	2.30	1.15	1.73	5.38

7. REMARKS:
 Report Counter Terrorism work performed only under 18R845.
 (1) Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards. Contact with jurisdictions to assist them with completing their self assessments, strategic plans, and verification audits performed directly by the FDA Food Specialists.
 (2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting risk-based inspections. Continued support of the ITP Program. FDA Food Specialists will be standardizing a few ITP Associate Standards.
 (3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections. Also included is the re-standardization of FDA Food Specialists by their respective Regional Associate Standard. The joint inspections required in the re-standardization process may be completed in one fiscal year or spread out over a three year period.
 (4) Allocation of time to work with CFSAN in the development and issuance of regulatory language for the Supplement to the 2005 Food Code.
 (5) Time allocated for team leaders of the National Retail Food Team Steering Committee for retail food program planning, development, coordination.
 (6) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards, and initiatives of national importance. Includes attendance and active participation in team conference calls and face -to-face meetings/planning sessions.
 (7) Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the annual Regional Retail Food Seminars.
 (8) Includes training workshops not limited to Food Code courses, pre-standardization workshops, HACCP workshops, and other identified training topics. Also includes time for the Specialists' to prepare candidates for standardization, as well as, the presentation and training sessions given to stakeholders groups via conference calls, seminars, conferences, web meetings, or other means.
 (9) Includes technical assistance and consultation to enrolled state and local jurisdictions performing self-assessments and developing strategic plans using the Program Standards as the foundation for enhancing the effectiveness of their retail food programs. Also includes interpretations and consultations on the Food Code and other food safety issues. Also includes planning and field activities related to food safety and security events working in conjunction with other federal agencies.

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1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18						
3. PROGRAM/ASSIGNMENT CODE(S) 18002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (1.0)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CONFERENCE FOR FOOD PRO- ACTIVITIES (10)	FOOD DEFENSE COORDINATION & CFSAN DIRECTED PROJECTS (11)						
	TOTAL FIELD	460	690						
NE	HEADQUARTERS								
	REGIONAL STAFF	80	120						
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF	80	120						
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF	80	120						
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF	100	150						
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF	120	180						
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION									
TOTAL HOURS		460	690						
CONVERSION FACTOR		1200	1200						
TOTAL OPERATIONAL FTEs		0.38	0.58						

7. REMARKS:

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

(11) Time allocated for the presentation and distribution of FDA materials related to food defense, such as guidance document, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures ", to state and local regulatory agencies and industry. Includes counter-terrorism presentations at seminars, meetings, conferences, etc. Also includes Specialists' activities related to CFSAN priority assignments in response to national food safety needs.

1. PROGRAM/ASSIGNMENT TITLE 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

To promote the adoption, implementation and enforcement of the uniform technical guidelines, administrative procedures and regulatory standards provided in the Pasteurized Milk Ordinance (PMO) and related documents through provision of technical assistance and consultation; conduct check ratings of IMS listed shippers and audits of listed single service facilities; participation in regional seminars, state workshops and other training courses and evaluate state programs to measure effectiveness in maintaining adequate level of conformity with the PMO and related documents.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER 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 19.1 (16.8)			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANT ¹	CHECK RATINGS TRANSFER AND RECEIVING ¹	CHECK RATING BTU ¹	SINGLE SERVICE AUDITS ¹	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICATION ²	TECHNICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION ³	STATE MILK SAMPLING SURVEILLANCE OFFICER INITIAL CONT ¹	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER ⁴
NE	HEADQUARTERS									
	REGIONAL STAFF	17	3	24	5	3	7	3	9	2
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF	37	20	109	17	13	15	5	6	6
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	20		20	13	2	9	3	5	3
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF	28	10	66	12	4	11	3	13	10
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF	44	1	34	11	15	9	3	2	10
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		24.0	12.0	20.0	8.0	40.0	100.0	120.0	24.0	40.0
TOTAL HOURS		3504	408	5060	464	1480	5100	2040	840	1240
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		2.92	0.34	4.22	0.39	1.23	4.25	1.70	0.70	1.03

7. REMARKS:

- 1/ Check Ratings of Plants and RS/TS Every 3 Years, BTUs Every 4 Years and Audits Every 5 Years
- 2/ Activities Include the Initial (Including HACCP) and Continuous Certifications of State Rating Officers and Sampling Surveillance Officers.
- 3/ State Program Evaluations Conducted of 1/3 of the States (Including Puerto Rico) Every 3 Years.
- 4/ Activities Include the National Steering Team Meetings and conference calls and time for team leader activities (2 RMSs with an additional 240 hours each identified).

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1. PROGRAM/ASSIGNMENT TITLE 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 (2.3)	
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	NCMS ⁵	Food Defense ⁶ COORDINATION	TRAINING GIVEN ⁷					
	TOTAL FIELD	19	19	19					
NE	HEADQUARTERS								
	REGIONAL STAFF	2	2	2					
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF	6	6	6					
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	3	3	3					
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF	4	4	4					
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF	4	4	4					
	LOS ANGELES								
	SAN FRANCISCO								
PA	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
	HOURS PER OPERATION	60.0	25.0	60.0					
	TOTAL HOURS	1140	475	1140					
	CONVERSION FACTOR	1200	1200	1200					
	TOTAL OPERATIONAL FTEs	0.95	0.40	0.95					

5/ Activities include time for RMS to prepare for and attend the NCIMS biennial conference.
 6/ Includes time for presentation and distribution of the food defense preventive measures guidance document for dairy products to the state regulatory agencies during check ratings routine field work and state program assessments. Presentations may be made at regional seminars or local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of food defense activities and field activities related to food defense. Report time against PAC 18R845.
 7/ Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops.

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Evaluate the shellfish sanitation program of 30 states and 5 nations for the sanitary control of shellfish intended for interstate and overseas commerce under the cooperative arrangements for the federal-state National Shellfish Sanitation Program (NSSP). Provide standardization, technical assistance, training, and evaluation of state and international shellfish control programs.	
5. PROGRAM JUSTIFICATION Shellfish, by virtue of their habitat, physiological characteristics, and the manner in which they are consumed, require specialized comprehensive sanitary control measures to ensure the safety of human consumption. The management of the program requires a cooperative federal-state effort as defined in the National Shellfish Sanitation Program (NSSP). Consumption of raw or partially cooked shellfish presents a high risk factor to a portion of the population, and requires specialized health control measures to oversee. The 1991 National Academy of Sciences report entitled "Seafood Safety" estimated that up to 85 percent of seafood-related illnesses originate with the consumption of molluscan shellfish. FDA is committed to improving the safety of molluscan shellfish through the NSSP, a program of newly developed safety controls. These initiatives are the direct result of Congressional and public comments directed toward the establishment of a "level playing field" for both domestic and international producers of molluscan shellfish. These program improvements are intended to provide improved shellfish safety through improved program criteria, procedures, and technical support under the NSSP. FDA is committed to improving the safety of shellfish through program enhancement activities. FDA has committed support to the NSSP both administratively and technically through an MOU with ISSC.	
6. FIELD OBLIGATIONS Provide technical assistance and training to states and foreign programs in the prevention of shellfish-borne illness and enforcement of appropriate public health controls. Oversee national standardization program for inspecting shellfish processing plants and evaluation of state and foreign shellfish growing areas. Participate in the evaluation of national shellfish control programs in countries applying to import molluscan shellfish into the U.S. Program time has been allocated for each Regional Shellfish Specialist to hold one regional workshop. Regional workshops provide the opportunity for the specialists to exchange information and provide technical assistance and guidance to their state counterparts. Time has been allocated to educate and evaluate state <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> management programs and to assist in the EU audit of the NSSP.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fresh and fresh frozen molluscan shellfish	d. INDUSTRY/PRODUCT CODE(S) 16, 52 B, Y
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE 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 13.0 (10.3)			
R O N	6	DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION (1)	PATROL EVALUATION (2)	VIBRIO SPECIES MANAGE- MENT (HOURS) (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	TRAINING WORKSHOPS (7)	PLANT EVALUATION (8)	STANDARD- IZATION & RE-STAN- DIZATION (9)
	TOTAL FIELD		167	22	500	2789	5	2	14	132	10
NE	HEADQUARTERS										
	REGIONAL STAFF		57	6	20	143	1	1	2	49	3
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF		45	4	80	475		1	3	45	3
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF		35	7	160	1576	2		4	13	1
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF		10	1	120	285	1		1		
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF		20	4	120	310	1		4	25	3
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION			20.0	80.0			200.0	400.0	50.0	8.0	40.0
TOTAL HOURS			3340	1760	500	2789	1000	800	700	1056	400
CONVERSION FACTOR			1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs			2.78	1.47	0.42	2.32	0.83	0.67	0.58	0.88	0.33

REMARKS:

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

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1. PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER						5. OPERATIONAL FTE POSITIONS						
Molluscan Shellfish Evaluation		Technical Assistance: Food and Cosmetics - 18						(2.7)						
3. PROGRAM/ASSIGNMENT CODE(S)		4. WORK ALLOCATION PLANNED BY												
18004		X												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM WORKSHOP (10)	CENTER INITIA- TIVES/LAB (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE COORDINATION (13)	ISSC COMMITTEE (14)								
	TOTAL FIELD	12	11	13	13	13								
NE	HEADQUARTERS													
	REGIONAL STAFF	2	1	3	3	3								
	NEW ENGLAND													
	NEW YORK													
	REGIONAL LAB													
CE	WEAC													
	REGIONAL STAFF	3	3	3	3	3								
	BALTIMORE													
	CHICAGO													
	CINCINNATI													
	DETROIT													
	MINNEAPOLIS													
	NEW JERSEY													
SE	PHILADELPHIA													
	FORENSIC CHEM. CTR													
	REGIONAL STAFF	4	4	4	4	4								
	ATLANTA													
	FLORIDA													
SW	NEW ORLEANS													
	SAN JUAN													
	REGIONAL LAB													
	REGIONAL STAFF	1	1	1	1	1								
	DALLAS													
PA	DENVER													
	KANSAS CITY													
	SOUTHWEST IMPORT DISTRICT													
	REGIONAL LAB													
	REGIONAL STAFF	2	2	2	2	2								
	LOS ANGELES													
SAN FRANCISCO														
SEATTLE														
PACIFIC REGIONAL LAB - SW														
PACIFIC REGIONAL LAB - NW														
HOURS PER OPERATION		30.0	80.0	40.0	15.0	100.0								
TOTAL HOURS		360	880	520	195	1300								
CONVERSION FACTOR		1200	1200	1200	1200	1200								
TOTAL OPERATIONAL FTE		0.30	0.73	0.43	0.16	1.08								

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

1. PROGRAM/ASSIGNMENT TITLE 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 and investigate passenger conveyances and their support facilities based on the Public Health Service Act, the Food Drug and Cosmetic Act (the Act), regulations, program guidance, Food Code, and in cooperation with the regulated industry and cooperating third party organizations. Also to identify risk factors related to environmental conditions or management practices that may lead to foodborne, waterborne illnesses, and the transmission of communicable diseases. The program includes administrative compliance and regulatory actions as appropriate to ensure conformance with the public health principles embodied in the Acts and their regulations. The goals of the program are to cooperate with the regulated industry, trade associates, and others to promote voluntary compliance, coordinate activities with FAA, CDC, DOT, EPA, Department of Homeland Security (USCG, TSA) and other domestic and foreign government health officials as much as possible to enhance the protection of the traveling public and crew of conveyances both during construction and in operation at watering points, caterers, commissaries, and service areas of conveyances.	
5. PROGRAM JUSTIFICATION This program directs Agency efforts in fulfilling Public Health Service Act responsibilities delegated to the Commissioner of Food and Drugs [21 CFR 5.10(a)(2) and (4)]. Sections 311, 361, and 368 of the Act address federal-state cooperation, the controls of communicable disease, and penalties of noncompliance. The Agency also bases the Interstate Travel Program, in part, on provisions of the Federal Food, Drug and Cosmetic Act and regulations.	
6. FIELD OBLIGATIONS The field is to perform the operations assigned in the Workplan, conduct comprehensive inspections of "high risk" food operations, initiate administrative or regulatory actions as needed to ensure compliance, establish and maintain technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication with CFSAN and ORA Headquarters regarding significant program issues and activities. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human food, water, and waste; conveyance environmental conditions	d. INDUSTRY/PRODUCT CODE(S) Inspections/Investigations: Industry 51, All food codes including water 29W (Y30).
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Food and water surveillance and contamination, mostly microbiological.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Catering point inspections will be conducted by persons standardized in the use of FDA's Food Code and in FDA procedures and specific guidelines established for the Interstate Travel Program.	

1. PROGRAM/ASSIGNMENT TITLE 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 22.7 (22.3)	

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	1550	1360	(666)	(466)	(308)	100	100	1550	950
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	97		42	25	26	6		86	
	NEW YORK	124		32	77	5	8		154	
	REGIONAL LAB WEAC							14		
CE	REGIONAL STAFF									
	BALTIMORE	70		36	15	17	5		84	
	CHICAGO	50		18	20	4	3		55	
	CINCINNATI	46		22	7	14	3		47	
	DETROIT	20		7	4	7			32	
	MINNEAPOLIS	62		25	20	13	4		68	
	NEW JERSEY	31		13	7	6	3		39	
	PHILADELPHIA	48		21	18	7	3		59	
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	62		32	14	13	6		80	
	FLORIDA	81		33	25	13	5		83	
	NEW ORLEANS	163		84	11	64	11		182	
	SAN JUAN	30		14	4	10			35	
REGIONAL LAB							43			
SW	REGIONAL STAFF									
	DALLAS	78	200	44	15	17	5		52	
	DENVER	26		13	11		4	9	25	
	KANSAS CITY	38		15	8	7			46	
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	110	440	57	26	22	7		111	250
	SAN FRANCISCO	227	80	79	118	16	15	15	183	350
	SEATTLE	187	640	79	41	47	12		129	350
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW							7 12		
HOURS PER OPERATION		10.5					4.0	8.0		
TOTAL HOURS		16275	1360				400	800	1550	950
CONVERSION FACTOR		950	950				950	1180	950	950
TOTAL OPERATIONAL FTEs		17.13	1.43				0.42	0.68	1.63	1.00

7. REMARKS:

Inspections in Columns A-C are included in Column 1. Columns will not add across since other firms may be covered under this program. Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B.

(*)Catering Point Insp. (B) is High Risk Priority.

DSCs should be randomly collected from on-board conveyances water systems outlets ex. faucets, as close to the water holding tank as possible.

(**)Time for Conveyance under Construction- time to be used for plan review, meetings, and final inspections. It includes galleys in DAL, LOS and Aircraft/Vessels in SAN & SEA.

Districts should focus inspections on new caterers per mandatory registration.

Districts should increase inspections for air line watering points because of pending new EPA regulations.

Districts should use INV hours to correct OEI, coordinate with other federal agencies and other 3RD parties within the district.

(***)ITP Specialist hours are provided to each of the districts (SAN, LOS and SEA) for specialized inspections of aircraft constructions, ship constructions and galley components.

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1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) 21002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.3		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8
		INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	IMPORT SAMPLE COLL *	DSAs MICRO	DSAs CHEM	ISAs CHEM **
TOTAL FIELD		22	44	25	19	8	19	25	8
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	1	2	1	1				
	NEW YORK	1	2	1	1	2			
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	2	4	3	1				
	CHICAGO	1	2	1	1				
	CINCINNATI	1	2	2		1			
	DETROIT	3	6	3	3	3			
	MINNEAPOLIS	4	8	4	4	1			
	NEW JERSEY	1	2	1	1				
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	1	2	1	1				
	FLORIDA	1	2	1	1				
	NEW ORLEANS	1	2	1	1	1			
	SAN JUAN								
W	REGIONAL LAB						19	25	8
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY	3	6	4	2				
	SOUTHWEST IMPORT OPERATION								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES	1	2	1	1				
	SAN FRANCISCO	1	2	1	1				
	SEATTLE								
	PACIFIC REGIONAL LABORTORY - SW PACIFIC REGIONAL LABORTORY - NW								
HOURS PER OPERATION		30.0	5.2			5.0	30.0	100.0	100.0
TOTAL HOURS		660	229			40	570	2500	800
CONVERSION FACTOR		950	950			950	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.69	0.24			0.04	0.48	2.12	0.68

7. REMARKS

CFSAN spreads inspections and DSCs. CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.

ORA spreads import operations.

Time to investigate import entries for admissibility is planned under the Imports Foods General Program (7303.819)

*Includes samples resulting from import entry review as well as samples collected during foreign inspections.

**May be used for microbiological analysis.

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

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21005, 03R833, 99R833 21R824, 21R829(Health Fraud)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 9.3		
6. REGION	DISTRICT/SPECIALIZED LABORATORY	1. DSC	2. DSCs (DOCUMENTARY)	3. DSCs (PHYSICAL)	4. DSAs	5. DOMESTIC FIELD EXAMS **	3. ISCs (PHYSICAL) OASIS #51 (SEE REMARKS) ****	ISAs	7. IMPORT INV HOURS (SEE REMARKS) ***	ISCs (PAPER) OASIS #41 (SEE REMARKS) *****
TOTAL FIELD		340	240	100	100	4000	125	125	2225	785
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	25	18	7		296	5		91	32
	NEW YORK	15	11	4		180	34		609	214
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	14	10	4		169	2		42	15
	CHICAGO	14	10	4		165	2		39	14
	CINCINNATI	16	11	5		190			5	
	DETROIT	17	12	5		197	14		244	86
	MINNEAPOLIS	20	14	6		230	3		15	7
	NEW JERSEY	12	8	4		141				
	PHILADELPHIA	11	8	3		135			14	5
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	16	11	5		192			19	7
	FLORIDA	13	9	4		156	8		106	37
	NEW ORLEANS	18	13	5		217			8	4
	SAN JUAN	9	6	3		71			13	4
REGIONAL LAB				100			125			
SW	REGIONAL STAFF									
	DALLAS	24	17	7		279				
	DENVER	10	7	3		122				
	KANSAS CITY	13	9	4		157				
	SOUTHWEST IMPORT OPERATION							32	570	201
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	23	16	7		274	11		198	70
	SAN FRANCISCO	21	15	6		250	5		94	33
	SEATTLE	49	35	14		579	9		158	56
	PACIFIC REGIONAL LABORATORY - SW									
PACIFIC REGIONAL LABORATORY - NW										
HOURS PER OPERATION		4.2			18.0	0.4	1.2	10.0		1.2
TOTAL HOURS		1428			1800	1600	150	1250	2225	942
CONVERSION FACTOR		950			1180	950	950	1180	950	950
TOTAL OPERATIONAL FTEs		1.50			1.53	1.68	0.16	1.06	2.34	0.99

7. REMARKS

*DSCs (Physical) includes both compliance (for cause) sampling and surveillance sampling. The field should attempt to collect sufficient surveillance sample as well as needed compliance samples to meet their workplan obligations. See compliance program for details.

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import	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 ensure compliance with the Infant Formula Act and regulations promulgated there under by inspection of domestic and foreign manufacturers of infant formula and collection and analysis of infant formula samples.

5. PROGRAM JUSTIFICATION

Serious infant health problems arising from inadequate nutrient content of infant formula prompted Congress to pass the Infant Formula Act of 1980. This inspection and analysis program assures adherence to the provisions of the Act. Violations and recalls over the past several years (and the continuing keen interest by Congress, as evidenced in part by the 1986 amendments to the Act) indicate the need for continued compliance monitoring. The large number of applications for approval of the formulas exempt from the Act requires expansion of oversight activities into this area.

Infant formulas are identified as "high-risk" foods under the Center's Food Safety Initiatives. Additional resources have been budgeted to allow annual inspections and sample collections from infant formula firms. Inspections of foreign infant formula firms are planned under PAC 03R233. Investigational time to determine admissibility of import lots of infant formula from foreign manufacturers are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots. Food security issues are to be covered during all inspections.

6. FIELD OBLIGATIONS

Districts will conduct inspections and collect samples. Atlanta Center for Nutrient Analysis (ACNA) will perform nutrient analyses and label reviews. Southeast Regional Laboratory, Microbiology Branch will perform microbiological analyses. CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed. Food security issues (see IOM) are to be covered during all inspections.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Infant Formula

d. INDUSTRY/PRODUCT CODE(S)
40C

e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*) Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE 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 4.3			
G I O N	DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS	2 INVEST IGATIONS (Hours)	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	4 IMPORT SAMPLES COLL *	8 IMPORT SAMPLES TO BE ANALYZED CHEM **
	TOTAL FIELD	22		30	20	10	20	10	15	15
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1		2	1	1				
	NEW YORK	2		2	2				2	
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	2		4	3	1				
	CHICAGO	1								
	CINCINNATI	3		2	2				5	
	DETROIT	4		6	4	2			4	
	MINNEAPOLIS	3		6	3	3				
	NEW JERSEY	1								
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB						20	10		15
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY	3		6	4	2				
PA	SOUTHWEST IMPORT DISTRICT								2	
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	2		2	1	1				
	SAN FRANCISCO									
PA	SEATTLE								2	
	PACIFIC REGIONAL LABORTORY-SW PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION		37.0		5.3			100.0	30.0	5.0	100.0
TOTAL HOURS		814		159			2000	300	75	1500
CONVERSION FACTOR		950		950			1180	1180	950	1180
TOTAL OPERATIONAL FTEs		0.86		0.17			1.69	0.25	0.08	1.27

7. REMARKS

CFSAN spreads inspections and DSCs, CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.

ORA spreads import operations

* Includes samples resulting from import entry review as well as samples collected during foreign inspections.

Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819)

** May also be used for microbiological analysis.

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To ensure compliance with the Dietary Supplement Health and Education Act and regulations promulgated there under by inspections of dietary supplement manufacturers and import label exams. Dietary supplements of both domestic and import origin will be collected and analyzed for nutrient content vs. label declarations. All non-exempt dietary supplements must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these requirements will be determined by domestic and import field exams and documentary sample collections.

5. PROGRAM JUSTIFICATION

Dietary supplements are a special class of products consisting of such dietary ingredients as vitamins, minerals, amino acids, glandulars, herbs, and other botanicals. These products are subject to specific safety and labeling requirements. This program provides guidance to FDA district offices regarding inspections, import investigations, sample collection and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994.

The Center has set aside resources for special headquarters initiated assignments to address emerging issues. Investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on their labels and supplements being marketed with claims to treat diseases.

Assignments will continue to issue to enforce the Agency's ban on ephedra containing dietary supplements.

6. FIELD OBLIGATIONS

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

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Dietary supplements	d. INDUSTRY/PRODUCT CODE(S) 54
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*) Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

Analyze selected nutrients and compare with levels declared on product label.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See compliance program.

1. PROGRAM/ASSIGNMENT TITLE 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)			
6. R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	INSP ECTIONS	DOMESTIC FIELD EXAMS	DOMESTIC SAMPLE COLL *	DOMESTIC SAMPLES TO BE ANALYZED	HQ INIT DOMESTIC SAMPLE COLL	HQ INIT DOMESTIC SAMPLE ANALYZED CHEM			INV HOURS
	TOTAL FIELD	250	900	200	100	50	50			3000
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	7	27	6		5				90
	NEW YORK	20	72	16		5				240
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3	9	2						30
	CHICAGO	18	63	14		5				210
	CINCINNATI	7	27	6						90
	DETROIT	7	27	6						90
	MINNEAPOLIS	15	54	12						180
	NEW JERSEY	23	81	18		5				240
	PHILADELPHIA	7	27	6						90
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	10	36	8						120
	FLORIDA	13	45	10		5				150
	NEW ORLEANS	6	18	4						60
	SAN JUAN	1	3	2						30
REGIONAL LAB				100		50				
SW	REGIONAL STAFF									
	DALLAS	10	36	8						120
	DENVER	18	63	14		5				210
	KANSAS CITY	20	72	16		5				240
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	37	141	30		5				450
	SAN FRANCISCO	10	36	8		5				120
	SEATTLE	18	63	14		5				240
	PACIFIC REGIONAL LABORTORY-SW PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION		22.0	0.5	4.2	20.0	4.2	20.0			
TOTAL HOURS		5500	450	840	2000	210	1000			3000
CONVERSION FACTOR		950	950	950	1180	950	1180			950
TOTAL OPERATIONAL FTEs		5.79	0.47	0.88	1.69	0.22	0.85			3.16

7. REMARKS

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

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

Investigational hours are planned primarily for CFSAN directed assignments.

Import resources planned in page 2.

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

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1. PROGRAM/ASSIGNMENT TITLE 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	DISTRICT/ SPECIALIZED LABORATORY	ISC PAPER OASIS #41	ISC PHYSICAL ...	IMPORT INV HOURS	ISA PHYSICAL CHEM		
						TOTAL FIELD	
NE	HEADQUARTERS						
	REGIONAL STAFF						
	NEW ENGLAND	4	1	27			
	NEW YORK	90	18	72			
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE	4	1	9			
	CHICAGO	6	2	63			
	CINCINNATI	4	1	27			
	DETROIT	18	4	27			
	MINNEAPOLIS	4	1	54			
	NEW JERSEY			81			
	PHILADELPHIA	6	2	27			
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA	3	1	36			
	FLORIDA	3	1	45			
	NEW ORLEANS	6	2	18			
	SAN JUAN			9			
	REGIONAL LAB				70		
SW	REGIONAL STAFF						
	DALLAS			36			
	DENVER			63			
	KANSAS CITY			72			
	SOUTHWEST IMPORT DISTRICT	15	2				
	REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES	97	18	135			
	SAN FRANCISCO	64	10	36			
	SEATTLE	36	6	63			
	PACIFIC REGIONAL LABORTORY-SW						
PACIFIC REGIONAL LABORTORY-NW							
HOURS PER OPERATION		1.6	1.6		20.0		
TOTAL HOURS		576	112	900	1400		
CONVERSION FACTOR		950	950	950	1180		
TOTAL OPERATIONAL FTEs		0.61	0.12	0.95	1.19		

7. REMARKS

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrients in Food Survey	2. PPS PROJECT NAME/NUMBER Foods Composition Standard Labeling and Economics-21
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To monitor the mineral nutrients in foods from typical American diets. To identify mineral and vitamin nutrient intake trends. To provide baseline data on mineral nutrient and vitamin intake for intervention studies and other nutrition studies. To function as an important component in the National Nutrition Monitoring System.

5. PROGRAM JUSTIFICATION

Congress has given the Secretaries of DHHS and USDA a mandate to set up a National Nutrition Monitoring System (NNMS). The current Selected Nutrients in Food Survey is an important segment of the NNMS that provides the only continuous analysis of nutrient minerals in the American food supply. This permits identification of trends in nutrient intake over time as well as information on the general nutritional status of the population at any point in time.

6. FIELD OBLIGATIONS

KAN-DO will analyze Total Diet Study foods from all market baskets for 12 nutrients identified below in 7F , and all TDS foods from one market basket annually for moisture.

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Various foods as required by the Total Diet Studies Program	d. INDUSTRY/PRODUCT CODE(S) 37, 40
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*) Label Review

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrient in Foods Survey - Total Diet				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) 21839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPOR T SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 WHARF EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM *	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO**
	TOTAL FIELD								1040
NE	HEADQUARTERS								
	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							1040	
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORTORY-SW								
PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION								3.8	
TOTAL HOURS								3952	
CONVERSION FACTOR								1180	
TOTAL OPERATIONAL FTEs								3.35	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE
Methods Validation/Development Program

2. PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports					2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29				
3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 7.6		
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECT- IONS	2 DOMESTIC INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT ENTRY REVIEW (HOURS)	4 IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	8 IMPORT SAMPLE ANALYSIS (CHEM)	8 IMPORT SAMPLE ANALYSIS (MICRO)
	TOTAL FIELD	100		60	60	1411	230	115	115
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	4		2		17	3		
	NEW YORK	9		5		774	126		
	REGIONAL LAB					7		68	63
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE	2		1		24	4		
	CHICAGO	6		4		13	2		
	CINCINNATI	3		2		28	4		
	DETROIT	3		2		64	10	5	
	MINNEAPOLIS	5		3		6	2		
	NEW JERSEY	11		7					
	PHILADELPHIA	3		2		3	2		
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA	5		3		32	5		
	FLORIDA	9		5		40	6		
	NEW ORLEANS	4		2		14	2		
	SAN JUAN	2		1		14	2		
REGIONAL LAB					23		8	13	
SW	REGIONAL STAFF								
	DALLAS	6		4					
	DENVER	3		2	8				8
	KANSAS CITY	4		2					
	SOUTHWEST IMPORT DISTRICT					92	15		
REGIONAL LAB					9		10	7	
PA	REGIONAL STAFF								
	LOS ANGELES	16		10		169	27		
	SAN FRANCISCO	2		1	3	34	6	24	10
	SEATTLE	3		2		87	14		
	PACIFIC REGIONAL LAB - SW					10			14
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		15.6		5.5	20.7		1.5	10.0	20.7
TOTAL HOURS		1560		330	1242	1411	345	1150	2381
CONVERSION FACTOR		950		950	1180	1200	950	1180	1180
OPERATIONAL FTEs		1.64		0.35	1.05	1.18	0.36	0.97	2.02

7. REMARKS

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

All Import Field Exams are to routinely include: verification that the imported product is the same as that which was declared (Reconciliation Exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety or label concerns. These activities are to be reported as single import field exam or label review under this compliance program and PAC. ONLY one exam should be reported per line entry.

ONLY in the event of a Pre-Determined "for cause" CT exam, or in the event that CT suspicions are raised while conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC 29R845. See IOM Section 5.4.1.4.1 for additional information on Food and Cosmetic Security Activities.

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

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2007**

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps) Inspection of Tissue Establishments	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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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 19.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 C B E R P R I O R I T Y E S T A B S	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)
	TOTAL FIELD	484	(178)							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	21	(4)							
	NEW YORK	30	(14)							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	26	(6)							
	CHICAGO	20	(4)							
	CINCINNATI	22	(9)							
	DETROIT	19	(8)							
	MINNEAPOLIS	21	(13)							
	NEW JERSEY	13	(2)							
	PHILADELPHIA	25	(4)							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	27	(17)							
	FLORIDA	28	(16)							
	NEW ORLEANS	34	(12)							
	SAN JUAN REGIONAL LAB	4	(2)							
SW	REGIONAL STAFF									
	DALLAS	49	(20)							
	DENVER	21	(7)							
	KANSAS CITY	25	(9)							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	51	(13)							
	SAN FRANCISCO	29	(11)							
	SEATTLE	19	(7)							
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		38.3								
TOTAL HOURS		18537								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		19.51								

9. REMARKS

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

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

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

PAC 41002B for Product Codes: 57K Reproductive Tissue
 PAC 41002C for Product Codes: 57M Hematopoietic Stem Cells
 PAC 41002D for Product Codes: 57J Musculoskeletal Tissue; 57 L Ocular Tissue;
 57 O Other Tissue (human skin, pericardium, dura mater, heart valves)

Personnel Types Required: Investigator

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

1. PROGRAM/ASSIGNMENT TITLE 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	2	3	4	5	6	7	8	9
		INSP EC T I O N S *	DOMESTIC INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OT H E R O P E R A T I O N S (Hours)
	TOTAL FIELD	76								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	8								
	NEW YORK	3								
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	8								
	CHICAGO	6								
	CINCINNATI	2								
	DETROIT	2								
	MINNEAPOLIS	6								
	NEW JERSEY	1								
	PHILADELPHIA	2								
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	6								
	FLORIDA									
	NEW ORLEANS	5								
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	9								
	DENVER	3								
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	8								
	SAN FRANCISCO	4								
	SEATTLE	3								
	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: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations: (a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products: (b) Licensed Blood Donor Centers which collect blood and ship to the Licensed Blood Banks of which they are a part; (c) Laboratories that perform testing on blood products and donors, e.g. donor screening for communicable disease agents (HIV 1 and 2, Hepatitis B and C, HTLV I and II, syphilis) and supplemental testing on reactive tests (HIV Western Blot, HCV RIBA). (d) Laboratories that perform quality control testing for licensed blood establishments, e.g., platelet q.c. GMP evaluation to determine the level of competency and adherence to contractual agreements with the licensed establishments.	
5. PROGRAM JUSTIFICATION Blood and Blood Products are vitally important products in medical treatment. Monitoring the collection of whole blood and the processing, manufacturing, and preparation of products derived from human blood assures consumer protection from defective products which may endanger public health.	
6. FIELD OBLIGATIONS ORA will perform the inspections, prepare and submit the certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed. Training of field personnel will be coordinated with CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Blood and Blood Products	d. INDUSTRY/PRODUCT CODE(S) 55, 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of 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 59.5		
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)
	TOTAL FIELD	1130		2469	12			2375		
NE	HEADQUARTERS			2469	3					
	REGIONAL STAFF									
	NEW ENGLAND	63								
	NEW YORK	62								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	65			3			2375		
	CHICAGO	51								
	CINCINNATI	53								
	DETROIT	57								
	MINNEAPOLIS	50								
	NEW JERSEY	25								
	PHILADELPHIA	65								
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	71								
	FLORIDA	83								
	NEW ORLEANS	83			3					
	SAN JUAN	12								
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	94			3					
	DENVER	40								
	KANSAS CITY	64								
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	72								
	SAN FRANCISCO	56								
SEATTLE	64									
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		45.3			40.0					
TOTAL HOURS		51189		2469	480			2375		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		53.88		2.60	0.51			2.50		

7. REMARKS

* All listed resources are planned under PAC 42001F. Resources cover all facilities listed in current compliance program. Pre-License Inspections for PPS 41, 42, 45 and Field Investigation Hours are not planned separately. Use above resources for these as needed, at district discretion.

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

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

*** Foreign Blood Bank Inspections spread by DFI.

Personnel Types Required: Investigator, National Experts

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

1. PROGRAM/ASSIGNMENT TITLE 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 9.9
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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)
	TOTAL FIELD	174	1331							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	1	10							
	NEW YORK	3	23							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	8	61							
	CHICAGO	6	46							
	CINCINNATI	13	99							
	DETROIT	12	92							
	MINNEAPOLIS	14	107							
	NEW JERSEY									
	PHILADELPHIA	7	54							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	10	76							
	FLORIDA	9	68							
	NEW ORLEANS	17	130							
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	30	229							
	DENVER	13	99							
	KANSAS CITY	10	76							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	9	69							
	SAN FRANCISCO	2	16							
	SEATTLE	10	76							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	46.4								
	TOTAL HOURS	8074	1331							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATION FTEs	8.50	1.40							

7. REMARKS

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

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

Personnel Types Required: Investigator, Team Biologics

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

1. PROGRAM/ASSIGNMENT TITLE 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 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 42R833 IMP O R T E N T R Y R E V I E W H O U R S	3 D O M E S T I C I N V E S T I G A T I O N S (H O U R S)	4 I M P O R T I N V E S T I G A T I O N S (H O U R S)	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 (H O U R S)
	TOTAL FIELD		3600							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		171							
	NEW YORK		511							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		142							
	CHICAGO		55							
	CINCINNATI		50							
	DETROIT		238							
	MINNEAPOLIS		111							
	NEW JERSEY									
	PHILADELPHIA		221							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		55							
	FLORIDA		111							
	NEW ORLEANS		699							
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB		224							
PA	REGIONAL STAFF									
	LOS ANGELES		724							
	SAN FRANCISCO		63							
	SEATTLE		225							
	PACIFIC REGIONAL LAB - NW PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION										
TOTAL HOURS			3600							
CONVERSION FACTOR			1200							
TOTAL OPERATION FTES			3.00							

9. REMARKS

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

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

Personnel Types Required: Investigator

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

4. OBJECTIVES

To evaluate the manufacturing process for licensed *in vitro* diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including the Quality System regulations (21 CFR 820), *In Vitro* Diagnostic Products regulations (21 CFR 809), Biologics regulations (21CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.

5. PROGRAM JUSTIFICATION

In Vitro Diagnostic Kits are important tools in medical treatment and blood and plasma donor screening. This program enables the Agency to continue to protect the public health by assuring safety, purity, potency, and efficacy of these products.

6. FIELD OBLIGATIONS

Conduct **comprehensive inspections** that assess the adequacy of all significant processes and systems. These inspections should be performed on **at least a Biennial Basis**. Inspections will be conducted by a Team Biologics Core Team member and may include a district representative and / or a Product Specialist from CBER.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

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 Inspection of Licensed Viral Marker Test Kits	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42008, A Domestic & Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Post-Licensed DOMESTIC INSP CTIONS	1 Post-Licensed FOREIGN INSP CTIONS	3 DOMESTIC INV (Hours)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	12	4	570						
	HEADQUARTERS	12	4							
NE	REGIONAL STAFF									
	NEW ENGLAND			30						
	NEW YORK			30						
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			30						
	CHICAGO			30						
	CINCINNATI			30						
	DETROIT			30						
	MINNEAPOLIS			30						
	NEW JERSEY			30						
	PHILADELPHIA			30						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA			30						
	FLORIDA			30						
	NEW ORLEANS			30						
	SAN JUAN			30						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS			30						
	DENVER			30						
	KANSAS CITY			30						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			30						
	SAN FRANCISCO			30						
	SEATTLE			30						
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	120.0	210.0							
	TOTAL HOURS	1440	840	570						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	1.52	0.88	0.60						

7. REMARKS

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

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

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE IRBs, Spon./Mon./ CROs, Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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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 thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

6. FIELD OBLIGATIONS

IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office.

Spon./Mon./CROs: Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office.

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE 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 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)
	TOTAL FIELD	38								
NE	HEADQUARTERS	3								
	REGIONAL STAFF									
	NEW ENGLAND	2								
	NEW YORK	2								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	6								
	CHICAGO	2								
	CINCINNATI	1								
	DETROIT	2								
	MINNEAPOLIS	1								
	NEW JERSEY									
	PHILADELPHIA	1								
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1								
	FLORIDA	2								
	NEW ORLEANS									
	SAN JUAN	1								
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	3								
	DENVER	1								
	KANSAS CITY	3								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3								
	SAN FRANCISCO	2								
	SEATTLE	2								
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		87.5								
TOTAL HOURS		3325								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		3.50								

9. REMARKS

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

Personnel Types Required: Investigator

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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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	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	16								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2								
	NEW YORK	2								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	1								
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS	1								
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA	1								
	NEW ORLEANS	1								
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3								
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2								
	SAN FRANCISCO	2								
	SEATTLE	1								
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		59.4								
TOTAL HOURS		950								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.00								

7. REMARKS

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

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

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE
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 biological products by evaluating, through inspections, the conditions under which plasma derivatives are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.

5. PROGRAM JUSTIFICATION

Plasma derivatives are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.

6. FIELD OBLIGATIONS

ORA will perform **inspections** that assess the adequacy of all significant processes and systems. These inspections should be performed on **at least a Biennial Basis**. Inspections will be conducted by a Team biologics Core Team member, and may include a district representative and/or a Product Specialist from CBER.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:
 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	7	7							
	HEADQUARTERS	7	7							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	207.1	200.0							
	TOTAL HOURS	1450	1400							
	CONVERSION FACTOR	950	950							
	OPERATIONAL FTEs	1.53	1.47							

7. REMARKS

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products (Post-Market & Pre-License)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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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
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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 SAMPLE COLL	4 IMPORT SAMPLE COLL	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	7	2							
	HEADQUARTERS	7	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		126.2	130.0							
TOTAL HOURS		883	260							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.93	0.27							

7. REMARKS

* New in FY05 Core Team Compliance Program - Inspection of Biological Drug Products (CBER) (Previously covered by PAC 45001):
 PAC 45848A Pre-License Inspection - 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: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To ensure the safety and effectiveness of biological products by determining through inspections, the conditions under which vaccines are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, Standards and commitments made in license applications and/or supplements, and applicable regulations.

5. PROGRAM JUSTIFICATION
Vaccine and vaccine related products are biological products which are administered to man for the diagnosis and prevention of microbial disease and for the therapeutic treatment. Products are manufactured from viral and bacterial organisms and components and may include live attenuated, inactivated, and recombinant vaccines. These products are used in the prevention of childhood diseases and in the treatment, diagnosis, and prevention of diseases and thus are of immeasurable value to the Consumer.

6. FIELD OBLIGATIONS
ORA will perform single, **inspections** that assess the adequacy of all significant processes and systems. These inspections should be performed on **at least a Biennial Basis**. Inspections will be conducted by a Team Biologics Core Team Member and may include a district representative and/or a Product Specialist from CBER.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:
 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 Vaccine Products (Post-Market)				2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45						
3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic/Foreign *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSP EC T I O N S	1 FOREIGN INSP EC T I O N S	2 DOMESTIC INVEST I G A T I O N S (Hours)	3 DOMESTIC INVEST I G A T I O N S (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	8	6	570						
NE	HEADQUARTERS	8	6							
	REGIONAL STAFF									
	NEW ENGLAND			30						
	NEW YORK			30						
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE			30						
	CHICAGO			30						
	CINCINNATI			30						
	DETROIT			30						
	MINNEAPOLIS			30						
	NEW JERSEY			30						
	PHILADELPHIA			30						
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA			30						
	FLORIDA			30						
	NEW ORLEANS			30						
	SAN JUAN			30						
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS			30						
	DENVER			30						
	KANSAS CITY			30						
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			30						
	SAN FRANCISCO			30						
SEATTLE			30							
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		300.0	140.9							
TOTAL HOURS		2400	845	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		2.53	0.89	0.60						

7. REMARKS

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

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