

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SE REGN

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	3690	118.24 *	89	29.95 *	2961	12.32 *	3722	9.73 *	1127	1.51 *
FOOD SAFETY/COS	1763	29.82 *	89	12.25 *	2220	8.99 *	2983	7.56 *	803	0.36 *
03	1279	23.74 *	89	10.95 *	540	2.30 *	2019	5.11 *	0	0.00 *
04	0	0.00 *	0	0.08 *	1201	4.56 *	783	2.12 *	6	0.00 *
07	0	0.00 *	0	0.00 *	327	1.41 *	90	0.19 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	60	0.10 *	0	0.00 *
18	433	5.06 *	0	0.50 *	25	0.11 *	0	0.00 *	0	0.00 *
21	33	0.66 *	0	0.61 *	109	0.50 *	16	0.02 *	797	0.36 *
29	18	0.36 *	0	0.11 *	18	0.11 *	15	0.02 *	0	0.00 *
BIOLOGICS	425	20.24 *	0	2.01 *	0	0.00 *	0	0.00 *	0	0.00 *
41	102	4.94 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	314	14.49 *	0	1.95 *	0	0.00 *	0	0.00 *	0	0.00 *
45	9	0.81 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	646	42.05 *	0	10.99 *	477	2.01 *	374	1.11 *	0	0.00 *
46	32	1.96 *	0	0.00 *	7	0.05 *	9	0.02 *	0	0.00 *
48	121	10.28 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	67	3.55 *	0	1.00 *	57	0.31 *	32	0.10 *	0	0.00 *
53	20	1.25 *	0	0.44 *	0	0.00 *	0	0.00 *	0	0.00 *
56	393	24.63 *	0	9.26 *	391	1.55 *	333	0.99 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	9	0.26 *	0	0.02 *	8	0.04 *	0	0.00 *	0	0.00 *
63	4	0.12 *	0	0.27 *	14	0.06 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	400	6.23 *	0	0.92 *	236	1.16 *	23	0.10 *	0	0.00 *
68	26	1.34 *	0	0.00 *	3	0.00 *	0	0.00 *	0	0.00 *
71	374	4.89 *	0	0.92 *	233	1.16 *	23	0.10 *	0	0.00 *
DEVICES & RAD H	456	19.90 *	0	3.78 *	28	0.16 *	342	0.96 *	324	1.15 *
81	4	0.04 *	0	0.01 *	1	0.01 *	0	0.00 *	0	0.00 *
82	268	13.01 *	0	1.63 *	26	0.15 *	342	0.96 *	0	0.00 *
83	93	5.89 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	65	0.51 *	0	1.22 *	0	0.00 *	0	0.00 *	0	0.00 *
86	26	0.45 *	0	0.92 *	1	0.00 *	0	0.00 *	324	1.15 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SE REGN

	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	6934	5.99 *	5597	69.76 *	5068	42.01 *	1273	31.65 *	204	10.98 *
FOOD SAFETY/COS	5451	4.87 *	4754	46.46 *	4994	40.87 *	455	24.97 *	44	1.42 *
03	4778	4.47 *	1021	17.54 *	3450	26.97 *	68	8.00 *	44	1.42 *
04	189	0.14 *	2093	8.90 *	1005	7.56 *	0	0.00 *	0	0.00 *
07	0	0.00 *	943	5.59 *	243	1.44 *	0	3.91 *	0	0.00 *
09	0	0.00 *	0	0.00 *	60	0.45 *	46	0.38 *	0	0.00 *
18	0	0.00 *	36	0.24 *	0	0.00 *	203	12.03 *	0	0.00 *
21	484	0.26 *	632	13.67 *	218	4.20 *	89	0.63 *	0	0.00 *
29	0	0.00 *	29	0.52 *	18	0.25 *	49	0.02 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.24 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.24 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	1285	1.00 *	603	20.75 *	26	0.84 *	686	1.98 *	96	6.17 *
46	0	0.00 *	9	1.61 *	0	0.00 *	0	0.00 *	33	2.00 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.66 *
52	0	0.00 *	8	1.63 *	0	0.00 *	0	1.04 *	15	0.93 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.20 *
56	1285	1.00 *	575	14.33 *	26	0.84 *	686	0.94 *	36	2.38 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	4	0.07 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	7	0.11 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	3.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	12	0.00 *	240	2.55 *	48	0.30 *	0	0.81 *	12	0.48 *
68	0	0.00 *	3	0.12 *	0	0.00 *	0	0.00 *	12	0.48 *
71	12	0.00 *	237	2.43 *	48	0.30 *	0	0.81 *	0	0.00 *
DEVICES & RAD H	186	0.12 *	0	0.00 *	0	0.00 *	132	3.89 *	46	2.67 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	164	0.11 *	0	0.00 *	0	0.00 *	132	0.62 *	27	1.85 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	14	0.79 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.76 *	5	0.03 *
86	22	0.01 *	0	0.00 *	0	0.00 *	0	2.51 *	0	0.00 *

REGION: SE REGN

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





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





WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SW REGN

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	3819	100.92 *	118	55.35 *	2732	12.00 *	7944	16.91 *	1002	1.40 *
FOOD SAFETY/COS	1048	19.41 *	118	35.86 *	1696	7.01 *	7606	15.83 *	705	0.32 *
03	819	16.00 *	118	34.54 *	322	1.43 *	3478	8.41 *	0	0.00 *
04	0	0.00 *	0	0.09 *	846	3.25 *	3673	6.63 *	0	0.00 *
07	0	0.00 *	0	0.00 *	375	1.61 *	156	0.34 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	248	0.37 *	0	0.00 *
18	163	2.05 *	0	0.19 *	10	0.04 *	0	0.00 *	0	0.00 *
21	53	1.10 *	0	0.95 *	130	0.60 *	38	0.06 *	705	0.32 *
29	13	0.26 *	0	0.09 *	13	0.08 *	13	0.02 *	0	0.00 *
BIOLOGICS	371	17.59 *	0	1.15 *	0	0.00 *	0	0.00 *	0	0.00 *
41	93	4.49 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	272	12.56 *	0	1.09 *	0	0.00 *	0	0.00 *	0	0.00 *
45	6	0.54 *	0	0.06 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	460	31.03 *	0	4.73 *	341	1.42 *	90	0.28 *	0	0.00 *
46	20	1.24 *	0	0.00 *	4	0.03 *	7	0.03 *	0	0.00 *
48	104	8.98 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	34	1.97 *	0	0.54 *	28	0.16 *	21	0.07 *	0	0.00 *
53	8	0.51 *	0	0.33 *	0	0.00 *	0	0.00 *	0	0.00 *
56	282	17.97 *	0	3.17 *	280	1.11 *	62	0.18 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	3	0.09 *	0	0.00 *	2	0.01 *	0	0.00 *	0	0.00 *
63	9	0.27 *	0	0.69 *	27	0.11 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	1453	16.30 *	0	1.91 *	675	3.44 *	51	0.24 *	0	0.00 *
68	42	2.18 *	0	0.00 *	3	0.01 *	0	0.00 *	0	0.00 *
71	1411	14.12 *	0	1.91 *	672	3.43 *	51	0.24 *	0	0.00 *
DEVICES & RAD H	487	16.59 *	0	11.70 *	20	0.13 *	197	0.56 *	297	1.08 *
81	3	0.03 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	206	10.11 *	0	8.57 *	19	0.12 *	197	0.56 *	0	0.00 *
83	67	4.68 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	188	1.34 *	0	1.13 *	0	0.00 *	0	0.00 *	0	0.00 *
86	23	0.43 *	0	2.00 *	1	0.01 *	0	0.00 *	297	1.08 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: SW REGN

	IMPORT	FIELD EXAMS	DOM SAMPL ANALYSIS	IMP SAMPL ANALYSIS	MISC	FOREIGN INSPECTIONS				
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *				
FIELD TOTAL	24310	22.57 *	8445	86.74 *	6902	52.42 *	1596	37.97 *	173	9.27 *
FOOD SAFETY/COS	23047	21.74 *	7165	62.35 *	6607	50.44 *	725	27.54 *	36	1.17 *
03	21670	20.97 *	1064	10.95 *	3300	27.21 *	18	7.18 *	36	1.17 *
04	144	0.11 *	4462	44.33 *	2680	18.88 *	0	6.50 *	0	0.00 *
07	0	0.00 *	555	3.29 *	322	1.91 *	0	0.50 *	0	0.00 *
09	0	0.00 *	0	0.00 *	282	2.11 *	191	0.94 *	0	0.00 *
18	0	0.00 *	19	0.13 *	0	0.00 *	248	12.10 *	0	0.00 *
21	1233	0.66 *	1044	3.27 *	0	0.00 *	221	0.30 *	0	0.00 *
29	0	0.00 *	21	0.38 *	23	0.33 *	47	0.02 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.37 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.37 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	240	0.18 *	240	9.44 *	5	0.16 *	133	0.78 *	73	4.70 *
46	0	0.00 *	0	0.92 *	0	0.00 *	5	0.44 *	23	1.39 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	9	0.66 *
52	0	0.00 *	4	1.05 *	0	0.00 *	0	0.00 *	11	0.68 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	3	0.20 *
56	240	0.18 *	219	7.21 *	5	0.16 *	128	0.34 *	27	1.77 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	1	0.02 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	16	0.24 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	24	0.02 *	1014	13.58 *	290	1.82 *	0	5.99 *	19	0.76 *
68	0	0.00 *	9	0.40 *	0	0.00 *	0	0.00 *	16	0.64 *
71	24	0.02 *	1005	13.18 *	290	1.82 *	0	5.99 *	3	0.12 *
DEVICES & RAD H	999	0.63 *	26	1.37 *	0	0.00 *	738	3.66 *	36	2.27 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	918	0.58 *	26	1.37 *	0	0.00 *	738	0.73 *	21	1.44 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	15	0.83 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.65 *	0	0.00 *
86	81	0.05 *	0	0.00 *	0	0.00 *	0	2.28 *	0	0.00 *

REGION: SW REGN

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







REGION: PA REGN

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	4967	135.28 *	193	50.92 *	4493	18.14 *	8393	21.18 *	1610	1.71 *
FOOD SAFETY/COS	2860	51.57 *	193	31.38 *	3823	14.91 *	7498	18.09 *	1345	0.60 *
03	2227	42.51 *	193	29.01 *	850	3.77 *	5688	13.96 *	0	0.00 *
04	0	0.00 *	0	0.21 *	2327	8.26 *	1083	2.79 *	9	0.00 *
07	0	0.00 *	0	0.00 *	389	1.67 *	400	0.86 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	223	0.33 *	0	0.00 *
18	542	7.19 *	0	0.61 *	29	0.13 *	0	0.00 *	0	0.00 *
21	70	1.46 *	0	1.34 *	207	0.95 *	59	0.08 *	1336	0.60 *
29	21	0.41 *	0	0.21 *	21	0.13 *	45	0.07 *	0	0.00 *
BIOLOGICS	323	15.76 *	0	2.10 *	0	0.00 *	0	0.00 *	0	0.00 *
41	76	4.12 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	239	10.92 *	0	1.98 *	0	0.00 *	0	0.00 *	0	0.00 *
45	8	0.72 *	0	0.12 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	435	28.97 *	0	8.61 *	325	1.39 *	139	0.43 *	0	0.00 *
46	14	0.86 *	0	0.00 *	3	0.02 *	7	0.03 *	0	0.00 *
48	102	8.81 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	24	1.41 *	0	0.43 *	20	0.11 *	21	0.07 *	0	0.00 *
53	18	1.13 *	0	0.33 *	0	0.00 *	0	0.00 *	0	0.00 *
56	245	15.80 *	0	5.90 *	217	0.88 *	111	0.33 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	7	0.20 *	0	0.46 *	6	0.03 *	0	0.00 *	0	0.00 *
63	25	0.76 *	0	1.49 *	79	0.35 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	685	9.64 *	0	3.51 *	299	1.57 *	230	1.05 *	0	0.00 *
68	16	0.80 *	0	0.00 *	1	0.00 *	0	0.00 *	0	0.00 *
71	669	8.84 *	0	3.51 *	298	1.57 *	230	1.05 *	0	0.00 *
DEVICES & RAD H	664	29.34 *	0	5.32 *	46	0.27 *	526	1.61 *	265	1.11 *
81	7	0.08 *	0	0.03 *	2	0.02 *	0	0.00 *	0	0.00 *
82	419	20.06 *	0	2.09 *	39	0.24 *	526	1.61 *	0	0.00 *
83	116	7.63 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	64	0.49 *	0	1.74 *	0	0.00 *	0	0.00 *	0	0.00 *
86	58	1.08 *	0	1.46 *	5	0.01 *	0	0.00 *	265	1.11 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

REGION: PA REGN

	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	19509	17.45 *	2688	29.96 *	13276	95.52 *	1456	45.08 *	163	9.37 *
FOOD SAFETY/COS	18718	16.85 *	2210	19.28 *	12327	87.93 *	1057	37.69 *	36	1.16 *
03	16220	15.36 *	741	11.29 *	8846	64.54 *	163	17.38 *	36	1.16 *
04	693	0.52 *	1280	6.67 *	2847	18.96 *	0	1.63 *	0	0.00 *
07	0	0.00 *	146	0.87 *	366	2.17 *	0	1.54 *	0	0.00 *
09	0	0.00 *	0	0.00 *	223	1.66 *	170	0.16 *	0	0.00 *
18	0	0.00 *	29	0.20 *	0	0.00 *	229	14.71 *	0	0.00 *
21	1805	0.97 *	0	0.00 *	0	0.00 *	336	2.20 *	0	0.00 *
29	0	0.00 *	14	0.25 *	45	0.60 *	159	0.07 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	433	0.34 *	220	8.63 *	69	1.56 *	230	0.46 *	77	5.04 *
46	0	0.00 *	6	1.40 *	0	0.00 *	0	0.00 *	20	1.21 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	12	0.89 *
52	0	0.00 *	6	1.09 *	0	0.00 *	0	0.00 *	12	0.75 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	6	0.40 *
56	433	0.34 *	167	5.51 *	69	1.56 *	230	0.46 *	27	1.79 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	3	0.05 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	38	0.58 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	105	0.11 *	258	2.05 *	230	1.44 *	0	2.43 *	3	0.12 *
68	0	0.00 *	1	0.06 *	0	0.00 *	0	0.00 *	3	0.12 *
71	105	0.11 *	257	1.99 *	230	1.44 *	0	2.43 *	0	0.00 *
DEVICES & RAD H	253	0.15 *	0	0.00 *	650	4.59 *	169	4.50 *	47	3.05 *
81	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
82	211	0.13 *	0	0.00 *	650	4.59 *	169	1.39 *	36	2.46 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	11	0.59 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	0.62 *	0	0.00 *
86	42	0.02 *	0	0.00 *	0	0.00 *	0	2.49 *	0	0.00 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
 FY 2005

REGION: PA REGN

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

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

TOTAL FIELD

	DOMESTIC INSPECTION		INVESTIGATIONS		DOM SAMPL COLL		IMP SAMPL COLL		FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
FIELD TOTAL	22807	660.31 *	700	277.83 *	17741	75.03 *	33297	80.79 *	6486	7.99 *
FOOD SAFETY/COS	10463	187.46 *	700	166.01 *	13177	53.54 *	29396	67.42 *	5000	2.26 *
03	8270	157.11 *	700	157.40 *	3300	14.46 *	19300	47.00 *	0	0.00 *
04	0	0.00 *	0	0.56 *	6973	26.11 *	7373	15.45 *	100	0.05 *
07	0	0.00 *	0	0.00 *	1875	8.05 *	1280	2.75 *	0	0.00 *
09	0	0.00 *	0	0.00 *	0	0.00 *	1025	1.54 *	0	0.00 *
18	1792	21.68 *	0	2.05 *	100	0.44 *	0	0.00 *	0	0.00 *
21	301	6.68 *	0	5.05 *	829	3.87 *	218	0.37 *	4900	2.21 *
29	100	1.99 *	0	0.95 *	100	0.61 *	200	0.31 *	0	0.00 *
BIOLOGICS	1966	100.93 *	0	11.99 *	0	0.00 *	0	0.00 *	0	0.00 *
41	442	22.90 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	1474	71.55 *	0	11.45 *	0	0.00 *	0	0.00 *	0	0.00 *
45	50	6.48 *	0	0.54 *	0	0.00 *	0	0.00 *	0	0.00 *
HUMAN DRUGS	2945	198.64 *	0	48.13 *	2340	9.82 *	1352	4.07 *	0	0.00 *
46	140	8.62 *	0	0.00 *	30	0.22 *	50	0.17 *	0	0.00 *
48	580	49.76 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
52	285	16.17 *	0	4.29 *	240	1.34 *	140	0.45 *	0	0.00 *
53	100	6.27 *	0	2.09 *	0	0.00 *	0	0.00 *	0	0.00 *
56	1755	115.29 *	0	37.11 *	1880	7.42 *	1162	3.45 *	0	0.00 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	34	0.99 *	0	0.65 *	30	0.14 *	0	0.00 *	0	0.00 *
63	51	1.54 *	0	3.99 *	160	0.70 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	4674	58.15 *	0	17.40 *	2060	10.66 *	1075	4.92 *	0	0.00 *
68	151	8.03 *	0	0.00 *	15	0.01 *	0	0.00 *	0	0.00 *
71	4523	50.12 *	0	17.40 *	2045	10.65 *	1075	4.92 *	0	0.00 *
DEVICES & RAD H	2759	115.13 *	0	34.30 *	164	1.01 *	1474	4.38 *	1486	5.73 *
81	25	0.28 *	0	0.06 *	3	0.03 *	0	0.00 *	0	0.00 *
82	1585	75.72 *	0	19.72 *	152	0.95 *	1474	4.38 *	0	0.00 *
83	485	32.20 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
85	479	3.59 *	0	8.01 *	0	0.00 *	0	0.00 *	0	0.00 *
86	185	3.34 *	0	6.51 *	9	0.03 *	0	0.00 *	1486	5.73 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

TOTAL FIELD

	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
FIELD	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *	OPRNS	OPR FTE'S *
TOTAL	86033	77.66 *	19237	272.77 *	36153	279.62 *	8309	197.31 *	1103	63.38 *
FOOD SAFETY/COS	79000	72.43 *	15218	150.83 *	33249	251.22 *	4428	146.91 *	200	6.45 *
03	70000	66.99 *	3300	45.89 *	22625	173.61 *	400	54.69 *	200	6.45 *
04	2750	2.08 *	8192	74.85 *	7901	55.53 *	0	10.56 *	0	0.00 *
07	0	0.00 *	1875	11.12 *	1280	7.59 *	0	6.53 *	0	0.00 *
09	0	0.00 *	0	0.00 *	1025	7.64 *	790	1.86 *	0	0.00 *
18	0	0.00 *	100	0.68 *	0	0.00 *	1393	68.89 *	0	0.00 *
21	6250	3.36 *	1676	16.94 *	218	4.20 *	1145	4.09 *	0	0.00 *
29	0	0.00 *	75	1.35 *	200	2.65 *	700	0.29 *	0	0.00 *
BIOLOGICS	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	39	3.59 *
41	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
42	0	0.00 *	0	0.00 *	0	0.00 *	0	2.50 *	32	2.41 *
45	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	7	1.18 *
HUMAN DRUGS	4498	3.48 *	2008	92.65 *	355	8.76 *	2406	8.20 *	534	34.52 *
46	0	0.00 *	74	10.75 *	50	1.27 *	6	0.53 *	173	10.49 *
48	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	63	4.64 *
52	0	0.00 *	140	11.93 *	155	3.31 *	0	1.04 *	77	4.79 *
53	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	26	1.73 *
56	4498	3.48 *	1699	56.49 *	150	4.18 *	2400	6.63 *	195	12.87 *
58	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *
61	0	0.00 *	15	0.26 *	0	0.00 *	0	0.00 *	0	0.00 *
63	0	0.00 *	80	1.22 *	0	0.00 *	0	0.00 *	0	0.00 *
88	0	0.00 *	0	12.00 *	0	0.00 *	0	0.00 *	0	0.00 *
ANIMAL D & F	500	0.48 *	1790	20.99 *	1075	6.73 *	0	11.37 *	60	2.40 *
68	0	0.00 *	15	0.65 *	0	0.00 *	0	0.00 *	50	2.00 *
71	500	0.48 *	1775	20.34 *	1075	6.73 *	0	11.37 *	10	0.40 *
DEVICES & RAD H	2035	1.27 *	221	8.30 *	1474	12.91 *	1475	28.33 *	270	16.42 *
81	0	0.00 *	3	0.08 *	0	0.00 *	0	0.00 *	0	0.00 *
82	1835	1.16 *	109	4.82 *	1474	12.91 *	1475	5.42 *	163	11.15 *
83	0	0.00 *	0	0.00 *	0	0.00 *	0	0.00 *	75	4.14 *
84	0	0.00 *	0	0.00 *	0	0.00 *	0	5.06 *	0	0.00 *
85	0	0.00 *	0	0.00 *	0	0.00 *	0	3.89 *	15	0.09 *
86	200	0.11 *	109	3.40 *	0	0.00 *	0	13.96 *	17	1.04 *

WORKPLAN SUMMARY / COMBINED OPERATIONS
FY 2005

TOTAL FIELD

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

FY 2005

PART III - PROGRAM FORECASTS



DEPT OF HEALTH & HUMAN SERVICES



FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE

MANAGEMENT BRANCH

ORA/ORM/DPEM

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2005**

February 1, 2005

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low-Acid Canned Foods, CP 7303.003, FY 2005	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 is projected that in FY 05, foreign manufacturers will comprise approximately 86% of total number of registered firms. Therefore, in FY 05, the number of Import Field Exams will double in number to 3000 (from 1500 in FY 04) and the number of Import Sample Collections will increase to 1300 (from 1000 in FY 04).	
6. FIELD OBLIGATIONS The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements. For FY 05 and beyond all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <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 Domestic and Imported Cheese and Cheese Products 03037 FY 2005	2. PMS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections of domestic soft cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered.	
5. PROGRAM JUSTIFICATION Cheese and cheese products have been demonstrated to contain pathogenic microorganisms and to cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.	
6. FIELD OBLIGATIONS The field is requested to conduct inspections of domestic cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings, as well as domestic surveillance sampling to meet the workplan obligation. The emphasis is on soft cheese manufacturers (soft, semi-soft, soft-ripened), and as resources permit, coverage of other cheese. The field is also requested to conduct sample collections and analyses of imported cheese. Refer to the guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections. Food security issues (see IOM) are to be covered during all inspections.	
NOTE: (For specialized micro testing below, see compliance program or contact DFS for additional details) DEN will perform Salmonella antibiotic resistance testing. ARL will perform Salmonella serotyping for isolates originating from all labs with the following exception:	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Hard and Soft Cheeses	d. INDUSTRY/PRODUCT CODE(S) 12
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES 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.	

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				28.5		
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 PHYSICAL (5)	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	8 IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (7)	
	TOTAL FIELD	500	350	400	700	400	75	700	
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) &	(b)(2) & (b)(7)(E)			
NE	REGIONAL STAFF				(b)(7)(E)				
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		16.5		4.0	2.0	18.0	7.1	16.0	
TOTAL HOURS		8250	350	1600	1400	7200	532.5	11200	
CONVERSION FACTOR		930	930	930	930	1180	1180	1180	
TOTAL OPERATIONAL FTEs		8.87	0.38	1.72	1.51	6.10	0.45	9.49	

9. REMARKS

(1) INSPECTIONS: BASED ON A 5/19/04 FACTS INVENTORY OF HIGH RISK FIRMS CONTAINING INDUSTRY CODE 12 (CHEESE) BUT NOT CONTAINING INDUSTRY CODE 16 (SEAFOOD). DISTRICTS WITH STATE CONTRACT RESOURCES ARE TO COORDINATE COVERAGE OF HIGH-RISK AND NON-HIGH RISK INVENTORIES PER PROGRAM PRIORITIES. HIGH RISK FIRMS WHOSE LAST INSPECTION WAS NAI MAY BE PLACED ON A 2 YEAR INSPECTION 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 TIME IS PROVIDED FOR AN ASSIGNMENT TO INVESTIGATE THE PRESENCE OF UNPASTEURIZED CHEESE PRODUCTS IN RETAIL STORES. DISTRIBUTION OF HOURS PER CFSAN.

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE National Drug Residue Milk Compliance Program 03039 FY 2005	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 The National Drug Residue Milk Compliance Program is a joint effort between CFSSAN, CVM and ORA. The program will provide an indication of animal residues in retail milk. Presently, sulfonamides are planned for testing in FY 05 for retail milk.	
5. PROGRAM JUSTIFICATION The National Drug Residue Milk compliance program will provide indications of drug residues in milk and extent of Compliance with Federal regulations. The results will help in the design of future compliance efforts for use by federal, state and local authorities. The initiative will enhance the National Conference on Interstate Milk Shipments (NCIMS) and industry residue testing program and provide information on which to focus regulatory priorities.	
6. FIELD OBLIGATIONS Five hundred (500) retail samples are anticipated for collection. The types of samples and locations for collections, as well as the analytes to be tested for, will be determined in the compliance program. The field is not to initiate any activities until the compliance program is issued. Denver Laboratory will analyze the retail samples for drugs directed in the compliance program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Pasteurized Grade "A" whole white milk as noted in the Compliance Program.	d. INDUSTRY/PRODUCT CODE(S) 09
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>)	
f. CHECK THE FOLLOWING ATTRIBUTES The analytes will be determined in the Compliance Program.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program for details (when issued).	

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low-Acid Canned Foods 03803A FY 2005	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 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act. To perform annual inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods. A continued priority will remain with out- of- compliance firms and special situation firms (e. g. newly registered, firms operating under Emergency Permit, etc.). Firms who have been in compliance are on a 3 year inspection cycle. See compliance program for guidance.	
5. PROGRAM JUSTIFICATION <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 inspections are needed to fulfill program obligations in FY 05. State contract inspections are to be used to increase firm coverage under this program. State inspections may be conducted in addition to the number of inspections assigned per district. Resources include coverage of food security issues at domestic processors.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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 14.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP ECTIONS (3)			3 INVEST IGATIONS (HOURS)	4 DOMESTIC SAMPLE COLLECTION (5)		7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 BETTER PROCESS ING SCHOOL (Training Hours) (4)
	HEADQUARTERS	(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			(b)(2)&b(7)(E)		
NE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	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		25.0				5.0		8.0	10.0	
TOTAL HOURS		10000			400	1000		160	1800	930
CONVERSION FACTOR		930			930	930		1180	1180	930
TOTAL OPERATIONAL FTEs		10.75			0.43	1.08		0.14	1.53	1.00

9. REMARKS

(1) Source of workload: Inspections, Investigation Hours and DSC's based on CFSAN Registration file, provided by CFSAN as of 5/2004.

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety 03803 FY 2005		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 2005 remains to inspect all high-risk firms annually, including added coverage for allergens. Ample resources have been provided to cover the full high-risk inventory covered by this program as well as to accomplish other program objectives (see compliance program). Allergen sample collections and analyses are planned for FY 05. Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate district, will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. During FY 2005, FDA will continue to monitor chicken eggs for <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. As of the 3 rd quarter in FY 04, allergen surveillance inspections are on hold pending finalization of the Agency’s allergen enforcement strategy. The field may do “for cause” allergen inspections as needed, but only proceed with surveillance inspections when new allergen guidance is issued by CFSAN. NOTE: <i>Ciguatera toxin</i> confirmation test will be done at the Pacific Regional Laboratory – NW. Confirmation tests for <i>Clostridium botulinum</i> , <i>Yersinia enterocolitica</i> & paralytic shellfish poison will be split between SRL & Pacific Regional Laboratory-NW. SRL will be the confirmation servicing laboratory for NE, CE, & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<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, 03R845 (2)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 94.9					
REG ION	DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS Including High Risk (1)	1 NON- CLINICAL GLP INSPEC TIONS (6)	1 INSPECTIONS SPROUT ASSIGN- MENT (TO BE ASSIGNED) (5)	1 EGG FARM INSP (9)	1 INSPEC- TIONS ALLERGEN 03803E (3)	2 INVESTI- GATIONS (HOURS) INCL NATL EXPERTS (1)	3 DOMESTIC SAMPLE COLL ALLERGEN (4)	3 DOMESTIC SAMPLE COLL (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 240	7 DOMESTIC SAMPLES TO BE ANALYZED MCRO 360	7 DOMESTIC SAMPLES TO BE ANALYZED ALLERGEN (CHEM) (7) 75
	TOTAL FIELD	3500	(6)	(400)	(5)	375	7207	75	600	240	360	75
HEADQUARTERS												
REGIONAL STAFF												
NEW ENGLAND												
NE	NEW YORK											
REGIONAL LAB												
WEAC												
REGIONAL STAFF												
BALTIMORE												
CHICAGO												
CINCINNATI												
CE	DETROIT											
MINNEAPOLIS												
NEW JERSEY												
PHILADELPHIA												
FORENSIC CHEM. CTR												
REGIONAL STAFF												
ATLANTA												
SE	FLORIDA											
NEW ORLEANS												
SAN JUAN												
REGIONAL LAB												
REGIONAL STAFF												
DALLAS												
SW	DENVER											
KANSAS CITY												
SOUTHWEST IMPORT DISTRICT												
REGIONAL LAB												
REGIONAL STAFF												
LOS ANGELES												
PA	SAN FRANCISCO											
SEATTLE												
PACIFIC REGIONAL LABORATORY-SW												
PACIFIC REGIONAL LABORATORY-NW												
HOURS PER OPERATION		18.5				12.5		3.0	5.2	15.0	15.0	4.0
TOTAL HOURS		64750				4688	7207	225	3120	3600	5400	300
CONVERSION FACTOR		930				930	930	930	930	1180	1180	1180
TOTAL OPERATIONAL FTES		69.62				5.04	7.75	0.24	3.35	3.05	4.58	0.25

9. REMARKS

(1) FY 2005 100% INSP, DSC AND INVESTIGATIONS BASED ON: OEI OF FIRMS FLAGGED AS HIGH RISK IN FACTS LESS FIRMS WITH ONLY INDUSTRY CODE 12, 16 OR 51 AS OF MAY 19, 2004. INCLUDES TIME FOR NATIONAL EXPERTS (4 FTES). RESOURCES HAVE BEEN ALLOCATED FOR 3500 TOTAL INSPECTIONS. HIGH RISK, SPROUT, AND GLP FIRMS ARE INCLUDED IN THIS TOTAL NUMBER. DISTRICTS SHOULD BE ABLE TO MEET HIGH RISK PERFORMANCE GOALS WITH THE ALLOCATED RESOURCES PLUS STATE CONTRACT INSPECTIONS. SAMPLE COLLECTIONS ARE "FOR CAUSE" UNLESS DIRECTED BY ASSIGNMENT.

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

(3) REPORT ALLERGEN INSPECTIONS UNDER PAC 03803E. DO NOT INITIATE INSPECTIONS UNTIL NEW ALLERGEN PROGRAM IS ISSUED. ALLERGEN INSPECTIONS BASED ON OEI OF ALLERGEN FIRMS PER CFSAN.

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

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

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

(7) PER DFS THE ANALYTE FOR DSA ALLERGEN IS CLASSIFIED AS CHEM.

(8) SALMONELA SEROTYPING: SAMPLES GENERATED FROM SRL & ARL GO TO ARL. SAMPLES GENERATED FROM OTHER LABS GO TO DENVER.

(9) EGG FARM INSPECTION: TO BE CONDUCTED BY A CFSAN FIELD ASSIGNMENT FOR INSPECTION OF EGG FARMS PREVIOUSLY IMPLICATED IN SE AND SH OUTBREAKS.

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1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03								
3. PROGRAM/ASSIGNMENT CODE(S) 03903,B,C,D,E; 04803 09903E,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	6. DISTRICT/ SPECIALIZED LABORATORY		DSA MICRO SALMONELA SERO TYPING	FY 2005 STATE CONTRACTS PER DIVISION FEDERAL STATE RELATIONS (INFO ONLY)						
	TOTAL FIELD		[8] 1180	(1) 8132						
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										
TOTAL HOURS			1180							
CONVERSION FACTOR			1180							
TOTAL OPERATIONAL FTEs			1.00							

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Import Foods – General 03819 FY 2005	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, MOUs, etc...), to ensure that future entries of products are in compliance.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.	
6. FIELD OBLIGATIONS To conduct activities directed by CFSAN, identified through program guidance, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth disease vector, or decomposition. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. NOTE TO LABS: (see compliance program or contact DFS for additional details) DEN will perform Salmonella antibiotic resistance testing. ARL will perform Salmonella serotyping for isolates originating from all labs.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <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.	

2005 ORA WORKPLAN

FEBRUARY 1, 2005

1. PROGRAM/ASSIGNMENT TITLE Import Foods General	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03819A,B,C (03R833/99R833/R824) (1)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 288.8
-----------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------	----------------------------------------------

REGION	DISTRICT/SPECIALIZED LABORATORY	2	2	9	2	4	2	4	6	8	8	8	8
		IMPORT ENTRY REVIEW HRS OPER 14 03R833 (2)	PRIOR NOTICE REVIEW HOURS OPER 14 03R833 (10)	IMPORT FILER EVAL HOURS OPER 95 99R833 (5)	IMPORT FOLLOW-UP-REFUSAL OPER 14 R824 (HOURS) (3)	IMPORT SAMPLE COLL PHYSICAL	BSE ENTRY REVIEW & FOLLOW UP (HOURS) (4)	IMPORT SAMPLE COLL ALLERGEN (9)	IMPORT FIELD EXAMS (6)	IMPORT SAMPLES TO BE ANALYZED MICRO (8)	IMPORT SAMPLES TO BE ANALYZED CHEM (8)	IMPORT SAMPLES TO BE ANALYZED ALLERGEN CHEM (8)	IMPORT SAMPLES TO BE ANALYZED SALM RESIST (7)
TOTAL FIELD		92000	33600	20000	8000	9000	9000	300	65000	6430	2570	300	1180

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

HOURS PER OPERATION					2.2		2.2	0.9	8.2	7.0	2.5	
TOTAL HOURS	92000	33600	20000	8000	19000	9000	660	58500	52726	17990	750	1180
CONVERSION FACTOR	1200	1200	930	930	930	1200	930	930	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs	76.67	28.00	21.51	8.60	21.29	7.50	0.71	62.90	44.68	15.25	0.64	1.00

9. REMARKS

- (1) Resources in this program can be used to report Import Food activities under the following PAC codes: 03R833- Import/Entry Review hours; 99R833 - Evaluation hours; R824 - Follow-up-to-Refusal.
- (2) Import Entry Review Hours: resources for these activities cover all Import Food programs.
- (3) Follow-up-to-Refusal hours: additional resources added for marking and tracking the disposition of detained lots.
- (4) BSE Entry Review & follow-up resources planned are to cover entry review products from BSE-affected or at-risk countries for product ingredients to determine whether they include ruminant material subject to USDA/APHIS prohibition. Entries of a product that appears to contain ruminant materials from BSE-affected or at-risk countries are referred to APHIS.
- (5) Import Filer Evaluation based on number of filers. Resources are provided to cover an estimated 1000 filers at 20 hours per evaluation.
- (6) For FY 05 and beyond all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.
- (7) Denver Laboratory: Salmonella Resistance
- (8) Per DFS the analyte for ISA allergens is classified as chem.
- (9) Sample collections for Allergens are to be directed by CFSAN assignment.
- (10) Resources in headquarters for review of prior notices at the Prior Notice Center.

FY 2005 WORKLOAD

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

IMPORT FILER EVALUATION HOURS: BASED ON NUMBER OF FILERS

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

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

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

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

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

ISA ALLERGEN BASED ON ISC ALLERGEN AND LAB SERVICING TABLE

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (03842) FY 2005	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. Inspectional resources should be utilized to cover processors according to the priorities directed in the compliance program. Districts should utilize state contract inspections to assist in inventory coverage.	
5. PROGRAM JUSTIFICATION FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices. Samples will be collected and analyzed only for cause and for HACCP verification when appropriate.	
6. FIELD OBLIGATIONS The field is to conduct inspections, but only make sample collections and analyses for cause or for HACCP verification samples as described in the compliance program. Verification of sampling/analysis must meet specific HACCP criteria. Total estimated inventory is approximately 4500. Resources have been provided for 3120 FDA inspections. The balance needs to be covered by States under contract to FDA. The high-risk inventory (scombrototoxic, smoked, vacuum packaged or ready-to-eat) of approximately 3,200 firms is to have priority for inspection. Between FDA and available State resources, districts need to ensure coverage of the high risk inventory. Remaining resources are to be applied according to the priorities set forth in the program. Food security issues (see IOM) are to be covered during all inspections. NOTE: <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. 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 Refer to the compliance program	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to the compliance program	

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 type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 75.0										
REG ION	DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS INCLUDING HIGH RISK (4)	STATE CONTRACTS IND 16 FY 2005 - INFO ONLY PER DIV FEDERAL STATE RELATIONS (6)	3 INV HOURS	3 DOMESTIC SAMPLES COLL (3)	7 DSAs ORGANO EXAMS (Hours) (2)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 EU CERTIFICATION (HOURS) (7)								
										TOTAL FIELD	3120	1137	1860	800	590	200	600
NE	HEADQUARTERS	(b)(2)&b(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
REGIONAL LAB																	
SW	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
REGIONAL LAB																	
PA	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										16.5			4.5		11.0	16.5	
TOTAL HOURS										51480		1860	3600	590	2200	9900	2790
CONVERSION FACTOR										.930		.930	.930	1.180	1.180	1.180	.930
TOTAL OPERATIONAL FTEs										55.35		2.00	3.87	0.50	1.86	8.39	3.00

3. REMARKS

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

(2) Organoleptic National Expert

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

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

SOURCE OF SEAFOOD WORKLOAD:

(5) OEI OF SEAFOOD FIRMS FLAGGED IN FACTS AS HIGH RISK EXCLUDING FIRMS WITH INDUSTRY CODE 12 AS OF MAY 19, 2004 (INFORMATION ONLY).
INSPECTIONS, INVESTIGATION HOURS AND DSCs BASED ON OEI.

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

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

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program 03844 FY 2005	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP Regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and Regulations promulgated under the Act To provide inspection coverage to importers, focusing on those that import high-risk products that could be health hazards, and to conduct follow-up inspection(s) on importers found to be in non-compliance with the HACCP regulations.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. Resources are provided for coverage of Imported seafood products for chemical hazards, pathogen contamination, decomposition, etc. The program also incorporates HACCP review by investigators, specially trained in HACCP, of importers' records for safety in conjunction with non-safety inspection for decomposition, filth, etc. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP regulation. Inspections along with import sample collection and analysis, will be conducted to assure conformity with current good manufacturing practices and other regulations promulgated under the FD&C Act.	
6. FIELD OBLIGATIONS HACCP trained investigators, will review importers' written verification procedures, product specifications and affirmative step documents, which demonstrate that the foreign processors' product was produced under HACCP, food safety hazards prevention program. Sample collection, analysis, and field exams are to focus on "substantial risk products, including scombrototoxic, smoked, vacuum Packaged or ready-to-eat products. NOTE: <i>Ciguatera toxin</i> confirmation which requires animals will be done at Pacific Regional Laboratory-NW NOTE: Confirmation tests which require animals for <i>Clostridium botulinum</i> will be split between Southeast Regional Laboratory (SRL) & Pacific Regional Laboratory- NW (PRL-NW). SRL will be the confirmation-servicing laboratory for NE, CE & SE Regions. PRL-NW will be the confirmation-servicing laboratory for SW & PA Regions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) (PSP, ASP, Standards, Economic Deception, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES See Compliance Program	
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 type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 101.4																
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP * 03844H (1)	4 IMPORT SAMPLE COLL PHYSICAL (2) / (6)	9 LABEL EXAM (2)	6 IMPORT FIELD EXAMS (2) / (3)	8 ISAs ORGANO ANALYSES (Hours) (5)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (4) / (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (4) / (6)														
	TOTAL FIELD	500	7500	400	2000	1180	5000	5750														
	HEADQUARTERS	(b)(2)&b(7)(E)																				
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										11.0	2.4	0.4	0.4		5.3	10.6					
	TOTAL HOURS										5500	18000	160	800	1180	26500	60950					
	CONVERSION FACTOR										930	930	930	930	1180	1180	1180					
	TOTAL OPERATIONAL FTEs										5.91	19.35	0.17	0.86	1.00	22.46	51.65					

9. REMARKS

(1) FY 2005 : IMPORTER INSPECTIONS: BASED ON OASIS CONSIGNEE DATA AS OF 5/21/04.
 PER CFSAN, INSPECTIONS OF IMPORTERS ARE TO ASCERTAIN THAT THE IMPORTER HAS COMPLIED WITH SEAFOOD HACCP REGULATIONS (NOT TO PERFORM FILER INSPECTIONS).

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

(3) FOR FY 05 AND BEYOND ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE:
 (a) VERIFICATION THAT THE IMPORTED PRODUCT IS THE SAME AS THAT WHICH WAS DECLARED (RECONCILIATION EXAM;
 (b) AN ASSESSMENT OF SECURITY CONCERNS RELATED TO LABELING AND SOURCE COUNTRY (INCLUDING CONTAINER INTEGRITY, SIGNS OF INTENTIONAL ADULTERATION, ETC.);
 (c) TRADITIONAL SAFETY CONCERNS.

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

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

(5) ORGANOLEPTIC NATIONAL EXPERT

(6) WEAC MICRO & CHEM: PER DFS AN INTERNAL AGREEMENT FOR FY 2005 (CARRIED OVER FROM FY 2004) BETWEEN THE WEAC LAB DIRECTOR AND THE NEW ENGLAND IB DIRECTOR TO HAVE 223 CHEM AND 112 MICRO SAMPLES SENT TO WEAC.

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

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program 03847, 03847H FY 2005	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.</p> <p>Resources have been provided for "for cause" samples and Juice HACCP verification samples (see revised Juice HACCP Inspection Program for details <i>when issued</i>). Districts should collect sufficient Juice HACCP verification samples, so that when added to their "for cause" collections, meets their full domestic sample collection Workplan obligation.</p> <p>State inspections may be conducted in addition to the number of inspections assigned per district.</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 Import and Domestic Micro Assignments 03F098 & 03F100 FY 2005	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 products of domestic and foreign origin for pathogenic microorganisms. Work will be directed by one or more CFSAN field assignments.	
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to food borne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. The assignment(s) will focus on commodities and pathogens that continue to be implicated in food borne outbreaks.	
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the assignment(s) issued by CFSAN.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: NA <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) 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 Refer to field assignment(s).	

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards -03
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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 27.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3. DOMESTIC SAMPLE COLLECTION	4. IMPORT DOMESTIC COLLECTION	7. DOMESTIC SAMPLE ANALYSIS MICRO	8. IMPORT SAMPLE ANALYSIS MICRO					9. OTHER OPERATIONS (Hours)
	TOTAL FIELD	500	500	500	500					
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
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	29.0	29.0					
	TOTAL HOURS	1500	1500	14500	14500					
	CONVERSION FACTOR	930	930	1180	1180					
	TOTAL OPERATIONAL FTEs	1.61	1.61	12.29	12.29					

8. REMARKS

Import and Domestic assignment's will be issued by CFSAN for the collection of cantaloupe, green onions specific leafy herbs (basil, cilantro, parsley, etc.), lettuce and tomatoes for analysis for pathogens
 Note: SWID samples collected for TX & NM are sent to ARL. SWID samples collected for CA & AZ are sent to DEN.
 Workload: Import & Domestic Sample Collection resource distribution per CFSAN.
 Domestic and Import Sample Analysis based on Domestic and Import Sample collection(s) and Laboratory Servicing Table.

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments 03R233 FY 2005	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 Hazard
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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 7.5
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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		930					
	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								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	30.0							
	TOTAL HOURS	6000		930					
	CONVERSION FACTOR	930		930					
	TOTAL OPERATIONAL FTEs	6.45		1.00					

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

1. PROGRAM/ASSIGNMENT TITLE Emergency Response to Foodborne Outbreaks and Illnesses 03R839 – FY 2005	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.	
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 Food State Contract Audits 03R843 FY 2005	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 perform joint audit investigations of states that are under contract with FDA to conduct food inspections.	
5. PROGRAM JUSTIFICATION About 9,300 food inspections are anticipated to be contracted out in FY 05 by FDA to the states. The Agency needs to ensure appropriate oversight of state food firm inspections is conducted.	
6. FIELD OBLIGATIONS To perform joint audit investigations of approximately 7% of state contract inspections in FY 05. Guidance for conducting an audit investigation is to be provided by the Division of Federal State Relations. Resources are provided for district management of state contracts. Report under Operation Code 13 (Domestic Investigation). These are not considered inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/A <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) 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 type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Follow DFSR guidance.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Follow DFSR guidance.	

2005 ORA WORKPLAN

FEBRUARY 1, 2005

1. PROGRAM/ASSIGNMENT TITLE Food State Contract Audits	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 22.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INV HOURS FOOD STATE CONTRACT AUDITS (2)	NUMBER OF FOOD STATE CONTRACT AUDITS (1)	2005 DOMESTIC FOOD STATE CONTRACTS LESS SEAFOOD (4)	2005 DOMESTIC SEAFOOD STATE CONTRACTS IND 16 (4)	2005 TOTAL STATE CONTRACTS (4)	7 DSAs ORGANO EXAMS (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 CONTRACT MANAGE- MENT HOURS (3)
	TOTAL FIELD	6305	(650)	8132	1137	9269				14880
	HEADQUARTERS	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION		(9.7)							
	TOTAL HOURS	6305	(6305)							14880
	CONVERSION FACTOR	930	(930)							930
	TOTAL OPERATIONAL FTEs	6.78	(6.78)							16.00

9. REMARKS

(1) Food State Contract Audits to be conducted at about 7% of state contract food firm inspections. Number of Food State Contract Audits: For information purposes and guidance.

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

(3) Time planned for contract management.

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

1. PROGRAM/ASSIGNMENT TITLE Counter-Terrorism Preparedness 03R845 FY 2005	2. PPS PROJECT NAME/NUMBER Food borne Biological Hazards
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3. PROGRAM TYPE: NA COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To maintain Counter-terrorism preparedness, by means of joint CFSAN/ORAs field assignments, FDA collection and analysis of proficiency samples for the Food Emergency Response Network, providing resources for general laboratory preparedness activities including instrument, reagent, and standards maintenance, and related activities.

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

Actual emergency and code-red alert status activities, when needed, will be directed jointly by CFSAN and ORA, and the Field will be instructed on planned work that will be halted.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

2005 ORA WORKPLAN

FEBRUARY 1, 2005

1. PROGRAM/ASSIGNMENT TITLE Counter Terrorism Preparedness				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03								
3. PROGRAM/ASSIGNMENT CODE(S) 03R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 11.6						
R E G I O N	6.	2	2	8	8							
	DISTRICT/ SPECIALIZED LABORATORY	CSO DOMESTIC HOURS	CSO IMPORT HOURS	IMPORT DOMESTIC CHEM HOURS	IMPORT DOMESTIC MICRO HOURS							
	TOTAL FIELD	1550	3100	3750	4000							
	HEADQUARTERS	(b)(2)&b(7)(E)										
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	REGIONAL LAB											
SW	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
PA	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW											
	PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION												
TOTAL HOURS		1550	3100	3750	4000							
CONVERSION FACTOR		930	930	1180	1180							
TOTAL OPERATIONAL FTEs		1.67	3.33	3.18	3.39							
9. REMARKS												
<p>Planned resources are for non-emergency and non-code red alert status CT preparedness activities. Resources may be used for CFSAN issued assignments for inspections, sample collections, and sample analysis for the Food Emergency Response Network (FERN). Lab resources may also be used for maintaining CT-related analytical capabilities. Note: SWID samples collected for TX & NM are sent to ARL. SWID samples collected for CA & AZ are sent to PRS. Resources for the lead FERN laboratory (FCC, NRL, and WEAC) activities have been pre-planned by ORA. Resources for the FERN lead labs are for general CT preparedness and CFSAN CT-related assignments. WORKLOAD: CSO DOMESTIC HOURS BASED ON TOTAL FOODS M/R OEI INCLUDING IND CODE 02-51 DATED 3/17/2004 CSO IMPORT HOURS BASED ON TOTAL FOODS ACS FDA REVIEW LINES (5/1/03 -4/30/04) LABORATORY RESOURCES PLANNED BY DFS.</p>												

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 there are 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, 04R833,99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 85.1 (46.0)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs			DSCs Dioxins	DSAs Dioxins MASS SPEC *	DSAs DIOXINS CALUX	DSCs SEAFOOD	DSAs SEAFOOD
	TOTAL FIELD	500	2700	2700			1505	1537	200	175	175
	HEADQUARTERS	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)				
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
SE	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB											
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY- SW										
PACIFIC REGIONAL LABORATORY- NW											
HOURS PER OPERATION			3.0	5.2			4.0	11.6	11.6	3.0	5.2
TOTAL HOURS		500	8100	14040			6020	17829	2320	525	910
CONVERSION FACTOR		930	930	1180			930	1180	1180	930	1180
TOTAL OPERATIONAL FTEs		0.54	8.71	11.90			6.47	15.11	1.97	0.56	0.77
7. REMARKS Report Counter Terrorism work performed only under 04R845 *Includes analysis of 232 Total Diet Study sample homogenates. CFSAN will issue collection schedule DSCs Seafood: See compliance program for collection details											

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1. PROGRAM/ASSIGNMENT TITLE 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,04R833,99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS (39.1)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY			ISCs	ISAs	ISCs SEAFOOD	ISAs SEAFOOD
	TOTAL FIELD			5300	5300	300	300
NE	HEADQUARTERS			(b)(2)&b(7)(E)		(b)(2)&b(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
MA	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
SEATTLE							
PACIFIC REGIONAL LABORATORY- SW							
PACIFIC REGIONAL LABORATORY- NW							
HOURS PER OPERATION				1.6	6.2	1.6	6.2
TOTAL HOURS				8480	32860	480	1860
CONVERSION FACTOR				930	1180	930	1180
TOTAL OPERATIONAL FTEs				9.12	27.85	0.52	1.58

9. REMARKS
 Page 2 of 2
 ISC Seafoods: See compliance program for collection details

1. PROGRAM/ASSIGNMENT TITLE 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 loss which contain unapproved chemical compounds.	
5. PROGRAM JUSTIFICATION Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. With the advent of this trend there will be incentives to protect investments and/or gain a competitive edge through the use of chemotherapeutic agents. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the U.S. and do not have adequate regulatory controls the prevent their export to the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products, and to initiate regulatory action when warranted.	
6. FIELD OBLIGATIONS Districts will collect and analyze domestic and import samples of aquacultured products specified in the program. Multiple analyses (chemotherapeutic agents) will be run on the majority of samples, therefore sample analyses outnumber sample collections. Only a single sample will need to go to labs assigned to perform multiple analyses. Please refer to revised Chemotherapeutics in Seafood Compliance Program (when issued), and if needed contact the assigned labs and/or DFS. Individual subsample analyses will only be required for shrimp samples being analyzed for Chloramphenicol. All of the remaining samples will be a composite of 12 sub samples. Collection and analytical resources for Nitrofurans will come from this compliance program in FY 05 in either the form of a field assignment or as a component of this compliance program when re-issued to the field.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved drugs per the Compliance Program, Non-permitted ingredients, microbiological/contaminants, labeling warnings.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

Chemotherapeutics in Seafood	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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3. PROGRAM/ASSIGNMENT CODE(S) 04018	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 17.9
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	6. DISTRICT/ SPECIALIZED LABORATORY		ISCs	DSCs	ISAs	ISA IND SUBS	ISA COMPOSITE	DSAs	DSAs IND SUBS	DSAs COMPOSITE
R E G I O N	TOTAL FIELD		752	224	752	(432)	(320)	224	(64)	(160)
	HEADQUARTERS		(b)(2)&b(7)(E)							
	REGIONAL STAFF									
N E	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
C E	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
S E	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
S W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
P A	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW									
	HOURS PER OPERATION		3.0	4.0	17.5			17.5		
	TOTAL HOURS		2256	896	13160			3920		
	CONVERSION FACTOR		930	930	1180			1180		
	TOTAL OPERATIONAL FTEs		2.43	0.96	11.15			3.32		

7. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE 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 and imported foods (including seafood,) and foodware. To take regulatory action against any food or foodware found to contain levels of toxic elements or radionuclides of regulatory significance.			
5. PROGRAM JUSTIFICATION Historical evidence mandates the continued monitoring of domestic and imported food (including seafood) and foodware for the presence of toxic elements (i.e., lead, cadmium and mercury). The continuing monitoring of radionuclides in food is necessary to guard against any dangerous level of radiochemical contamination of domestic and imported foods. This monitoring will also provide continuing background data to identify any upward trend in tritium, gamma-ray emitters and Sr levels.			
6. FIELD OBLIGATIONS Raw agricultural products and their processed derivatives and seafood are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" program and assignments (to be issued). Planned assignments include mercury in tuna and other seafood species. CFSAN issued collection schedules will direct other FY 05 food work. Sample collections, analyses and other activities relating to domestic and imported foodware will continue as directed by the "Toxic Element" program. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) 02 - 41, 52A	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Radiochemical Analysis			
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 and ⁹⁰ Sr			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Radiochemical analysis capability. (Available only at WEAC.) Graphite furnace atomic absorption with Zeeman background correction.			

1. PROGRAM/ASSIGNMENT TITLE 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 16.1 (8.2)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSC NON- SEAFOOD <small>*</small>	ISC NON- SEAFOOD <small>**</small>	DSA NON- SEAFOOD	ISA NON- SEAFOOD	DSCs SEAFOOD <small>***</small>	DSAs SEAFOOD	DSC MERCURY IN SEAFOOD <small>****</small>	DSA MERCURY IN SEAFOOD	ISC SEAFOOD <small>***</small>
		TOTAL FIELD	120	100	120	100	100	100	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									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION	3.5	1.8	12.0	12.0	4.5	12.0	4.5	12.0	4.5
	TOTAL HOURS	420	180	1440	1200	450	1200	900	2400	765
	CONVERSION FACTOR	930	930	1180	1180	930	1180	930	1180	930
	TOTAL OPERATIONAL FTEs	0.45	0.19	1.22	1.02	0.48	1.02	0.97	2.03	0.82
7. REMARKS										
*DSC (NON-SEAFOOD): CFSAN TO ISSUE COLLECTION SCHEDULE FOR LEAD IN NON-SEAFOOD.										
**ISC RESOURCES FOR SWID ARE "FOR CAUSE" SAMPLING, E.G. MEXICAN CANDY AND BOTTLE WATER FOR LEAD.										
***DSC (SEAFOOD): CFSAN WILL ISSUE COLLECTION SCHEDULE FOR CADMIUM IN MOLLUSCS.										
***ISC (SEAFOOD): CFSAN WILL ISSUE COLLECTION SCHEDULE FOR BOTH LEAD AND CADMIUM IN SEAFOOD.										
****TO BE ISSUED AS CFSAN FIELD ASSIGNMENT.										

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1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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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 (7.9)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISA SEAFOOD	DISC MERCURY IN TUNA ****	DISA MERCURY IN TUNA			DISC MERCURY IN SEAFOOD ****	DISA MERCURY IN SEAFOOD		
	TOTAL FIELD	170	150	150			270	270		
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									
	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	12.0	3.5	12.0			4.5	12.0		
	TOTAL HOURS	2040	525	1800			1215	3240		
	CONVERSION FACTOR	1180	930	1180			930	1180		
	TOTAL OPERATIONAL FTEs	1.73	0.56	1.53			1.31	2.75		

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

1. PROGRAM/ASSIGNMENT TITLE 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 (6.9)												
R E G I O N	6.		3	4	5	6	7	8											
	DISTRICT/ SPECIALIZED LABORATORY		DSCs (Houseware)	ISCs (Houseware)	DOMESTIC FIELD EXAMS	IMPORT FIELD EXAMS *	DSAs	ISAs											
	TOTAL FIELD		50	400	100	2750	50	400											
	HEADQUARTERS	(b)(2)&b(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
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											3.5	1.8	0.7	0.7	10.0	10.0		
	TOTAL HOURS											175	720	70.0	1925	500	4000		
	CONVERSION FACTOR											930	930	930	930	1180	1180		
	TOTAL OPERATIONAL FTEs											0.19	0.77	0.08	2.07	0.42	3.39		

7. REMARKS

* For FY 05 and beyond all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

1. PROGRAM/ASSIGNMENT TITLE 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 WEAC									
CE	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									
PACIFIC REGIONAL LABORTORY-SW										
PACIFIC REGIONAL LABORTORY-NW										
HOURS PER OPERATION				2.5	1.7			13.0	4.2	
TOTAL HOURS				40	143			208	353	
CONVERSION FACTOR				930	930			1180	1180	
TOTAL OPERATIONAL FTEs				0.04	0.15			0.18	0.30	

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE 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 occurrence and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex groups through analyses of table-ready foods, to observe differences or trends in the intake of these chemicals, and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.	
5. PROGRAM JUSTIFICATION The continuing study has provided valuable information on dietary intakes of residues and nutrients and has been often used to gauge intakes in ready-to-eat foods. EPA relies on the data for hazard assessment in special review and other proceedings. Portions of the Total Diet samples are used for other analysis (e.g., radionuclides, selected nutrients, pesticides, industrial chemicals, and toxic elements). Additionally, selected Total Diet Study foods are analyzed for acrylamide and dioxins under the pesticide program.	
6. FIELD OBLIGATIONS The collection and analysis of four market baskets, each consisting of three separate samplings of 286 items food items, which are to be collected from three locales in the region, over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, and toxic elements. WEAC will analyze all foods from the first market basket for radionuclides.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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							25.0	20.0	2800.0		
TOTAL HOURS							1500	22880	2800		
CONVERSION FACTOR							930	1180	1180		
TOTAL OPERATIONAL FTEs							1.61	19.39	2.37		

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical contaminants
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 products of domestic and foreign origin for chemical contaminants as directed by CFSAN field assignments. Assignments are anticipated for perchlorates, acrylamides, chloramphenicol in selected foods, and general pesticide and toxic element analysis in dietary supplements. Resources have been provided for a field assignment for coverage of an additional Contaminant to be determined prior to the start of FY 05.	
5. PROGRAM JUSTIFICATION Monitoring of foods for suspected chemical contaminants is necessary to ensure a safe food supply. Perchlorates and acrylamides have recently been identified as suspect contaminants and monitoring is required to provide the Agency with incidence and level data to properly evaluate their presence in the food supply. Chloramphenicol is a banned drug in the U.S. for food-producing animals but its presence has been detected in imported honey and suspected in imported dried milk. There are concerns regarding pesticides and toxic elements in dietary supplements yet there are minimal 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 <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) Selected human foods and dietary supplements	d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignments
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 Chemical contaminants as directed by CFSAN field assignments.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by the assignments.	

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1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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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
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISA PESTICIDE & TOXIC ELEMNT IN DIETARY SUPP. ***	ISC CAP N' DRIED MILK **	ISA CAP N' DRIED MIL **	DSC NITRO- FURANS IN HONEY **	DSA NITRO FURANS IN HONEY **	DSC FURAN IN FOODS ***	DSA FURAN IN FOODS ***
	TOTAL FIELD	150	25	25	25	25	500	500
	HEADQUARTERS	(b)(2)&b(7)	(b)(2)&b(7)(E)					
NE	REGIONAL STAFF	(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 LABORATORY- SW							
	PACIFIC REGIONAL LABORATORY- NW							
	HOURS PER OPERATION	24.0	3.0	4.0	3.0	6.5	3.0	3.0
	TOTAL HOURS	3600	75	100	75	163	1500	1500
	CONVERSION FACTOR	1180	930	1180	930	1180	930	1180
	TOTAL OPERATIONAL FTEs	3.05	0.08	0.08	0.08	0.14	1.61	1.27

7. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04					
3. PROGRAM/ASSIGNMENT CODE(S) 04R838			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 10.8		
R E G I O N	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							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
PA	REGIONAL LAB							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORTORY - SW							
	PACIFIC REGIONAL LABORTORY - NW							
HOURS PER OPERATION								
TOTAL HOURS			1180	11800				
CONVERSION FACTOR			1205	1205				
TOTAL OPERATIONAL FTEs			0.98	9.79				

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

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods		2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins: Foods and Cosmetics - 07	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To collect and analyze domestic samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin. To remove from interstate commerce those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. To detain those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance.			
5. PROGRAM JUSTIFICATION Mycotoxins are metabolic products of specific molds commonly found on foods, some (the aflatoxins) are hepatocarcinogens in a number of animal species, and until proven otherwise must be assumed to be carcinogenic to man. The FDA, in conjunction with other agencies and the food industries, has devised and will continue to improve on practical programs for ensuring minimum exposure of the population to mycotoxins without jeopardizing the food supply. Aflatoxins may occur in food as a result of mold growth in a number of susceptible commodities, including peanuts and corn. The current action level for aflatoxins in human food is 20 ppb. Fumonisin B ₁ and B ₂ are naturally occurring toxic metabolites produced mainly by the fungus, <i>Fusarium verticillioides</i> , which are found ubiquitously on corn from around the world. Because of their potential carcinogenicity and frequent occurrence in corn-based feeds and foods, their presence should be monitored, especially for incidence data. Deoxynivalenol (DON) is a trichothecene mycotoxin produced by several strains of <i>Fusarium</i> , which under certain climate conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated gastrointestinal illnesses in China and India. FDA has issued an advisory level of 1ppm for DON in finished wheat products. There is a need for continuous monitoring of this toxin. Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera <i>Aspergillus</i> and <i>Penicillium</i> . It is mainly a contaminant in cereal grains and is carcinogenic in mice and rats. There is a need for current information on the incidence and levels of this toxin in the U.S. food supply. Patulin is a mold metabolite produced by several species of mold fungi including <i>Penicillium expansum</i> , the casual organism of apple rot. Apple juice prepared from rotten apples is a possible source of patulin in the human diet. Patulin is regulated in at least 10 countries so far. There is a need for more exposure data to further review the international standards for patulin. The current action level for patulin in apple juice and apple juice components is 50 ppb.			
6. FIELD OBLIGATIONS The field will conduct follow-up investigations that may be requested by CFSAN, and collect and analyze samples of domestic products as directed by the Compliance Program. Mycotoxins in Domestic Foods (07001) and Mycotoxins in Import (07002) Compliance Programs will be combined in FY 05 into one Program Mycotoxins in Domestic and Import Foods under a single Program Assignment code (07001). In FY 05 and beyond, all program activities to be reported under PAC 07001.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT(S) See Attachment "A" C.P. 7307.001 for list of Products.		d. INDUSTRY/PRODUCT CODE(S) 02, 03, 05, 07, 09, 12, 13, 23, 24	
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 (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Aflatoxins, Fumonisin B ₁ and B ₂ , Deoxynivalenol (DON), Ochratoxin A, and Patulin.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins: Food and Cosmetics -07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (29.6) 19.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSCs	DSCs	DSCs	DSCs	DSCs	ALL DOMESTIC ANALYSIS	DSAs	DSAs	DSAs									
		AFLA	FUM	DON	OCHRA	PATULIN		AFLA	FUM	DON									
	TOTAL FIELD	800	400	250	125	300	1875	(800)	(400)	(250)									
	HEADQUARTERS	(b)(2)&b(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
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										4.0	4.0	4.0	4.0	4.0	7.0			
	TOTAL HOURS										3200	1600	1000	500	1200	13125			
	CONVERSION FACTOR										930	930	930	930	930	1180			
	TOTAL OPERATIONAL FTEs										3.44	1.72	1.08	0.54	1.29	11.12			

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins: Food and Cosmetics -07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (2.8)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSAs OCHRA	DSAs PATULIN	ISCS AFLA	ISCS PEANUT BUTTER	ISCS FUM	ISCS DON	ISCS OCHRA	ISCS PATULIN	ISCS SPECIAL SURV.
	TOTAL FIELD	(125)	(300)	500	(105)	200	160	80	300	40

HEADQUARTERS		(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
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									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
PACIFIC REGIONAL LABORTORY-NW										

HOURS PER OPERATION			2.0		2.0	2.0	2.0	2.0	2.0	2.0
TOTAL HOURS			1000		400	320	160	600	80	80
CONVERSION FACTOR			930		930	930	930	930	930	930
TOTAL OPERATIONAL FTEs			1.08		0.43	0.34	0.17	0.65	0.09	0.09

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods				2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins: Food and Cosmetics -07							
3. PROGRAM/ASSIGNMENT CODE(S) 07001			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> X <input type="checkbox"/> ORA <input checked="" type="checkbox"/> X <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (7.6)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ALL IMPORT SAMPLE ANALYSIS	ISAs AFLA	ISAs FUM	ISAs DON	ISAs OCHRA	ISAs PATULIN	ISAs SPECIAL SURV.			
	TOTAL FIELD	1280	(600)	(200)	(160)	(80)	(300)	(40)			
N E	HEADQUARTERS	(b)(2)&b(7)(E)									
	REGIONAL STAFF										
N E	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
C E	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
S E	FORENSIC CHEM. CTR										
	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										
P A	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORTORY-SW										
	PACIFIC REGIONAL LABORTORY-NW										
HOURS PER OPERATION		7.0									
TOTAL HOURS		8960									
CONVERSION FACTOR		1180									
TOTAL OPERATIONAL FTEs		7.59									
7. REMARKS											

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

2. PMS PROJECT NAME/NUMBER
Molecular Biology and Natural Toxins:
Foods and Cosmetics - 07

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Research

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins: Food and Cosmetics - 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 6.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEMIST	RESEARCH CENTER RESEARCH MICRO				
	TOTAL FIELD	3053		4130	590				
	HEADQUARTERS	(b)(2)&b(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	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								
	TOTAL HOURS	3053		4130	590				
	CONVERSION FACTOR	1205		1180	1180				
	TOTAL OPERATIONAL FTEs	2.53		3.50	0.50				

7. REMARKS:

1. PROGRAM/ASSIGNMENT TITLE Imported Foods-Foods and Color Additives 09006A, B	2. PPS PROJECT NAME/NUMBER Food and Color Additives-09
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To direct coverage of imported food products to determine their compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and regulations promulgated under the Act, with respect to food and color additives..	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the Act and the regulations for food and color additives. The compliance program directs sample collections and label review of imported products for unsafe food additives and non-permitted food or undeclared color additives to insure that these foods meet the requirements of the law.	
6. FIELD OBLIGATIONS Districts should conduct label reviews and collect and analyze imported foods for known potential food and color additive violations, and take appropriate regulatory actions when violations are found. For FY 05 and beyond all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container Integrity signs of intentional adulteration, etc.) and traditional safety concerns. These activities are to be reported as a single import field under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined for cause CT exam or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845,04845,ETC). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: NA N/A <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 type="checkbox"/> OTHERS (<i>Specify</i>)	
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 and Color Additives Petition Review and Policy Development - 09							
3. PROGRAM/ASSIGNMENT CODE(S) 09006 A,B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 10.0			
R E G I O N	6.	2	4	9	8	4	9	8	9	
	DISTRICT/ SPECIALIZED LABORATORY		ISCs COLOR ADDITIVES	LABEL REVIEW COLOR ADDITIVES	ISAs COLOR ADDITIVES	ISCs FOOD ADDITIVES	LABEL REVIEW FOOD ADDITIVES	ISAs FOOD ADDITIVES	OTHER OPERATIONS (Hours)	
TOTAL FIELD			755	250	755	270	540	270		
HEADQUARTERS			(b)(2)&b(7)(E)							
REGIONAL STAFF										
N E	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
C E	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
S E	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
S W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
P A	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY- SW									
PACIFIC REGIONAL LABORTORY- NW										
HOURS PER OPERATION			1.4	0.5	8.0	1.4	1.1	11.0		
TOTAL HOURS			1057	125	6040	378	594	2970		
CONVERSION FACTOR			930	930	1180	930	930	1180		
TOTAL OPERATIONAL FTEs			1.14	0.13	5.12	0.41	0.64	2.52		

7. REMARKS

NOTE: Resources for Entry Review and Filer Evaluation are planned under the Import Foods- General Program (03819). For FY 05 and beyond all Import Field Exams are to routinely include verification that the imported products is the same as that which was declared (reconciliation exams); an assessment of security concerns related to labeling and source country (including container integrity signs of intentional adulteration, etc.); and traditonal safety concerns. These activities are to be reported as a single Import Field Exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or in the event CT suspicious are raised conducting routine work requiring follow up should and additional exam and time be reported under CT PAC (03R845,04R845, etc.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

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

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	<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	<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 Retail Food Protection - State Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To provide guidance, support, and assistance to the federal, state, tribal, and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in foodborne illnesses. For FY 04 this program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, the 2004 Baseline Data Collection and Analysis of Foodborne Illness Risk Factors at retail and report thereof, the on-going egg safety initiative, CFSAN-directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.

5. PROGRAM JUSTIFICATION

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

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: N/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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL FOOD PROGRAM STANDARDS	STANDARD- IZATION (ITP CDC IHS, STATE AND LOCAL) *	RE-STANDARD- IZATION (ITP, STATE AND LOCAL) **	NATL CFSAN DIRECTED PROJECTS SECURITY	TEAM LEADERS SC/NATIONAL	NATL TEAM WORK GROUP	REGIONAL SEMINARS	TRAINING WORKSHOPS	TECHNICAL ASSISTANCE
	TOTAL FIELD	11250	1960	3467	600	1200	2080	1040	2070	7531
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION										
TOTAL HOURS		11250	1960	3467	600	1200	2080	1040	2070	7531
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		9.38	1.63	2.89	0.50	1.00	1.73	0.87	1.73	6.28

7. REMARKS:

Report Counter Terrorism work performed only under 18R845.

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

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

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

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

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

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

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

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

FY 2005 ORA WORKPLAN

February 1, 2005

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 (22.3)						
R E G I O N	6.	DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANT ¹	CHECK RATINGS TRANSFER AND RECEIVING ¹	CHECK RATING FARMS	SINGLE SERVICE AUDITS	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICATION ²	TECHINICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION ³	STATE MILK SAMPLING SURVELLANCE OFFICER INITIAL CONT	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER ⁴	
	TOTAL FIELD		214	66	361	78	39	51	17	44	28	
		(b)(2)&b(7)(E)										
NE	HEADQUARTERS											
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
		WEAC										
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR.											
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	REGIONAL LAB											
SW	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
PA	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW											
		PACIFIC REGIONAL LAB - NW										
		HOURS PER OPERATION		24.0	12.0	20.0	8.0	40.0	120.0	120.0	24.0	80.0
		TOTAL HOURS		5136	792	7220	624	1560	6120	2040	1056	2240
		CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
		TOTAL OPERATIONAL FTEs		4.28	0.66	6.02	0.52	1.30	5.10	1.70	0.88	1.87
7. REMARKS:												
<p>1/ Check Ratings of Plants and RS/TS Every 3 Years, BTUs Every 4 Years and Audits Every 5 Years</p> <p>2/ Activities Include the Initial (Including HACCP) and Continuous Certifications of State Rating Officers and Sampling Surveillance Officers.</p> <p>3/ State Program Evaluations Conducted of 1/3 of the States (Including Puerto Rico) Every 3 Years.</p> <p>4/ Activities Include the National Steering Team Meetings and Conference Calls.</p>												

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1. PROGRAM/ASSIGNMENT TITLE Milk Safety Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S) 18003	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	OPERATIONAL FTE POSITIONS (3.7)
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R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	RMS STANDARD- IZATION ⁵	NCMS	TRAINING GIVEN ⁶						
	TOTAL FIELD	17	22	22						
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	50.0	80.0	80.0						
	TOTAL HOURS	850	1760	1760						
	CONVERSION FACTOR	1200	1200	1200						
	TOTAL OPERATIONAL FTEs	0.71	1.47	1.47						

^{5/} Activities include the Initial and Re-standardization (Individual Audits and Group Field Exercise) of RMSs
^{6/} Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops.

1. PROGRAM/ASSIGNMENT TITLE 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 (10.5)												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION	PATROL EVALUATION	VIBRIO SPECIES MANAGE- MENT HOURS	TECHNICAL ASSISTANCE	FOREIGN EVALUATION	NATIONAL TEAM REPS	TRAINING WORKSHOPS	PLANT EVALUATION	STANDARD- IZATION & RE-STAN- IZATION									
	TOTAL FIELD	167	17	500	14	5	2	20	122	5									
	HEADQUARTERS	(b)(2)&b(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
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											20.0	80.0		248.0	200.0	400.0	50.0	8.0	40.0
TOTAL HOURS											3340	1360	500	3472	1000	800	1000	976	200
CONVERSION FACTOR											1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs											2.78	1.13	0.42	2.89	0.83	0.67	0.83	0.81	0.17
7. REMARKS:																			

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1. PROGRAM/ASSIGNMENT TITLE 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 (3.5)				
R E G I O N	B	DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM MEETING	CENTER INITIA- TIVES	REGIONAL SEMINARS	EU AUDIT	ISSC COMMITTEE	LABORATORY EVALUATION			
	TOTAL FIELD		14	14	14	14	14	12			
N E	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 LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION		30.0	80.0	40.0	40.0	100.0	8.0			
	TOTAL HOURS		420	1120	560	560	1400	96			
	CONVERSION FACTOR		1200	1200	1200	1200	1200	1200			
	TOTAL OPERATIONAL FTE		0.35	0.93	0.47	0.47	1.17	0.08			

1. PROGRAM/ASSIGNMENT TITLE 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 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 27.8 (25.8)			
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	INSP ECTIONS	CONVEY UNDER CONSTRUC HOURS (*)	WATERING POINTS INSP (A)	CATERING POINTS INSP (B) (**)	VESSELS INSP (C)	DSCs	DSAs MICRO	INV (HOURS)	ITP SPECIALIST TIME (HOURS)
	TOTAL FIELD	1792	1360	(710)	(380)	(300)	100	100	1900	930
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									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		10.5					4.0	8.0		
TOTAL HOURS		18816	1360				400	800	1900	930
CONVERSION FACTOR		930	930				930	1180	930	930
TOTAL OPERATIONAL FTEs		20.23	1.46				0.43	0.68	2.04	1.00
7. REMARKS: <p>Inspections in Columns (A), (B) and (C) are included in Column 1. Report Counter Terrorism work performed only under 18R845. Time is allocated for Food Code promotion coverage of Food Security issues and completion of Application of Food Code, Attachment B. Catering Point Insp. (B) is High Risk Priority and full inventory should be inspected per workplan. DSCs should be randomly collected from on-board conveyances water systems ex. faucets, as close to the water holding tank as possible. At least 2 of the samples per district should be taken from aircraft. ** Time for Conveyance under Construction- Time to be used for plan review, meetings, and final inspections. It includes galleys in ATL,DAL,LOS and Aircraft/Vessels in SAN & SEA. *** Includes High Risk and some Potential Food Allergen Firms identified by the District. **** 5 of these inspections are scheduled for the Nashville Branch.</p>										

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1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18			
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (1.9)	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	STEERING COMMITTEE (HOURS) <small>(****)</small>	STANDARD & RE-STANDARD FOOD CODES (HOURS) <small>(****)</small>			
	TOTAL FIELD	400	1395			
NE	HEADQUARTERS	(b)(2)&b(7)(E)				
	REGIONAL STAFF					
CE	NEW ENGLAND					
	NEW YORK					
SE	REGIONAL LAB					
	WEAC					
	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
	PHILADELPHIA					
FORENSIC CHEM. CTR						
SW	REGIONAL STAFF					
	ATLANTA					
	FLORIDA					
	NEW ORLEANS					
PA	SAN JUAN					
	REGIONAL LAB					
	REGIONAL STAFF					
	DALLAS					
	DENVER					
PA	KANSAS CITY					
	SOUTHWEST IMPORT DISTRICT					
	REGIONAL LAB					
	REGIONAL STAFF					
	LOS ANGELES					
PA	SAN FRANCISCO					
	SEATTLE					
	PACIFIC REGIONAL LAB - SW					
	PACIFIC REGIONAL LAB - NW					
HOURS PER OPERATION						
TOTAL HOURS		400	1395			
CONVERSION FACTOR		930	930			
TOTAL OPERATIONAL FTEs		0.43	1.50			
7. REMARKS: <p>*****Steering Committee - 80 hours provided to each districts (NWE,CIN,FLA,DAL and SAN) for discussing Regionalization of ITP.</p> <p>***** Standardizing and Re-standardizing of ITP Personnel in the Food Code.</p>						

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 under processing With potential microbiological hazards. Medical foods are identified as "high risk" foods under the Center's Food Safety Initiatives. Additional resources have been budgeted to allow annual inspections and sample collections from medical foods firms. Inspections of foreign manufacturers of medical foods are planned under PAC 03R833. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from These imported lots.	
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food Security issues are to be covered during all inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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 5.1			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL CHEM	4 DOMESTIC SAMPLE COLL MICRO	5 IMPORT SAMPLE COLL **	7 DSAs MICRO	7 DSAs CHEM	8 ISAs CHEM ***	8
	TOTAL FIELD	27	54	(32)	(22)	8	12	34	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		810	281			40	360	3400	800	
CONVERSION FACTOR		930	930			930	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.87	0.30			0.04	0.31	2.88	0.68	

7. REMARKS

CFSAN spreads inspections and DSCs.

ORA spreads import operations.

* Includes an estimated 15% overage to allow for compliance follow-up inspections

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

***May be used for microbiological analysis.

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis And General Food Labeling Program	2. PPS PROJECT NAME/NUMBER Food Composition Standards Labeling and Economics - 21
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

6. FIELD OBLIGATIONS
District will review import and domestic product labels for NLEA compliance and other mandatory label requirements by conducting field exams. Districts will collect "violative" labels for review by the district's compliance branch. Physical samples will be collected for lab analyses as follows: (1) compliance samples that do not appear to qualify for labeled health or nutrient content claims (see C.P. Area of Emphasis #2); and (2) surveillance samples collected for general nutrient analyses (see C.P. Area of Emphasis #6).

Domestic Field Exams and sample collections to be conducted during inspections under the following compliance programs: 7303.803, 7303.803A, 7303.037, 7303.842 and 7303.847.
For FY 05 and beyond all import field exams are routinely include: verification that the imported product is the same as that which was Declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity signs of intentional adulteration, etc.) and traditional safety concerns. These activities are to be reported as single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined for cause CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should and additional exam and Time be reported under the CT PAC (03R845, 04R845,etc). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

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

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

b. INSPECTION TYPE: NA COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) All food Products (except vitamins/minerals)	d. INDUSTRY/PRODUCT CODE(S) 20-41
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES
All food products (except vitamins/minerals)

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

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21																	
3. PROGRAM/ASSIGNMENT CODE(S) 21005, 03R833, 99R833 21R824, 21R829(Health Fraud)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 9.4												
REGION	DISTRICT/SPECIALIZED LABORATORY	DSC	DSCs (DOCUMENTARY)	DSCs (PHYSICAL)	DSAs	DOMESTIC FIELD EXAMS	ISCs (PHYSICAL) OASIS #61 (SEE REMARKS)	ISAs	IMPORT FIELD EXAMS (SEE REMARKS)	ISCs (PAPER) OASIS #41 (SEE REMARKS)									
	TOTAL FIELD	340	(240)	(100)	100	4000	125	125	4450	785									
NE	HEADQUARTERS	(b)(2)&b(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
CE	WEAC																		
	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
SE	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 OPERATION																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY - SW																		
	PACIFIC REGIONAL LABORATORY - NW																		
	HOURS PER OPERATION										4.2			18.0	0.4	1.2	10.0	0.5	1.2
	TOTAL HOURS										1428			1800	1600	150	1250	2225	942
	CONVERSION FACTOR										930			1180	930	930	1180	930	930
	TOTAL OPERATIONAL FTEs										1.54			1.53	1.72	0.16	1.06	2.39	1.01

7. REMARKS

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

**Domestic operations to be conducted during inspections conducted under CP 7303.803,7303.803A,7303.037 and 7303.843.

***Import Field Exams are time spent reviewing import labels that do not result in Import Sample Collection.

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

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

For FY05 and beyond all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc); and safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under CT PAC (03R845, 04R845, etc.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

1. PROGRAM/ASSIGNMENT TITLE 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 imports lots of infant Formula from unregistered foreign manufacturers in plan under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots. Food security issues are to be covered during all inspections.	
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples. Atlanta Center for Nutrient Analysis (ACNA) will perform nutrient analyses and label reviews. Southeast Regional Laboratory, Microbiology Branch will perform microbiological analyses. Resources are set aside in FY 05 for a special field assignment to investigate ethnic retail establishments for counterfeit, diverted, or unregistered infant formulas. Food security issues (see IOM) are to be covered during all inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <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						
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 6.3			
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		50	(21)	(31)	21	31	15	15
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
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-									
	PACIFIC REGIONAL LABORTORY-									
	HOURS PER OPERATION	37.0		5.3			100.0	30.0	5.0	100.0
	TOTAL HOURS	888		276			2100	930	75	1500
	CONVERSION FACTOR	930		930			1180	1180	930	1180
	TOTAL OPERATIONAL FTEs	0.95		0.28			1.78	0.79	0.08	1.27

7. REMARKS

ORA spreads import operations
 * Includes an estimated 15% overage to allow for compliance follow-up inspections and food security during all inspections
 Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819)
 *** May also be used for microbiological analysis
 Numbers in parenthesis are included in DSCs

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1. PROGRAM/ASSIGNMENT TITLE Infant Formula Program			2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21								
3. PROGRAM/ASSIGNMENT CODE(S) 21006		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS						
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-										
	PACIFIC REGIONAL LABORTORY-										
	HOURS PER OPERATION					5.3	100.0				
	TOTAL HOURS				200	53	1000				
	CONVERSION FACTOR				930	930	1180				
	TOTAL OPERATIONAL FTEs				0.22	0.06	0.85				

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

1. PROGRAM/ASSIGNMENT TITLE 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 supplements must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these requirements will be determined by domestic and import field exams and documentary sample collections.	
5. PROGRAM JUSTIFICATION Dietary supplements are a special class of products consisting of such dietary ingredients as vitamins, minerals, amino acids, glandulars, herbs and other botanicals. These products are subject to specific safety and labeling requirements. This program provides guidance to FDA district offices regarding inspections, import investigations, sample collection and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994. The Center has set aside resources for special headquarters initiated assignments to address emerging issues. Specifically, the Center plans to issue a special assignment to target domestic and import glandular products for Microbiological analyses. In addition, investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on their labels and supplements being marketed with claims to treat diseases. Food security issues are to be covered during all inspections.	
6. FIELD OBLIGATIONS Field obligations include inspections, domestic and import investigations, sample collections and analyses of dietary ingredients in dietary supplements.	
7a. SELECTION OF ESTABLISHMENTS TO BE <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) Dietary supplements	d. INDUSTRY/PRODUCT CODE(S) 54
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 Analyze selected nutrients and compare with levels declared on product label. Analyze botanicals as directed for microbiological Contamination.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.	

1. PROGRAM/ASSIGNMENT TITLE 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 checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 19.5 (16.5)						
R E G I O N	b- DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	FIELD EX A M S	DOMESTIC S A M P L E C O L L	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	HQ I N T D O M E S T I C S A M P L E C O L L	HQ I N T D O M E S T I C S A M P L E A N A L Y Z E D C H E M				I N V H O U R S
		TOTAL FIELD	250	900	200	100	175	175			
NE	HEADQUARTERS	(b)(2)&b(7)(E)									(b)(2)
	REGIONAL STAFF	(b)(2)&b(7)(E)									&b(7)
	NEW ENGLAND	(b)(2)&b(7)(E)									(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)									
SE	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)									
SW	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)									
PA	REGIONAL LAB	(b)(2)&b(7)(E)									
	REGIONAL STAFF	(b)(2)&b(7)(E)									
	DALLAS	(b)(2)&b(7)(E)									
	DENVER	(b)(2)&b(7)(E)									
	KANSAS CITY	(b)(2)&b(7)(E)									
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)									
	REGIONAL LAB	(b)(2)&b(7)(E)									
	REGIONAL STAFF	(b)(2)&b(7)(E)									
	LOS ANGELES	(b)(2)&b(7)(E)									
	SAN FRANCISCO	(b)(2)&b(7)(E)									
	SEATTLE	(b)(2)&b(7)(E)									
	PACIFIC REGIONAL LABORTORY-SW	(b)(2)&b(7)(E)									
	PACIFIC REGIONAL LABORTORY-NW	(b)(2)&b(7)(E)									
HOURS PER OPERATION		18.0	0.6	4.2	20.0	4.2	20.0				
TOTAL HOURS		4500	450	840	2000	735	3500				4500
CONVERSION FACTOR		930	930	930	1180	930	1180				930
TOTAL OPERATIONAL FTEs		4.84	0.48	0.90	1.69	0.79	2.97				4.84

7. REMARKS

ORA spreads import Operations. CFSAN spreads the remaining operations.

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

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

Investigational hours are planned primarily for CFSAN directed assignments.

*Includes resources for a special assignment to target domestic and import animal glandulars for micro contamination.

Import resources planned in page 2.

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1. PROGRAM/ASSIGNMENT TITLE 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 (3.0)													
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	I S C P A P E R O A S I S #	I S C P H Y S I C A L	I M P O R T F I E L D E X A M	I S A P H Y S I C A L C H E M														
	TOTAL FIELD	360	70	1800	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																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB																			
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
REGIONAL LAB																			
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORTORY-SW																		
PACIFIC REGIONAL LABORTORY-NW																			
HOURS PER OPERATION											1.6	1.6	0.5	20.0					
TOTAL HOURS											576	112	900	1400					
CONVERSION FACTOR											930	930	930	1180					
TOTAL OPERATIONAL FTEs											0.62	0.12	0.97	1.19					
7. REMARKS Includes resources for a special assignment to target domestic and import botanicals for micro, contamination. *Time spent reviewing import labels that does not result in an import sample collection. **Time spent collecting labels, records, or other documentation for submission to Compliance. Does not include time spent reviewing the import labels. Time spent reviewing the label will be included as OASIS # 27 and reported along with compliance review time as OASIS #43. ***Physical samples collected and forwarded to the laboratory for analyses to support violations. For FY 05 and beyond, all import field exams are to routinely include verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concern related to labeling and source country (including container integrity, signs of intention adulteration, etc.); and traditional safety concerns. These activities are reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event suspicious are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845,04R845, etc.) See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.																			

1. PROGRAM/ASSIGNMENT TITLE 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,manganese,nickel,potassium,sodium,iodine,water and folate.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See TDS Compliance Program	

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 Cosmetics; Domestic and Import	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine by inspection, sample collection and label exam if domestic cosmetic manufacturing of repacking establishments and cosmetics offered for importation comply with regulations enforced by the Food and Drug Administration. To initiate corrective action when violations of the FD&C Act are identified.	
5. PROGRAM JUSTIFICATION Both domestically manufactured and imported cosmetic products must be: (1) safe under intended conditions of use, (2) properly labeled and (3) not otherwise adulterated or misbranded under the provisions of the Act. Major safety concerns associated with cosmetic involve microbial contamination of eye-area products and the use of non-approved color additives. Many cosmetic violations also involve products which fail to comply with the labeling regulations of 21 CFR701. Resources are set aside for assignments to address cosmetics making drug claims on their labels. The Center will issue assignments for special investigations and documentary sample collections as products are identified.	
6. FIELD OBLIGATIONS Districts will perform inspections and conduct import field exams, collect and analyze samples for non-permitted ingredients, conduct microbiological analyses, and perform evaluations for labeling compliance. Food security issues (see IOM) are to be covered during all Inspections.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Cosmetic Products	d. INDUSTRY/PRODUCT CODE(S) 53
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Specify</i>) Label Review	
f. CHECK THE FOLLOWING ATTRIBUTES Non-permitted ingredients(including color additives), microbiological/contaminants, labeling warnings.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

3. PROGRAM/ASSIGNMENT CODE(S) 29001,29R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REV HOURS 29R833 *	IMPORT LABEL EXAMS	IMPORT SAMPLE COLLECTIONS	IMPORT SAMPLE ANALYSIS (CHEM)	IMPORT SAMPLE ANALYSIS (MICRO)	DOMESTIC INSPECTION	DOMESTIC SAMPLE COLL **	DOMESTIC SAMPLE ANALYSIS (MICRO)	INVESTI- GATIONAL HOURS ***																																																						
	TOTAL FIELD	700	700	200	100	100	100	100	75	350																																																						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																																																														
	REGIONAL STAFF																																																															
	NEW ENGLAND																																																															
	NEW YORK																																																															
	REGIONAL LAB																																																															
WEAC																																																																
CE	REGIONAL STAFF										(b)(2) & (b)(7)(E)																																																					
	BALTIMORE																																																															
	CHICAGO																																																															
	CINCINNATI																																																															
	DETROIT																																																															
	MINNEAPOLIS																																																															
	NEW JERSEY																																																															
	PHILADELPHIA																																																															
	FORENSIC CHEM. CTR																																																															
	S																			REGIONAL STAFF	(b)(2) & (b)(7)(E)																																											
ATLANTA																																																																
FLORIDA																																																																
NEW ORLEANS																																																																
SAN JUAN																																																																
M	REGIONAL STAFF																			(b)(2) & (b)(7)(E)																																												
	DALLAS																																																															
	DENVER																																																															
	KANSAS CITY																																																															
	SOUTHWEST IMPORT DISTRICT																																																															
W	REGIONAL LAB																													(b)(2) & (b)(7)(E)																																		
	REGIONAL STAFF																																																															
	LOS ANGELES																																																															
	SAN FRANCISCO																																																															
	SEATTLE																																																															
PA	PACIFIC REGIONAL LABORTORY-SW																																						(b)(2) & (b)(7)(E)																									
	PACIFIC REGIONAL LABORTORY-NW																																																															
HOURS PER OPERATION																																																	0.40	1.5	10.0	21.2	18.2	5.5	21.2									
TOTAL HOURS																																																700	280	300	1000	2120	1820	550	1590	350								
CONVERSION FACTOR																																																1200	930	930	1180	1180	930	930	1180	930								
TOTAL OPERATIONAL FTEs																																																0.58	0.30	0.32	0.85	1.80	1.96	0.59	1.35	0.38								

7. REMARKS

*Filer evaluation hours (99R833) and Follow-up to Refusal (29R824) are included in Entry Review Hours.
 ** Includes resources for approximately 25 samples for special assignment to cover drug claims on cosmetics.
 *** Time set aside for special assignment to cover drug claims on cosmetics.

For FY 05 and beyond all import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the even of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc). See IOM Section 530.04 for additional information on Food and Cosmetic Defense Activities.

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2005**

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

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

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

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

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 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 thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

6. FIELD OBLIGATIONS

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

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

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

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE 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	74								
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		91.0								
TOTAL HOURS		6734								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTES		7.40								

9. REMARKS

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

Inspections spread by Biologics Field Committee.

Personnel Types Required: Investigator

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	1177		4787	24			2275		
NE	HEADQUARTERS	(b)(2)&b(7)		(b)(2)&b(7)(E)				(b)(2)&b(7)		
	REGIONAL STAFF	(E)						(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									
HOURS PER OPERATION		40.0			37.9					
TOTAL HOURS		47080		4787	910			2275		
CONVERSION FACTOR		910		910	910			910		
TOTAL OPERATIONAL FTEs		51.74		5.26	1.00			2.50		

7. REMARKS

* All listed resources are planned under PAC 42001F. Resources cover all facilities listed in current compliance program. Pre-License Inspections are not planned separately. Use above resources for any Pre-License Inspections in PPS 41, 42, 45 as needed, at district discretion.
Domestic Inspectional Module Includes Time for AIDS.
Blood Bank PAC's: 42001F, Level 1 Inspection and 42001G, Level 2 Inspection.
Use Operation Code 11 for all Foreign Inspections.

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

Personnel Types Required: Investigator, National Experts

1. PROGRAM/ASSIGNMENT TITLE
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 11.4					
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		193	1432								
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		46.4										
TOTAL HOURS		8955	1432									
CONVERSION FACTOR		910	910									
TOTAL OPERATION FTEs		9.84	1.57									

7. REMARKS

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

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

Personnel Types Required: Investigator, Team Biologics

1. PROGRAM/ASSIGNMENT TITLE Examination of Blood and Blood Components Offered for Import	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Blood and Blood Components	d. INDUSTRY/PRODUCT CODE(S) 57
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Examination of Blood and Blood Components 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	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 42R833 IMPORT ENTRY REVIEW HOURS	3 DOMESTIC INVESTI- GATIONS (Hours)	4 IMPORT INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	TOTAL FIELD		4800								
NE	HEADQUARTERS		(b)(2)&b (7)(E)								
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - NW										
	PACIFIC REGIONAL LAB - SW										
	HOURS PER OPERATION										
	TOTAL HOURS		4800								
	CONVERSION FACTOR		1200								
	TOTAL OPERATION FTES		4.00								

9. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE
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																																																			
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																																																	
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	13	3	216																																																			
NE	HEADQUARTERS	(b)(2)&b(7)(E)																																																					
	REGIONAL STAFF																																																						
	NEW ENGLAND																																																						
	NEW YORK																																																						
	REGIONAL LAB																																																						
WEAC																																																							
CE	REGIONAL STAFF										(b)(2)&b(7)(E)																																												
	BALTIMORE																																																						
	CHICAGO																																																						
	CINCINNATI																																																						
	DETROIT																																																						
	MINNEAPOLIS																																																						
	NEW JERSEY																																																						
	PHILADELPHIA																																																						
SE	FORENSIC CHEM. CTR																			(b)(2)&b(7)(E)																																			
	REGIONAL STAFF																																																						
	ATLANTA																																																						
	FLORIDA																																																						
	NEW ORLEANS																																																						
SAN JUAN																																																							
REGIONAL LAB																																																							
SW	REGIONAL STAFF																												(b)(2)&b(7)(E)																										
	DALLAS																																																						
	DENVER																																																						
	KANSAS CITY																																																						
	SOUTHWEST IMPORT DISTRICT																																																						
REGIONAL LAB																																																							
PA	REGIONAL STAFF																																					(b)(2)&b(7)(E)																	
	LOS ANGELES																																																						
	SAN FRANCISCO																																																						
	SEATTLE																																																						
	PACIFIC REGIONAL LAB - SW																																																						
PACIFIC REGIONAL LAB - NW																																																							
HOURS PER OPERATION																																															160.0	145.0							
TOTAL HOURS																																															2080	435	216						
CONVERSION FACTOR																																															910	910	910						
TOTAL OPERATIONAL FTEs																																															2.29	0.48	0.24						

7. REMARKS

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

Field hours spread by Biologics Field Committee.

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE
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 thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Biologics

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

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)
NEW 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 2.5					
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	45									
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		50.6									
TOTAL HOURS		2277									
CONVERSION FACTOR		910									
TOTAL OPERATIONAL FTEs		2.50									

7. REMARKS

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

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

Personnel Types Required: Investigator

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

1. PROGRAM/ASSIGNMENT TITLE 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 SPECIALIZED	1 INSP EC T I O N S *	2 INVE ST I G A T I O N S (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	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (H O U R S)	
	TOTAL FIELD		33								
N E	HEADQUARTERS	(b)(2)&b(7) (E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
C E	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										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT OPERATION										
P A	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION		82.7									
TOTAL HOURS		2729									
CONVERSION FACTOR		910									
TOTAL OPERATIONAL FTEs		3.00									

7. REMARKS

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

Inspections spread by Biologics Field Committee.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE
Inspection of Licensed Allergenic Products
NEW 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 INSP CTIONS	FOREIGN INSP CTIONS	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		131.8	85.0							
TOTAL HOURS		923	170							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		1.01	0.19							

7. REMARKS

* NEW PACs - NEW Compliance Program - Inspection of Biological Drug Products (CBER):
 (Previously covered by PAC 45001):
 PAC 45848A Pre-License Inspection - 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.

Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products NEW 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 INSPEC- TIONS	1 FOREIGN INSPEC- TIONS	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	10	5	477						
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
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		227.0	180.0							
TOTAL HOURS		2270	900	477						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		2.49	0.99	0.52						

7. REMARKS

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

Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator, Core Team Biologics

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

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

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

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

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

FY 2005

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 2005

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	

FY 2005

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	

FY2005 ORA WORKPLAN

February 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 **	1 INSPEC- TIONS AIDS RELIEF ++FOREIGN	4 IMPORT SAMPLE COLL ***	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES ANALYSES PROFILE (CHEM) ****	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	158	2788	15	50			50	
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								
SW	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		55.0		60.0	3.0			30.0	
TOTAL HOURS		8690	2788	900	150			1500	
CONVERSION FACTOR		910	910	910	910			1180	
TOTAL OPERATIONAL FTEs		9.55	3.06	0.99	0.16			1.27	

7. REMARKS
 * Report as follows: Insp./Chem on Insp. under foreign operation code 11 Pac Code 46832;
 M. Valid -46832; Profile ISC & ISAs -46832B; Biotest ISC & 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).

FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Not Covered by Approved NDAs				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52						
3. PROGRAM/ASSIGNMENT CODE(S) 52002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVEST- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL. *	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	TOTAL FIELD	109	1232	100						
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		30.0		5.0						
TOTAL HOURS		3270	1232	500						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		3.59	1.35	0.55						

7. REMARKS

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

FY 2005

1. PROGRAM/ASSIGNMENT TITLE 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 2005

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	

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Inv. Methods Validation - Domestic	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 24.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	3	7	7	7	9
		ANDAs TO INSPECT Domestic	CHEMIST INSPECT. (Hours) *	DOMESTIC INVEST (Hours)	DOMESTIC SAMPLE COLL **	PROFILE/ PORTION OF DSCs FOR DDA **	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	BIOTEST (Chem) ***	DSAs (METH) (VALID) (Chem) (Hours)	MISC. HOURS
	TOTAL FIELD	176	1931	1590	140	(50)	45	45	50	

	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	NEW ENGLAND	(b)(2)&b(7)(E)								
	NEW YORK	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	WEAC	(b)(2)&b(7)(E)								
CE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	BALTIMORE	(b)(2)&b(7)(E)								
	CHICAGO	(b)(2)&b(7)(E)								
	CINCINNATI	(b)(2)&b(7)(E)								
	DETROIT	(b)(2)&b(7)(E)								
	MINNEAPOLIS	(b)(2)&b(7)(E)								
	NEW JERSEY	(b)(2)&b(7)(E)								
	PHILADELPHIA	(b)(2)&b(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&b(7)(E)								
SE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	ATLANTA	(b)(2)&b(7)(E)								
	FLORIDA	(b)(2)&b(7)(E)								
	NEW ORLEANS	(b)(2)&b(7)(E)								
	SAN JUAN	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
SW	REGIONAL STAFF	(b)(2)&b(7)(E)								
	DALLAS	(b)(2)&b(7)(E)								
	DENVER	(b)(2)&b(7)(E)								
	KANSAS CITY	(b)(2)&b(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
PA	REGIONAL STAFF	(b)(2)&b(7)(E)								
	LOS ANGELES	(b)(2)&b(7)(E)								
	SAN FRANCISCO	(b)(2)&b(7)(E)								
	SEATTLE	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LAB - NW	(b)(2)&b(7)(E)								
	HOURS PER OPERATION	65.0			5.0		50.0	30.0	105.0	
	TOTAL HOURS	11440	1931	1590	700		2250	1350	5250	
	CONVERSION FACTOR	910	910	910	910		1180	1180	1180	
	TOTAL OPERATIONAL FTEs	12.57	2.12	1.75	0.77		1.91	1.14	4.45	

7. REMARKS

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

FY 2005

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

ANDA Pre - Approval Inspections/Investigations (Methods Validation) - Foreign				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52							
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B, 52832C, 52832E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.1				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	5	6	8	8	8	
		INSP. TIONS (Foreign) *	CHEMIST INSP. (Hours) (Foreign) **	INVEST. HRS	INSP. TIONS AIDS RELIEF ++FOREIGN	IMPORT SAMPLE COLL ***	IMPORT FIELD EXAMS	IMPORT SAMPLE ANALYSES (Chem) ****	IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****	IMPORT SAMPLE ANALYSES METH. VALID. ****	
	TOTAL FIELD	46	2095	1083	31	140		70	70	15	
	HEADQUARTERS	(b)(2)&b(7)(E)							(b)(2)&b(7)(E)		
NE	REGIONAL STAFF	(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 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 REGIONAL LAB	(b)(2)&b(7)(E)							(b)(2)&b(7)(E)		
SW	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)		
	Southwest Import District REGIONAL LAB	(b)(2)&b(7)(E)							(b)(2)&b(7)(E)		
PA	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 LAB - SW PACIFIC REGIONAL LAB - NW	(b)(2)&b(7)(E)							(b)(2)&b(7)(E)		
HOURS PER OPERATION		55.0			60.0	3.0		30.0	15.0	50.0	
TOTAL HOURS		2530	2095	1083	1860	420		2100	1050	750	
CONVERSION FACTOR		910	910	910	910	910		1180	1180	1180	
TOTAL OPERATIONAL FTEs		2.78	2.30	1.19	2.04	0.46		1.78	0.89	0.64	

7. REMARKS

* Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;
Meth. Valid. under PAC 52832; Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C.
** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers.
**** NRL analyzes all Profile/Biotest ISCs and methods Validation ISAs.
Use CT PAC 52R845 only when specific CT work is performed.

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

FY 2005

<p>1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project</p>	<p>2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation-52</p>
<p>3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.</p>	
<p>5. PROGRAM JUSTIFICATION Research</p>	
<p>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.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S)</p>	<p>d. INDUSTRY/PRODUCT CODE(S)</p>
<p>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>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS								
	TOTAL FIELD	1250								
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									
PA	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
TOTAL HOURS	1250									
CONVERSION FACTOR	1205									
TOTAL OPERATIONAL FTEs	1.04									

7. REMARKS

FY 2005

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