

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2006

Page: 94
Date: 2-DEC-2005

REGION: SW REGN

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	3511	93.53 *	82	68.98 *	2369	10.31 *	7342	15.12 *	970	1.26 *
FOOD SAFETY/COS	906	17.00 *	82	42.24 *	1394	5.71 *	7044	14.36 *	705	0.32 *
03	685	13.80 *	82	40.16 *	279	1.28 *	2919	6.96 *	0	0.00 *
04	0	0.00 *	0	0.28 *	622	2.31 *	3583	6.45 *	0	0.00 *
07	0	0.00 *	0	0.00 *	367	1.54 *	226	0.48 *	0	0.00 *
09	0	0.00 *	0	0.26 *	0	0.00 *	271	0.40 *	0	0.00 *
18	155	1.90 *	0	0.05 *	10	0.04 *	0	0.00 *	0	0.00 *
21	53	1.09 *	0	1.44 *	106	0.49 *	33	0.05 *	705	0.32 *
29	13	0.21 *	0	0.05 *	10	0.05 *	12	0.02 *	0	0.00 *
BIOLOGICS	347	17.15 *	0	1.17 *	0	0.00 *	0	0.00 *	0	0.00 *
41	82	3.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	259	12.80 *	0	1.08 *	0	0.00 *	0	0.00 *	0	0.00 *
45	6	0.54 *	0	0.09 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	418	27.95 *	0	4.43 *	289	1.32 *	38	0.13 *	0	0.00 *
46	17	1.00 *	0	0.00 *	4	0.03 *	8	0.03 *	0	0.00 *
48	100	8.63 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	23	1.46 *	0	0.47 *	23	0.12 *	22	0.08 *	0	0.00 *
53	10	0.60 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	255	15.84 *	0	3.32 *	240	1.07 *	8	0.02 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	13	0.42 *	0	0.64 *	22	0.10 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	1385	14.96 *	0	1.78 *	666	3.14 *	37	0.09 *	0	0.00 *
68	32	1.52 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	1353	13.44 *	0	1.78 *	666	3.14 *	37	0.09 *	0	0.00 *
DEVICES & RAD H	455	16.47 *	0	19.36 *	20	0.14 *	223	0.54 *	265	0.94 *
81	4	0.06 *	0	0.02 *	0	0.00 *	0	0.00 *	0	0.00 *
82	206	10.67 *	0	14.06 *	20	0.14 *	223	0.54 *	0	0.00 *
83	61	4.27 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	167	1.16 *	0	1.23 *	0	0.00 *	0	0.00 *	0	0.00 *
86	17	0.31 *	0	4.05 *	0	0.00 *	0	0.00 *	265	0.94 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2006

Page: 95
Date: 2-DEC-2005

REGION: SW REGN

	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	0	0.37 *	6936	81.74 *	6217	48.58 *	487	34.77 *	172	9.67 *
FOOD SAFETY/COS	0	0.37 *	5663	60.87 *	5930	46.58 *	482	26.45 *	36	1.15 *
03	0	0.37 *	528	10.30 *	2749	25.20 *	0	7.09 *	36	1.15 *
04	0	0.00 *	3592	44.47 *	2510	16.77 *	0	6.90 *	0	0.00 *
07	0	0.00 *	459	2.33 *	342	2.03 *	0	0.20 *	0	0.00 *
09	0	0.00 *	0	0.00 *	310	2.31 *	0	0.00 *	0	0.00 *
18	0	0.00 *	19	0.13 *	0	0.00 *	277	12.00 *	0	0.00 *
21	0	0.00 *	1044	3.27 *	0	0.00 *	205	0.26 *	0	0.00 *
29	0	0.00 *	21	0.37 *	19	0.27 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.12 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.12 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	0	0.00 *	192	8.47 *	5	0.16 *	5	0.74 *	68	4.28 *
46	0	0.00 *	0	1.12 *	0	0.00 *	5	0.44 *	25	1.45 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.66 *
52	0	0.00 *	2	0.83 *	0	0.00 *	0	0.00 *	9	0.58 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.19 *
56	0	0.00 *	183	6.40 *	5	0.16 *	0	0.30 *	21	1.40 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	7	0.12 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	1064	11.51 *	282	1.84 *	0	4.94 *	18	1.29 *
68	0	0.00 *	0	0.19 *	0	0.00 *	0	0.00 *	16	1.21 *
71	0	0.00 *	1064	11.32 *	282	1.84 *	0	4.94 *	2	0.08 *
DEVICES & RAD H	0	0.00 *	17	0.89 *	0	0.00 *	0	2.64 *	47	2.83 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	17	0.89 *	0	0.00 *	0	0.00 *	32	2.19 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	10	0.61 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.75 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.89 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
 FY 2006

Page: 96
 Date: 2-DEC-2005

REGION: SW REGN

TOTALS

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

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



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



WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2006

Page: 115
Date: 2-DEC-2005

REGION: PA REGN

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	4656	134.47 *	242	92.63 *	3181	13.30 *	8703	20.86 *	1570	1.47 *
FOOD SAFETY/COS	2515	46.58 *	242	69.08 *	2590	10.39 *	7907	18.86 *	1346	0.59 *
03	1911	38.17 *	242	65.31 *	673	2.97 *	6002	14.39 *	0	0.00 *
04	0	0.00 *	0	0.98 *	1352	4.97 *	1255	3.29 *	10	0.00 *
07	0	0.00 *	0	0.00 *	349	1.47 *	324	0.68 *	0	0.00 *
09	0	0.00 *	0	0.22 *	0	0.00 *	222	0.33 *	0	0.00 *
18	514	6.67 *	0	0.15 *	29	0.12 *	0	0.00 *	0	0.00 *
21	69	1.40 *	0	2.25 *	173	0.78 *	66	0.11 *	1336	0.59 *
29	21	0.34 *	0	0.17 *	14	0.08 *	38	0.06 *	0	0.00 *
BIOLOGICS	327	16.39 *	0	1.49 *	0	0.00 *	0	0.00 *	0	0.00 *
41	94	4.71 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	226	11.05 *	0	1.40 *	0	0.00 *	0	0.00 *	0	0.00 *
45	7	0.63 *	0	0.09 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	447	30.10 *	0	10.25 *	275	1.26 *	37	0.13 *	0	0.00 *
46	11	0.65 *	0	0.00 *	2	0.02 *	6	0.03 *	0	0.00 *
48	101	8.90 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	12	0.76 *	0	0.29 *	12	0.06 *	17	0.06 *	0	0.00 *
53	20	1.20 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	275	17.70 *	0	7.54 *	199	0.91 *	14	0.04 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	28	0.89 *	0	2.42 *	62	0.27 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	687	8.88 *	0	4.53 *	273	1.38 *	242	0.61 *	0	0.00 *
68	17	0.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	670	8.07 *	0	4.53 *	273	1.38 *	242	0.61 *	0	0.00 *
DEVICES & RAD H	680	32.52 *	0	7.28 *	43	0.27 *	517	1.26 *	224	0.88 *
81	6	0.09 *	0	0.03 *	2	0.02 *	0	0.00 *	0	0.00 *
82	452	22.71 *	0	3.00 *	37	0.24 *	517	1.26 *	0	0.00 *
83	130	8.61 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	48	0.34 *	0	1.60 *	0	0.00 *	0	0.00 *	0	0.00 *
86	44	0.77 *	0	2.65 *	4	0.01 *	0	0.00 *	224	0.88 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
 FY 2006

Page: 116
 Date: 2-DEC-2005

REGION: PA REGN

	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	0	1.00 *	2387	29.43 *	12538	87.42 *	625	34.92 *	187	10.42 *
FOOD SAFETY/COS	0	1.00 *	1925	19.58 *	11588	80.22 *	625	30.46 *	36	1.13 *
03	0	1.00 *	640	12.76 *	8506	61.00 *	0	11.55 *	36	1.13 *
04	0	0.00 *	1114	5.72 *	2522	15.27 *	0	2.40 *	0	0.00 *
07	0	0.00 *	128	0.65 *	298	1.77 *	0	1.00 *	0	0.00 *
09	0	0.00 *	0	0.00 *	222	1.66 *	0	0.00 *	0	0.00 *
18	0	0.00 *	29	0.20 *	0	0.00 *	244	13.95 *	0	0.00 *
21	0	0.00 *	0	0.00 *	0	0.00 *	381	1.56 *	0	0.00 *
29	0	0.00 *	14	0.25 *	40	0.52 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.12 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.12 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	0	0.00 *	184	7.67 *	68	1.53 *	0	0.50 *	76	4.85 *
46	0	0.00 *	3	1.09 *	0	0.00 *	0	0.00 *	21	1.22 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	15	0.99 *
52	0	0.00 *	5	0.97 *	0	0.00 *	0	0.00 *	7	0.45 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.38 *
56	0	0.00 *	149	5.15 *	68	1.53 *	0	0.50 *	27	1.81 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	27	0.46 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	278	2.18 *	242	1.58 *	0	1.33 *	5	0.34 *
68	0	0.00 *	0	0.04 *	0	0.00 *	0	0.00 *	4	0.30 *
71	0	0.00 *	278	2.14 *	242	1.58 *	0	1.33 *	1	0.04 *
DEVICES & RAD H	0	0.00 *	0	0.00 *	640	4.09 *	0	2.63 *	67	3.98 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	0	0.00 *	640	4.09 *	0	0.00 *	42	2.87 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	20	1.08 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.70 *	5	0.03 *
86	0	0.00 *	0	0.00 *	0	0.00 *	0	1.93 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
 FY 2006

Page: 117
 Date: 2-DEC-2005

REGION: PA REGN

TOTALS

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

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2006

Page: 118
Date: 2-DEC-2005

TOTAL FIELD

FIELD	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	21230	640.00 *	700	405.84 *	13366	58.65 *	31886	72.91 *	6297	6.97 *
FOOD SAFETY/COS	9148	168.95 *	700	269.33 *	9091	38.21 *	28986	65.46 *	5000	2.21 *
03	7055	140.82 *	700	255.84 *	2385	10.99 *	18400	43.90 *	0	0.00 *
04	0	0.00 *	0	3.21 *	4151	16.08 *	7829	16.64 *	100	0.05 *
07	0	0.00 *	0	0.00 *	1710	7.21 *	1164	2.46 *	0	0.00 *
09	0	0.00 *	0	1.13 *	0	0.00 *	1175	1.74 *	0	0.00 *
18	1700	20.21 *	0	0.53 *	100	0.43 *	0	0.00 *	0	0.00 *
21	293	6.28 *	0	7.74 *	670	3.07 *	218	0.42 *	4900	2.16 *
29	100	1.64 *	0	0.88 *	75	0.43 *	200	0.30 *	0	0.00 *
BIOLOGICS	1895	99.49 *	0	10.17 *	0	0.00 *	0	0.00 *	0	0.00 *
41	461	22.92 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	1387	70.61 *	0	9.60 *	0	0.00 *	0	0.00 *	0	0.00 *
45	47	5.96 *	0	0.57 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	2852	191.28 *	0	56.80 *	2072	9.47 *	340	1.09 *	0	0.00 *
46	129	7.59 *	0	0.00 *	30	0.20 *	50	0.19 *	0	0.00 *
48	520	45.73 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	137	8.69 *	0	2.87 *	140	0.74 *	140	0.47 *	0	0.00 *
53	138	8.28 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
56	1802	116.98 *	0	47.90 *	1689	7.53 *	150	0.43 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	126	4.01 *	0	6.03 *	213	1.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	4617	55.94 *	0	21.15 *	2040	9.90 *	1120	2.81 *	0	0.00 *
68	141	6.88 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
71	4476	49.06 *	0	21.15 *	2040	9.90 *	1120	2.81 *	0	0.00 *
DEVICES & RAD H	2718	124.34 *	0	48.39 *	163	1.07 *	1440	3.55 *	1297	4.76 *
81	23	0.33 *	0	0.11 *	3	0.03 *	0	0.00 *	0	0.00 *
82	1679	85.70 *	0	28.56 *	154	1.03 *	1440	3.55 *	0	0.00 *
83	499	33.31 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	385	2.71 *	0	7.75 *	0	0.00 *	0	0.00 *	0	0.00 *
86	132	2.29 *	0	11.97 *	6	0.01 *	0	0.00 *	1297	4.76 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2006

Page: 119
Date: 2-DEC-2005

TOTAL FIELD

FIELD	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	0	3.35 *	15232	246.83 *	34726	270.90 *	2803	159.07 *	1150	68.40 *
FOOD SAFETY/COS	0	3.35 *	11501	136.08 *	31811	243.22 *	2797	121.74 *	200	6.32 *
03	0	3.35 *	2225	41.50 *	21225	165.13 *	0	34.99 *	200	6.32 *
04	0	0.00 *	5868	70.54 *	7829	55.61 *	0	11.78 *	0	0.00 *
07	0	0.00 *	1710	8.69 *	1164	6.91 *	0	4.60 *	0	0.00 *
09	0	0.00 *	0	0.00 *	1175	8.76 *	0	0.00 *	0	0.00 *
18	0	0.00 *	100	0.68 *	0	0.00 *	1652	67.48 *	0	0.00 *
21	0	0.00 *	1523	13.34 *	218	4.20 *	1145	2.89 *	0	0.00 *
29	0	0.00 *	75	1.33 *	200	2.61 *	0	0.00 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	43	4.84 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	35	3.21 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	8	1.63 *
HUMAN DRUGS	0	0.00 *	1739	84.22 *	355	8.75 *	6	4.13 *	538	33.95 *
46	0	0.00 *	53	8.65 *	50	1.27 *	6	0.53 *	183	10.58 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	71	4.65 *
52	0	0.00 *	119	9.86 *	155	3.31 *	0	0.00 *	62	3.96 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	27	1.71 *
56	0	0.00 *	1508	52.70 *	150	4.17 *	0	3.60 *	195	13.05 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	59	1.01 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	12.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	0	0.00 *	1770	18.30 *	1120	7.30 *	0	7.61 *	57	3.96 *
68	0	0.00 *	0	0.32 *	0	0.00 *	0	0.00 *	47	3.56 *
71	0	0.00 *	1770	17.98 *	1120	7.30 *	0	7.61 *	10	0.40 *
DEVICES & RAD H	0	0.00 *	222	8.23 *	1440	11.63 *	0	23.09 *	312	19.33 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	0	0.00 *	105	4.74 *	1440	11.63 *	0	2.34 *	207	14.17 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	71	4.02 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	5.13 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	4.35 *	15	0.09 *
86	0	0.00 *	114	3.41 *	0	0.00 *	0	11.27 *	19	1.05 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
 FY 2006

Page: 120
 Date: 2-DEC-2005

TOTAL FIELD

TOTALS

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

FY 2006

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 2006**

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

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

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

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

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

October 1, 2005

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low-Acid Canned Foods, CP 7303.003 FY 2006		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <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.			
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. It was projected that in FY 05, foreign manufacturers will comprise approximately 86% of total number of registered firms. Therefore, in FY 06, the number of planned Import Field Exams will continue to increase in number to 3200 (from 3000 in FY 05) and the number of Import Sample Collections will increase to 1400 (from 1300 in FY 05).			
6. FIELD OBLIGATIONS The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots and/or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements. In FY 06, as in FY 05, all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <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) 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 checked="" 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	4	4	4	8	8	
			IMPORT FIELD EXAMS (Hours) *	IMPORT SAMPLE COLLECTION	IMPORT SAMPLE COLL MICRO GUIDANCE	IMPORT SAMPLE COLL CHEM GUIDANCE	IMPORT SAMPLES TO BE ANALYZED MICRO **	IMPORT SAMPLES TO BE ANALYZED CHEM **	
	TOTAL FIELD		3200	1400	1230	170		1230	170
	HEADQUARTERS		(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)	(b)(2) & (b)(7)(E)
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
PA	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION				1.8				7.0	10.0
TOTAL HOURS			3200	2520				8610	1700
CONVERSION FACTOR			950	950				1180	1180
TOTAL OPERATIONAL FTEs			3.37	2.65				7.30	1.44

9. REMARKS

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

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

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

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

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

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

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

NOTE: (For specialized micro testing below, see compliance program or contact DFS for additional details)
DEN will perform Salmonella serotyping for isolates originating from the following labs: DEN, SAN, PRL-SW, PRL-NW.
ARL will perform Salmonella serotyping for isolates originating from all labs: ARL, SRL, NRL

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
See Compliance Program.

2006 ORA WORKPLAN

OCTOBER 1, 2005

1. PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER							
Domestic and Imported Cheese and Cheese Products		Foodborne Biological Hazards							
3. PROGRAM/ASSIGNMENT CODE(S)		4. WORK ALLOCATION PLANNED BY						5. OPERATIONAL FTE POSITIONS	
03037, 03037B, 03037D		<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						26.3	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)	2 INVESTI- GATIONS (Hours) (3)	3 DOMESTIC SAMPLE COLLECTION (2)	4 IMPORT SAMPLE COLL MICRO (5)	4 IMPORT SAMPLE COLL CHEM GUIDANCE	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	8 IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (7)
	TOTAL FIELD	400	350	400	700	75	400	75	700
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)				
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		17.0		4.0	2.0		17.0	6.1	16.0
TOTAL HOURS		6800	350	1600	1400		6800	457.5	11200
CONVERSION FACTOR		950	950	950	950		1180	1180	1180
TOTAL OPERATIONAL FTEs		7.16	0.37	1.68	1.47		5.76	0.39	9.49

9. REMARKS

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

PRIORITIZE INSPECTIONS TO LOOK AT SMALL MANUFACTURERS I.E. 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 2 YEAR INSPECTION FREQUENCY.

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

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

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

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

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

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

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

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

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

9. REMARKS

- (1) Source of workload: Inspections, Investigation Hours and DSC's provided by CFSAN. Resource distribution based on CFSAN's LACF database as of 3/2005.
- (2) Report all resources expended for NLEA under PAC 21005.
- (3) NAI firms will go to a 3-year inspection cycle. State inspections may be conducted in addition to the number of inspections assigned per district.
- (4) Attendance at Better Processing Schools (BPS).
- (5) Planned collections are for projected "for cause" sampling.

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety 03803 FY 2006		2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards – 03	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE	<input type="checkbox"/> PROGRAM <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. The top program priority for FY 2006 remains to inspect all high-risk firms annually. Coverage for allergens remains “for cause” only, until such time as new allergen inspection guidance is issued by CFSAN. Ample resources have been provided to cover the full high-risk inventory covered by this program as well as to accomplish other program objectives (see compliance program). Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate district, will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. During FY 2006, FDA will continue to monitor chicken eggs for <i>Salmonella</i> Enteritidis and needed follow-up assignments will utilize resources of this program. Also, needed inspections for FDA E.U. certification will be covered here. Food security issues are to be covered during all inspections.			
5. PROGRAM JUSTIFICATION Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibilities of assuring that manufacturers produce these products under current Good Manufacturing Practices.			
6. FIELD OBLIGATIONS To conduct domestic inspections, focusing on high-risk firms and allergen firms, and with additional program resources to provide coverage with the priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk, allergen, and other firms. Sample collections will typically be “for cause,” i.e., no surveillance sampling is to be conducted. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations. Only those “for cause” collections needed to support regulatory inspections are to be conducted. Currently, allergen surveillance inspections are on hold pending finalization of the Agency’s allergen enforcement strategy. The field may do “for cause” allergen inspections as needed, but only proceed with surveillance inspections when new allergen guidance is issued by CFSAN. 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.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) All Food Products (Except 12 & 16)		d. INDUSTRY/PRODUCT CODE (S) 02-11, 13-15, 17-41, 45-46, 50	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Filth, Decomposition and Microbiological Contamination (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety						2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03803,B,C,D,E, 04803 09803E,F (2) (8)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 88.6			
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1 INSP ECTIONS Including High Risk	1 NON- CLINICAL GLP INSPECTIONS	2 INVESTI- GATIONS (HOURS) INCL NATL EXPERTS	3 DOMESTIC SAMPLE COLL	3 DSC CERTIFIED COLOR SAMPLING ASSIGN	DOMESTIC SAMPLE COLLECTION MICRO GUIDANCE	DOMESTIC SAMPLE COLLECTION CHEM GUIDANCE	FOOD SAFETY METHOD VALIDATION MICRO	FOOD SAFETY METHOD VALIDATION CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	(1) (3) (6)	(4)	(1)	(1)	(10)			(9)	(9)	(5)	
		3400	5	7207	800	180	360	240	1500	1500	240	360
HEADQUARTERS (b)(2) & (b)(7)(E)												
REGIONAL STAFF												
NEW ENGLAND												
NEW YORK												
REGIONAL LAB												
WEAC												
REGIONAL STAFF												
BALTIMORE												
CHICAGO												
CINCINNATI												
DETROIT												
MINNEAPOLIS												
NEW JERSEY												
PHILADELPHIA												
FORENSIC CHEM. CTR												
REGIONAL STAFF												
ATLANTA												
FLORIDA												
NEW ORLEANS												
SAN JUAN												
REGIONAL LAB												
REGIONAL STAFF												
DALLAS												
DENVER												
KANSAS CITY												
SOUTHWEST IMPORT DISTRICT												
REGIONAL LAB												
REGIONAL STAFF												
LOS ANGELES												
SAN FRANCISCO												
SEATTLE												
PACIFIC REGIONAL LABORATORY-SW												
PACIFIC REGIONAL LABORATORY-NW												
HOURS PER OPERATION		18.5			5.2	2.0					15.0	15.0
TOTAL HOURS		62800		7207	3120	320			1500	1500	3600	5400
CONVERSION FACTOR		950		950	950	950			1180	1180	1180	1180
TOTAL OPERATIONAL FTES		66.21		7.58	3.28	0.34			1.27	1.27	3.05	4.58
9. REMARKS												
<p>(1) FY 2006 100% INSP, DSC AND INVESTIGATIONS BASED ON: OEI OF FIRMS FLAGGED AS HIGH RISK IN FACTS LESS FIRMS WITH ONLY INDUSTRY CODE 12, 16 OR 51 AS OF MAY 16, 2005. INCLUDES TIME FOR NATIONAL EXPERTS (4 FTES). RESOURCES HAVE BEEN ALLOCATED FOR 3500 TOTAL INSPECTIONS. HIGH RISK AND GLP FIRMS ARE INCLUDED IN THIS TOTAL NUMBER. DISTRICTS SHOULD BE ABLE TO MEET HIGH RISK PERFORMANCE GOALS WITH THE ALLOCATED RESOURCES PLUS STATE CONTRACT INSPECTIONS.</p> <p>(2) RESOURCES FOR 04803, 09803E, F ARE INCLUDED. RESOURCES FOR AUDITS ARE UNDER STATE CONTRACTS PROGRAM 03R843.</p> <p>(3) NO ALLERGEN INSPECTIONS ARE PLANNED AT THIS TIME IN FY 2006. DO NOT INITIATE SURVEILLANCE (ALLERGEN) INSPECTIONS UNTIL NEW ALLERGEN PROGRAM IS ISSUED. ALLERGEN INSPECTIONS MAY BE TAKEN FROM GENERAL INSPECTIONS. REPORT ALLERGEN INSPECTIONS UNDER PAC 03803E. "FOR CAUSE" ALLERGEN INSPECTIONS ARE TO BE CONDUCTED AS NEEDED.</p> <p>(4) NON-CLINICAL GOOD LABORATORY PRACTICE INSPECTIONS: CFSAN WILL CONTACT AFFECTED DISTRICTS TO ARRANGE INSPECTIONS DURING THE COURSE OF THE YEAR.</p> <p>(5) PER DFS THE ANALYTE FOR DSA ALLERGEN IS CLASSIFIED AS CHEM.</p> <p>(6) RESOURCES FOR SPECIAL CFSAN INSPECTIONAL ASSIGNMENTS FOR SPROUT PRODUCERS, EGG FARMS, AND GAME MEAT PROCESSORS, IF NEEDED IN FY 06, WILL BE TAKEN FROM THIS PROGRAM.</p> <p>(7) SALMONELLA SEROTYPING: SAMPLES GENERATED FROM NRL, SRL & ARL GO TO ARL. SAMPLES GENERATED FROM OTHER LABS GO TO DENVER.</p> <p>(8) NON SEAFOOD INSPECTIONS FOR EU AND CHILEAN CERTIFICATIONS WILL BE HANDLED BY CFSAN ASSIGNMENT AND COUNTED AGAINST THE INSPECTIONAL OBLIGATIONS OF THIS PROGRAM.</p> <p>(9) FOOD SAFETY METHOD VALIDATION FOR CHEM AND MICRO: RESOURCES PRO RATED BASED ON THE CHEM AND MICRO LABS IN THE ORA FIELD WORKPLAN LAB SERVICING TABLE.</p> <p>(10) PER CFSAN, SAMPLES WILL BE ANALYZED BY THE OFFICE OF FOOD ADDITIVE SAFETY, COLOR CERTIFICATION GROUP.</p>												

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1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) 03803,B,C,D, E, 04803 09803E,F, 03R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS N/A	
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	DSA MCR O SALMONELA SER OTYPING	FY 2006 STATE CONTRACTS PER DIVISION FEDERAL STATE RELATIONS (INFO ONLY)						
	TOTAL FIELD	1180	7847						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		1180							
CONVERSION FACTOR		1.180							
TOTAL OPERATIONAL FTES		1.00							
9. REMARKS									
(1) RESOURCES FOR AUDITS ARE UNDER STATE CONTRACTS PROGRAM 03R843.									

1. PROGRAM/ASSIGNMENT TITLE Import Foods – General 03819 FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.	
6. FIELD OBLIGATIONS To conduct activities directed by CFSAN, identified through program guidance, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth disease vector, or decomposition. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. 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.	

2006 ORA WORKPLAN

OCTOBER 1, 2005

1. PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER											
Import Foods - General		Foodborne Biological Hazards - 03											
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY						5. OPERATIONAL FTE POSITIONS				
03R19A,B,C (03R833/99R833/R824) (1)			<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						282.2				
R E G I O N	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	2	2	2	2	4	4	4	8	8	8	8	
		IMPORT ENTRY REVIEW HRS OPER 14 03R833 (2)	PRIOR NOTICE REVIEW HOURS 03R833 (6)	INVEST- IGATION HOURS (3)	BSE ENTRY REVIEW & FOLLOW UP (HOURS) (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	IMPORT SAMPLES TO BE ANALYZED CHEM (ACKEE SUBSET) (7)	IMPORT SAMPLES TO BE (HOURS) ANALYZED SALM RESIST (5)
TOTAL FIELD		92000	38000	86500	9000	8300	40	5730	2530	5730	2570	40	1180
HEADQUARTERS (HQ PRIOR NOTICE CTR)		(b)(2) & (b)(7)(E)											
NE	REGIONAL STAFF												
	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB												
	WEAC												
CE	REGIONAL STAFF												
	BALTIMORE												
	CHICAGO												
	CINCINNATI												
	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA												
	FORENSIC CHEM. CTR												
SE	REGIONAL STAFF												
	ATLANTA												
	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
SW	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
	DENVER												
	KANSAS CITY												
PA	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
	SAN FRANCISCO												
PA	SEATTLE												
	PACIFIC REGIONAL LABORATORY-SW												
	PACIFIC REGIONAL LABORATORY-NW												
	REGIONAL STAFF												
HOURS PER OPERATION						2.2				8.2	7.0		
TOTAL HOURS		92000	38000	86500	9000	18260				46986	17990		1180
CONVERSION FACTOR		1200	1200	950	1200	950				1180	1180		1180
TOTAL OPERATIONAL FTEs		76.67	31.67	91.05	7.50	19.22				39.82	15.25		1.00

9. REMARKS

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

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

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

ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:

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

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

(c) TRADITIONAL SAFETY CONCERNS.

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

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

(5) Denver Laboratory: Salmonella Resistance

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

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

FY 2006 WORKLOAD

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

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

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

ISC PHYSICAL: BASED ON 100% ACS FDA REVIEW LINES

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (03842) FY 2006	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the ACT.	
5. PROGRAM JUSTIFICATION FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices, the Seafood HACCP Regulation, and the FD&C Act.	
6. FIELD OBLIGATIONS Effective this fiscal year, HACCP verification samples are no longer to be routinely collected. Sample collections and analyses are to be made only for cause or as part of a 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. There are obligations to provide the states with standards and instructions for sampling/analyzing for PSP/ASP in seafood.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Domestic Fish and Fishery Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) (PSP, ASP, Standards, Economic Deception, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

3. PROGRAM/ASSIGNMENT CODE(S) 03842, B, C, D, H (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 57.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	STATE CONTRACTS IND 16 FY 2006 - INFO ONLY PER DIV FEDERAL STATE RELATIONS (5)	3	3	3	7	7	7	9
		INSPECTIONS INCLUDING HIGH RISK (4)		DOMESTIC SAMPLES COLL (3)	DOMESTIC SAMPLES COLL MICRO GUIDANCE	DOMESTIC SAMPLES COLL CHEM GUIDANCE	DSAs ORGANO EXAMS (Hours) (2)	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	EU CERTIFICATION (HOURS) (6)
	TOTAL FIELD	2480	1037	300	225	75	400	75	225	1860
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)						
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	19.0		5.0				11.0	16.5	
	TOTAL HOURS	47120		1500			400	825	3713	1860
	CONVERSION FACTOR	950		950			1180	1180	1180	950
	TOTAL OPERATIONAL FTEs	49.60		1.58			0.34	0.70	3.15	1.96

9. REMARKS

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

(2) ORGANOLEPTIC NATIONAL EXPERT

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

SOURCE OF SEAFOOD WORKLOAD:

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

INSPECTIONS, INVESTIGATION HOURS AND DSCs BASED ON OEI.

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

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

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program 03844 FY 2006		2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP Regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and Regulations promulgated under the Act			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety in conjunction with non-safety inspection for decomposition, filth, etc. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP regulation.			
6. FIELD OBLIGATIONS The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. It is equally important that products be analyzed for the health hazard as identified in the HACCP Guide – i.e. raw scombroid fish should be analyzed for histamine not for parasites or micro; raw shrimp should be analyzed for undeclared sulfites, not for micro. During the fiscal year, CFSAN may issue one or more assignments calling for the collection of specific products from specific districts based on suspected problem areas. In that case, these collections assume priority over the compliance program guidelines and the samples will count against the district's sample obligations. HACCP trained investigators, will review importers' written verification procedures, product specifications and affirmative step documents, which demonstrate that the foreign processors' product was produced under HACCP, food safety hazards prevention program. Inspectional priorities should be based on those listed in the current compliance program. NOTE: <i>Ciguatera toxin</i> confirmation which requires animals will be done at Pacific Regional Laboratory-NW. NOTE: Confirmation tests which require animals for <i>Clostridium botulinum</i> will be split between Southeast Regional Laboratory (SRL) & Pacific Regional Laboratory– NW (PRL-NW). SRL will be the confirmation-servicing laboratory for NE, CE & SE. Regions. PRL-NW will be the confirmation-servicing laboratory for SW & PA Regions.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED
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"/> MICROANALYTICAL	<input checked="" type="checkbox"/> PHYSICAL
		<input type="checkbox"/> ENGINEERING	
		<input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) (PSP, ASP, Standards, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES See the HACCP Guidance for hazards associated with each specific seafood product.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

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

9. REMARKS

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

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

(3) IMPORT INVESTIGATION HOURS ARE FOR FIELD EXAMS, LABEL EXAMS AND OTHER OPERATIONS AS REQUIRED BY THE DISTRICT TO COVER PROGRAM PRIORITIES. DISTRICTS SHOULD REPORT TIME UNDER THE APPROPRIATE OPERATION AND PAC FOR THE ACTIVITIES PERFORMED.
 ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:
 (a) VERIFICATION THAT THE IMPORTED PRODUCT IS THE SAME AS THAT WHICH WAS DECLARED (RECONCILIATION EXAM;
 (b) AN ASSESSMENT OF SECURITY CONCERNS RELATED TO LABELING AND SOURCE COUNTRY (INCLUDING CONTAINER INTEGRITY, SIGNS OF INTENTIONAL ADULTERATION, ETC.);
 (c) TRADITIONAL SAFETY CONCERNS.

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

(4) MULTIPLE ANALYSES (I.E., CHEM AND MICRO) WILL BE RUN ON NUMEROUS SAMPLES, THEREFORE, ANALYSES OUTNUMBER COLLECTIONS.
 (5) ORGANOLEPTIC NATIONAL EXPERT
 (6) WEAC MICRO & CHEM: PER DFS AN INTERNAL AGREEMENT FOR FY 2006 (CARRIED OVER FROM FY 2005) BETWEEN THE WEAC LAB DIRECTOR AND THE NEW ENGLAND IB DIRECTOR TO HAVE 223 CHEM AND 112 MICRO SAMPLES SENT TO WEAC.
 NOTE: SWID SAMPLES COLLECTED FOR TX & NM ARE SENT TO ARL. SWID SAMPLES COLLECTED FOR CA & AZ ARE SENT TO PRS.

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program 03847, 03847H FY 2006	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure that domestic and import juice processing establishments are in compliance with the Juice HACCP Regulations as well as the FD&C Act and other regulations promulgated under the Act.	
5. PROGRAM JUSTIFICATION <p>The Juice HACCP regulation was adopted to ensure safe and sanitary processing of fruit and vegetable juices after reports of many outbreaks of foodborne illnesses, some of which directly affected children.</p> <p>FDA is responsible for assuring that juice processing firms establish and implement the principles of HACCP. HACCP plans must include a minimum five-log pathogen reduction process control (or performance standard) for juices that are not shelf-stable according to the regulation. The collection of verification samples will be implemented this fiscal year to help further validate firms' HACCP plans.</p>	
6. FIELD OBLIGATIONS <p>As of January 20, 2004, all juice processing firms are subject to the Juice HACCP Regulation. Inspectional priority should be the following: Unpasteurized juice firms, large or small firms whose previous inspections were OAI, and followed by firms that have not been inspected. HACCP-trained investigators will also review importers' verification procedures and product specifications, which demonstrate that the foreign processor's product was produced according to HACCP principles. Juice importers are also to be inspected under the program.</p> <p>Resources have been provided for "for cause" samples.</p> <p>State inspections may be conducted in addition to the number of inspections assigned per district. Resources have also been added to cover food security issues (see IOM) at domestic processors.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT (S) Juice Products	d. INDUSTRY/PRODUCT CODE (S) 20-22, 24, 25
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Importer Verification of HACCP	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to compliance program.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to Compliance Program.	

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03847H, 03847 (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.2		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS	4 DOMESTIC SAMPLE COLLECTION	DOMESTIC SAMPLE COLLECTION CHEM GUIDE ONLY	DOMESTIC SAMPLE COLLECTION MICRO GUIDE ONLY	7 DOMESTIC SAMPLES ANALYZED CHEM	7 DOMESTIC SAMPLES ANALYZED MICRO	1 IMPORTER INSPECTIONS	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	(2)	(3)	60	165	60	165	(4)	
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		18.5	6.2			11.0	15.0	13.0	
TOTAL HOURS		6938	1395			660	2475	2600	
CONVERSION FACTOR		950	950			1180	1180	950	
TOTAL OPERATIONAL FTEs		7.30	1.47			0.56	2.10	2.74	

9. REMARKS

- (1) Additional related PAC's: 03847, 04847H, 07847H, 09847H, 21847H. 03847 would be used for general sanitation issues (non-HACCP) and the "H" PACs for HACCP related food borne biological hazards, pesticides/chem contaminants, mycotoxins, additives, and labeling.
- (2) Per CFSAN, Domestic Inspections based on OEI juice processor data as of 4/19/05. State inspections may be conducted in addition to the number of inspections assigned per district.
Resources added to cover food security issues at all domestic processor inspections.
- (3) Per CFSAN, DSC resources based on OEI juice processor data as of 4/19/05.
Resources have been provided for anticipated "for cause" samples.
- (4) Importer inspections based on FDA review lines (5/31/04- 5/31/05) of juice products and adjusted to account for physical locations of importers. Inspections assigned to SWID will be shared with DAL-DO as necessary.

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

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03F098 (Import) 03F100 (Domestic)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 24.3		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLLECTION	4 IMPORT SAMPLE COLLECTION	7 DOMESTIC SAMPLE ANALYSIS MICRO	8 IMPORT SAMPLE ANALYSIS MICRO			9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	500	500	500	500			
	HEADQUARTERS	(b)(2) & (b)(7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
SE	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION	3.0	3.0	25.0	25.0			
	TOTAL HOURS	1500	1500	12500	12500			
	CONVERSION FACTOR	950	950	1180	1180			
	TOTAL OPERATIONAL FTEs	1.58	1.58	10.59	10.59			

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

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

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments 03R233 FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, will take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety.	
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to food borne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. To the best of our knowledge, approximately half of the foods that have been associated with food borne illness, have been imported. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. An important aspect of this new initiative is to increase our knowledge of the conditions under which a variety of foods are manufactured in foreign countries.	
6. FIELD OBLIGATIONS ORA shall provide imported food entry and compliance data to assist CFSAN in determining the countries and firms whose inspections would be of greatest value to the Agency. ORA shall plan inspections of foreign firms (selected by CFSAN) in so far as contacting the firms and foreign governments and working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN review and classification. The Investigator shall prepare and, after obtaining any CFSAN team member concurrence, submit the entire original EIR to the Imports Branch no later than 30 days following the trip. Submit individual EIRs as they are completed. Don't delay until all EIRs from a particular trip are completed; rather submit each EIR individually as they are completed due to workflow issues. Prioritize submission of EIRs based on classification (i.e., OAI and VAI before NAI). 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
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3. PROGRAM/ASSIGNMENT CODE(S) 03R233	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	2 INVESTIG- ATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) *					9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	200		950					
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)					
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	30.0							
	TOTAL HOURS	6000		950					
	CONVERSION FACTOR	950		950					
	TOTAL OPERATIONAL FTEs	6.32		1.00					

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Emergency Response to Foodborne Outbreaks and Illnesses 03R839 – FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct investigations, inspections, sample collections and sample analyses in response to food borne outbreaks and illnesses from food of domestic or foreign origin.	
5. PROGRAM JUSTIFICATION Approximately 450 food borne outbreaks and 13,000 individual cases of food poisoning, due to microbial pathogens are reported to the Centers for Disease Control annually. FDA must provide an emergency response to serious outbreaks and illnesses to help identify the causative agent(s) and Food(s) involved, and remove the affected foods from commerce to protect the public health. When the source of outbreaks are determined, conduct inspections, investigations, and/or visits to attempt to determine conditions leading up to the outbreak.	
6. FIELD OBLIGATIONS The field will conduct investigations, inspections, sample collections and analyses as directed by ORA headquarters and CFSAN. To ensure proper reporting, the field is to use PACs 03R839, 04R839, etc.. Activities will usually be directed by the Office of Crisis Management and/or CFSAN's Emergency Coordination & Response Staff.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: NA <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) To be directed by assignment	d. INDUSTRY/PRODUCT CODE(S) All human food codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES As directed by assignment	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by assignment.	

1. PROGRAM/ASSIGNMENT TITLE Emergency Response to Foodborne Outbreaks and Illnesses			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03					
3. PROGRAM/ASSIGNMENT CODE(S) 03R839 *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2	2				9
			INVESTIGATIONS (Hours)	MICRO-BIOLOGIST ON INVESTIGATION (Hours)				
	TOTAL FIELD		5700	950				
	HEADQUARTERS		(b)(2) & (b)(7)(E)					
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION							
	TOTAL HOURS		5700	950				
	CONVERSION FACTOR		950	950				
	TOTAL OPERATIONAL FTEs		6.00	1.00				

9. REMARKS

NOTE: This program provides resources for emergency response and containment of foodborne outbreaks and illnesses of foods of both domestic and foreign origin. Resources can be used for Investigations, & Inspections, and will usually be directed by the Office of Crisis Management and/or CFSAN's Emergency Coordination and Response Staff.

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

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

1. PROGRAM/ASSIGNMENT TITLE Contract Management 03R843 FY 2006	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT By DFSR	
4. OBJECTIVES To conduct an effective state contract inspection program, augmenting regulatory inspections conducted by Agency investigators. To perform audits of inspections by states that are under contract to FDA to conduct food inspections.	
5. PROGRAM JUSTIFICATION Over 9,000 food inspections are anticipated to be contracted out in FY 06 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.	
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the district. To perform audits of approximately 7% of state contract inspections in FY 06. Guidance for conducting an audit investigation is to be provided by the Division of Federal State Relations. Resources are also provided for district management of state contracts. Report under Operation Code 13 (Domestic Investigation). These 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	

2006 ORA WORKPLAN

OCTOBER 1, 2005

1. PROGRAM/ASSIGNMENT TITLE Contract Management	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R843	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INFO ONLY	2006 DOMESTIC FOOD STATE CONTRACTS LESS SEAFOOD	2006 DOMESTIC SEAFOOD STATE CONTRACTS IND 16	2006 TOTAL STATE CONTRACTS	7 DSAs ORGANO EXAMS (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 CONTRACT MANAGE- MENT HOURS
		(1)	(3)	(3)	(3)				(2)
	TOTAL FIELD	612	7847	1037	8884				15200
	HEADQUARTERS	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	NEW ENGLAND	(b)(2) & (b)(7)(E)							
	NEW YORK	(b)(2) & (b)(7)(E)							
	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	WEAC	(b)(2) & (b)(7)(E)							
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	BALTIMORE	(b)(2) & (b)(7)(E)							
	CHICAGO	(b)(2) & (b)(7)(E)							
	CINCINNATI	(b)(2) & (b)(7)(E)							
	DETROIT	(b)(2) & (b)(7)(E)							
	MINNEAPOLIS	(b)(2) & (b)(7)(E)							
	NEW JERSEY	(b)(2) & (b)(7)(E)							
	PHILADELPHIA	(b)(2) & (b)(7)(E)							
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)							
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	ATLANTA	(b)(2) & (b)(7)(E)							
	FLORIDA	(b)(2) & (b)(7)(E)							
	NEW ORLEANS	(b)(2) & (b)(7)(E)							
	SAN JUAN	(b)(2) & (b)(7)(E)							
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	DALLAS	(b)(2) & (b)(7)(E)							
	DENVER	(b)(2) & (b)(7)(E)							
	KANSAS CITY	(b)(2) & (b)(7)(E)							
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL LAB	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF	(b)(2) & (b)(7)(E)							
	LOS ANGELES	(b)(2) & (b)(7)(E)							
	SAN FRANCISCO	(b)(2) & (b)(7)(E)							
	SEATTLE	(b)(2) & (b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)							
	PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)							
	HOURS PER OPERATION								
	TOTAL HOURS								15200
	CONVERSION FACTOR								950
	TOTAL OPERATIONAL FTEs								16.00

9. REMARKS

(1) Food State Contract Audits to be conducted at about 7% of state contract food firm inspections. Number of Food State Contract Audits provided by Division Federal-State Relations: For information purposes and guidance. Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.

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

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

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

4. OBJECTIVES

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

- special CFSAN/ORA field assignments,
- incorporating food defense activities into compliance programs and planned food safety field assignments,
- FDA collection and analysis of proficiency samples for the Food Emergency Response Network,
- providing resources for general laboratory preparedness activities including instrument, reagent, and standards maintenance, and related activities.

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

The field is to maintain food defense readiness and conduct special assignments. CFSAN will be issuing guidance and directives to incorporate food defense activities into existing programs and planned assignments. Actual emergency and code-red alert status activities, when needed, will be directed jointly by CFSAN and ORA, and the Field will be instructed on planned work that will be halted.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) All food products.	d. INDUSTRY/PRODUCT CODE(S) All food industry/product codes.
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*Specify*) All food security examinations

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04						
3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 77.1 (38.2)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs		DSCs DIOXINS *	DSAs DIOXINS	DSAs DIOXINS **	DSCs SEAFOOD	DSAs SEAFOOD
	TOTAL FIELD	1100	2400	2400		750	750	232	100	100
N E	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)				
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
C E	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
S E	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
S W	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
P A	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY- SW										
PACIFIC REGIONAL LABORATORY- NW										
HOURS PER OPERATION			3.0	5.2		4.0	20.0	11.6	3.0	5.2
TOTAL HOURS		1100	7200	12480		3000	15000	2691	300	520
CONVERSION FACTOR		950	950	1180		950	1180	1180	950	1180
TOTAL OPERATIONAL FTEs		1.16	7.58	10.58		3.16	12.71	2.28	0.32	0.44

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

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

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

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1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04			
3. PROGRAM/ASSIGNMENT CODE(S) 04019A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (7.8)	
R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	ISA SEAFOOD	DISC MERCURY IN TUNA <small>***</small>	DISA MERCURY IN TUNA <small>***</small>		DISC MERCURY IN SEAFOOD <small>***</small>	DISA MERCURY IN SEAFOOD <small>***</small>
	TOTAL FIELD	170	150	150		270	270
	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	NEW ENGLAND	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	NEW YORK	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	REGIONAL LAB	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	WEAC	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	BALTIMORE	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	CHICAGO	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	CINCINNATI	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	DETROIT	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	MINNEAPOLIS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	NEW JERSEY	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	PHILADELPHIA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	ATLANTA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	FLORIDA	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	NEW ORLEANS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	SAN JUAN	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	DALLAS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	DENVER	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	KANSAS CITY	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	REGIONAL LAB	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	REGIONAL STAFF	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	LOS ANGELES	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	SAN FRANCISCO	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	SEATTLE	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	PACIFIC REGIONAL LABORTORY - SW	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	PACIFIC REGIONAL LABORTORY - NW	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	HOURS PER OPERATION	12.0	3.5	12.0		4.5	12.0
	TOTAL HOURS	2040	525	1800		1215	3240
	CONVERSION FACTOR	1180	950	1180		950	1180
	TOTAL OPERATIONAL FTEs	1.73	0.55	1.53		1.28	2.75
7. REMARKS ***TO BE ISSUED AS CFSAN FIELD ASSIGNMENT.							

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

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

1. PROGRAM/ASSIGNMENT TITLE Radionuclides in Foods (Domestic and Import)				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) 04019C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (0.7)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Inspections	2 INV	3 DSC	4 ISC	5 Field Exams	6 Import Field Exams	7 DSAs	8 ISAs	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD			16	84			16	84	
NE	HEADQUARTERS			(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
SE	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SW	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION				2.5	1.7			13.0	4.2	
TOTAL HOURS				40	143			208	353	
CONVERSION FACTOR				950	950			1180	1180	
TOTAL OPERATIONAL FTEs				0.04	0.15			0.18	0.30	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex groups through analyses of table-ready foods. In addition, to observe differences or trends in the intake of these chemicals and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.	
5. PROGRAM JUSTIFICATION The continuing study has provided valuable information on dietary intakes of residues and nutrients and has been often used to gauge intakes in ready-to-eat foods. EPA relies on the data for hazard assessment in special review and other proceedings. Portions of the Total Diet samples are used for other analysis (e.g., radionuclides, selected nutrients, pesticides, industrial chemicals, and toxic elements). Additionally, selected Total Diet Study foods are analyzed for acrylamide and dioxins under the pesticide program.	
6. FIELD OBLIGATIONS The collection and analysis of four market baskets which each consisting of three separate samplings of 286 food items to be collected from three locales in a region over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, and toxic elements. WEAC will analyze all foods from the first market basket for radionuclides.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Various Human Foods	d. INDUSTRY/PRODUCT CODE(S) All Human Food Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Radiochemical Analysis	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04							
3. PROGRAM/ASSIGNMENT CODE(S) 04839		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 23.4					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DSCs (TOTAL) (DIET) *	2 DOMESTIC SAMPLE TO BE ANALYZED **	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) ***						
	TOTAL FIELD	60	1144	1						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORTORY-SW										
PACIFIC REGIONAL LABORTORY-NW										
HOURS PER OPERATION						26.0	20.0	2800.0		
TOTAL HOURS						1560	22880	2800		
CONVERSION FACTOR						950	1180	1180		
TOTAL OPERATIONAL FTEs						1.64	19.39	2.37		

7. REMARKS

* Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over five week period and involves 3 separate districts.
 ** Represents the total number of food items analyzed for various attributes.
 *** All TDS food items from one market basket analyzed by WEAC for selected radionuclides
 CFSAN will issue an FY 06 TDS sample collection schedule.

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical contaminants
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To collect and analyze selected food products of domestic and foreign origin for chemical contaminants as directed by CFSAN field assignments. Assignments are anticipated for chloramphenicol in selected foods and general pesticide and toxic element analysis in dietary supplements. Total Diet Study(TDS) program will supply samples for perchlorate, acrylamide and furan analysis.

5. PROGRAM JUSTIFICATION
Monitoring of foods for suspected chemical contaminants is necessary to ensure a safe food supply. Perchlorates and acrylamides have recently been identified as suspect contaminants and monitoring is required to provide the Agency with incidence and level data to properly evaluate their presence in the food supply. Chloramphenicol is a banned drug in the U.S. for food-producing animals but its presence has been detected in imported honey and suspected in imported dried milk. There are concerns regarding pesticides and toxic elements in dietary supplements yet there are minimal monitoring data available to the Agency for these products.

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

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

b. INSPECTION TYPE: NA COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Selected human foods and dietary supplements	d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignments
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES
Chemical contaminants as directed by CFSAN field assignments.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
As directed by the assignments.

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

7. REMARKS

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

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

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

****Time to analyze 800-900 TDS samples for Perchlorate collected under TDS program and time for analyses of approximately 100 additional F/U samples as directed by CFSAN. Collections for Perchlorate and Dietary Supplements will be directed by CFSAN field assignments.

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

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

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

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM TYPE:	N/A	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES
Develop new and/or improved methodology in support of regulatory analysis.

5. PROGRAM JUSTIFICATION
Research

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	N/A A	<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	N/A A	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
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e. EXAM TYPE:	N/A	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS <i>(Specify)</i>		

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.8
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	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION							
	TOTAL FIELD	1180	11800							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SW	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1180	11800							
	CONVERSION FACTOR	1205	1205							
	TOTAL OPERATIONAL FTEs	0.98	9.79							

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

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To collect and analyze domestic samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin.
To remove from interstate commerce those food that contain aflatoxins and patulin at levels judged to be of regulatory significance.
To detain those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established.

5. PROGRAM JUSTIFICATION
Mycotoxins are metabolic products of specific molds commonly found on foods, some (the aflatoxins) are hepatocarcinogens in a number of animal species, and until proven otherwise must be assumed to be carcinogenic to man. The FDA, in conjunction with other agencies and the food industries, has devised and will continue to improve on practical programs for ensuring minimum exposure of the population to mycotoxins without jeopardizing the food supply. Aflatoxins may occur in food as a result of mold growth in a number of susceptible commodities, including peanuts and corn. The current action level for aflatoxins in human food is 20 ppb.
Fumonisin B₁ and B₂ are naturally occurring toxic metabolites produced mainly by the fungus, *Fusarium verticilloides*, which are found ubiquitously on corn from around the world. Because of their potential carcinogenicity and frequent occurrence in corn-based feeds and foods, their presence should be monitored, especially for incidence data.
Deoxynivalenol (DON) is a trichothecene mycotoxin produced by several strains of *Fusarium*, which under certain climate conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated gastrointestinal illnesses in China and India. FDA has issued an advisory level of 1ppm for DON in finished wheat products. There is a need for continuous monitoring of this toxin.
Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera *Aspergillus* and *Penicillium*. It is mainly a contaminant in cereal grains and is carcinogenic in mice and rats. There is a need for current information on the incidence and levels of this toxin in the U.S. food supply.
Patulin is a mold metabolite produced by several species of mold fungi including *Penicillium expansum*, the casual organism of apple rot. Apple juice prepared from rotten apples is a possible source of patulin in the human diet. Patulin is regulated in at least 10 countries so far. There is a need for more exposure data to further review the international standards for patulin. The current action level for patulin in apple juice and apple juice components is 50 ppb.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES
Aflatoxins, Fumonisin B₁ and B₂, Deoxynivalenol (DON), Ochratoxin A, and Patulin.

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

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

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

HOURS PER OPERATION			2.0		2.0	2.0	2.0	2.0	2.0
TOTAL HOURS			1000		320	320	128	480	78
CONVERSION FACTOR			950		950	950	950	950	950
TOTAL OPERATION FTEs			1.05		0.34	0.34	0.13	0.51	0.08

7. REMARKS

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

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

7. REMARKS

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Research

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives PAC 09006A,B	2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 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 promulgated under the Act with respect to food and color additives.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the Act and its regulations for food and color additives. The compliance program directs sample collections and label review of imported products for unsafe food additives and non-permitted food or undeclared color additives to insure that these foods meet the requirements of the law.	
6. FIELD OBLIGATIONS Districts should conduct label reviews, collect and analyze imported foods for known potential food and color additive violations and take appropriate regulatory actions when violations are found. For FY05 and beyond, all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.	
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 Food and Color Additives	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

7. REMARKS

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

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

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

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

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

OBJECTIVES

To provide guidance, support, and assistance to the federal, state, tribal, and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in foodborne illnesses. For FY 06 this program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, National Food Safety needs at retail level, CFSAN directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.

PROGRAM JUSTIFICATION

There are more than 3,000 federal, tribal, state and local food control agencies which together represent the regulatory resource through which federal food policy is implemented at the retail level. This segment totals more than one million commercial and institutional food establishments, locations and operations.

Each year the Centers for Disease Control and Prevention's Annual Report shows that a major percentage of foodborne outbreaks, where mishandling of food is implicated, occur in retail food establishments. Therefore, an important part of FDA's mission is to provide assistance to federal, tribal, state and local regulatory agencies with control over this segment of the food industry.

FIELD OBLIGATIONS

Provide technical assistance to federal, tribal, state, and local regulatory food agencies. Provide technical assistance to CFSAN and Headquarters in the preparation of position papers. Conduct periodic baseline and follow-up studies to measure trends on the occurrence of foodborne illness risk factors nationwide in selected food service and retail food establishment. Promote the adoption of uniform retail program standard. Provide training on the provisions of FDA Food Code, HACCP, Facility Plan Review, the Egg Rule, and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events impacting retail food safety. Participate in the FDA Retail Food Steering Committee, the National Conference for Food Protection committees, and other conferences and industry events to share information and present FDA's position on issues concerning retail food protection. Specialists will participate in the National Team Workgroups. These workgroups will address issues which include the Voluntary National Retail Food Regulatory Program Standards, standardization procedures, prestandardization workshops, HACCP, and Retail Specialist certification, etc. Maintain a cadre of trained FDA Food Specialists.

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

b. INSPECTION TYPE: /A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Foods	d. INDUSTRY/PRODUCT CODE(S) Inspections: 51 NY
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*) N/A

f. CHECK THE FOLLOWING ATTRIBUTES

Reduction in the occurrence of CDC identified risk factors associated with foodborne illness in retail establishments, and national promotion of Food Code Interventions.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Work assigned in this program is to be conducted by persons who are Center standardized in the application of the relevant retail Food Code provisions, and related program documents.

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

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

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:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input checked="" type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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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
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e. EXAM TYPE:	<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (<i>Specify</i>)		

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

7. REMARKS:

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

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

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

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

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

^{5/} Activities include the Initial and Re-standardization (Group Field Exercise) of RMSs

^{6/} Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops

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

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

4. OBJECTIVES

Evaluate the shellfish sanitation program of 30 states and 5 nations for the sanitary control of shellfish intended for interstate and overseas commerce under the cooperative arrangements of the federal-state National Shellfish Sanitation Program (NSSP).

Provide standardization, technical assistance, training, and evaluation of state and international shellfish control programs.

5. PROGRAM JUSTIFICATION

Shellfish, by virtue of their habitat, physiological characteristics, and the manner in which they are consumed, require specialized comprehensive sanitary control measures to ensure the safety of human consumption. The management of the program requires a cooperative federal-state effort as defined in the National Shellfish Sanitation Program (NSSP). Consumption of raw or partially cooked shellfish presents a high risk factor to a portion of the population, and requires specialized health control measures to oversee. The 1991 National Academy of Sciences report entitled "Seafood Safety" estimated that up to 85 percent of seafood-related illnesses originate with the consumption of molluscan shellfish. FDA is committed to improving the safety of molluscan shellfish through the NSSP, a program of newly developed safety controls. These initiatives are the direct result of Congressional and public comments directed toward the establishment of a "level playing field" for both domestic and international producers of molluscan shellfish. These program improvements are intended to provide improved shellfish safety through improved program criteria, procedures, and technical support under the NSSP.

FDA is committed to improving the safety of shellfish through program enhancement activities. FDA has committed support to the NSSP both administratively and technically through an MOU with ISSC.

6. FIELD OBLIGATIONS

Provide technical assistance and training to states and foreign programs in the prevention of shellfish-borne illness and enforcement of appropriate public health controls. Oversee national standardization program for inspecting shellfish processing plants and evaluation of state and foreign shellfish growing areas. Participate in the evaluation of national shellfish control programs in countries applying to import molluscan shellfish into the U.S.

Program time has been allocated for each Regional Shellfish Specialist to hold one regional workshop. Regional workshops provide the opportunity for the specialists to exchange information and provide technical assistance and guidance to their state counterparts. Time has been allocated to educate and evaluate state *Vibrio vulnificus* and *Vibrio parahaemolyticus* management programs and to assist in the EU audit of the NSSP.

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Fresh and fresh frozen molluscan shellfish	d. INDUSTRY/PRODUCT CODE(S) 16, 52 B,Y
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e. EXAM TYPE: N/A CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18																	
3. PROGRAM/ASSIGNMENT CODE(S) 18004		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 14.0 (11.7)											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION (1)	PATROL EVALUATION (2)	VIBRIO SPECIES MANAGE- MENT (HOURS) (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	TRAINING WORKSHOPS (7)	PLANT EVALUATION (8)	STANDARD- IZATION & RE-STAN- IZATION (9)									
	TOTAL FIELD	184	16	500	2918	5	2	20	287	15									
	HEADQUARTERS	(b)(2) & (b)(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
PA	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	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										3680	1280	500	2918	1000	800	1000	2296	600
	CONVERSION FACTOR										1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs										3.07	1.07	0.42	2.43	0.83	0.67	0.83	1.91	0.50
7. REMARKS:																			
(1) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity to the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO).																			
(2) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity to the requirements of the NSSP MO. Illnesses and outbreaks have been attributed to the illegal harvest of shellfish from closed waters.																			
(3) Activities include technical assistance, education, and evaluation of state shellfish programs <i>Vibrio vulnificus</i> and <i>vibrio parahaemolyticus</i> education and management programs.																			
(4) Includes interpretations and consultation on NSSP MO requirements related to program administration, risk management, laboratory, shellfish growing areas, shellstock relaying, shellfish aquaculture, shellfish wet storage and depuration, patrol, shellfish harvest and transportation, HACCP, and general sanitation in processing plants.																			
(5) Activities include planning, field evaluations, file reviews, and report writing for countries with MOUs with the FDA. Current MOU countries include Canada, Chile, South Korea Mexico, and New Zealand.																			
(6) Includes time for shellfish program planning, development and coordination responsibilities assigned to two specialists selected as team representatives of the Regional Shellfish Specialists' team.																			
(7) Includes training workshops coordinated and delivered by the specialists, including but not limited to basic shellfish plant and program courses applied concepts for shellfish growing areas courses and HACCP workshops.																			
(8) Includes time for planning, field evaluations of processing plants, file reviews, and final report writing to determine state conformity with the NSSP MO. Plant evaluations include a full evaluation of HACCP, including plan implementation and adherence to the sanitation requirements of the NSSP MO.																			
(9) Standardization conducted every 5 years for all FDA and state standardization officers. Restandardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs																			

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

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

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To inspect interstate passenger conveyances and their support facilities based on the Public Health Service Act, the Food Drug and Cosmetic Act (The Act), regulations, program guidance, and Food Code. 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 or regulatory actions as appropriate to ensure conformance with the public health principles embodied in the Act and implementing its regulations. The goal of the program is to cooperate with the regulated industry, trade associations and others to promote voluntary compliance; coordinate activities with CDC, DOT, EPA and other domestic and foreign government health officials as much as possible to enhance the public health protection of the traveling public and crew or conveyances both during construction and in operation, watering points, vessels, and servicing areas.	
5. PROGRAM JUSTIFICATION This program directs Agency efforts in fulfilling Public Health Service Act responsibilities delegated to the Commissioner of Food And Drugs [21 CFR 5.10(a)(2) and (4)]. Sections 311, 361, and 368 of the Act address federal-state cooperation, the control of communicable disease, and penalties of noncompliance. The Agency also bases the Interstate Travel Program, in part, on provisions of the Federal Food, Drug and Cosmetic Act.	
6. FIELD OBLIGATIONS The field is to perform the operations assigned in the Workplan, conduct comprehensive inspections of "high risk" food operations, initiate administrative or regulatory actions as needed to ensure compliance, establish and maintain technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication with CFSAN and ORA Headquarters regarding significant program issues and activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Environmental Conditions, Human Food, Water and Wastes	d. INDUSTRY/PRODUCT CODE(S) Inspections/Investigations: Industry 51 All food codes, including water 29W (Y30).
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Food and water surveillance and contamination, mostly microbiological.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING These field assignments will be conducted by persons standardized in the use of FDA's Food Code and in accordance with established FDA procedures and specific guidelines established for the IT Program.	

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18																	
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 23.3 (22.9)											
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	CONVEY UNDER CONSTRUCTION HOURS (*)	WATERING POINTS INSP (A)	CATERING POINTS INSP (B) (**)	VESSELS INSP (C)	DSCs	DSAs MICRO	INV (HOURS)	ITP SPECIALIST TIME (HOURS) (***)									
	TOTAL FIELD	1700	1360	(710)	(380)	(300)	100	100	500	950									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB																			
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
REGIONAL LAB																			
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LAB - SW																		
PACIFIC REGIONAL LAB - NW																			
HOURS PER OPERATION											10.5					4.0	8.0		
TOTAL HOURS											17850	1360				400	800	500	950
CONVERSION FACTOR											950	950				950	1180	950	950
TOTAL OPERATIONAL FTEs											18.79	1.43				0.42	0.68	0.53	1.00

7. REMARKS:

Inspections in Columns A-C are included in Column 1. Columns will not add across since other firms may be covered under this program.
 Report Counter Terrorism work performed only under 18R845.
 Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B.
 Catering Point Insp. (B) is High Risk Priority and full inventory should be inspected per workplan.
 DSCs should be randomly collected from on-board conveyances water systems outlets ex. faucets, as close to the water holding tank as possible.
 At least 2 of the samples per district should be taken from aircraft.
 * Time for Conveyance under Construction- time to be used for plan review, meetings, and final inspections. It includes galleys in ATL,DAL,LOS and Aircraft/Vessels in SAN & SEA.
 *** Includes High Risk and some Potential Food Allergen Firms identified by the District.
 **** 5 of these inspections are scheduled for the Nashville Branch.
 *****ITP Specialist-475 hours provided to each of districts (SAN and SEA) for specialized inspections of aircraft constructions, cruise ship constructions and their galley components.

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1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods. Coverage is also provided to imported lots of medical foods from foreign firms not being routinely inspected under the Compliance program.	
5. PROGRAM JUSTIFICATION Medical Foods are nutrition support food products for oral or tube feeding that have associated therapeutic claims and are to be used under medical supervision. The products are often used for life support and are subject to compositional and microbiological errors (as evidenced by four infant deaths in 1986). In addition to the infant deaths in 1986, there have been a number of recalls of medical foods in recent years associated with significant compositional deviations and processing with potential microbiological hazards. Medical foods are identified as "high risk" foods under the Center's Food Safety Initiatives. Additional resources have been budgeted to allow annual inspections and sample collections for medical foods firms. Inspections of foreign manufacturers of medical foods are planned under PAC 03R233. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots.	
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food Security issues are to be covered during all inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Medical Foods	d. INDUSTRY/PRODUCT CODE(S) 41G[] [] [] Use appropriate product identification number
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , and Aerobic Plate Count (APC).	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program	

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import			2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21																
3. PROGRAM/ASSIGNMENT CODE(S) 21002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.7												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8									
		INSPEC- TIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	IMPORT SAMPLE COLL *	DSAs MICRO	DSAs CHEM	ISAs CHEM										
	TOTAL FIELD	19	38	21	17	8	17	21	8										
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
PA	SOUTHWEST IMPORT OPERATION																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
SEATTLE																			
PACIFIC REGIONAL LABORTORY - SW																			
PACIFIC REGIONAL LABORTORY - NW																			
HOURS PER OPERATION											30.0	5.2			5.0	30.0	100.0	100.0	
TOTAL HOURS											570	198			40	510	2100	800	
CONVERSION FACTOR											950	950			950	1180	1180	1180	
TOTAL OPERATIONAL FTEs											0.60	0.21			0.04	0.43	1.78	0.68	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis And General Food Labeling Program	2. PPS PROJECT NAME/NUMBER Food Composition Standards Labeling and Economics - 21
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES
To determine the compliancy of domestic and imported foods with: (1) labeling regulations promulgated by the NLEA of 1990; (2) to monitor the compliancy of FDA's notice to manufacturers regarding label declaration of allergic substances in foods; and (3) regulations promulgated under the Federal Food, Drug, and Cosmetic Act (the Act) and the Fair Packaging and Labeling Act (FPLA) for other mandatory label information. In addition, the program provides for compliance and surveillance sample collections and analyses to assure the products contain appropriate amounts of declared nutrients and that they are in compliance with health claims that appear on their label.

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

6. FIELD OBLIGATIONS
District will review import and domestic product labels for NLEA compliance and other mandatory label requirements by conducting field exams. Districts will collect "violative" labels for review by the district's compliance branch. Physical samples will be collected for lab analyses as follows: (1) compliance samples that do not appear to qualify for labeled health or nutrient content claims (see C.P. Area of Emphasis #2); and (2) surveillance samples collected for general nutrient analyses (see C.P. Area of Emphasis #6). Beginning January 2006, CFSAN anticipates adding coverage for Trans fat and additional allergen labeling. CFSAN will issue guidance in this regard. Domestic Field Exams and sample collections to be conducted during inspections under the following compliance programs: 7303.803, 7303.803A, 7303.037, 7303.842 and 7303.847. For all import field exams, see note under "Remarks" section for the program 21005

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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b. INSPECTION TYPE: NA	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) All food Products (except vitamins/minerals)	d. INDUSTRY/PRODUCT CODE(S) 02-41
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e. EXAM TYPE:	<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL	<input checked="" type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (<i>Specify</i>)		

f. CHECK THE FOLLOWING ATTRIBUTES
Label review and nutrient analyses as appropriate

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
Samples for nutrient analysis to be sent to SRL/ACNA. See compliance program for other details.

1. PROGRAM/ASSIGNMENT TITLE 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"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.3			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DSC	2 DSCs (DOCUMENTARY)	3 DSCs (PHYSICAL)	4 DSAs	5 DOMESTIC FIELD EXAMS **	6 ISCs (PHYSICAL) OASIS #51 (SEE REMARKS) ****	7 ISAs	8 IMPORT INV HOURS (SEE REMARKS) ***	9 ISCs (PAPER) OASIS #41 (SEE REMARKS) *****
	TOTAL FIELD	340	240	100	100	4000	125	125	2225	785
(b)(2) & (b)(7)(E)										
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION	4.2			18.0	0.4	1.2	10.0		1.2
	TOTAL HOURS	1428			1800	1600	150	1250	2225	942
	CONVERSION FACTOR	950			1180	950	950	1180	950	950
	TOTAL OPERATIONAL FTEs	1.50			1.53	1.68	0.16	1.06	2.34	0.99

7. REMARKS

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

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

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

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

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

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

Starting in January 2006, FDA will begin to review product labels for trans fat and/or allergen declarations, contact CFSAN prior to collecting any samples.

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

1. PROGRAM/ASSIGNMENT TITLE Infant Formula Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21006	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.6 (4.5)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	4 IMPORT SAMPLES COLL *	8 IMPORT SAMPLES TO BE ANALYZED CHEM **
	TOTAL FIELD	24		32	21	11	21	11	15	15
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)						
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORTORY-SW										
PACIFIC REGIONAL LABORTORY-NW										
	HOURS PER OPERATION	37.0		5.3			100.0	30.0	5.0	100.0
	TOTAL HOURS	888		170			2100	330	75	1500
	CONVERSION FACTOR	950		950			1180	1180	950	1180
	TOTAL OPERATIONAL FTEs	0.93		0.18			1.78	0.28	0.08	1.27

7. REMARKS

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

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1. PROGRAM/ASSIGNMENT TITLE Infant Formula Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21006	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (1.1)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INVEST- GATION (Hours)	2 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE ANALYZED	3	3	7	4	8
	TOTAL FIELD	200	10	10					
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORTORY-S								
	PACIFIC REGIONAL LABORTORY-N								
	HOURS PER OPERATION		5.3	100.0					
	TOTAL HOURS	200	53	1000					
	CONVERSION FACTOR		950	1180					
	TOTAL OPERATIONAL FTEs	0.21	0.06	0.85					

Resources set aside for a Center-directed field assignment to investigate ethnic retail establishments for counterfeit diverted or unregistered infant formulas.

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements – Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure compliance with the Dietary Supplement Health and Education Act and regulations promulgated there under by inspections of dietary supplement manufacturers and import label exams. Dietary supplements of both domestic and import origin will be collected and analyzed for nutrient content vs. label declarations. All non-exempt dietary supplement must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these requirements will be determined by domestic and import field exams and documentary sample collections.	
5. PROGRAM JUSTIFICATION Dietary supplements are a special class of products consisting of such dietary ingredients as vitamins, minerals, amino acids, glandulars, herbs and other botanicals. These products are subject to specific safety and labeling requirements. This program provides guidance to FDA district offices regarding inspections, import investigations, sample collection and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994. The Center has set aside resources for special headquarters initiated assignments to address emerging issues. Investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on their labels and supplements being marketed with claims to treat diseases. Food security issues are to be covered during all inspections.	
6. FIELD OBLIGATIONS Field obligations include inspections, domestic and import investigations, sample collections and analyses of dietary ingredients in dietary supplements.	
7a. SELECTION OF ESTABLISHMENTS TO BE <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Dietary supplements	d. INDUSTRY/PRODUCT CODE(S) 54
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Analyze selected nutrients and compare with levels declared on product label. Review labels as directed in Part III of C.P. 7321.008	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.	

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

7. REMARKS

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

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

Investigational hours are planned primarily for CFSAN directed assignments

Import resources planned in page 2.

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

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

7. REMARKS

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrient in Foods Survey - Total Diet				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 WHARF EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM*	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO**	
	TOTAL FIELD								1044	149
NE	HEADQUARTERS							(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
PACIFIC REGIONAL LABORTORY-NW										
HOURS PER OPERATION								3.7	7.0	
TOTAL HOURS								3863	1043	
CONVERSION FACTOR								1180	1180	
TOTAL OPERATIONAL FTEs								3.27	0.88	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 21
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3. PROGRAM TYPE: N/A COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Research

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

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
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e. EXAM TYPE: N/A CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS
(Specify)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

ORA/Center Directed Research Projects

2. PPS PROJECT NAME/NUMBER

Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)

21R816

4. WORK ALLOCATION PLANNED BY

ORA

CENTER

5. OPERATIONAL FTE POSITIONS

1.3

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

7. REMARKS

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

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

4. OBJECTIVES

To determine by inspection, sample collection, and label exam, if 1) cosmetic manufacturers or repackers, 2) cosmetics offered for importation, comply with regulations enforced by the Food and Drug Administration.

To initiate corrective action when violations of the FD & C Act are identified.

5. PROGRAM JUSTIFICATION

Both domestically manufactured and imported cosmetic products must be: 1) safe under intended conditions of use, 2) properly labeled, and 3) not otherwise adulterated or misbranded under the provisions of the ACT. Major safety concerns associated with microbial contamination of eye-area products and the use of non-approved color additives. Many cosmetic violations also involve products which fail to comply with the labeling regulations of 21 CFR701.

6. FIELD OBLIGATIONS

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

Food security issues (see IOM) are to be covered during all inspections.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

MICROANALYTICAL OTHERS (*Specify*) Label Reviews

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29
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3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833,	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	7	8	4	8	8
		DOMESTIC INSPECT- IONS	DOMESTIC INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT ENTRY REVIEW (HOURS) *	IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	IMPORT SAMPLE ANALYSIS (CHEM)	IMPORT SAMPLE ANALYSIS (MICRO)
	TOTAL FIELD	100		75	75	1050	200	100	100
	HEADQUARTERS	(b)(2) &		(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF	(b)(7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
	HOURS PER OPERATION	15.6		5.5	20.7		1.5	10.0	20.7
	TOTAL HOURS	1560		413	1553	1050	300	1000	2070
	CONVERSION FACTOR	950		950	1180	1200	950	1180	1180
	OPERATIONAL FTEs	1.64		0.43	1.32	0.88	0.32	0.85	1.75

7. REMARKS

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

For FY06 and beyond All Import Field Exams Are to Routinely Include: verification that the imported product is the same as that which was declared (Reconciliation Exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as SINGLE Import Field Exam under this compliance program and PAC. ONLY one exam should be reported per line entry.

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

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

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE
Tissue Establishments

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Human tissues for transplantation are important products for medical treatment. Monitoring the recovery of processing of human tissue and the testing and screening of the donors is critical to assure consumer protection from unsuitable tissue products which may endanger public health.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Biologics

d. INDUSTRY/PRODUCT CODE(S)
57 J - 57M, 57 O, 57 P

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Tissue Establishments	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41 002B, C, D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L	4 I M P O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours)	
	TOTAL FIELD	385									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
REGIONAL LAB											
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB											
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION		38.3									
TOTAL HOURS		14746									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTES		15.52									

9. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE GLPs (Nonclin. Lab), IRBs, Spon./Mon., Clin. Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

GLP: To assure compliance with GLP regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.

IRB: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).

Spon/Mon.: To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.

Clin. Inv.: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).

5. PROGRAM JUSTIFICATION

GLP: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.

IRB: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.

Spon/Mon.: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.

Clin. Inv.: The Kefauver Harris amendment to the Act and the regulations promulgated there under, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

6. FIELD OBLIGATIONS

GLP: Conduct inspections and forward report(s) to the assigning office in CBER.

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

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

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products n.e.c.
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

9. REMARKS

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

Personnel Types Required: Investigator

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations:
(a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products; (b) Licensed Blood Donor Centers which collect blood and ship to the Licensed Blood Banks of which they are a part; (c) Reference Laboratories that perform testing on blood products and donors, e.g., hepatitis, HIV antibody, Western Blot on donors for re-entry purposes, serum electrophoresis, and STS;
(d) Reference Laboratories that perform quality control testing for licensed blood establishments, e.g., platelet q.c., GMP evaluation to determine the level of competency and adherence to contractual agreements with the licensed establishments.

5. PROGRAM JUSTIFICATION
Blood and Blood Products are vitally important products in medical treatment. Monitoring the collection of whole blood and the processing, manufacturing, and preparation of products derived from human blood assures consumer protection from defective products which may endanger public health.

6. FIELD OBLIGATIONS
ORA will perform the inspections, prepare and submit the certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed. Training of field personnel will be coordinated with CBER.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Blood and Blood Products

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign) *				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42						
3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G 42R825			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 60.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSPEC- TIONS	1	2 DOMESTIC INVESTI- GATIONS (Hours) ***	1 FOREIGN BLOOD BANK INSPEC- TIONS ***	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDIN- ATION (Hours)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	1131		2926	24			2375		
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF	(7)(E)						(7)(E)		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		45.3			39.6					
TOTAL HOURS		51234		2926	950			2375		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		53.93		3.08	1.00			2.50		

7. REMARKS

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

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

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

*** Foreign Blood Bank Inspections spread by DFI.

Personnel Types Required: Investigator, National Experts

1. PROGRAM/ASSIGNMENT TITLE
Inspection of Source Plasma Establishments

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To determine through inspections if plasmapheresis establishments are operating in compliance with applicable regulations to assure donor protection and to assure that Source Plasma is safe, effective, and adequately labeled.

5. PROGRAM JUSTIFICATION
The collection of Source Plasma as source material for further manufacturing into products used in the prevention and treatment of disease is of immeasurable value to the consumer.
Through this program the Agency can accomplish its objectives of donor protection and product safety, purity, and potency.

6. FIELD OBLIGATIONS
ORA will perform inspections, prepare and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Source Plasma

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments					2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42					
3. PROGRAM/ASSIGNMENT CODE(S) 42002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 10.4			
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		164	2271						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
HOURS PER OPERATION		46.4								
TOTAL HOURS		7610	2271							
CONVERSION FACTOR		950	950							
TOTAL OPERATION FTEs		8.01	2.39							

7. REMARKS

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

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

Personnel Types Required: Investigator, Team Biologics

1. PROGRAM/ASSIGNMENT TITLE
Examination of Biological Products Offered for Import

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

- 1) Determine if import entries comply with the requirements of appropriate Federal regulations.
- 2) Assure that import entries declared as Import for Export are CBER approved pursuant to section 801(d)(4) of FD & C Act.
- 3) Detain all import entries intended for transfusion, or source plasma for further manufacture, by manufacturer NOT holding a US license.
- 4) Detain all import entries of unlicensed blood products which are intended for further manufacture which are NOT covered by a valid short supply agreement.
- 5) Examine import entries intended for further manufacture into unlicensed products for adequate labeling.
- 6) Identify foreign manufacturers of blood and blood components offering import entries.

5. PROGRAM JUSTIFICATION

In 1995, a Blood Working Group (consisting of personnel from CBER and ORA) reviewed cases in which imported blood and blood components were identified as being illegally distributed in domestic commerce. Analysis of available information identified a need for a compliance program to clarify existing CBER procedures for the importation of blood products and ensure consistent handling of imported blood products by the field.

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

6. FIELD OBLIGATIONS

To review electronic line entries or examine entry documentation for imported biological products offered for entry into the United States. To determine the type and amount of product, its intended use, and whether it is licensed or unlicensed: conduct investigations as necessary and determine whether entry is in compliance with Federal Regulations.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Biological Products

d. INDUSTRY/PRODUCT CODE(S)
57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Examination of Biological Products Offered for Import	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42007, 42R833, 42R824, 99R833 41R824, 45R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 42R833 IMPORT ENTRY REVIEW HOURS	3 DOMESTIC INVESTI- GATIONS (HOURS)	4 IMPORT INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		4200							
	HEADQUARTERS		(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION										
TOTAL HOURS			4200							
CONVERSION FACTOR			1200							
TOTAL OPERATION FTES			3.50							

9. REMARKS

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

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

Personnel Types Required: Investigator

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To evaluate the manufacturing process for in vitro diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and those used for patient diagnosis, monitoring, or prognosis, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including Device GMP regulations (21 CFR 809), Biologics regulations (21CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.

5. PROGRAM JUSTIFICATION
In vitro diagnostic kits are important tools in medical treatment. This program enables the Agency to continue to protect the public health by assuring safety, purity, potency, and efficacy of these products.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE 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 INSPEC- TIONS	1 Post-Licensed FOREIGN INSPEC- TIONS	3 DOMESTIC INV (Hours)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	11	4	570						
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	123.0	235.0							
	TOTAL HOURS	1353	940	570						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	1.42	0.99	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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).
Spon./Mon./CROs: To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.
Clin. Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).

5. PROGRAM JUSTIFICATION
IRBs: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of biological products are protected.
Spon./Mon./CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.
Clin. Investigators: The Kefauver Harris amendment to the Act and the regulations promulgated there under, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

6. FIELD OBLIGATIONS
IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office.
Spon./Mon./CROs: Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office.
Clin. Investigators: Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Biologics

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE
Inspection of Medical Device Manufacturers (Biologics)
PACs 42845A,B,C

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To evaluate the manufacturing processes for those medical devices and in vitro diagnostic products which were transferred to the Center for Biologics Evaluation and Research (CBER) under the 4/1/1982 Working Relationships Agreement with CDRH.

5. PROGRAM JUSTIFICATION
As a result of the 4/1/1982 Working Relationship Agreement, the Center for Biologics Evaluation and Research (CBER) became the focal point for the review and evaluation of 23 categories of medical devices. Our strategy for inspecting those firms which manufacture products in the 23 categories are for biennial inspection. The product categories are primarily in the area of devices used in blood banking.

6. FIELD OBLIGATIONS
Conduct inspections pursuant to the instructions in the OMD Program - Inspection of Medical Device Manufacturers, CP 7382.845. Report findings/observations to the Center for Biologics Evaluation and Research (CBER). Recommend/initiate Regulatory follow-up consistent with the compliance program guidance and Agency policy.

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

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

7. REMARKS

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

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

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

Personnel Types Required: Investigator

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To ensure the safety and effectiveness of plasma derivatives by evaluating, through inspections, the conditions under which a particular class of biological/drug products, plasma derivatives of human origin, is manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.

5. PROGRAM JUSTIFICATION
Plasma derivatives of human origin are products used in the prevention and treatment of disease and thus are of immeasurable value to the Consumer.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Fractionation Products

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

IRBs: To ensure the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).

Spon./Mon./CROs: To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.

Clin. Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).

5. PROGRAM JUSTIFICATION

IRBs: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.

Spon./Mon./CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.

Clin. Investigators: The Kefauver Harris amendment to the Act and the regulations promulgated there under, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

6. FIELD OBLIGATIONS

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

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

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Biologics

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

7. REMARKS

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

Personnel Types Required: Investigator

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To ensure the safety and effectiveness of allergenic products by evaluating, through inspections, the conditions under which a particular class of biological/drug products, allergenic products and unlicensed source materials suppliers, is manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, standards and commitments made in license applications and/or supplements, and applicable regulations.

5. PROGRAM JUSTIFICATION

Allergenic products are biological products which are administered to man for the diagnosis, prevention, or treatment of allergies. The products are manufactured from source materials that may include pollen, insects, mold, food, and animals, used in the prevention and treatment of disease and thus are of immeasurable value to the Consumer.

6. FIELD OBLIGATIONS

ORA will perform single, **comprehensive inspections** that assess the adequacy of all significant processes and systems. Inspections will be conducted as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Biologics

d. INDUSTRY/PRODUCT CODE(S)
57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

7. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products PACs 45848B,C,D	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure the safety and effectiveness of licensed vaccines by determining that they are manufactured in compliance with current Good Manufacturing Practice regulations and that they comply with standards and commitments made in license applications and/or supplements. To encourage voluntary compliance by identifying practices which establish and implement programs. To give regulatory/administrative guidance to ensure that appropriate enforcement actions are initiated against those manufacturers found to be in significant noncompliance with applicable laws and regulations. To provide information and guidance to investigators assigned to perform biennial GMP or for cause inspections of manufacturers of licensed vaccines.	
5. PROGRAM JUSTIFICATION Vaccine and vaccine related products are biological products which are administered to man for the diagnosis and prevention of microbial disease and for the therapeutic treatment. Products are manufactured from viral and bacterial organisms and components and may include live attenuated, inactivated, and recombinant vaccines. These products are used in the prevention of childhood diseases and in the treatment, diagnosis, and prevention of diseases and thus are of immeasurable value to the Consumer.	
6. FIELD OBLIGATIONS ORA will perform single, comprehensive inspections that assess the adequacy of all significant processes and systems. These should be performed on at least a Biennial Basis . Inspections will be conducted as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)				2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45						
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 CTIONS	1 FOREIGN INSP CTIONS	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	7	6	570						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		300.0	191.0							
TOTAL HOURS		2100	1146	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		2.21	1.21	0.60						

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

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

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

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

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

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

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

FY 2006

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

FY 2006

1. PROGRAM/ASSIGNMENT TITLE NDA Methods Validations	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Validate NDA methodology before approval. This includes NDAs for radioactive drugs.	
5. PROGRAM JUSTIFICATION A validated analytical method is needed for compliance purposes after approval of an NDA.	
6. FIELD OBLIGATIONS Assigned district laboratory performs the validation study according to instructions in the assignment from the Division of Field Science (HFC-140).	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Inv. Methods Validation-Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46832M <input checked="" type="checkbox"/>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	5	7	7	7	7
		NDA TO INSPECT (Domestic)	CHEMIST INSPECT (HOURS) (Domestic)	INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) **	DSAs METH. VALID. (MICRO) ***		DSAs (METH.) (VALID) CHEM ****
	TOTAL FIELD	129	2275		30		30	6		23
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	56.0			5.0		50.0	105.0		105.0
	TOTAL HOURS	7224	2275		150		1500	630		2415
	CONVERSION FACTOR	950	950		950		1180	1180		1180
	TOTAL OPERATIONAL FTES	7.60	2.39		0.16		1.27	0.53		2.05

7. REMARKS

* Includes Microbiologists on Inspections.

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

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

**** Meth. Valid DSAs

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

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

FY 2006

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

FY2006 ORA WORKPLAN

October 1, 2005

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations (Methods Validation) - Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46						
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46832D			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 15.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS ++ FOREIGN	1 CHEMIST INSPS (Hours) FOREIGN **	4 IMPORT SAMPLE COLL ***	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES ANALYSES PROFILE (CHEM) ****	9 OTHER OPERATIONS (Hours)	
	TOTAL FIELD	183	2788	50			50		
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
PHILADELPHIA									
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		55.0		3.0			30.0		
TOTAL HOURS		10065	2788	150			1500		
CONVERSION FACTOR		950	950	950			1180		
TOTAL OPERATIONAL FTEs		10.59	2.93	0.16			1.27		

7. REMARKS
*** Report as follows: Insp./Chem on Insp. under foreign operation code 11 Pac Code 46832;**
M. Valid.-46832; Profile ISCs & ISAs -46832B; Biotest ISCs & ISAs (not planned) if collected -46832C.
** Includes microbiologists on inspections. *** Profile samples are collected at foreign manufacturers.
**** NRL analyzes all Profile ISCs and ISAs.
Use CT PAC 46R845 only when specific CT work is performed.
++Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

7. REMARKS

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

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

Personnel Types Required: Investigator

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

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)				2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48811; 48001D,E; 48811D NDA &, ANDA *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSP EC- TIONS (PDUFA)	1 FOREIGN 48001 ANDA INSP EC- TIONS (PRE-APPR)	2 IMPORT INVESTIGATION HOURS	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	TOTAL FIELD	41	30							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SW	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
REGIONAL STAFF										
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		60.7	62.7							
TOTAL HOURS		2489	1881							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.62	1.98							
7. REMARKS										
* Planned inspections include: 48001,A In Vivo Bioequivalence, 48811 Clinical Investigators, 48808 GLPs (PDUFA) and NEW PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence, and 48811D PEPFAR Clinical Investigator.										
Report Inspections under Appropriate PAC, Foreign Inspections under Operation Code 11.										
HIGH PRIORITY for NDA inspections.										
** President's Emergency Plan for AIDS Relief (PEPFAR): 48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator. NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001. We are not planning separate PEPFAR work.										
Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs. Data audit under PEPFAR will be verified by on site inspections.										
Personnel Types Required: Investigator, National Expert										

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To assure compliance with current Good Laboratory Practice Regulations (21 CFR 58) by nonclinical laboratories and to assure validity of data through associated data audits.

5. PROGRAM JUSTIFICATION
Animal Studies are vital prerequisites to human clinical trials of drugs and other FDA regulated products. Past experience has shown serious deficiencies in the conduct of nonclinical laboratories in recordkeeping, adherence to study protocol, and in some cases fraudulent practices.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48808	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 NAT'L EXPERT INVESTI- GATIONS (Hours)	2 IMPORT INVESTIGATION HOURS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	38	646							
NE	HEADQUARTERS	(b & () t 2)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		88.0								
TOTAL HOURS		3344	646							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		3.52	0.68							

9. REMARKS

Resources planned for Inspections may also be used for DSCs.

Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER. CDER assignments, i.e. Directed Inspections, cover studies associated with IND's and NDA's.

Personnel Types Required: Investigator, National Expert

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

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

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To assure adherence by sponsors, contract research organizations, and monitors to the regulations (21 CFR 312) and to assess their interaction with clinical investigators and the sponsors development of safety and efficacy data in NDAs.

5. PROGRAM JUSTIFICATION
Sections of the FD&C Act and the Public Health Service Act require the submission of data to FDA ensuring the safety of human drugs, as well as the filing of an Investigational New Drug Application and New Drug Applications. An inspectional program is required to assess compliance with current regulations.

6. FIELD OBLIGATIONS
Conduct inspections of sponsors, contract research organizations, and monitors for the IND/NDAs identified in the assignments. Forward reports directly to the Division of Scientific Investigations, CDER, for final classification, including District recommendations for compliance follow-up.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations and Monitors (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48810	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.7
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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)	2 IMPORT I N V E S T I G A T I O N H O U R 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	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	38								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	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		68.4								
TOTAL HOURS		2599								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		2.74								

7. REMARKS

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE
Clinical Investigators

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

FY 2006

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

FY 2006

1. PROGRAM/ASSIGNMENT TITLE ANDA - Methods Validation (DESI and Post 1962)	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To validate the methodology of the drug products submitted as Abbreviated New Drug Applications (ANDAs) as described in the submissions. To examine the drug samples for those ANDAs for any special testing (potency, purity, etc.) as required.	
5. PROGRAM JUSTIFICATION ANDAs are required per (21 CFR 314.55) for: 1) 1938-1962 (DESI) drug products determined by the FDA to be safe, effective, and acceptable, and 2) As a result of the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, for drugs approved after October 10, 1962. Approval for marketing is contingent upon, among other requirements, adequate analytical methodology and any special testing Requirements.	
6. FIELD OBLIGATIONS Perform tests of methodology (USP or other specifications) on samples submitted to the District Laboratories identified by ORA (HFC-140).	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Validate methods, potency, purity, and other requirements	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	