WORKPLAN SUMMARY / POSITION CLASS (SE E RESEARCH RESOURCES)
FY 2001

Output Reflec : OPR FTE'S

DISTRICT: PRL-NW

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	21.46	14.50	0.00	3.43	7.00	46.39	54826.00
FOOD SAFETY/COS	0.00	10.36	14.50	0.00	3.43	6.00	34.29	40552.40
03	0.00	3.42	13.98	0.00	3.06	4.00	24.46	28942.70
04	0.00	5.51	0.40	0.00	0.00	0.00	5.91	6972.50
07	0.00	1.43	0.00	0.00	0.37	1.00	2.80	3320.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.12	0.00	0.00	0.00	0.12	137.20
21	0.00	0.00	0.00	0.00	0.00	1.00	1.00	1180.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	9.15	0.00	0.00	0.00	0.00	9.15	10788.00
46	0.00	2.32	0.00	0.00	0.00	0.00	2.32	2740.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	1.47	0.00	0.00	0.00	0.00	1.47	1730.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	5.19	0.00	0.00	0.00	0.00	5.19	6122.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.17	0.00	0.00	0.00	0.00	0.17	196.00
ANIMAL D & F	0.00	1.95	0.00	0.00	0.00	1.00	2.95	3485.60
68	0.00	0.30	0.00	0.00	0.00	0.00	0.30	359.80
71	0.00	1.65	0.00	0.00	0.00	1.00	2.65	3125.80
DEVICES & RAD H	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (SEPARATE RESEARCH RESOURCES)
FY 2001

Output Reflects: OPR FTE'S

REGION: PA REGN

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	214.31	55.63	56.10	0.00	7.03	7.00	340.07	355921.80
FOOD SAFETY/COS	122.47	36.95	55.34	0.00	7.03	6.00	227.79	243929.10
03	92.50	12.31	54.18	0.00	6.16	4.00	169.15	178928.80
04	5.46	22.20	0.40	0.00	0.00	0.00	28.06	31742.20
07	1.67	1.43	0.00	0.00	0.87	1.00	4.97	5473.60
09	0.38	1.01	0.00	0.00	0.00	0.00	1.39	1535.90
18	19.68	0.00	0.12	0.00	0.00	0.00	19.80	21671.00
21	1.99	0.00	0.00	0.00	0.00	1.00	2.99	3026.90
29	0.79	0.00	0.64	0.00	0.00	0.00	1.43	1550.70
BIOLOGICS	19.01	0.00	0.00	0.00	0.00	0.00	19.01	17519.70
41	4.14	0.00	0.00	0.00	0.00	0.00	4.14	3764.00
42	14.23	0.00	0.00	0.00	0.00	0.00	14.23	13172.00
45	0.64	0.00	0.00	0.00	0.00	0.00	0.64	583.70
HUMAN DRUGS	28.33	12.31	0.51	0.00	0.00	0.00	41.15	41253.80
46	2.45	2.59	0.00	0.00	0.00	0.00	5.04	5290.00
48	8.40	0.00	0.00	0.00	0.00	0.00	8.40	7631.90
52	1.84	2.36	0.00	0.00	0.00	0.00	4.20	4466.00
53	0.77	0.00	0.00	0.00	0.00	0.00	0.77	705.00
56	13.04	7.19	0.51	0.00	0.00	0.00	20.74	21295.90
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.83	0.17	0.00	0.00	0.00	0.00	2.00	1865.00
ANIMAL D & F	7.47	2.38	0.25	0.00	0.00	1.00	11.10	11842.90
68	0.97	0.30	0.00	0.00	0.00	0.00	1.27	1322.40
71	6.50	2.08	0.25	0.00	0.00	1.00	9.83	10520.50
DEVICES & RAD H	37.03	3.99	0.00	0.00	0.00	0.00	41.02	41376.30
81	0.59	0.00	0.00	0.00	0.00	0.00	0.59	552.70
82	19.58	3.99	0.00	0.00	0.00	0.00	23.57	23609.00
83	7.70	0.00	0.00	0.00	0.00	0.00	7.70	7315.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.32	0.00	0.00	0.00	0.00	0.00	3.32	3853.00
86	5.84	0.00	0.00	0.00	0.00	0.00	5.84	6046.60

WORKPLAN SUMMARY / POSITION CLASS (SE E RESEARCH RESOURCES)
FY 2001

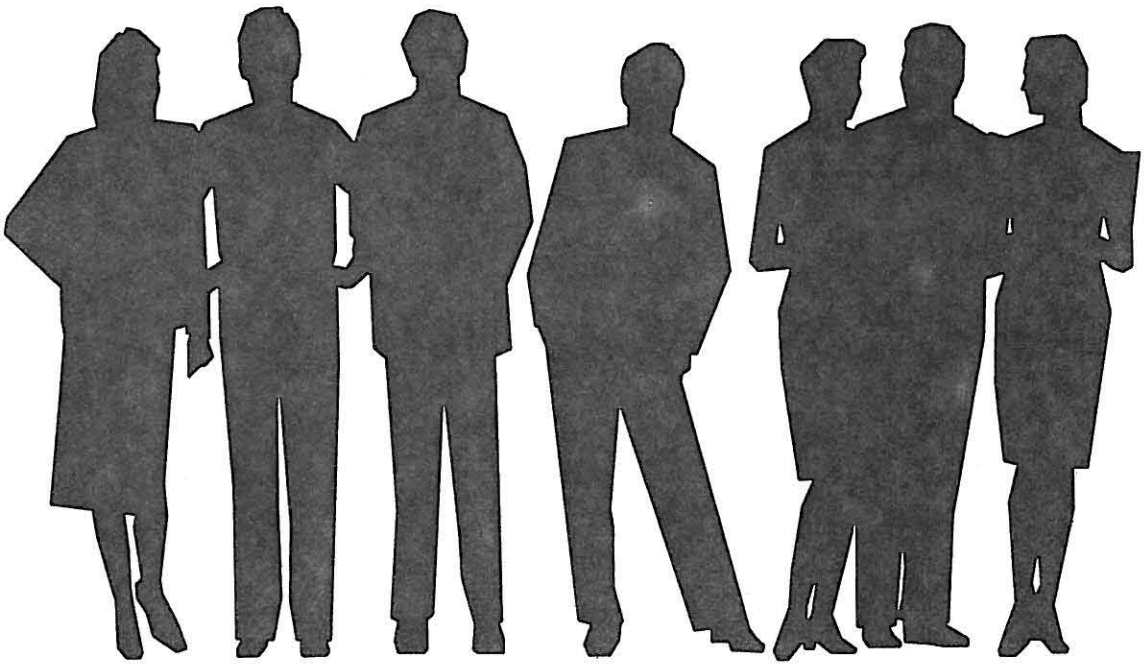
Output Refle. .: OPR FTE'S

TOTAL FIELD

Lapsed

	INVEST	ANALYTICAL CHEM	ANALYTICAL MICRO	ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	1085.29	286.10	173.23	15.80	29.44	21.00	1610.86	1671437.00
FOOD SAFETY/COS	514.70	149.67	155.33	0.00	15.99	14.00	849.69	902992.60
03	380.29	32.37	149.05	0.00	12.99	4.00	578.70	598419.50
04	21.25	85.89	1.19	0.00	1.29	5.00	114.62	130222.00
07	8.67	12.49	0.00	0.00	1.29	4.00	26.45	29070.00
09	1.88	5.12	0.00	0.00	0.00	0.00	7.00	7797.00
18	90.52	0.00	0.43	0.00	0.00	0.00	90.95	102658.40
21	8.61	13.80	1.68	0.00	0.42	1.00	25.51	27930.70
29	3.48	0.00	2.98	0.00	0.00	0.00	6.46	6895.00
BIOLOGICS	120.96	0.00	0.00	0.00	0.50	0.00	121.46	111411.20
41	21.00	0.00	0.00	0.00	0.00	0.00	21.00	19102.00
42	88.83	0.00	0.00	0.00	0.50	0.00	89.33	82168.90
45	11.13	0.00	0.00	0.00	0.00	0.00	11.13	10140.30
HUMAN DRUGS	235.09	112.52	4.49	0.00	5.31	0.00	357.41	361954.50
46	26.55	29.21	0.53	0.00	0.00	0.00	56.29	59265.00
48	54.22	0.00	0.00	0.00	0.00	0.00	54.22	49325.50
52	20.53	26.99	0.09	0.00	0.42	0.00	48.03	51126.00
53	7.97	0.00	0.00	0.00	0.00	0.00	7.97	7275.00
56	112.95	55.66	3.87	0.00	4.89	0.00	177.37	182469.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	12.87	0.66	0.00	0.00	0.00	0.00	13.53	12494.00
ANIMAL D & F	45.45	13.89	4.88	0.00	1.00	5.00	70.22	74925.60
68	11.05	2.38	0.00	0.00	0.00	0.00	13.43	13852.00
71	34.40	11.51	4.88	0.00	1.00	5.00	56.79	61073.60
DEVICES & RAD H	169.09	10.02	8.53	15.80	6.64	2.00	212.08	220153.10
81	1.68	0.15	0.07	0.16	0.00	0.00	2.06	2025.40
82	90.64	9.31	6.69	5.92	6.22	0.59	119.37	122382.90
83	29.92	0.00	0.00	0.00	0.00	0.00	29.92	28429.00
84	0.00	0.56	1.77	3.68	0.42	1.41	7.84	9237.00
85	21.82	0.00	0.00	0.00	0.00	0.00	21.82	25292.00
86	25.03	0.00	0.00	6.04	0.00	0.00	31.07	32786.80

PART II
WORKPLAN SUMMARY



POSITION CLASS

COMBINED ANALYTICAL & DISTRICT RESEARCH

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: HDQTRS

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	33.51	0.00	0.00	0.00	0.00	0.00	33.51	30789.30
FOOD SAFETY/COS	4.00	0.00	0.00	0.00	0.00	0.00	4.00	3720.00
03	4.00	0.00	0.00	0.00	0.00	0.00	4.00	3720.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	20.77	0.00	0.00	0.00	0.00	0.00	20.77	18905.40
41	3.50	0.00	0.00	0.00	0.00	0.00	3.50	3185.00
42	10.52	0.00	0.00	0.00	0.00	0.00	10.52	9576.90
45	6.75	0.00	0.00	0.00	0.00	0.00	6.75	6143.50
HUMAN DRUGS	4.34	0.00	0.00	0.00	0.00	0.00	4.34	3953.70
46	0.97	0.00	0.00	0.00	0.00	0.00	0.97	880.00
48	1.49	0.00	0.00	0.00	0.00	0.00	1.49	1358.70
52	0.42	0.00	0.00	0.00	0.00	0.00	0.42	385.00
53	0.26	0.00	0.00	0.00	0.00	0.00	0.26	240.00
56	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1090.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.57	0.00	0.00	0.00	0.00	0.00	0.57	568.00
68	0.04	0.00	0.00	0.00	0.00	0.00	0.04	40.00
71	0.53	0.00	0.00	0.00	0.00	0.00	0.53	528.00
DEVICES & RAD H	3.83	0.00	0.00	0.00	0.00	0.00	3.83	3642.20
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	3.83	0.00	0.00	0.00	0.00	0.00	3.83	3642.20
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec . OPR FTE'S

REGION: HDQTRS

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	33.51	0.00	0.00	0.00	0.00	0.00	33.51	30789.30
FOOD SAFETY/COS	4.00	0.00	0.00	0.00	0.00	0.00	4.00	3720.00
03	4.00	0.00	0.00	0.00	0.00	0.00	4.00	3720.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	20.77	0.00	0.00	0.00	0.00	0.00	20.77	18905.40
41	3.50	0.00	0.00	0.00	0.00	0.00	3.50	3185.00
42	10.52	0.00	0.00	0.00	0.00	0.00	10.52	9576.90
45	6.75	0.00	0.00	0.00	0.00	0.00	6.75	6143.50
HUMAN DRUGS	4.34	0.00	0.00	0.00	0.00	0.00	4.34	3953.70
46	0.97	0.00	0.00	0.00	0.00	0.00	0.97	880.00
48	1.49	0.00	0.00	0.00	0.00	0.00	1.49	1358.70
52	0.42	0.00	0.00	0.00	0.00	0.00	0.42	385.00
53	0.26	0.00	0.00	0.00	0.00	0.00	0.26	240.00
56	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1090.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.57	0.00	0.00	0.00	0.00	0.00	0.57	568.00
68	0.04	0.00	0.00	0.00	0.00	0.00	0.04	40.00
71	0.53	0.00	0.00	0.00	0.00	0.00	0.53	528.00
DEVICES & RAD H	3.83	0.00	0.00	0.00	0.00	0.00	3.83	3642.20
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	3.83	0.00	0.00	0.00	0.00	0.00	3.83	3642.20
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: NE RO

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	12.60	0.00	0.00	0.00	0.00	0.00	12.60	14967.50
FOOD SAFETY/COS	10.96	0.00	0.00	0.00	0.00	0.00	10.96	13158.00
03	0.10	0.00	0.00	0.00	0.00	0.00	0.10	120.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	10.86	0.00	0.00	0.00	0.00	0.00	10.86	13038.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
DEVICES & RAD H	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50

WORKPLAN SUMMARY / POSITION CLASS (COMP ANAL & DISTR RESEARCH)
FY 2001

Output Refle : OPR FTE'S

DISTRICT: NWE

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	57.57	0.00	0.00	0.00	0.00	0.00	57.57	54494.00
FOOD SAFETY/COS	28.47	0.00	0.00	0.00	0.00	0.00	28.47	26833.80
03	25.47	0.00	0.00	0.00	0.00	0.00	25.47	24043.40
04	0.88	0.00	0.00	0.00	0.00	0.00	0.88	817.70
07	0.27	0.00	0.00	0.00	0.00	0.00	0.27	252.80
09	0.08	0.00	0.00	0.00	0.00	0.00	0.08	72.10
18	1.27	0.00	0.00	0.00	0.00	0.00	1.27	1182.80
21	0.29	0.00	0.00	0.00	0.00	0.00	0.29	270.80
29	0.21	0.00	0.00	0.00	0.00	0.00	0.21	194.20
BIOLOGICS	4.93	0.00	0.00	0.00	0.00	0.00	4.93	4513.00
41	0.53	0.00	0.00	0.00	0.00	0.00	0.53	481.60
42	3.68	0.00	0.00	0.00	0.00	0.00	3.68	3373.40
45	0.72	0.00	0.00	0.00	0.00	0.00	0.72	658.00
HUMAN DRUGS	11.14	0.00	0.00	0.00	0.00	0.00	11.14	10238.70
46	1.51	0.00	0.00	0.00	0.00	0.00	1.51	1374.00
48	2.81	0.00	0.00	0.00	0.00	0.00	2.81	2560.70
52	0.77	0.00	0.00	0.00	0.00	0.00	0.77	704.00
53	0.48	0.00	0.00	0.00	0.00	0.00	0.48	435.00
56	4.91	0.00	0.00	0.00	0.00	0.00	4.91	4566.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.66	0.00	0.00	0.00	0.00	0.00	0.66	599.00
ANIMAL D & F	1.62	0.00	0.00	0.00	0.00	0.00	1.62	1632.30
68	0.37	0.00	0.00	0.00	0.00	0.00	0.37	367.00
71	1.25	0.00	0.00	0.00	0.00	0.00	1.25	1265.30
DEVICES & RAD H	11.41	0.00	0.00	0.00	0.00	0.00	11.41	11276.20
81	0.13	0.00	0.00	0.00	0.00	0.00	0.13	124.10
82	6.95	0.00	0.00	0.00	0.00	0.00	6.95	6661.80
83	1.96	0.00	0.00	0.00	0.00	0.00	1.96	1861.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.71	0.00	0.00	0.00	0.00	0.00	1.71	1982.00
86	0.66	0.00	0.00	0.00	0.00	0.00	0.66	647.30

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: NYK

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	76.70	0.00	0.00	0.00	0.00	0.00	76.70	75335.30
FOOD SAFETY/COS	36.25	0.00	0.00	0.00	0.00	0.00	36.25	35939.40
03	30.53	0.00	0.00	0.00	0.00	0.00	30.53	30590.20
04	1.90	0.00	0.00	0.00	0.00	0.00	1.90	1769.70
07	0.85	0.00	0.00	0.00	0.00	0.00	0.85	787.60
09	0.40	0.00	0.00	0.00	0.00	0.00	0.40	371.00
18	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1112.40
21	0.94	0.00	0.00	0.00	0.00	0.00	0.94	875.40
29	0.43	0.00	0.00	0.00	0.00	0.00	0.43	433.10
BIOLOGICS	5.30	0.00	0.00	0.00	0.00	0.00	5.30	4947.90
41	0.98	0.00	0.00	0.00	0.00	0.00	0.98	891.20
42	3.87	0.00	0.00	0.00	0.00	0.00	3.87	3648.80
45	0.45	0.00	0.00	0.00	0.00	0.00	0.45	407.90
HUMAN DRUGS	23.09	0.00	0.00	0.00	0.00	0.00	23.09	22045.80
46	2.28	0.00	0.00	0.00	0.00	0.00	2.28	2076.00
48	3.26	0.00	0.00	0.00	0.00	0.00	3.26	2971.50
52	2.66	0.00	0.00	0.00	0.00	0.00	2.66	2419.00
53	0.87	0.00	0.00	0.00	0.00	0.00	0.87	795.00
56	13.03	0.00	0.00	0.00	0.00	0.00	13.03	12880.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.99	0.00	0.00	0.00	0.00	0.00	0.99	904.00
ANIMAL D & F	2.96	0.00	0.00	0.00	0.00	0.00	2.96	3023.70
68	0.59	0.00	0.00	0.00	0.00	0.00	0.59	589.60
71	2.37	0.00	0.00	0.00	0.00	0.00	2.37	2434.10
DEVICES & RAD H	9.10	0.00	0.00	0.00	0.00	0.00	9.10	9378.50
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	38.10
82	5.58	0.00	0.00	0.00	0.00	0.00	5.58	5654.00
83	0.82	0.00	0.00	0.00	0.00	0.00	0.82	775.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.32	0.00	0.00	0.00	0.00	0.00	1.32	1527.00
86	1.34	0.00	0.00	0.00	0.00	0.00	1.34	1384.40

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec .. OPR FTE'S

DISTRICT: NRL

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.04	48.68	39.14	0.00	0.00	0.00	87.86	103867.80
FOOD SAFETY/COS	0.04	20.18	36.40	0.00	0.00	0.00	56.62	66922.00
03	0.00	8.02	35.11	0.00	0.00	0.00	43.13	50999.00
04	0.00	7.48	0.34	0.00	0.00	0.00	7.82	9226.70
07	0.00	2.70	0.00	0.00	0.00	0.00	2.70	3195.00
09	0.00	1.56	0.00	0.00	0.00	0.00	1.56	1840.70
18	0.04	0.00	0.04	0.00	0.00	0.00	0.08	87.00
21	0.00	0.42	0.00	0.00	0.00	0.00	0.42	500.00
29	0.00	0.00	0.91	0.00	0.00	0.00	0.91	1073.60
BIOLOGICS	0.00	0.00	0.50	0.00	0.00	0.00	0.50	603.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.50	0.00	0.00	0.00	0.50	603.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	27.48	2.09	0.00	0.00	0.00	29.57	34949.00
46	0.00	6.35	0.09	0.00	0.00	0.00	6.44	7600.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	8.63	0.09	0.00	0.00	0.00	8.72	10285.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	12.43	1.91	0.00	0.00	0.00	14.34	16980.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.07	0.00	0.00	0.00	0.00	0.07	84.00
ANIMAL D & F	0.00	1.02	0.15	0.00	0.00	0.00	1.17	1393.80
68	0.00	0.26	0.00	0.00	0.00	0.00	0.26	312.40
71	0.00	0.76	0.15	0.00	0.00	0.00	0.91	1081.40
DEVICES & RAD H	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: WEAC

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	9.84	8.44	18.04	0.00	2.00	38.32	45370.10
FOOD SAFETY/COS	0.00	2.83	0.00	0.00	0.00	0.00	2.83	3334.00
03	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
04	0.00	2.83	0.00	0.00	0.00	0.00	2.83	3334.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	2.15	0.15	0.00	0.00	0.00	2.30	2721.00
46	0.00	1.00	0.00	0.00	0.00	0.00	1.00	1180.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	1.15	0.15	0.00	0.00	0.00	1.30	1541.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
DEVICES & RAD H	0.00	4.86	8.29	18.04	0.00	2.00	33.19	39315.10
81	0.00	0.15	0.07	0.16	0.00	0.00	0.38	445.00
82	0.00	4.15	6.45	7.75	0.00	0.59	18.94	22504.10
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.56	1.77	4.09	0.00	1.41	7.83	9237.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	6.04	0.00	0.00	6.04	7129.00

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec. . OPR FTE'S

REGION: NE REGN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	146.91	58.52	47.58	18.04	0.00	2.00	273.05	294034.70
FOOD SAFETY/COS	75.72	23.01	36.40	0.00	0.00	0.00	135.13	146187.20
03	56.10	8.02	35.11	0.00	0.00	0.00	99.23	105752.60
04	2.78	10.31	0.34	0.00	0.00	0.00	13.43	15148.10
07	1.12	2.70	0.00	0.00	0.00	0.00	3.82	4235.40
09	0.48	1.56	0.00	0.00	0.00	0.00	2.04	2283.80
18	13.37	0.00	0.04	0.00	0.00	0.00	13.41	15420.20
21	1.23	0.42	0.00	0.00	0.00	0.00	1.65	1646.20
29	0.64	0.00	0.91	0.00	0.00	0.00	1.55	1700.90
BIOLOGICS	10.23	0.00	0.50	0.00	0.00	0.00	10.73	10063.90
41	1.51	0.00	0.00	0.00	0.00	0.00	1.51	1372.80
42	7.55	0.00	0.50	0.00	0.00	0.00	8.05	7625.20
45	1.17	0.00	0.00	0.00	0.00	0.00	1.17	1065.90
HUMAN DRUGS	34.23	29.63	2.24	0.00	0.00	0.00	66.10	69954.50
46	3.79	7.35	0.09	0.00	0.00	0.00	11.23	12230.00
48	6.07	0.00	0.00	0.00	0.00	0.00	6.07	5532.20
52	3.43	8.63	0.09	0.00	0.00	0.00	12.15	13408.00
53	1.35	0.00	0.00	0.00	0.00	0.00	1.35	1230.00
56	17.94	13.58	2.06	0.00	0.00	0.00	33.58	35967.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.65	0.07	0.00	0.00	0.00	0.00	1.72	1587.00
ANIMAL D & F	4.58	1.02	0.15	0.00	0.00	0.00	5.75	6049.80
68	0.96	0.26	0.00	0.00	0.00	0.00	1.22	1269.00
71	3.62	0.76	0.15	0.00	0.00	0.00	4.53	4780.80
DEVICES & RAD H	22.15	4.86	8.29	18.04	0.00	2.00	55.34	61779.30
81	0.17	0.15	0.07	0.16	0.00	0.00	0.55	607.20
82	12.53	4.15	6.45	7.75	0.00	0.59	31.47	34819.90
83	2.78	0.00	0.00	0.00	0.00	0.00	2.78	2636.00
84	0.00	0.56	1.77	4.09	0.00	1.41	7.83	9237.00
85	3.03	0.00	0.00	0.00	0.00	0.00	3.03	3509.00
86	3.64	0.00	0.00	6.04	0.00	0.00	9.68	10970.20

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: CE RO

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	20.79	0.00	0.00	0.00	0.00	0.00	20.79	24789.70
FOOD SAFETY/COS	19.15	0.00	0.00	0.00	0.00	0.00	19.15	22980.20
03	0.10	0.00	0.00	0.00	0.00	0.00	0.10	120.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	19.05	0.00	0.00	0.00	0.00	0.00	19.05	22860.20
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
DEVICES & RAD H	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Refle. . OPR FTE'S

DISTRICT: BLT

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	40.51	0.00	0.00	0.00	0.00	0.00	40.51	38239.80
FOOD SAFETY/COS	16.17	0.00	0.00	0.00	0.00	0.00	16.17	15357.90
03	12.92	0.00	0.00	0.00	0.00	0.00	12.92	12337.30
04	0.79	0.00	0.00	0.00	0.00	0.00	0.79	736.00
07	0.31	0.00	0.00	0.00	0.00	0.00	0.31	290.00
09	0.06	0.00	0.00	0.00	0.00	0.00	0.06	58.30
18	1.76	0.00	0.00	0.00	0.00	0.00	1.76	1632.40
21	0.30	0.00	0.00	0.00	0.00	0.00	0.30	275.20
29	0.03	0.00	0.00	0.00	0.00	0.00	0.03	28.70
BIOLOGICS	6.78	0.00	0.00	0.00	0.00	0.00	6.78	6183.20
41	1.44	0.00	0.00	0.00	0.00	0.00	1.44	1312.30
42	5.03	0.00	0.00	0.00	0.00	0.00	5.03	4588.90
45	0.31	0.00	0.00	0.00	0.00	0.00	0.31	282.00
HUMAN DRUGS	10.68	0.00	0.00	0.00	0.00	0.00	10.68	9858.30
46	1.07	0.00	0.00	0.00	0.00	0.00	1.07	974.00
48	3.74	0.00	0.00	0.00	0.00	0.00	3.74	3405.00
52	1.02	0.00	0.00	0.00	0.00	0.00	1.02	923.00
53	0.31	0.00	0.00	0.00	0.00	0.00	0.31	285.00
56	4.09	0.00	0.00	0.00	0.00	0.00	4.09	3859.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.45	0.00	0.00	0.00	0.00	0.00	0.45	412.00
ANIMAL D & F	1.51	0.00	0.00	0.00	0.00	0.00	1.51	1513.00
68	0.52	0.00	0.00	0.00	0.00	0.00	0.52	524.60
71	0.99	0.00	0.00	0.00	0.00	0.00	0.99	988.40
DEVICES & RAD H	5.37	0.00	0.00	0.00	0.00	0.00	5.37	5327.40
81	0.03	0.00	0.00	0.00	0.00	0.00	0.03	26.00
82	2.44	0.00	0.00	0.00	0.00	0.00	2.44	2330.00
83	1.24	0.00	0.00	0.00	0.00	0.00	1.24	1177.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.04	0.00	0.00	0.00	0.00	0.00	1.04	1201.00
86	0.62	0.00	0.00	0.00	0.00	0.00	0.62	593.40

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: CIN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	36.02	0.00	0.00	0.00	0.00	0.00	36.02	33937.60
FOOD SAFETY/COS	13.93	0.00	0.00	0.00	0.00	0.00	13.93	12999.70
03	11.26	0.00	0.00	0.00	0.00	0.00	11.26	10521.90
04	0.68	0.00	0.00	0.00	0.00	0.00	0.68	631.10
07	0.61	0.00	0.00	0.00	0.00	0.00	0.61	564.40
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.93	0.00	0.00	0.00	0.00	0.00	0.93	863.60
21	0.29	0.00	0.00	0.00	0.00	0.00	0.29	269.00
29	0.16	0.00	0.00	0.00	0.00	0.00	0.16	149.70
BIOLOGICS	4.25	0.00	0.00	0.00	0.00	0.00	4.25	3877.10
41	0.87	0.00	0.00	0.00	0.00	0.00	0.87	788.80
42	3.38	0.00	0.00	0.00	0.00	0.00	3.38	3088.30
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	9.98	0.00	0.00	0.00	0.00	0.00	9.98	9164.60
46	1.17	0.00	0.00	0.00	0.00	0.00	1.17	1062.00
48	2.99	0.00	0.00	0.00	0.00	0.00	2.99	2716.90
52	0.87	0.00	0.00	0.00	0.00	0.00	0.87	794.00
53	0.23	0.00	0.00	0.00	0.00	0.00	0.23	210.00
56	4.16	0.00	0.00	0.00	0.00	0.00	4.16	3876.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.56	0.00	0.00	0.00	0.00	0.00	0.56	505.00
ANIMAL D & F	2.05	0.00	0.00	0.00	0.00	0.00	2.05	2064.10
68	0.40	0.00	0.00	0.00	0.00	0.00	0.40	402.60
71	1.65	0.00	0.00	0.00	0.00	0.00	1.65	1661.50
DEVICES & RAD H	5.81	0.00	0.00	0.00	0.00	0.00	5.81	5832.10
81	0.08	0.00	0.00	0.00	0.00	0.00	0.08	73.10
82	2.73	0.00	0.00	0.00	0.00	0.00	2.73	2623.40
83	1.04	0.00	0.00	0.00	0.00	0.00	1.04	988.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.27	0.00	0.00	0.00	0.00	0.00	1.27	1468.00
86	0.69	0.00	0.00	0.00	0.00	0.00	0.69	679.60

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: DET

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	43.34	2.92	0.00	0.00	0.00	0.00	46.26	44988.70
FOOD SAFETY/COS	17.51	0.00	0.00	0.00	0.00	0.00	17.51	16717.50
03	14.41	0.00	0.00	0.00	0.00	0.00	14.41	13832.30
04	0.86	0.00	0.00	0.00	0.00	0.00	0.86	796.70
07	0.89	0.00	0.00	0.00	0.00	0.00	0.89	828.20
09	0.08	0.00	0.00	0.00	0.00	0.00	0.08	77.50
18	0.45	0.00	0.00	0.00	0.00	0.00	0.45	419.20
21	0.63	0.00	0.00	0.00	0.00	0.00	0.63	584.40
29	0.19	0.00	0.00	0.00	0.00	0.00	0.19	179.20
BIOLOGICS	4.99	0.00	0.00	0.00	0.00	0.00	4.99	4564.20
41	0.81	0.00	0.00	0.00	0.00	0.00	0.81	741.60
42	4.04	0.00	0.00	0.00	0.00	0.00	4.04	3693.70
45	0.14	0.00	0.00	0.00	0.00	0.00	0.14	128.90
HUMAN DRUGS	10.86	2.92	0.00	0.00	0.00	0.00	13.78	13598.80
46	0.82	0.08	0.00	0.00	0.00	0.00	0.90	848.00
48	2.51	0.00	0.00	0.00	0.00	0.00	2.51	2282.20
52	1.07	1.87	0.00	0.00	0.00	0.00	2.94	3176.00
53	0.31	0.00	0.00	0.00	0.00	0.00	0.31	285.00
56	5.69	0.95	0.00	0.00	0.00	0.00	6.64	6557.60
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.46	0.02	0.00	0.00	0.00	0.00	0.48	450.00
ANIMAL D & F	2.51	0.00	0.00	0.00	0.00	0.00	2.51	2548.50
68	0.73	0.00	0.00	0.00	0.00	0.00	0.73	731.50
71	1.78	0.00	0.00	0.00	0.00	0.00	1.78	1817.00
DEVICES & RAD H	7.47	0.00	0.00	0.00	0.00	0.00	7.47	7559.70
81	0.10	0.00	0.00	0.00	0.00	0.00	0.10	93.80
82	3.30	0.00	0.00	0.00	0.00	0.00	3.30	3187.20
83	1.39	0.00	0.00	0.00	0.00	0.00	1.39	1320.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.84	0.00	0.00	0.00	0.00	0.00	1.84	2135.00
86	0.84	0.00	0.00	0.00	0.00	0.00	0.84	823.70

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: CHI

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	43.25	0.00	0.00	0.00	0.00	0.00	43.25	41001.50
FOOD SAFETY/COS	16.29	0.00	0.00	0.00	0.00	0.00	16.29	15440.80
03	13.53	0.00	0.00	0.00	0.00	0.00	13.53	12869.10
04	0.85	0.00	0.00	0.00	0.00	0.00	0.85	792.20
07	0.57	0.00	0.00	0.00	0.00	0.00	0.57	528.80
09	0.06	0.00	0.00	0.00	0.00	0.00	0.06	52.00
18	0.77	0.00	0.00	0.00	0.00	0.00	0.77	717.80
21	0.28	0.00	0.00	0.00	0.00	0.00	0.28	259.00
29	0.23	0.00	0.00	0.00	0.00	0.00	0.23	221.90
BIOLOGICS	4.97	0.00	0.00	0.00	0.00	0.00	4.97	4555.50
41	0.64	0.00	0.00	0.00	0.00	0.00	0.64	584.00
42	3.88	0.00	0.00	0.00	0.00	0.00	3.88	3563.60
45	0.45	0.00	0.00	0.00	0.00	0.00	0.45	407.90
HUMAN DRUGS	12.97	0.00	0.00	0.00	0.00	0.00	12.97	12023.90
46	1.37	0.00	0.00	0.00	0.00	0.00	1.37	1249.00
48	2.54	0.00	0.00	0.00	0.00	0.00	2.54	2315.60
52	1.19	0.00	0.00	0.00	0.00	0.00	1.19	1082.00
53	0.31	0.00	0.00	0.00	0.00	0.00	0.31	285.00
56	6.97	0.00	0.00	0.00	0.00	0.00	6.97	6557.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.59	0.00	0.00	0.00	0.00	0.00	0.59	535.00
ANIMAL D & F	2.02	0.00	0.00	0.00	0.00	0.00	2.02	2013.40
68	0.43	0.00	0.00	0.00	0.00	0.00	0.43	425.30
71	1.59	0.00	0.00	0.00	0.00	0.00	1.59	1588.10
DEVICES & RAD H	7.00	0.00	0.00	0.00	0.00	0.00	7.00	6967.90
81	0.10	0.00	0.00	0.00	0.00	0.00	0.10	90.90
82	4.22	0.00	0.00	0.00	0.00	0.00	4.22	4131.00
83	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1143.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.84	0.00	0.00	0.00	0.00	0.00	0.84	977.00
86	0.64	0.00	0.00	0.00	0.00	0.00	0.64	626.00

WORKPLAN SUMMARY / POSITION CLASS (COMB. ANAL & DISTR RESEARCH)
FY 2001

Output Reflec . OPR FTE'S

DISTRICT: MIN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	50.04	0.00	0.00	0.00	0.00	0.00	50.04	47204.60
FOOD SAFETY/COS	25.92	0.00	0.00	0.00	0.00	0.00	25.92	24198.70
03	22.66	0.00	0.00	0.00	0.00	0.00	22.66	21175.90
04	0.82	0.00	0.00	0.00	0.00	0.00	0.82	759.50
07	0.42	0.00	0.00	0.00	0.00	0.00	0.42	393.80
09	0.03	0.00	0.00	0.00	0.00	0.00	0.03	25.40
18	1.14	0.00	0.00	0.00	0.00	0.00	1.14	1056.80
21	0.65	0.00	0.00	0.00	0.00	0.00	0.65	604.70
29	0.20	0.00	0.00	0.00	0.00	0.00	0.20	182.60
BIOLOGICS	4.32	0.00	0.00	0.00	0.00	0.00	4.32	3941.20
41	0.76	0.00	0.00	0.00	0.00	0.00	0.76	689.90
42	3.56	0.00	0.00	0.00	0.00	0.00	3.56	3251.30
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	6.50	0.00	0.00	0.00	0.00	0.00	6.50	5980.00
46	0.27	0.00	0.00	0.00	0.00	0.00	0.27	247.00
48	1.79	0.00	0.00	0.00	0.00	0.00	1.79	1625.80
52	0.24	0.00	0.00	0.00	0.00	0.00	0.24	222.00
53	0.08	0.00	0.00	0.00	0.00	0.00	0.08	75.00
56	3.59	0.00	0.00	0.00	0.00	0.00	3.59	3331.20
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.53	0.00	0.00	0.00	0.00	0.00	0.53	479.00
ANIMAL D & F	3.56	0.00	0.00	0.00	0.00	0.00	3.56	3567.60
68	0.63	0.00	0.00	0.00	0.00	0.00	0.63	628.60
71	2.93	0.00	0.00	0.00	0.00	0.00	2.93	2939.00
DEVICES & RAD H	9.74	0.00	0.00	0.00	0.00	0.00	9.74	9517.10
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	41.00
82	5.88	0.00	0.00	0.00	0.00	0.00	5.88	5637.90
83	2.27	0.00	0.00	0.00	0.00	0.00	2.27	2156.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.99	0.00	0.00	0.00	0.00	0.00	0.99	1148.00
86	0.56	0.00	0.00	0.00	0.00	0.00	0.56	534.20

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: NWJ

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	43.79	0.00	0.00	0.00	0.00	0.00	43.79	40561.30
FOOD SAFETY/COS	9.97	0.00	0.00	0.00	0.00	0.00	9.97	9261.90
03	8.32	0.00	0.00	0.00	0.00	0.00	8.32	7735.30
04	0.08	0.00	0.00	0.00	0.00	0.00	0.08	75.20
07	0.14	0.00	0.00	0.00	0.00	0.00	0.14	129.20
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.67	0.00	0.00	0.00	0.00	0.00	0.67	623.40
21	0.54	0.00	0.00	0.00	0.00	0.00	0.54	496.50
29	0.22	0.00	0.00	0.00	0.00	0.00	0.22	202.30
BIOLOGICS	2.41	0.00	0.00	0.00	0.00	0.00	2.41	2192.40
41	0.43	0.00	0.00	0.00	0.00	0.00	0.43	394.00
42	1.73	0.00	0.00	0.00	0.00	0.00	1.73	1572.50
45	0.25	0.00	0.00	0.00	0.00	0.00	0.25	225.90
HUMAN DRUGS	23.89	0.00	0.00	0.00	0.00	0.00	23.89	21734.50
46	3.63	0.00	0.00	0.00	0.00	0.00	3.63	3300.00
48	2.75	0.00	0.00	0.00	0.00	0.00	2.75	2500.50
52	3.44	0.00	0.00	0.00	0.00	0.00	3.44	3126.00
53	1.12	0.00	0.00	0.00	0.00	0.00	1.12	1020.00
56	12.05	0.00	0.00	0.00	0.00	0.00	12.05	10968.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.90	0.00	0.00	0.00	0.00	0.00	0.90	820.00
ANIMAL D & F	2.13	0.00	0.00	0.00	0.00	0.00	2.13	2131.80
68	0.95	0.00	0.00	0.00	0.00	0.00	0.95	948.40
71	1.18	0.00	0.00	0.00	0.00	0.00	1.18	1183.40
DEVICES & RAD H	5.39	0.00	0.00	0.00	0.00	0.00	5.39	5240.70
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	35.20
82	3.28	0.00	0.00	0.00	0.00	0.00	3.28	3115.70
83	1.16	0.00	0.00	0.00	0.00	0.00	1.16	1107.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.53	0.00	0.00	0.00	0.00	0.00	0.53	619.00
86	0.38	0.00	0.00	0.00	0.00	0.00	0.38	363.80

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec : OPR FTE'S

DISTRICT: PHI

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	43.93	25.61	0.83	0.00	0.00	0.00	70.37	72583.50
FOOD SAFETY/COS	15.93	0.00	0.00	0.00	0.00	0.00	15.93	14975.80
03	13.50	0.00	0.00	0.00	0.00	0.00	13.50	12698.80
04	0.81	0.00	0.00	0.00	0.00	0.00	0.81	758.20
07	0.43	0.00	0.00	0.00	0.00	0.00	0.43	401.80
09	0.03	0.00	0.00	0.00	0.00	0.00	0.03	32.80
18	0.76	0.00	0.00	0.00	0.00	0.00	0.76	711.40
21	0.37	0.00	0.00	0.00	0.00	0.00	0.37	345.50
29	0.03	0.00	0.00	0.00	0.00	0.00	0.03	27.30
BIOLOGICS	5.19	0.00	0.00	0.00	0.00	0.00	5.19	4740.90
41	0.88	0.00	0.00	0.00	0.00	0.00	0.88	795.80
42	3.96	0.00	0.00	0.00	0.00	0.00	3.96	3628.20
45	0.35	0.00	0.00	0.00	0.00	0.00	0.35	316.90
HUMAN DRUGS	13.67	25.61	0.83	0.00	0.00	0.00	40.11	43796.50
46	1.95	8.79	0.00	0.00	0.00	0.00	10.74	12146.00
48	3.64	0.00	0.00	0.00	0.00	0.00	3.64	3313.80
52	1.02	6.77	0.00	0.00	0.00	0.00	7.79	8923.00
53	0.40	0.00	0.00	0.00	0.00	0.00	0.40	360.00
56	5.93	9.93	0.83	0.00	0.00	0.00	16.69	18245.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.73	0.12	0.00	0.00	0.00	0.00	0.85	808.00
ANIMAL D & F	2.35	0.00	0.00	0.00	0.00	0.00	2.35	2338.80
68	0.49	0.00	0.00	0.00	0.00	0.00	0.49	483.60
71	1.86	0.00	0.00	0.00	0.00	0.00	1.86	1855.20
DEVICES & RAD H	6.79	0.00	0.00	0.00	0.00	0.00	6.79	6731.50
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	38.10
82	3.70	0.00	0.00	0.00	0.00	0.00	3.70	3566.90
83	1.39	0.00	0.00	0.00	0.00	0.00	1.39	1319.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.08	0.00	0.00	0.00	0.00	0.00	1.08	1257.00
86	0.58	0.00	0.00	0.00	0.00	0.00	0.58	550.50

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: FCC

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	30.13	0.00	0.00	0.00	0.00	30.13	36073.00
FOOD SAFETY/COS	0.00	10.77	0.00	0.00	0.00	0.00	10.77	12980.00
03	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
04	0.00	10.77	0.00	0.00	0.00	0.00	10.77	12980.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	18.34	0.00	0.00	0.00	0.00	18.34	21864.00
46	0.00	1.08	0.00	0.00	0.00	0.00	1.08	1275.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	2.48	0.00	0.00	0.00	0.00	2.48	2920.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	14.78	0.00	0.00	0.00	0.00	14.78	17669.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.73	0.00	0.00	0.00	0.00	0.73	875.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.73	0.00	0.00	0.00	0.00	0.73	875.00
DEVICES & RAD H	0.00	0.29	0.00	0.00	0.00	0.00	0.29	354.00
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.29	0.00	0.00	0.00	0.00	0.29	354.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMP ANAL & DISTR RESEARCH)
FY 2001

Output Refl : OPR FTE'S

REGION: CE REGN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	321.67	58.66	0.83	0.00	0.00	0.00	381.16	379379.70
FOOD SAFETY/COS	134.87	10.77	0.00	0.00	0.00	0.00	145.64	144912.50
03	96.70	0.00	0.00	0.00	0.00	0.00	96.70	91290.60
04	4.89	10.77	0.00	0.00	0.00	0.00	15.66	17528.90
07	3.37	0.00	0.00	0.00	0.00	0.00	3.37	3136.20
09	0.26	0.00	0.00	0.00	0.00	0.00	0.26	246.00
18	25.53	0.00	0.00	0.00	0.00	0.00	25.53	28884.80
21	3.06	0.00	0.00	0.00	0.00	0.00	3.06	2834.30
29	1.06	0.00	0.00	0.00	0.00	0.00	1.06	991.70
BIOLOGICS	32.91	0.00	0.00	0.00	0.00	0.00	32.91	30054.50
41	5.83	0.00	0.00	0.00	0.00	0.00	5.83	5306.40
42	25.58	0.00	0.00	0.00	0.00	0.00	25.58	23386.50
45	1.50	0.00	0.00	0.00	0.00	0.00	1.50	1361.60
HUMAN DRUGS	88.55	46.87	0.83	0.00	0.00	0.00	136.25	138020.60
46	10.28	9.95	0.00	0.00	0.00	0.00	20.23	21101.00
48	19.96	0.00	0.00	0.00	0.00	0.00	19.96	18159.80
52	8.85	11.12	0.00	0.00	0.00	0.00	19.97	21166.00
53	2.76	0.00	0.00	0.00	0.00	0.00	2.76	2520.00
56	42.48	25.66	0.83	0.00	0.00	0.00	68.97	71064.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	4.22	0.14	0.00	0.00	0.00	0.00	4.36	4009.00
ANIMAL D & F	16.13	0.73	0.00	0.00	0.00	0.00	16.86	17052.20
68	4.15	0.00	0.00	0.00	0.00	0.00	4.15	4144.60
71	11.98	0.73	0.00	0.00	0.00	0.00	12.71	12907.60
DEVICES & RAD H	49.21	0.29	0.00	0.00	0.00	0.00	49.50	49339.90
81	0.43	0.00	0.00	0.00	0.00	0.00	0.43	398.10
82	25.55	0.29	0.00	0.00	0.00	0.00	25.84	24946.10
83	9.69	0.00	0.00	0.00	0.00	0.00	9.69	9210.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	7.59	0.00	0.00	0.00	0.00	0.00	7.59	8805.00
86	5.95	0.00	0.00	0.00	0.00	0.00	5.95	5980.70

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: SE RO

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	14.90	0.00	0.00	0.00	0.00	0.00	14.90	17725.50
FOOD SAFETY/COS	13.26	0.00	0.00	0.00	0.00	0.00	13.26	15916.00
03	0.10	0.00	0.00	0.00	0.00	0.00	0.10	120.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	13.16	0.00	0.00	0.00	0.00	0.00	13.16	15796.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
DEVICES & RAD H	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec...: OPR FTE'S

DISTRICT: ATL

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	56.27	0.00	0.00	0.00	0.00	0.00	56.27	52861.80
FOOD SAFETY/COS	24.40	0.00	0.00	0.00	0.00	0.00	24.40	22856.70
03	21.65	0.00	0.00	0.00	0.00	0.00	21.65	20299.30
04	0.59	0.00	0.00	0.00	0.00	0.00	0.59	551.30
07	0.63	0.00	0.00	0.00	0.00	0.00	0.63	582.00
09	0.04	0.00	0.00	0.00	0.00	0.00	0.04	42.70
18	1.10	0.00	0.00	0.00	0.00	0.00	1.10	1019.60
21	0.19	0.00	0.00	0.00	0.00	0.00	0.19	173.70
29	0.20	0.00	0.00	0.00	0.00	0.00	0.20	188.10
BIOLOGICS	5.70	0.00	0.00	0.00	0.00	0.00	5.70	5177.50
41	1.01	0.00	0.00	0.00	0.00	0.00	1.01	915.50
42	4.44	0.00	0.00	0.00	0.00	0.00	4.44	4039.10
45	0.25	0.00	0.00	0.00	0.00	0.00	0.25	222.90
HUMAN DRUGS	14.68	0.00	0.00	0.00	0.00	0.00	14.68	13457.60
46	2.19	0.00	0.00	0.00	0.00	0.00	2.19	1997.00
48	3.45	0.00	0.00	0.00	0.00	0.00	3.45	3137.90
52	1.32	0.00	0.00	0.00	0.00	0.00	1.32	1200.00
53	0.48	0.00	0.00	0.00	0.00	0.00	0.48	435.00
56	6.47	0.00	0.00	0.00	0.00	0.00	6.47	5985.70
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.77	0.00	0.00	0.00	0.00	0.00	0.77	702.00
ANIMAL D & F	2.62	0.00	0.00	0.00	0.00	0.00	2.62	2623.90
68	1.04	0.00	0.00	0.00	0.00	0.00	1.04	1037.90
71	1.58	0.00	0.00	0.00	0.00	0.00	1.58	1586.00
DEVICES & RAD H	8.87	0.00	0.00	0.00	0.00	0.00	8.87	8746.10
81	0.10	0.00	0.00	0.00	0.00	0.00	0.10	91.80
82	4.73	0.00	0.00	0.00	0.00	0.00	4.73	4534.90
83	1.56	0.00	0.00	0.00	0.00	0.00	1.56	1482.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.28	0.00	0.00	0.00	0.00	0.00	1.28	1479.00
86	1.20	0.00	0.00	0.00	0.00	0.00	1.20	1158.40

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: FLA

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	61.48	0.00	0.00	0.00	0.00	0.00	61.48	58171.50
FOOD SAFETY/COS	33.50	0.00	0.00	0.00	0.00	0.00	33.50	31802.90
03	29.68	0.00	0.00	0.00	0.00	0.00	29.68	28244.50
04	1.57	0.00	0.00	0.00	0.00	0.00	1.57	1453.20
07	0.24	0.00	0.00	0.00	0.00	0.00	0.24	218.60
09	0.08	0.00	0.00	0.00	0.00	0.00	0.08	76.40
18	1.33	0.00	0.00	0.00	0.00	0.00	1.33	1241.00
21	0.50	0.00	0.00	0.00	0.00	0.00	0.50	464.50
29	0.10	0.00	0.00	0.00	0.00	0.00	0.10	104.70
BIOLOGICS	6.29	0.00	0.00	0.00	0.00	0.00	6.29	5733.70
41	0.78	0.00	0.00	0.00	0.00	0.00	0.78	714.00
42	5.37	0.00	0.00	0.00	0.00	0.00	5.37	4887.80
45	0.14	0.00	0.00	0.00	0.00	0.00	0.14	131.90
HUMAN DRUGS	10.10	0.00	0.00	0.00	0.00	0.00	10.10	9284.80
46	0.34	0.00	0.00	0.00	0.00	0.00	0.34	305.00
48	2.76	0.00	0.00	0.00	0.00	0.00	2.76	2510.30
52	0.85	0.00	0.00	0.00	0.00	0.00	0.85	772.00
53	0.31	0.00	0.00	0.00	0.00	0.00	0.31	285.00
56	4.82	0.00	0.00	0.00	0.00	0.00	4.82	4482.50
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.02	0.00	0.00	0.00	0.00	0.00	1.02	930.00
ANIMAL D & F	1.10	0.00	0.00	0.00	0.00	0.00	1.10	1103.80
68	0.34	0.00	0.00	0.00	0.00	0.00	0.34	344.00
71	0.76	0.00	0.00	0.00	0.00	0.00	0.76	759.80
DEVICES & RAD H	10.49	0.00	0.00	0.00	0.00	0.00	10.49	10246.30
81	0.10	0.00	0.00	0.00	0.00	0.00	0.10	95.40
82	6.09	0.00	0.00	0.00	0.00	0.00	6.09	5829.30
83	2.16	0.00	0.00	0.00	0.00	0.00	2.16	2058.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.00	0.00	0.00	0.00	0.00	0.00	1.00	1155.00
86	1.14	0.00	0.00	0.00	0.00	0.00	1.14	1108.60

DISTRICT: NOL

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	47.73	0.00	0.00	0.00	0.00	0.00	47.73	45566.80
FOOD SAFETY/COS	22.13	0.00	0.00	0.00	0.00	0.00	22.13	20719.50
03	19.13	0.00	0.00	0.00	0.00	0.00	19.13	17923.90
04	0.78	0.00	0.00	0.00	0.00	0.00	0.78	724.00
07	0.45	0.00	0.00	0.00	0.00	0.00	0.45	415.40
09	0.02	0.00	0.00	0.00	0.00	0.00	0.02	24.10
18	1.54	0.00	0.00	0.00	0.00	0.00	1.54	1430.20
21	0.05	0.00	0.00	0.00	0.00	0.00	0.05	49.70
29	0.16	0.00	0.00	0.00	0.00	0.00	0.16	152.20
BIOLOGICS	7.42	0.00	0.00	0.00	0.00	0.00	7.42	6940.60
41	1.07	0.00	0.00	0.00	0.00	0.00	1.07	974.00
42	6.21	0.00	0.00	0.00	0.00	0.00	6.21	5834.70
45	0.14	0.00	0.00	0.00	0.00	0.00	0.14	131.90
HUMAN DRUGS	10.05	0.00	0.00	0.00	0.00	0.00	10.05	9586.60
46	0.50	0.00	0.00	0.00	0.00	0.00	0.50	455.00
48	2.62	0.00	0.00	0.00	0.00	0.00	2.62	2384.30
52	0.39	0.00	0.00	0.00	0.00	0.00	0.39	358.00
53	0.08	0.00	0.00	0.00	0.00	0.00	0.08	75.00
56	5.66	0.00	0.00	0.00	0.00	0.00	5.66	5590.30
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.80	0.00	0.00	0.00	0.00	0.00	0.80	724.00
ANIMAL D & F	1.93	0.00	0.00	0.00	0.00	0.00	1.93	1935.90
68	0.34	0.00	0.00	0.00	0.00	0.00	0.34	341.30
71	1.59	0.00	0.00	0.00	0.00	0.00	1.59	1594.60
DEVICES & RAD H	6.20	0.00	0.00	0.00	0.00	0.00	6.20	6384.20
81	0.07	0.00	0.00	0.00	0.00	0.00	0.07	65.10
82	2.44	0.00	0.00	0.00	0.00	0.00	2.44	2530.60
83	1.38	0.00	0.00	0.00	0.00	0.00	1.38	1315.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.23	0.00	0.00	0.00	0.00	0.00	1.23	1430.00
86	1.08	0.00	0.00	0.00	0.00	0.00	1.08	1043.50

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: SJN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	20.59	12.04	0.00	0.00	0.00	0.00	32.63	33418.50
FOOD SAFETY/COS	4.44	0.00	0.00	0.00	0.00	0.00	4.44	4207.00
03	3.74	0.00	0.00	0.00	0.00	0.00	3.74	3552.50
04	0.20	0.00	0.00	0.00	0.00	0.00	0.20	184.50
07	0.10	0.00	0.00	0.00	0.00	0.00	0.10	91.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.25	0.00	0.00	0.00	0.00	0.00	0.25	230.20
21	0.09	0.00	0.00	0.00	0.00	0.00	0.09	83.60
29	0.06	0.00	0.00	0.00	0.00	0.00	0.06	65.20
BIOLOGICS	0.70	0.00	0.00	0.00	0.00	0.00	0.70	632.20
41	0.06	0.00	0.00	0.00	0.00	0.00	0.06	51.70
42	0.64	0.00	0.00	0.00	0.00	0.00	0.64	580.50
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	12.93	12.04	0.00	0.00	0.00	0.00	24.97	26110.10
46	3.63	6.53	0.00	0.00	0.00	0.00	10.16	11005.00
48	0.36	0.00	0.00	0.00	0.00	0.00	0.36	328.00
52	1.34	1.49	0.00	0.00	0.00	0.00	2.83	2969.00
53	1.12	0.00	0.00	0.00	0.00	0.00	1.12	1020.00
56	5.88	4.02	0.00	0.00	0.00	0.00	9.90	10243.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.60	0.00	0.00	0.00	0.00	0.00	0.60	545.00
ANIMAL D & F	0.67	0.00	0.00	0.00	0.00	0.00	0.67	667.30
68	0.23	0.00	0.00	0.00	0.00	0.00	0.23	229.00
71	0.44	0.00	0.00	0.00	0.00	0.00	0.44	438.30
DEVICES & RAD H	1.85	0.00	0.00	0.00	0.00	0.00	1.85	1801.90
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	1.22	0.00	0.00	0.00	0.00	0.00	1.22	1163.90
83	0.34	0.00	0.00	0.00	0.00	0.00	0.34	322.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.23	0.00	0.00	0.00	0.00	0.00	0.23	261.00
86	0.06	0.00	0.00	0.00	0.00	0.00	0.06	55.00

WORKPLAN SUMMARY / POSITION CLASS (COMP ANAL & DISTR RESEARCH)
FY 2001

Output Refle : OPR FTE'S

DISTRICT: SRL

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	48.06	41.66	0.00	0.00	3.00	92.72	109494.30
FOOD SAFETY/COS	0.00	35.08	39.90	0.00	0.00	3.00	77.98	92096.90
03	0.00	7.21	36.90	0.00	0.00	0.00	44.11	52115.10
04	0.00	9.96	0.45	0.00	0.00	0.00	10.41	12308.60
07	0.00	5.44	0.00	0.00	0.00	3.00	8.44	9960.00
09	0.00	0.43	0.00	0.00	0.00	0.00	0.43	501.30
18	0.00	0.00	0.15	0.00	0.00	0.00	0.15	176.40
21	0.00	12.04	1.68	0.00	0.00	0.00	13.72	16190.70
29	0.00	0.00	0.72	0.00	0.00	0.00	0.72	844.80
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	8.94	1.05	0.00	0.00	0.00	9.99	11791.00
46	0.00	2.24	0.00	0.00	0.00	0.00	2.24	2645.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	1.96	0.00	0.00	0.00	0.00	1.96	2310.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	4.60	1.05	0.00	0.00	0.00	5.65	6668.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.14	0.00	0.00	0.00	0.00	0.14	168.00
ANIMAL D & F	0.00	2.50	0.71	0.00	0.00	0.00	3.21	3783.40
68	0.00	0.43	0.00	0.00	0.00	0.00	0.43	508.40
71	0.00	2.07	0.71	0.00	0.00	0.00	2.78	3275.00
DEVICES & RAD H	0.00	1.54	0.00	0.00	0.00	0.00	1.54	1823.00
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	1.54	0.00	0.00	0.00	0.00	1.54	1823.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

REGION: SE REGN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	200.97	60.10	41.66	0.00	0.00	3.00	305.73	317238.40
FOOD SAFETY/COS	97.73	35.08	39.90	0.00	0.00	3.00	175.71	187599.00
03	74.30	7.21	36.90	0.00	0.00	0.00	118.41	122255.30
04	3.14	9.96	0.45	0.00	0.00	0.00	13.55	15221.60
07	1.42	5.44	0.00	0.00	0.00	3.00	9.86	11267.00
09	0.14	0.43	0.00	0.00	0.00	0.00	0.57	644.50
18	17.38	0.00	0.15	0.00	0.00	0.00	17.53	19893.40
21	0.83	12.04	1.68	0.00	0.00	0.00	14.55	16962.20
29	0.52	0.00	0.72	0.00	0.00	0.00	1.24	1355.00
BIOLOGICS	20.11	0.00	0.00	0.00	0.00	0.00	20.11	18484.00
41	2.92	0.00	0.00	0.00	0.00	0.00	2.92	2655.20
42	16.66	0.00	0.00	0.00	0.00	0.00	16.66	15342.10
45	0.53	0.00	0.00	0.00	0.00	0.00	0.53	486.70
HUMAN DRUGS	47.76	20.98	1.05	0.00	0.00	0.00	69.79	70230.10
46	6.66	8.77	0.00	0.00	0.00	0.00	15.43	16407.00
48	9.19	0.00	0.00	0.00	0.00	0.00	9.19	8360.50
52	3.90	3.45	0.00	0.00	0.00	0.00	7.35	7609.00
53	1.99	0.00	0.00	0.00	0.00	0.00	1.99	1815.00
56	22.83	8.62	1.05	0.00	0.00	0.00	32.50	32969.60
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	3.19	0.14	0.00	0.00	0.00	0.00	3.33	3069.00
ANIMAL D & F	6.32	2.50	0.71	0.00	0.00	0.00	9.53	10114.30
68	1.95	0.43	0.00	0.00	0.00	0.00	2.38	2460.60
71	4.37	2.07	0.71	0.00	0.00	0.00	7.15	7653.70
DEVICES & RAD H	29.05	1.54	0.00	0.00	0.00	0.00	30.59	30811.00
81	0.27	0.00	0.00	0.00	0.00	0.00	0.27	252.30
82	14.48	1.54	0.00	0.00	0.00	0.00	16.02	15881.70
83	5.44	0.00	0.00	0.00	0.00	0.00	5.44	5177.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.74	0.00	0.00	0.00	0.00	0.00	3.74	4325.00
86	5.12	0.00	0.00	0.00	0.00	0.00	5.12	5175.00

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec . OPR FTE'S

DISTRICT: SW RO

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	17.43	0.00	0.00	0.00	0.00	0.00	17.43	20586.50
FOOD SAFETY/COS	11.65	0.00	0.00	0.00	0.00	0.00	11.65	13977.00
03	0.10	0.00	0.00	0.00	0.00	0.00	0.10	120.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	11.55	0.00	0.00	0.00	0.00	0.00	11.55	13857.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
DEVICES & RAD H	5.78	0.00	0.00	0.00	0.00	0.00	5.78	6609.50
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.14	0.00	0.00	0.00	0.00	0.00	4.14	4800.00
86	1.64	0.00	0.00	0.00	0.00	0.00	1.64	1809.50

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: DAL

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	55.24	0.00	0.00	0.00	0.00	0.00	55.24	51321.90
FOOD SAFETY/COS	21.62	0.00	0.00	0.00	0.00	0.00	21.62	20106.40
03	18.80	0.00	0.00	0.00	0.00	0.00	18.80	17486.80
04	0.57	0.00	0.00	0.00	0.00	0.00	0.57	527.60
07	0.46	0.00	0.00	0.00	0.00	0.00	0.46	428.40
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	1.41	0.00	0.00	0.00	0.00	0.00	1.41	1314.40
21	0.16	0.00	0.00	0.00	0.00	0.00	0.16	146.90
29	0.22	0.00	0.00	0.00	0.00	0.00	0.22	202.30
BIOLOGICS	8.75	0.00	0.00	0.00	0.00	0.00	8.75	7963.80
41	1.56	0.00	0.00	0.00	0.00	0.00	1.56	1418.20
42	6.89	0.00	0.00	0.00	0.00	0.00	6.89	6272.60
45	0.30	0.00	0.00	0.00	0.00	0.00	0.30	273.00
HUMAN DRUGS	13.76	0.00	0.00	0.00	0.00	0.00	13.76	12514.40
46	0.90	0.00	0.00	0.00	0.00	0.00	0.90	815.00
48	4.99	0.00	0.00	0.00	0.00	0.00	4.99	4538.40
52	0.40	0.00	0.00	0.00	0.00	0.00	0.40	365.00
53	0.30	0.00	0.00	0.00	0.00	0.00	0.30	270.00
56	6.20	0.00	0.00	0.00	0.00	0.00	6.20	5644.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.97	0.00	0.00	0.00	0.00	0.00	0.97	882.00
ANIMAL D & F	3.73	0.00	0.00	0.00	0.00	0.00	3.73	3719.10
68	0.89	0.00	0.00	0.00	0.00	0.00	0.89	884.30
71	2.84	0.00	0.00	0.00	0.00	0.00	2.84	2834.80
DEVICES & RAD H	7.38	0.00	0.00	0.00	0.00	0.00	7.38	7018.20
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	41.00
82	4.39	0.00	0.00	0.00	0.00	0.00	4.39	4173.40
83	1.68	0.00	0.00	0.00	0.00	0.00	1.68	1595.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	1.27	0.00	0.00	0.00	0.00	0.00	1.27	1208.80

Output Ref. .: OPR FTE'S

DISTRICT: DEN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	26.50	13.48	22.36	0.00	0.00	4.00	66.34	71692.60
FOOD SAFETY/COS	9.52	3.26	13.74	0.00	0.00	0.00	26.52	28907.30
03	8.06	0.78	13.40	0.00	0.00	0.00	22.24	24223.00
04	0.51	0.79	0.00	0.00	0.00	0.00	1.30	1400.70
07	0.08	0.00	0.00	0.00	0.00	0.00	0.08	74.80
09	0.00	1.69	0.00	0.00	0.00	0.00	1.69	1996.30
18	0.72	0.00	0.06	0.00	0.00	0.00	0.78	734.20
21	0.15	0.00	0.00	0.00	0.00	0.00	0.15	143.90
29	0.00	0.00	0.28	0.00	0.00	0.00	0.28	334.40
BIOLOGICS	3.30	0.00	0.00	0.00	0.00	0.00	3.30	3001.00
41	0.52	0.00	0.00	0.00	0.00	0.00	0.52	468.30
42	2.64	0.00	0.00	0.00	0.00	0.00	2.64	2400.80
45	0.14	0.00	0.00	0.00	0.00	0.00	0.14	131.90
HUMAN DRUGS	6.93	6.40	0.94	0.00	0.00	0.00	14.27	14960.40
46	0.41	0.25	0.44	0.00	0.00	0.00	1.10	1197.00
48	1.57	0.00	0.00	0.00	0.00	0.00	1.57	1424.40
52	0.76	1.77	0.00	0.00	0.00	0.00	2.53	2778.00
53	0.23	0.00	0.00	0.00	0.00	0.00	0.23	210.00
56	3.48	4.26	0.50	0.00	0.00	0.00	8.24	8778.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.48	0.12	0.00	0.00	0.00	0.00	0.60	573.00
ANIMAL D & F	1.64	3.82	3.71	0.00	0.00	4.00	13.17	15284.70
68	0.52	0.11	0.00	0.00	0.00	0.00	0.63	657.30
71	1.12	3.71	3.71	0.00	0.00	4.00	12.54	14627.40
DEVICES & RAD H	5.11	0.00	3.97	0.00	0.00	0.00	9.08	9539.20
81	0.07	0.00	0.00	0.00	0.00	0.00	0.07	71.30
82	3.36	0.00	3.97	0.00	0.00	0.00	7.33	7875.30
83	1.29	0.00	0.00	0.00	0.00	0.00	1.29	1226.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.39	0.00	0.00	0.00	0.00	0.00	0.39	366.60

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: KAN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	38.39	33.32	0.00	0.00	0.00	5.00	76.71	81039.90
FOOD SAFETY/COS	13.00	29.19	0.00	0.00	0.00	5.00	47.19	52425.50
03	10.16	1.41	0.00	0.00	0.00	0.00	11.57	11114.50
04	1.00	22.68	0.00	0.00	0.00	5.00	28.68	33597.80
07	0.31	3.34	0.00	0.00	0.00	0.00	3.65	4230.60
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.88	0.00	0.00	0.00	0.00	0.00	0.88	814.80
21	0.48	1.76	0.00	0.00	0.00	0.00	2.24	2512.90
29	0.17	0.00	0.00	0.00	0.00	0.00	0.17	154.90
BIOLOGICS	5.69	0.00	0.00	0.00	0.00	0.00	5.69	5187.90
41	1.02	0.00	0.00	0.00	0.00	0.00	1.02	932.10
42	4.57	0.00	0.00	0.00	0.00	0.00	4.57	4161.80
45	0.10	0.00	0.00	0.00	0.00	0.00	0.10	94.00
HUMAN DRUGS	10.24	0.57	0.00	0.00	0.00	0.00	10.81	10005.60
46	1.09	0.30	0.00	0.00	0.00	0.00	1.39	1345.00
48	2.55	0.00	0.00	0.00	0.00	0.00	2.55	2319.60
52	0.93	0.08	0.00	0.00	0.00	0.00	1.01	949.00
53	0.31	0.00	0.00	0.00	0.00	0.00	0.31	285.00
56	4.83	0.17	0.00	0.00	0.00	0.00	5.00	4598.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.53	0.02	0.00	0.00	0.00	0.00	0.55	509.00
ANIMAL D & F	4.93	3.56	0.00	0.00	0.00	0.00	8.49	9123.90
68	1.57	1.13	0.00	0.00	0.00	0.00	2.70	2900.80
71	3.36	2.43	0.00	0.00	0.00	0.00	5.79	6223.10
DEVICES & RAD H	4.53	0.00	0.00	0.00	0.00	0.00	4.53	4297.00
81	0.11	0.00	0.00	0.00	0.00	0.00	0.11	102.80
82	2.50	0.00	0.00	0.00	0.00	0.00	2.50	2370.80
83	1.34	0.00	0.00	0.00	0.00	0.00	1.34	1270.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.58	0.00	0.00	0.00	0.00	0.00	0.58	553.40

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Refle. . OPR FTE'S

DISTRICT: SWID

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	30.36	0.00	0.00	0.00	0.00	0.00	30.36	32572.70
FOOD SAFETY/COS	24.12	0.00	0.00	0.00	0.00	0.00	24.12	25462.80
03	19.57	0.00	0.00	0.00	0.00	0.00	19.57	21208.70
04	2.90	0.00	0.00	0.00	0.00	0.00	2.90	2696.70
07	0.24	0.00	0.00	0.00	0.00	0.00	0.24	224.00
09	0.62	0.00	0.00	0.00	0.00	0.00	0.62	581.30
18	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
21	0.71	0.00	0.00	0.00	0.00	0.00	0.71	657.40
29	0.08	0.00	0.00	0.00	0.00	0.00	0.08	94.70
BIOLOGICS	0.19	0.00	0.00	0.00	0.00	0.00	0.19	231.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.19	0.00	0.00	0.00	0.00	0.00	0.19	231.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.95	0.00	0.00	0.00	0.00	0.00	0.95	1061.40
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.95	0.00	0.00	0.00	0.00	0.00	0.95	1061.40
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.08	0.00	0.00	0.00	0.00	0.00	0.08	77.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.08	0.00	0.00	0.00	0.00	0.00	0.08	77.00
DEVICES & RAD H	5.02	0.00	0.00	0.00	0.00	0.00	5.02	5740.50
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	4.42	0.00	0.00	0.00	0.00	0.00	4.42	5064.50
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.60	0.00	0.00	0.00	0.00	0.00	0.60	676.00

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: ARL

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	14.41	16.83	0.00	0.00	0.00	31.24	36859.50
FOOD SAFETY/COS	0.00	13.54	16.77	0.00	0.00	0.00	30.31	35765.80
03	0.00	2.64	16.28	0.00	0.00	0.00	18.92	22319.20
04	0.00	10.47	0.00	0.00	0.00	0.00	10.47	12358.40
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.43	0.00	0.00	0.00	0.00	0.43	509.20
18	0.00	0.00	0.06	0.00	0.00	0.00	0.06	68.60
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.43	0.00	0.00	0.00	0.43	510.40
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.87	0.06	0.00	0.00	0.00	0.93	1093.70
68	0.00	0.15	0.00	0.00	0.00	0.00	0.15	173.00
71	0.00	0.72	0.06	0.00	0.00	0.00	0.78	920.70
DEVICES & RAD H	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COM ANAL & DISTR RESEARCH)
FY 2001

Output Refl. :: OPR FTE'S

REGION: SW REGN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	167.92	61.21	39.19	0.00	0.00	9.00	277.32	294073.10
FOOD SAFETY/COS	79.91	45.99	30.51	0.00	0.00	5.00	161.41	176644.80
03	56.69	4.83	29.68	0.00	0.00	0.00	91.20	96472.20
04	4.98	33.94	0.00	0.00	0.00	5.00	43.92	50581.20
07	1.09	3.34	0.00	0.00	0.00	0.00	4.43	4957.80
09	0.62	2.12	0.00	0.00	0.00	0.00	2.74	3086.80
18	14.56	0.00	0.12	0.00	0.00	0.00	14.68	16789.00
21	1.50	1.76	0.00	0.00	0.00	0.00	3.26	3461.10
29	0.47	0.00	0.71	0.00	0.00	0.00	1.18	1296.70
BIOLOGICS	17.93	0.00	0.00	0.00	0.00	0.00	17.93	16383.70
41	3.10	0.00	0.00	0.00	0.00	0.00	3.10	2818.60
42	14.29	0.00	0.00	0.00	0.00	0.00	14.29	13066.20
45	0.54	0.00	0.00	0.00	0.00	0.00	0.54	498.90
HUMAN DRUGS	31.88	6.97	0.94	0.00	0.00	0.00	39.79	38541.80
46	2.40	0.55	0.44	0.00	0.00	0.00	3.39	3357.00
48	9.11	0.00	0.00	0.00	0.00	0.00	9.11	8282.40
52	2.09	1.85	0.00	0.00	0.00	0.00	3.94	4092.00
53	0.84	0.00	0.00	0.00	0.00	0.00	0.84	765.00
56	15.46	4.43	0.50	0.00	0.00	0.00	20.39	20081.40
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.98	0.14	0.00	0.00	0.00	0.00	2.12	1964.00
ANIMAL D & F	10.38	8.25	3.77	0.00	0.00	4.00	26.40	29298.40
68	2.98	1.39	0.00	0.00	0.00	0.00	4.37	4615.40
71	7.40	6.86	3.77	0.00	0.00	4.00	22.03	24683.00
DEVICES & RAD H	27.82	0.00	3.97	0.00	0.00	0.00	31.79	33204.40
81	0.22	0.00	0.00	0.00	0.00	0.00	0.22	215.10
82	14.67	0.00	3.97	0.00	0.00	0.00	18.64	19484.00
83	4.31	0.00	0.00	0.00	0.00	0.00	4.31	4091.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	4.14	0.00	0.00	0.00	0.00	0.00	4.14	4800.00
86	4.48	0.00	0.00	0.00	0.00	0.00	4.48	4614.30

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: PA RO

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	14.92	0.00	0.00	0.00	0.00	0.00	14.92	17434.50
FOOD SAFETY/COS	12.03	0.00	0.00	0.00	0.00	0.00	12.03	14442.00
03	0.10	0.00	0.00	0.00	0.00	0.00	0.10	120.00
04	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	11.93	0.00	0.00	0.00	0.00	0.00	11.93	14322.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
46	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
DEVICES & RAD H	2.89	0.00	0.00	0.00	0.00	0.00	2.89	2992.50
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	2.89	0.00	0.00	0.00	0.00	0.00	2.89	2992.50

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Refle OPR FTE'S

DISTRICT: LOS

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	86.17	0.00	0.00	0.00	0.00	0.00	86.17	82560.70
FOOD SAFETY/COS	38.33	0.00	0.00	0.00	0.00	0.00	38.33	36915.90
03	32.10	0.00	0.00	0.00	0.00	0.00	32.10	31071.40
04	2.01	0.00	0.00	0.00	0.00	0.00	2.01	1870.90
07	0.48	0.00	0.00	0.00	0.00	0.00	0.48	449.60
09	0.20	0.00	0.00	0.00	0.00	0.00	0.20	183.40
18	1.95	0.00	0.00	0.00	0.00	0.00	1.95	1817.00
21	1.02	0.00	0.00	0.00	0.00	0.00	1.02	947.70
29	0.57	0.00	0.00	0.00	0.00	0.00	0.57	575.90
BIOLOGICS	9.06	0.00	0.00	0.00	0.00	0.00	9.06	8370.30
41	2.72	0.00	0.00	0.00	0.00	0.00	2.72	2476.30
42	5.90	0.00	0.00	0.00	0.00	0.00	5.90	5498.30
45	0.44	0.00	0.00	0.00	0.00	0.00	0.44	395.70
HUMAN DRUGS	16.12	0.00	0.00	0.00	0.00	0.00	16.12	14882.70
46	1.51	0.00	0.00	0.00	0.00	0.00	1.51	1374.00
48	3.65	0.00	0.00	0.00	0.00	0.00	3.65	3315.90
52	1.47	0.00	0.00	0.00	0.00	0.00	1.47	1336.00
53	0.46	0.00	0.00	0.00	0.00	0.00	0.46	420.00
56	7.88	0.00	0.00	0.00	0.00	0.00	7.88	7391.80
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.15	0.00	0.00	0.00	0.00	0.00	1.15	1045.00
ANIMAL D & F	2.05	0.00	0.00	0.00	0.00	0.00	2.05	2064.10
68	0.37	0.00	0.00	0.00	0.00	0.00	0.37	367.00
71	1.68	0.00	0.00	0.00	0.00	0.00	1.68	1697.10
DEVICES & RAD H	20.61	0.00	0.00	0.00	0.00	0.00	20.61	20327.70
81	0.45	0.00	0.00	0.00	0.00	0.00	0.45	426.70
82	11.86	0.00	0.00	0.00	0.00	0.00	11.86	11427.40
83	4.74	0.00	0.00	0.00	0.00	0.00	4.74	4502.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	2.22	0.00	0.00	0.00	0.00	0.00	2.22	2580.00
86	1.34	0.00	0.00	0.00	0.00	0.00	1.34	1391.60

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: SAN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	51.04	5.26	10.31	0.00	0.00	0.00	66.61	67059.50
FOOD SAFETY/COS	27.76	4.98	9.55	0.00	0.00	0.00	42.29	43519.10
03	22.56	1.66	9.28	0.00	0.00	0.00	33.50	34451.80
04	1.46	2.31	0.00	0.00	0.00	0.00	3.77	4083.80
07	0.48	0.00	0.00	0.00	0.00	0.00	0.48	446.40
09	0.10	1.01	0.00	0.00	0.00	0.00	1.11	1278.30
18	2.59	0.00	0.00	0.00	0.00	0.00	2.59	2406.40
21	0.40	0.00	0.00	0.00	0.00	0.00	0.40	371.30
29	0.17	0.00	0.27	0.00	0.00	0.00	0.44	481.10
BIOLOGICS	4.18	0.00	0.00	0.00	0.00	0.00	4.18	3811.90
41	0.65	0.00	0.00	0.00	0.00	0.00	0.65	587.00
42	3.43	0.00	0.00	0.00	0.00	0.00	3.43	3130.90
45	0.10	0.00	0.00	0.00	0.00	0.00	0.10	94.00
HUMAN DRUGS	7.23	0.00	0.51	0.00	0.00	0.00	7.74	7261.70
46	0.67	0.00	0.00	0.00	0.00	0.00	0.67	614.00
48	2.80	0.00	0.00	0.00	0.00	0.00	2.80	2544.70
52	0.30	0.00	0.00	0.00	0.00	0.00	0.30	276.00
53	0.23	0.00	0.00	0.00	0.00	0.00	0.23	210.00
56	2.84	0.00	0.51	0.00	0.00	0.00	3.35	3259.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.39	0.00	0.00	0.00	0.00	0.00	0.39	358.00
ANIMAL D & F	3.15	0.28	0.25	0.00	0.00	0.00	3.68	3777.50
68	0.39	0.00	0.00	0.00	0.00	0.00	0.39	389.60
71	2.76	0.28	0.25	0.00	0.00	0.00	3.29	3387.90
DEVICES & RAD H	8.72	0.00	0.00	0.00	0.00	0.00	8.72	8689.30
81	0.10	0.00	0.00	0.00	0.00	0.00	0.10	89.90
82	4.64	0.00	0.00	0.00	0.00	0.00	4.64	4520.50
83	2.06	0.00	0.00	0.00	0.00	0.00	2.06	1953.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	1.10	0.00	0.00	0.00	0.00	0.00	1.10	1273.00
86	0.82	0.00	0.00	0.00	0.00	0.00	0.82	852.90

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Refle . OPR FTE'S

DISTRICT: SEA

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	62.18	0.00	0.00	0.00	0.00	0.00	62.18	58696.50
FOOD SAFETY/COS	44.35	0.00	0.00	0.00	0.00	0.00	44.35	41772.40
03	37.74	0.00	0.00	0.00	0.00	0.00	37.74	35620.10
04	1.99	0.00	0.00	0.00	0.00	0.00	1.99	1850.50
07	0.71	0.00	0.00	0.00	0.00	0.00	0.71	657.60
09	0.08	0.00	0.00	0.00	0.00	0.00	0.08	74.20
18	3.21	0.00	0.00	0.00	0.00	0.00	3.21	2988.40
21	0.57	0.00	0.00	0.00	0.00	0.00	0.57	527.90
29	0.05	0.00	0.00	0.00	0.00	0.00	0.05	53.70
BIOLOGICS	5.77	0.00	0.00	0.00	0.00	0.00	5.77	5337.50
41	0.77	0.00	0.00	0.00	0.00	0.00	0.77	700.70
42	4.90	0.00	0.00	0.00	0.00	0.00	4.90	4542.80
45	0.10	0.00	0.00	0.00	0.00	0.00	0.10	94.00
HUMAN DRUGS	4.98	0.00	0.00	0.00	0.00	0.00	4.98	4590.40
46	0.27	0.00	0.00	0.00	0.00	0.00	0.27	247.00
48	1.95	0.00	0.00	0.00	0.00	0.00	1.95	1771.30
52	0.07	0.00	0.00	0.00	0.00	0.00	0.07	68.00
53	0.08	0.00	0.00	0.00	0.00	0.00	0.08	75.00
56	2.32	0.00	0.00	0.00	0.00	0.00	2.32	2163.10
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.29	0.00	0.00	0.00	0.00	0.00	0.29	266.00
ANIMAL D & F	2.27	0.00	0.00	0.00	0.00	0.00	2.27	2333.80
68	0.21	0.00	0.00	0.00	0.00	0.00	0.21	206.00
71	2.06	0.00	0.00	0.00	0.00	0.00	2.06	2127.80
DEVICES & RAD H	4.81	0.00	0.00	0.00	0.00	0.00	4.81	4662.40
81	0.04	0.00	0.00	0.00	0.00	0.00	0.04	36.10
82	3.08	0.00	0.00	0.00	0.00	0.00	3.08	2956.70
83	0.90	0.00	0.00	0.00	0.00	0.00	0.90	860.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.79	0.00	0.00	0.00	0.00	0.00	0.79	809.60

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

DISTRICT: PRL - SW

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	29.41	34.40	0.00	0.00	0.00	63.81	75344.60
FOOD SAFETY/COS	0.00	22.11	34.40	0.00	0.00	0.00	56.51	66727.30
03	0.00	7.23	34.03	0.00	0.00	0.00	41.26	48722.80
04	0.00	14.38	0.00	0.00	0.00	0.00	14.38	16964.50
07	0.00	0.50	0.00	0.00	0.00	0.00	0.50	600.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29	0.00	0.00	0.37	0.00	0.00	0.00	0.37	440.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	3.16	0.00	0.00	0.00	0.00	3.16	3731.00
46	0.00	0.27	0.00	0.00	0.00	0.00	0.27	315.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	0.89	0.00	0.00	0.00	0.00	0.89	1056.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	2.00	0.00	0.00	0.00	0.00	2.00	2360.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
ANIMAL D & F	0.00	0.15	0.00	0.00	0.00	0.00	0.15	181.90
68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
71	0.00	0.15	0.00	0.00	0.00	0.00	0.15	181.90
DEVICES & RAD H	0.00	3.99	0.00	0.00	0.00	0.00	3.99	4704.40
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	3.99	0.00	0.00	0.00	0.00	3.99	4704.40
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec. . OPR FTE'S

DISTRICT: PRL-NW

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	0.00	21.84	17.56	0.00	0.00	7.00	46.40	54826.00
FOOD SAFETY/COS	0.00	10.74	17.56	0.00	0.00	6.00	34.30	40552.40
03	0.00	3.42	17.04	0.00	0.00	4.00	24.46	28942.70
04	0.00	5.51	0.40	0.00	0.00	0.00	5.91	6972.50
07	0.00	1.81	0.00	0.00	0.00	1.00	2.81	3320.00
09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18	0.00	0.00	0.12	0.00	0.00	0.00	0.12	137.20
21	0.00	0.00	0.00	0.00	0.00	1.00	1.00	1180.00
29	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BIOLOGICS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
HUMAN DRUGS	0.00	9.15	0.00	0.00	0.00	0.00	9.15	10788.00
46	0.00	2.32	0.00	0.00	0.00	0.00	2.32	2740.00
48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
52	0.00	1.47	0.00	0.00	0.00	0.00	1.47	1730.00
53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
56	0.00	5.19	0.00	0.00	0.00	0.00	5.19	6122.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	0.00	0.17	0.00	0.00	0.00	0.00	0.17	196.00
ANIMAL D & F	0.00	1.95	0.00	0.00	0.00	1.00	2.95	3485.60
68	0.00	0.30	0.00	0.00	0.00	0.00	0.30	359.80
71	0.00	1.65	0.00	0.00	0.00	1.00	2.65	3125.80
DEVICES & RAD H	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
82	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

WORKPLAN SUMMARY / POSITION CLASS (COMB ANAL & DISTR RESEARCH)
FY 2001

Output Reflec... OPR FTE'S

TOTAL FIELD

Lapsed

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	TOTALS PERSNHRS
FIELD TOTAL	1085.29	295.00	191.53	18.04	0.00	21.00	1610.86	1671437.00
FOOD SAFETY/COS	514.70	152.68	168.32	0.00	0.00	14.00	849.70	902992.60
03	380.29	32.37	162.04	0.00	0.00	4.00	578.70	598419.50
04	21.25	87.18	1.19	0.00	0.00	5.00	114.62	130222.00
07	8.67	13.79	0.00	0.00	0.00	4.00	26.46	29070.00
09	1.88	5.12	0.00	0.00	0.00	0.00	7.00	7797.00
18	90.52	0.00	0.43	0.00	0.00	0.00	90.95	102658.40
21	8.61	14.22	1.68	0.00	0.00	1.00	25.51	27930.70
29	3.48	0.00	2.98	0.00	0.00	0.00	6.46	6895.00
BIOLOGICS	120.96	0.00	0.50	0.00	0.00	0.00	121.46	111411.20
41	21.00	0.00	0.00	0.00	0.00	0.00	21.00	19102.00
42	88.83	0.00	0.50	0.00	0.00	0.00	89.33	82168.90
45	11.13	0.00	0.00	0.00	0.00	0.00	11.13	10140.30
HUMAN DRUGS	235.09	116.76	5.57	0.00	0.00	0.00	357.42	361954.50
46	26.55	29.21	0.53	0.00	0.00	0.00	56.29	59265.00
48	54.22	0.00	0.00	0.00	0.00	0.00	54.22	49325.50
52	20.53	27.41	0.09	0.00	0.00	0.00	48.03	51126.00
53	7.97	0.00	0.00	0.00	0.00	0.00	7.97	7275.00
56	112.95	59.48	4.95	0.00	0.00	0.00	177.38	182469.00
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	12.87	0.66	0.00	0.00	0.00	0.00	13.53	12494.00
ANIMAL D & F	45.45	14.88	4.88	0.00	0.00	5.00	70.21	74925.60
68	11.05	2.38	0.00	0.00	0.00	0.00	13.43	13852.00
71	34.40	12.50	4.88	0.00	0.00	5.00	56.78	61073.60
DEVICES & RAD H	169.09	10.68	12.26	18.04	0.00	2.00	212.07	220153.10
81	1.68	0.15	0.07	0.16	0.00	0.00	2.06	2025.40
82	90.64	9.97	10.42	7.75	0.00	0.59	119.37	122382.90
83	29.92	0.00	0.00	0.00	0.00	0.00	29.92	28429.00
84	0.00	0.56	1.77	4.09	0.00	1.41	7.83	9237.00
85	21.82	0.00	0.00	0.00	0.00	0.00	21.82	25292.00
86	25.03	0.00	0.00	6.04	0.00	0.00	31.07	32786.80

WORKPLAN SUMMARY / POSITION CLASS (COMBINED ANAL & DISTR RESEARCH)
FY 2001

Output Reflects: OPR FTE'S

REGION: PA REGN

	INVEST	DIST RES & ANALYTICAL CHEM	DIST REG & ANALYTICAL MICRO	DIST REG & ANALYTICAL ENG/PHY	DISTRICT RESEARCH	RESEARCH CENTER	TOTALS OPR FTE'S	PERSNHRS
FIELD TOTAL	214.31	56.51	62.27	0.00	0.00	7.00	340.09	355921.80
FOOD SAFETY/COS	122.47	37.83	61.51	0.00	0.00	6.00	227.81	243929.10
03	92.50	12.31	60.35	0.00	0.00	4.00	169.16	178928.80
04	5.46	22.20	0.40	0.00	0.00	0.00	28.06	31742.20
07	1.67	2.31	0.00	0.00	0.00	1.00	4.98	5473.60
09	0.38	1.01	0.00	0.00	0.00	0.00	1.39	1535.90
18	19.68	0.00	0.12	0.00	0.00	0.00	19.80	21671.00
21	1.99	0.00	0.00	0.00	0.00	1.00	2.99	3026.90
29	0.79	0.00	0.64	0.00	0.00	0.00	1.43	1550.70
BIOLOGICS	19.01	0.00	0.00	0.00	0.00	0.00	19.01	17519.70
41	4.14	0.00	0.00	0.00	0.00	0.00	4.14	3764.00
42	14.23	0.00	0.00	0.00	0.00	0.00	14.23	13172.00
45	0.64	0.00	0.00	0.00	0.00	0.00	0.64	583.70
HUMAN DRUGS	28.33	12.31	0.51	0.00	0.00	0.00	41.15	41253.80
46	2.45	2.59	0.00	0.00	0.00	0.00	5.04	5290.00
48	8.40	0.00	0.00	0.00	0.00	0.00	8.40	7631.90
52	1.84	2.36	0.00	0.00	0.00	0.00	4.20	4466.00
53	0.77	0.00	0.00	0.00	0.00	0.00	0.77	705.00
56	13.04	7.19	0.51	0.00	0.00	0.00	20.74	21295.90
58	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
63	1.83	0.17	0.00	0.00	0.00	0.00	2.00	1865.00
ANIMAL D & F	7.47	2.38	0.25	0.00	0.00	1.00	11.10	11842.90
68	0.97	0.30	0.00	0.00	0.00	0.00	1.27	1322.40
71	6.50	2.08	0.25	0.00	0.00	1.00	9.83	10520.50
DEVICES & RAD H	37.03	3.99	0.00	0.00	0.00	0.00	41.02	41376.30
81	0.59	0.00	0.00	0.00	0.00	0.00	0.59	552.70
82	19.58	3.99	0.00	0.00	0.00	0.00	23.57	23609.00
83	7.70	0.00	0.00	0.00	0.00	0.00	7.70	7315.00
84	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
85	3.32	0.00	0.00	0.00	0.00	0.00	3.32	3853.00
86	5.84	0.00	0.00	0.00	0.00	0.00	5.84	6046.60

FY 2001

PART III - PROGRAM FORECASTS

DEPT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD & DRUG ADMINISTRATION

PROGRAM PLANNING & WORKFORCE
MANAGEMENT BRANCH
DPEM/ORM/ORA

PART III
RESOURCE SUMMARY BY PROGRAM CATEGORY
FY 2001

	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
	DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
TOTAL ALL PROGRAMS	1200.9	316.0	95.1	1612.0	2347.0	611.0	191.2	3149
FOOD AND COSMETICS	587.6	249.1	14.8	851.5	1069.1	458.2	24.9	1552
BIOLOGICS	111.0	2.5	8.0	121.5	219.2	5.3	10.5	235
HUMAN DRUGS	273.5	31.0	52.8	357.3	577.1	67.8	112.1	757
ANIMAL DRUGS AND FEEDS	65.0	2.8	2.0	69.8	137.4	5.6	4.0	147
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	163.8	30.6	17.5	211.9	344.2	74.1	39.7	458

Note: Supported FTEs includes Operational (Workplan) and Program Direction & Assistance (Non-Workplan) positions

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2001

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	587.6	249.1	14.8	851.5	1069.1	458.2	24.9	1552.2
03	FOODBORNE BILOGICAL HAZARDS	384.6	179.3	14.8	578.7	682.4	336.8	24.9	1044.1
04	PESTICIDES AND CHEMICAL CONTAMINANTS	66.5	48.5		115.0	127.7	80.3		208.0
07	MOLECULAR BIOLOGY AND NATURAL TOXINS	19.9	6.6		26.5	33.5	12.5		46.0
09	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		7.0		7.0		14.0		14.0
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	90.7	0.2		90.9	176.6	0.4		177.0
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	22.4	4.6		27.0	42.3	8.7		51.0
29	COLOR AND COSMETICS TECHNOLOGY	3.5	2.9		6.4	6.6	5.5		12.1

Note: Supported FTEs includes Operational (Workplan) and Program Direction & Assistance (Non-Workplan) positions

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Foods and Cosmetics	Foodborne Biological Hazards - 03

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		384.6	179.3	14.8	578.7	1044.3	
1	Import Acidified and Low Acid Canned Foods	03003,A,		6.8		6.8	13.2	2-3
2	Domestic and Imported Cheese & Cheese Products	03037,D,**	14.4	9.1		23.5	45.6	4-5
3	National Drug Residue Milk Monitoring Program	03039	2.6			2.6	5.0	6-7
4	Domestic Acidified and Low Acid Canned Food	03803A, **	62.0			62.0	120.3	8-9
5	Domestic Food Safety	03803,B,**	130.5			130.5	253.2	10-11
6	Import Foods - General	03819A,B*		83.5		83.5	162.0	12-13
7	Domestic Fish and Fishery Products Inspection	03842,B***	122.0			122.0	183.2	14-15
8	Import Seafood Products	03844,B,****		70.4		70.4	127.3	16-17
9	Foreign Inspections/Assessments	03R233			10.8	10.8	21.0	18-19
(9)	National Expert	03R233			4.0	4.0	4.0	18-19
10	Import & Domestic Micro Assignment *****	03F098	19.1	9.5		28.6	55.5	20-21
11	Emergency Response to Foodborne Outbreaks	03R839	13.0			13.0	25.2	22-23
	and Illnesses							
12	Food State Contract Audits	03R843	4.0			4.0	7.8	24-25
13	Minnesota Department of Agriculture	N/A	(3)			(3)	(5)	26-27
	Laboratory Partnership (INFORMATION ONLY)							
14	ORA/Center Directed Research Projects	03R816	12.6			12.6	12.6	28-29
(14)	Food Safety Initiative (FSI) Risk Assessment	03R816	4.4			4.4	8.5	28-29
	Collaborative Research							
	* 03819C, 03R833, 03R824, 04R824, 07R824,							
	09R824, 21R824, 99R833							
	** See Workplanning Sheets (2621a) for							
	additional PACs.							
	*** 03842, B,C,D,H, 04842A, H, 07842, H,							
	09842E, H, 21R811, 21R839 / NOTE: 58 HACCP							
	FTEs not supported.							
	**** 03844B, C, D, H, 07844, 21R829, 09844E, F,							
	21844, 21R811 / NOTE: 10.8 HACCP FTEs not							
	supported.							
	***** 03F098 Planned as Import							
	03F100 Planned as Domestic							
	NOTE:							
	National Expert and Research FTEs							
	are not supported. FSI Risk Assessment Research							
	is supported.							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy 202-205-2262	Stephen F. Burt 301-827-1633

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Acidified and Low-Acid Canned Foods	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To detain Acidified and Low-Acid Canned Foods which are packed in food canning establishments not in compliance with 21 CFR 108, 113 and 114.

5. PROGRAM JUSTIFICATION

Acidified and Low-Acid Canned Foods continue to be the source of sporadic problems from improper processing (e.g., underprocessing, inadequate pH or water activity control, leakage). Importation of these potentially dangerous products has received program coverage by the field since FY 74. Inspections of foreign plants have shown many of them to be out of compliance with 21 CFR Parts 108, 113 and 114.

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 plants that do not comply with registration and filing requirements.

NOTE: Confirmation tests for *Clostridium botulinum* will be split between SRL & Pacific Regional Laboratory-NW.
SRL will be the confirmation servicing laboratory for NE, CE and SE Regions.
The Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW and PA regions.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Compliance Program (7303.003)	03-04, 09, 12-18, 20-25, 27, 29, 30-31, 33-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

pH, water activity, salinity, soluble solids.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import Acidified and Low Acid Canned Foods	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03003, 03003A	[X] ORA [ ] CENTER	6.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTION	4 IMPORT SAMPLE COLL	5 FIELD EXAM TESTS	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED CHEM
	TOTAL FIELD				600		600	480		120
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND				19		19			
	NEW YORK				191		191			
	REGIONAL LAB							175		44
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE				48		48			
	CHICAGO				12		12			
	CINCINNATI									
	DETROIT				15		15			
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA				10		10			
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				10		10			
	FLORIDA				36		36			
	NEW ORLEANS									
	SAN JUAN				16		16			
	REGIONAL LAB							88		22
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				21		21			
	REGIONAL LAB							22		6
PA	REGIONAL STAFF									
	LOS ANGELES				158		158			
	SAN FRANCISCO				39		39	31		8
	SEATTLE				25		25			
	PACIFIC REGIONAL LABORATORY-SW							143		35
	PACIFIC REGIONAL LABORATORY-NW							21		5
	HOURS PER OPERATION				1.5		1.0	11.0		7.0
	TOTAL HOURS				900		600	5280		840
	CONVERSION FACTOR				930		930	1180		1180
	TOTAL OPERATIONAL FTEs				0.97		0.65	4.47		0.71

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

Workload : March 1, 1999 - April 30, 2000 ACS FDA Review Lines

1. PROGRAM/ASSIGNMENT TITLE	2. PMS PROJECT NAME/NUMBER
Domestic and Imported Cheese and Cheese Products	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To examine samples of domestic and imported hard and soft cheeses (i.e., soft, semi-soft, soft ripened) for Salmonella, Listeria, E. coli, Etec, Eivec/Shigella, S. Aureus, phosphatase, and filth so that appropriate action can be taken when violations are encountered. To perform annual inspections of all U.S. soft, semi-soft, and soft-ripened cheese producers to ensure domestic products are free of the above mentioned pathogens.

5. PROGRAM JUSTIFICATION

During the past few years, pasteurized fluid milk, milk products and cheese products have been demonstrated to contain pathogenic microorganisms and to have caused human illness. A number of deaths have been associated with the consumption of these products.

6. FIELD OBLIGATIONS

The field is to conduct inspections of domestic soft cheese manufacturers and, as necessary, sample collections and analysis to document and support inspectional findings. The field is to conduct sample collections and sample analysis of imported and soft cheese.

The field is requested to complete all domestic sample collections and analysis to support the Agency's listeria risk assessment.

See program guidance regarding the collection of domestic samples not resulting from inspections.

NOTE:

NRL will perform Salmonella serotyping.
DEN will perform Salmonella resistance testing.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Hard and Soft Cheeses	12

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

f. CHECK THE FOLLOWING ATTRIBUTES

Salmonella, Listeria, E. coli, Etec, Eivec/Shigella, S. Aureus phosphatase, and filth.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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	[ ] ORA [X] CENTER	23.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS *	2 INVESTIGATIONS (Hours) **	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL PHYSICAL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	300		500	600				500	600
	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3		5	16					
NE	NEW YORK	9		15	438					
	REGIONAL LAB								20	454
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	3		5						
	CHICAGO	18		30	24					
	CINCINNATI	16		27						
CE	DETROIT	3		5	16					
	MINNEAPOLIS	170		284						
	NEW JERSEY	11		18						
	PHILADELPHIA	3		5						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	3		5						
SE	FLORIDA	9		15	29					
	NEW ORLEANS	3		5						
	SAN JUAN	3		5						
	REGIONAL LAB								85	29
	REGIONAL STAFF									
	DALLAS	3		5						
SW	DENVER								5	
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				5					
	REGIONAL LAB								319	40
	REGIONAL STAFF									
	LOS ANGELES	8		13	26					
PA	SAN FRANCISCO	21		35	46					
	SEATTLE	14		23						
	PACIFIC REGIONAL LABORATORY-SW								13	
	PACIFIC REGIONAL LABORATORY-NW								58	77
	HOURS PER OPERATION	16.0		3.0	1.5				18.0	16.0
	TOTAL HOURS	4800		1500	900				9000	9600
	CONVERSION FACTOR	930		930	930				1180	1180
	TOTAL OPERATIONAL FTEs	5.16		1.61	0.97				7.63	8.14

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

Resources provided to inspect all soft cheese manufacturers annually and anticipated re-inspections.

** Investigation hours changed to Import Entry Review hours, Import Filer Evaluation hours, Follow-up to Refusal hours under Import Foods - General (03819 A,B,C)

DOMESTIC WORKLOAD: OEI HIGH RISK (SOFT CHEESES) PER CFSAN AS OF 12/2000.

IMPORT WORKLOAD: BASED ON MARCH 1, 1999 - APRIL 30, 2000 ACS FDA REVIEW LINES IND CODE 12

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

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

4. OBJECTIVES

The National Drug Residue Milk Monitoring Program (a joint venture program between CFSAN, CVM, ORA and participating states) will provide an indication of the animal drug residues in milk.

In FY 2001, a retail sampling component has been added to determine whether or not antibiotics are present in finished products. The presence of antibiotics may suggest inadequate sampling at processors.

5. PROGRAM JUSTIFICATION

The National Drug Residue Milk Monitoring Program will provide indications of drug residues in milk and the extent of Compliance with federal regulations. The results will help in the design of future educational and compliance efforts for use by federal, state and local authorities. This 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

This will be a joint FDA/State effort in analyzing samples for the presence of sulfonamides, tetracyclines, Chloramphenicol, Novobiocin, Ivermectin, and Clorulson. Follow-up visits/collections/inspections are anticipated by states and FDA for samples found with detectable residues.

Fifty percent of samples will be collected at retail. The Regional Milk Specialist will collect retail samples or make arrangement for their collections.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Grade "A" and non-Grade "A" Milk	09

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

f. CHECK THE FOLLOWING ATTRIBUTES

Samples will be analyzed for sulfonamides, three tetracyclines, Novobiocin and Chloramphenicol, Florfenicol, Ivermectin and Clorsulon.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
3039	[ ] ORA [X] CENTER	2.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL *	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD				300			600		
	HEADQUARTERS									
NE	REGIONAL STAFF				60					
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF				60					
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF				60					
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF				60					
	DALLAS									
	DENVER							600		
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF				60					
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION				2.0			4.1		
	TOTAL HOURS				600			2460		
	CONVERSION FACTOR				1200			1180		
	TOTAL OPERATIONAL FTEs				0.50			2.08		

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE		
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

Resources planned represent CFSAN's requirement under this program. This is a joint venture between CVM and CFSAN. See compliance program 7371.008 for additional guidance. Field sample collections are not planned by District. If sample collection is necessary consult your Regional Milk Specialist before collecting samples. 300 domestic samples will be collected at retail. The Regional Milk Specialists will collect these samples or make arrangements to have them collected.

* An additional 300 samples will be collected by NCIMS participating states at dairy processors.

All sampling schedules will be developed by the Laboratory Quality Assurance Branch (LQAB, HFH-450) in Moffet, IL.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Acidified and Low-Acid Canned Foods	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To determine if the firms comply with 21 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act. To perform annual inspections to ensure that interstate marketing of acidified and low-acid canned foods manufactured under conditions that do not comply with these requirements.

5. PROGRAM JUSTIFICATION

Low-Acid Canned Foods: Inspections conducted in prior year's programs have demonstrated that the degree of compliance of low-acid canned food regulations relates 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 reinspection of the remaining portions of the industry are needed to establish and maintain compliance with the low-acid canned food regulations.

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

6. FIELD OBLIGATIONS

Conduct inspections, collect and analyze samples where appropriate.
Report all work under the Domestic Acidified and Low-Acid Canned Foods PAC.
Beginning in FY 2001, the program priority is to inspect all LACF and Acidified Food Firms annually.
NOTE: Confirmation tests for *Clostridium botulinum* which require animals will be split between SRL and and Pacific Regional Laboratory-NW.
SRL will be the confirmation servicing laboratory for NE, CE & SE Regions.
The Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Compliance Program	16, 20-22, 24-25, 27, 35, 37, 38, 40-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Acidified and Low Acid Canned Food	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
3803A , 03F103*	[X] ORA [ ] CENTER	62.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DSA's SPORE HEAT DETERM (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 BETTER PROCESSING SCHOOL (Training) (Hours) **
	TOTAL FIELD	1435	400	935				235	700	930
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	83	23	54						49
NE	NEW YORK	59	17	39						49
NE	REGIONAL LAB							39	118	
NE	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE	65	18	42						49
CE	CHICAGO	49	14	32						49
CE	CINCINNATI	51	14	32						49
CE	DETROIT	70	20	46						49
CE	MINNEAPOLIS	96	27	63						49
CE	NEW JERSEY	32	9	20						49
CE	PHILADELPHIA	67	19	44						49
CE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA	90	25	58						49
SE	FLORIDA	23	6	15						49
SE	NEW ORLEANS	51	14	33						49
SE	SAN JUAN	18	5	12						49
SE	REGIONAL LAB							49	144	
	REGIONAL STAFF									
SW	DALLAS	201	56	132						49
SW	DENVER	45	13	30				52	146	49
SW	KANSAS CITY	52	14	34				9		49
SW	SOUTHWEST IMPORT DISTRICT									
SW	REGIONAL LAB							24	105	
	REGIONAL STAFF									
PA	LOS ANGELES	76	21	49						49
PA	SAN FRANCISCO	109	30	71				18	53	49
PA	SEATTLE	198	55	129						48
PA	PACIFIC REGIONAL LABORATORY-SW							12	37	
PA	PACIFIC REGIONAL LABORATORY-NW							32	97	
	HOURS PER OPERATION	30.0		4.0				10.0	14.0	
	TOTAL HOURS	43050	400	3740				2350	9800	930
	CONVERSION FACTOR	930	930	930				1180	1180	930
	TOTAL OPERATIONAL FTEs	46.29	0.43	4.02				1.99	8.31	1.00

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

* Report all resources expended for NLEA under PAC 21005 AND LACF/AF Targeted Inspections Assignment under 03F103.

Resources above include the coverage for industry code 16 (Fishery/Seafood Products) and to inspect all LACF and acidified firms annually in FY 2001 plus anticipated re-inspections. ** Attendence at Better Processing Schools (BPS)

NOTE: Workload provided by CFSAN

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Food Safety	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 program priority for FY 2001 is to inspect all high-risk firms annually.

5. PROGRAM JUSTIFICATION

Domestic, as well as imported products, must comply with the provisions of the FD&C Act and the regulations covering the manufacture and handling of food products. FDA is charged with the responsibilities of assuring that manufacturers produce these products under current Good Manufacturing Practices.

6. FIELD OBLIGATIONS

The field is to conduct inspections/investigations and necessary sample collections and analyses to document and support inspectional findings. During FY 2001, FDA will continue to monitor chicken/eggs for Salmonella, Enteritidis, Serotype Enteritidis. The level and type of coverage will be dictated by the nature of events requiring FDA investigation when they occur. Beginning in FY 2001, firms producing high-risk products are scheduled to be inspected annually.

NOTE: *Ciguatera toxin* confirmation test will be done at the Pacific Regional Laboratory – NW. Confirmation tests for *Clostridium botulinum, Yersinia enterocolitica & paralytic shellfish poison* will be split between SRL & Pacific Regional Laboratory-NW. SRL will be the confirmation servicing laboratory for NE, CE, & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products (Except 12 & 16)	02-11, 13-15, 17-41, 45-46, 50

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

f. CHECK THE FOLLOWING ATTRIBUTES

Filth, Decomposition and Microbiological Contamination (See Compliance Program)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Food Safety	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03803,B,C,D; 04803 09803E,F *	[X] ORA [ ] CENTER	130.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS **	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DSA PFGE ANALYSIS MICRO ***			7 MICRO BIOLOGIST INSPTION TIME (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	7 DSA SALMO-SERO - TYPING (Hours)
	TOTAL FIELD	4400	4000	2200	2950			1900	730	1470	1180
	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	210	191	104							
NE	NEW YORK	175	159	88							
	REGIONAL LAB				590			171	129	128	
	WEAC										
	REGIONAL STAFF										
	BALTIMORE	144	131	71							
	CHICAGO	247	225	123							
	CINCINNATI	263	239	131							
CE	DETROIT	267	243	133							
	MINNEAPOLIS	399	363	199							
	NEW JERSEY	120	109	60							
	PHILADELPHIA	273	248	137							
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	258	235	129							
SE	FLORIDA	219	199	110							
	NEW ORLEANS	275	250	138							
	SAN JUAN	47	43	24							
	REGIONAL LAB				590			689	200	535	
	REGIONAL STAFF										
	DALLAS	246	224	123							
SW	DENVER	193	175	97				297	32	231	
	KANSAS CITY	250	227	125					126		
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB							393	107	304	1180
	REGIONAL STAFF										
	LOS ANGELES	216	196	108							
PA	SAN FRANCISCO	185	168	93	590			80	31	62	
	SEATTLE	413	375	207							
	PACIFIC REGIONAL LABORATORY-SW				590			93	36	72	
	PACIFIC REGIONAL LABORATORY-NW				590			177	69	138	
	HOURS PER OPERATION	17.5		4.9					12.5	15.2	
	TOTAL HOURS	77000	4000	10780	2950			1900	9125	22344	1180
	CONVERSION FACTOR	930	930	930	1180			1180	1180	1180	1180
	TOTAL OPERATIONAL FTES	82.80	4.30	11.6	2.50			1.61	7.73	18.94	1.00

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

* Resources for 04803, 09803E,F are included.

** 100% of inspections based on OEI of high risk firms per compliance program. Includes 15% follow-up.

Resources provided to inspect all high-risk firms annually and follow-up inspections.

Workload of High Risk firms provided by CFSAN.

*** Pulsed-Field Gel Electrophoresis (PFGE): required for all listoria Monocytogenes, Salmonella, & Enterohemorrhagic (EHEC) positive.

NOTE: Resources included to cover egg safety activities.

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

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

4. OBJECTIVES

To direct coverage of imported food products in order to determine their compliance with the FD&C Act and regulations promulgated under the Act.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C 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 thereunder.

6. FIELD OBLIGATIONS

To conduct import field examinations of products most likely to be out of compliance. Collect samples for determination of filth, decomposition or microbiological contamination. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. Import Acidified & Low -Acid Canned Foods will report under PAC (03003, 03003A).

NOTE:
ARL will perform Salmonella serotyping.
DEN will perform Salmonella resistance testing.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products (except seafood and cheese)	02-09, 13-15, 17-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

Filth, Decomposition and Microbiological Contamination (See Compliance Program)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

,OGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03819A,B,C (03R833/99R833/R824**)	[X] ORA [ ] CENTER	83.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REV HOURS OPER 14 03R833	9 IMPORT FILER EVAL HOURS OPER 95 99R833	2 IMPORT FOLLOW - UP-REFUSAL OPER 14 RB24 *	4 IMPORT SAMPLE COLL PHYSICAL		9 IMPORT LABEL EXAMS	8 IMPORT FIELD EXAMS	8 IMPORT SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED SALM RESIST (Hours) ***
	TOTAL FIELD	45150	7970	9168	2930		5000	1500	2130	800	1180
	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	1581	169	14	70		120	36			
NE	NEW YORK	9780	1505	2274	575		982	295			
	REGIONAL LAB								498	187	
	WEAC										
	REGIONAL STAFF										
	BALTIMORE	1442	362	163	92		157	47			
	CHICAGO	1237	480	236	66		113	35			
	CINCINNATI	224	222	77	5		9				
CE	DETROIT	1923	224	144	148		252	76			
	MINNEAPOLIS	440	222	49	34		58	17			
	NEW JERSEY										
	PHILADELPHIA	647	180	76	39		66	20			
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	703	672	148	38		64	19			
SE	FLORIDA	2839	723	420	146		249	75			
	NEW ORLEANS	555	302	96	19		32				
	SAN JUAN	346	65	31	27		47	24			
	REGIONAL LAB								238	99	
	REGIONAL STAFF										
	DALLAS										
SW	DENVER								180		1180
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT	13368	845	2973	1146		1956	587			
	REGIONAL LAB									58	
	REGIONAL STAFF										
	LOS ANGELES	5414	1021	1501	263		448	135			
PA	SAN FRANCISCO	2333	507	622	138		236	71	100	38	
	SEATTLE	2318	471	344	124		211	63			
	PACIFIC REGIONAL LABORATORY-SW								1024	384	
	PACIFIC REGIONAL LABORATORY-NW								90	34	
	HOURS PER OPERATION				1.2		0.3	0.3	9.3	5.6	
	TOTAL HOURS	45150	7970	9168	3516		1500	450	19809	4480	1180
	CONVERSION FACTOR	1200	930	930	930		930	930	1180	1180	1180
	TOTAL OPERATIONAL FTEs	37.63	8.57	9.86	3.78		1.61	0.48	16.79	3.80	1.00

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-		
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN	TIONAL	10/01/00	09/30/01
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-	10/15/00	09/30/01
X	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL		

9. REMARKS **Import activities include resources from the following import programs: 03844/03819/03037/03003/09006/04016A/03R233**

NOTE: Workload based on 3/1/99-4/30/00 ACS FDA Review Lines.

* Follow-Up To Refusal hours: Additional resources added for marking and tracking the disposition of detained lots.

Resources in this program can be used to report Import Food activities under the following PAC Codes:

IMPORT ENTRY REVIEW HOURS; 03R833 / FILER EVALUATION HOURS 99R833 / FOLLOW-UP TO REFUSAL UNDER THE APPROPRIATE FOODS R824 PAC. * Denver Laboratory: Salmonella Resistance**

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

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

4. OBJECTIVES

To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the ACT.

Resources provided to cover all seafood processors annually less non high-risk warehouses.

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. There are specific sampling/analysis obligations for PSP/ASP, and verification sampling/analysis must meet specific criteria. Priority inspections are required of firms processing scombrotoxic products, smoked products, vacuum packaged products, and ready-to-eat products, and to follow-up on firms found to be in noncompliance with the HACCP regulation.

NOTE:

Confirmation tests which require animals for *Clostridium botulinum* will be split between SRL & Pacific Regional Laboratory–NW. SRL will be the confirmation servicing laboratory for NE, CE & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Domestic Fish and Fishery Products	16

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [X] OTHERS *(Specify)* (PSP, ASP, Standards, Economic Deception, Labeling)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03842, B, C, D, H*	[X] ORA [ ] CENTER	122.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS ****	2 INV HOURS	3 DOMESTIC SAMPLES COLL ***	4 IMPORT SAMPLE COLL	7 MICRO BIOL ON INSP (Hours)	7 DSAs ORGANO EXAMS (Hours) **	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	9 E.U. CERTIFICATE PROCESSING (Hours) *****
	TOTAL FIELD	4715	1830	1150		2360	885	380	770	2790
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	488	189	119						1200
	NEW YORK	218	85	53						56
	REGIONAL LAB					484	590	77	157	
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	143	56	35						56
	CHICAGO	105	41	26						56
	CINCINNATI	58	23	14						56
	DETROIT	82	32	20						56
	MINNEAPOLIS	190	74	46						56
	NEW JERSEY	128	50	31						56
	PHILADELPHIA	132	51	32						56
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	435	169	106						56
	FLORIDA	628	244	153						100
	NEW ORLEANS	408	158	100						56
	SAN JUAN	28	11	7						55
	REGIONAL LAB					849		137	277	
SW	REGIONAL STAFF									
	DALLAS	197	76	48						55
	DENVER	52	20	14		150			50	55
	KANSAS CITY	50	19	12						55
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB					189		55	62	
PA	REGIONAL STAFF									
	LOS ANGELES	419	163	102						55
	SAN FRANCISCO	333	129	81		167		27	54	55
	SEATTLE	621	240	151						600
	PACIFIC REGIONAL LABORATORY-SW					210		34	69	
	PACIFIC REGIONAL LABORATORY-NW					311	295	50	101	
	HOURS PER OPERATION	18.5		4.5				11.0	17.5	
	TOTAL HOURS	87228	1830	5175		2360	885	4180	13475	2790
	CONVERSION FACTOR	930	930	930		1180	1180	1180	1180	930
	TOTAL OPERATIONAL FTEs	93.79	1.97	5.56		2.00	0.75	3.54	11.42	3.00

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
X	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	X	OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

* Additional PACs: 04842A, H, 07842, H, 09842E, H, 21842, 21R811, 21R839. ** Organoleptic National Expert.

*** Seafood collections are on a "For Cause" basis to document and support inspectional findings and for HACCP verification.

**** Resources provided to cover all processors annually except non high-risk warehouses. Workload of High/Low Risk firms provided by CFSAN. ***** European Certificate processing - resource distribution per CFSAN (use reporting operation code 92).

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

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

4. OBJECTIVES

To ensure a safe and wholesome imported seafood supply in the U.S. by enforcing importer compliance with the seafood HACCP regulation and to direct coverage of imported seafood products in order to determine their compliance with the FD&C Act and regulations promulgated under the Act.

To provide inspection coverage to as many importers as possible that import high-risk products could be health hazards. In addition, conduct follow-up inspection with firms found in noncompliance with the HACCP regulations.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C Act and its regulations. In FY 2001 the Agency will follow the approach begun in FY 98. This approach incorporated 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 the sample collection and analysis will be conducted to assure product conformity with current good manufacturing practices and other regulations promugulated under the FD&C Act.

6. FIELD OBLIGATIONS

HACCP trained investigators will review importer's written verification procedures, product specifications and affirmative step documents, which demonstrate the foreign processor's product was produced under HACCP, food safety hazards prevention program. Top priority is assigned to "substantial risk potential" products, including ready-to-eat processed products, scombrotoxic products, smoked products and vacuum packaged products.

NOTE: *Ciguatera toxin* confirmation test which require animals will be done at Pacific Regional Laboratory-NW.
Confirmation tests for *Clostridium botulinum & paralytic shellfish poison* will be split between SRL & Pacific Regional Laboratory-NW.
SRL will be the confirmation servicing laboratory for NE, CE & SE Regions.
Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	16

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

f. CHECK THE FOLLOWING ATTRIBUTES

See Compliance Program

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03844B, C, D, H; 07844: 09844E,F;	[X] ORA [ ] CENTER	70.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP * 03844H	4 IMPORT SAMPLE COLL PHYSICAL ***	9 LABEL EXAM	6 IMPORT FIELD EXAMS	8 ISAs ORGANO ANALYSES (Hours) **	8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED MICRO			
	TOTAL FIELD	700	5500	388	1552	904	4850	2730			
	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	113	506	36	143						
NE	NEW YORK	100	915	63	257						
	REGIONAL LAB					600	1278	719			
	WEAC										
	REGIONAL STAFF										
	BALTIMORE	19	234	17	66						
	CHICAGO	24	56	6	15						
	CINCINNATI	9	17		5						
CE	DETROIT	14	138	11	39						
	MINNEAPOLIS	8	7		3						
	NEW JERSEY	37									
	PHILADELPHIA	10	28		8						
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	13	32		9						
SE	FLORIDA	71	832	66	234						
	NEW ORLEANS	7	20		7						
	SAN JUAN	6	42		12						
	REGIONAL LAB						1038	584			
	REGIONAL STAFF										
	DALLAS										
SW	DENVER	5									
	KANSAS CITY	4									
	SOUTHWEST IMPORT DISTRICT	41	362	26	102						
	REGIONAL LAB						177	100			
	REGIONAL STAFF										
	LOS ANGELES	89	1490	105	421						
PA	SAN FRANCISCO	68	294	21	83		259	146			
	SEATTLE	62	527	37	148						
	PACIFIC REGIONAL LABORATORY-SW						1633	919			
	PACIFIC REGIONAL LABORATORY-NW					304	465	262			
	HOURS PER OPERATION	11.0	2.4	0.4	0.4		5.3	10.6			
	TOTAL HOURS	7700	13200	155	621	904	25705	28938			
	CONVERSION FACTOR	930	930	930	930	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	8.28	14.19	0.17	0.67	0.77	21.78	24.52			

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST	X	NATIONAL EXPERT		MILK/FOOD SPEC			ANALYTICAL	10/15/00	09/30/01
X	ENTOMOLOGIST	X	OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

* Per CFSAN, inspections of importers to ascertain that the importer has complied with Seafood HACCP regulations (not to perform filer inspections).

** Organoleptic National Expert

*** Includes resources for ISC Process Seafood / Processed Shrimp / V. Chol.

NOTE: Workload for ISC/Label Exam/Import Field Exams based on 3/1/99 - 4/30/00 FDA Review Lines (per prorities outlined in compliance program). Importer Inspection workload based on OASIS Consignee data as of 4/28/00.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections/Assessments	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

Conduct inspections at foreign firms actually exporting food to the U.S. in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, will take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety.

5. PROGRAM JUSTIFICATION

The number of illnesses and deaths related to foodborne 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 foodborne 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 inspectors, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN, for technical and compliance revi

PAC REPORTING INSTRUCTIONS: All CFSAN foreign inspection time is planned under PAC 03R233. The field should re accomplishments against PAC 03R233 (per CFSAN), using the Foreign Inspection Operation Code 11.

Technical Assistance hours planned under 03R233 includes time for grass roots meetings,

Follow-Up to Refusals, etc., and other operational activities not planned under this program. The activities should be reported under the appropriate PODS Operation Code.

!REMEMBER!: Follow-up to Refusal time should be reported against the appropriate PMS Follow Up to Refusal PAC (i.e. 03R824, 04R824, 07R824, 09R824 and 21R824).

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection outbreaks, infant formulas, seafood, cheese, etc.	02-50, 54

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

All methodology is in the IOM and BAM. Resources for samples generated as part of infant formula and medical foods progran are planned in those respective programs.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections/Assessments	Foodborne Biological Hazard

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R233	[X] ORA [ ] CENTER	14.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FOREIGN *	2 INVESTIGATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) * NATIONAL EXPERT						9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	250		3720						
	HEADQUARTERS			3720						
NE	REGIONAL STAFF									
	NEW ENGLAND	19								
	NEW YORK	10								
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	10								
	CHICAGO	10								
	CINCINNATI	9								
	DETROIT	10								
	MINNEAPOLIS	19								
	NEW JERSEY	10								
	PHILADELPHIA	10								
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	10								
	FLORIDA	10								
	NEW ORLEANS	28								
	SAN JUAN	9								
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	9								
	DENVER	10								
	KANSAS CITY	19								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	10								
	SAN FRANCISCO	19								
	SEATTLE	19								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	40.0								
	TOTAL HOURS	10000		3720						
	CONVERSION FACTOR	930		930						
	TOTAL OPERATIONAL FTEs	10.75		4.00						

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	x	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	x	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

9. REMARKS

Foreign activities per DEIO inspection distribution. Technical Assistance can include but are 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.

* Includes HQ CSO National Expert.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import and Domestic Micro Assignments	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To collect and analyze selected food commodities of domestic and foreign origin for pathogenic microorganisms. To determine the typical bioburden of various microbial pathogens on these products.

5. PROGRAM JUSTIFICATION

The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S.

The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it.

6. FIELD OBLIGATIONS

To collect samples and perform analyses as specified in the assignments issued by CFSAN.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fresh fruits and vegetables as specified in the assignments.	20-22, 24-25

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

f. CHECK THE FOLLOWING ATTRIBUTES

Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

All methodology is in the IOM and BAM except for Shegella and Salmonella which is contained in the assignments.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import and Domestic Micro Assignments	Foodborne Biological Hazards -03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F098 (Import) 03F100 (Domestic)	[X] ORA [X] CENTER	28.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		3 DOMESTIC SAMPLE COLLECTION PRODUCE SUREVY	7 DOMESTIC SAMPLE ANALYSIS MICRO	4 IMPORT SAMPLE COLLECTION PRODUCE SURVEY	8 IMPORT SAMPLE ANALYSIS MICRO				9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		600	600	300	300				
	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK				13					
	REGIONAL LAB			96		13				
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT		18							
	MINNEAPOLIS									
	NEW JERSEY		6							
	PHILADELPHIA				10					
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		26							
SE	FLORIDA		274		42					
	NEW ORLEANS									
	SAN JUAN				7					
	REGIONAL LAB			119		99				
	REGIONAL STAFF									
	DALLAS		27							
SW	DENVER			80						
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				162					
	REGIONAL LAB			65						
	REGIONAL STAFF									
	LOS ANGELES		170		66					
PA	SAN FRANCISCO		79	58						
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW			97		188				
	PACIFIC REGIONAL LABORATORY-NW			85						
	HOURS PER OPERATION		2.8	34.0	2.8	34.0				
	TOTAL HOURS		1680	20400	840	10200				
	CONVERSION FACTOR		930	1180	930	930				
	TOTAL OPERATIONAL FTEs		1.81	17.29	0.90	8.64				

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
x	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

See Domestic and Import Produce Assignments for Sample Collection and Analytical schedules.

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

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Approximately 450 foodborne 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 public health.

6. FIELD OBLIGATIONS

Field Districts will conduct investigations and inspection and collect and analyze the food samples as directed/coordinated by ORA headquarters and CFSAN.

NOTE: To ensure proper reporting of this time use PACs 03R829, 04R829 etc...

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
To be directed by assignments.	02-41, 45-47, 50, 52, 54

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

f. CHECK THE FOLLOWING ATTRIBUTES

To be determined by the nature of each assignment.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

To be determined by the nature of each assignment.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
3R839	[X] ORA [ ] CENTER	13.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1990 CENSUS RESIDENT POPULATION DATA	2 INVESTI-GATIONS (Hours)	2 MICRO-BIOLOGIST ON INVESTIGATION (Hours)						9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	285230516	8370	4720						
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	13922517	409							
	NEW YORK	18976457	557							
	REGIONAL LAB			545						
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	14755404	433							
	CHICAGO	12419293	364							
	CINCINNATI	15394909	452							
	DETROIT	16018929	470							
	MINNEAPOLIS	11680198	343							
	NEW JERSEY	8414350	247							
	PHILADELPHIA	13064654	383							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	20247778	594							
	FLORIDA	15982378	469							
	NEW ORLEANS	17450017	512							
	SAN JUAN	3808610	112							
	REGIONAL LAB			2469						
SW	REGIONAL STAFF									
	DALLAS	26975874	792							
	DENVER	8847258	260	807						
	KANSAS CITY	12921216	379							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	25182442	738							
	SAN FRANCISCO	17029632	500	282						
	SEATTLE	12138600	356							
	PACIFIC REGIONAL LABORATORY-SW			416						
	PACIFIC REGIONAL LABORATORY-NW			201						
	HOURS PER OPERATION									
	TOTAL HOURS		8370	4720						
	CONVERSION FACTOR		930	1180						
	TOTAL OPERATIONAL FTEs		9.00	4.00						

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-		
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN	TIONAL	10/01/00	09/30/01
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL		

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Food State Contract Audits	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Currently, about 5,000 food inspections are contracted out each year 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 2001. Guidance for conducting an audit investigation is to be provided by the Division of Federal State Relations.

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products	02-41, 45-46, 50

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Food State Contract Audits	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R843	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INV ** HOURS FOOD STATE CONTRACT AUDITS	* NUMBER OF FOOD STATE CONTRACT AUDITS	3 DOMESTIC SAMPLES COLL	4 IMPORT SAMPLE COLL	7 MICRO BIOL ON INSP (Hours)	7 DSAs ORGANO EXAMS (Hours) **	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO	
	TOTAL FIELD	3720	(372)							
	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	210	(21)							
NE	NEW YORK	160	(16)							
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	280	(28)							
	CHICAGO	210	(21)							
	CINCINNATI	280	(28)							
CE	DETROIT	100	(10)							
	MINNEAPOLIS	240	(24)							
	NEW JERSEY	220	(22)							
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	190	(19)							
SE	FLORIDA	150	(15)							
	NEW ORLEANS	280	(28)							
	SAN JUAN	50	(5)							
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	410	(41)							
SW	DENVER	120	(12)							
	KANSAS CITY	240	(24)							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE	580	(58)							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION		(10.0)							
	TOTAL HOURS	3720	(3720)							
	CONVERSION FACTOR	930	(930)							
	TOTAL OPERATIONAL FTEs	4.00	(4.00)							

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

9. REMARKS

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.

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Minnesota Department of Agriculture Laboratory Partnership	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

The Minnesota Department of Agriculture Laboratory Partnership is designed to "test" the viability of involving State laboratories in FDA's analytical activities.

5. PROGRAM JUSTIFICATION

The Minnesota Department of Agriculture Laboratory Partnership is an outgrowth of the food safety movement to integrate FDA's analytical activities with state and local representatives.

NOTE: CONTACT DFS REGARDING ANY QUESTIONS: 301-827-1032.

6. FIELD OBLIGATIONS

Not applicable

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products	02-41, 45-46, 50

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Minnesota Department of Agriculture Laboratory Partnership	Foodborne Biological Hazard

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
*	[X] ORA [ ] CENTER	*SEE REMARKS SECTION

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES ANALYZED PARTNERSHIP HRS								9 OTHER OPERATIONS (Hours)
	TOTAL FIELD									
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	3540								
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	3540								
	CONVERSION FACTOR	1180								
	TOTAL OPERATIONAL FTEs	3.00								

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE			8. WORK SCHEDULE		
								PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC-		
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN	TIONAL		
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL	10/15/2000	9/30/2001

9. REMARKS

* THIS SHEET IS FOR INFOMRATION AND GUIDANCE ONLY

These resources represent the Minnesota Department of Agriculture Laboratory Partnership.

This Partnership is designed to "test" the viability of involving State laboratories in FDA's analytical activities.

This work will be done outside the workplan. Contact DFS regarding any questions: 301-827-1032.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: N/A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
3R816	[X] ORA [ ] CENTER	17.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 DISTRICT RESEARCH CHEMIST (Hours)	9 RESEARCH CENTER RESEARCH CHEMIST (Hours)	9 DISTRICT RESEARCH MICRO (Hours) *	9 RESEARCH CENTER RESEARCH MICRO (Hours)	9 FSI RISK ASSESSMENT COLLABORATIVE RESEARCH MICRO (Hours) **				
	TOTAL FIELD			10300	4720	5352				
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB			3850		1338				
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CIINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB			1700		1338				
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO			1900						
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW			500		1338				
	PACIFIC REGIONAL LABORATORY-NW			2350	4720	1338				
	HOURS PER OPERATION									
	TOTAL HOURS			10300	4720	5352				
	CONVERSION FACTOR			1205	1180	1205				
	TOTAL OPERATIONAL FTEs			8.55	4.00	4.44				

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE		
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL		
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

NOTE: * DISTRICT RESEARCH MICRO (HOURS) FOR FOOD SAFETY INITIATIVE
** FOOD SAFETY INITIATIVE (FSI) RISK ASSESSMENTS/COLLABORATIVE RESEARCH
REPORT UNDER PAC 03R816

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME-NUMBER
Food and Cosmetics	Pesticides and Chemical Contaminants - 04

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		66.5	48.5		115.0	207.7	
1	Pesticides and Industrial Chemicals in Domestic Foods	04004A,D	19.7	5.9		25.6	49.7	2-3
2	Pesticides and Industrial Chemicals in Imported Foods	04016A*		28.8		28.8	56.9	4-5
	Seafood Chemotherapeutic Sampling Assignment	04018	1.8	2.0		3.8	7.2	6-7
3	Toxic Elements in Food and Foodware		2.7	11.8		14.5	28.1	
	Toxic Elements in Foods (Domestic and Import)*	04019A**	(0.7)	(7.4)		(8.1)	(15.8)	8-11
	Toxic Elements in Foodware (Domestic and Import)	04019B	(1.8)	(3.9)		(5.7)	(11.0)	
	Radionuclides in Foods (Domestic and Import)	04019C	(0.2)	(0.5)		(0.7)	(1.3)	
4	Total Diet Study	04839	22.9			22.9	44.4	12-13
5	Genetically Modified Corn Assignments	04F102	2.1			2.1	4.1	14-15
6	Science Advisor Research Assoc. Program(SARAP)	04R813	1.0			1.0	1.0	16-17
7	ORA-Center Directed Research Projects	04R816	5.3			5.3	5.3	18-19
8	Forensic Evaluation and Sample Analysis	04R838	11.0			11.0	11.0	20-21

* 04R833, 99R833,04R824

** Includes DISC and DISA FTEs

CENTER PROJECT MANAGER-TELEPHONE	ORA PLANNER-TELEPHONE
Ronald R. Roy (202) 205-2262	Lorraine B. Jefferson, 301-827-1630

FORM FDA 2622 (9-98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Domestic Foods	Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNM'

4. OBJECTIVES

To enforce tolerances and other regulatory limits for pesticides and industrial chemicals in domestically produced foods shipped in interstate commerce. To determine incidence and levels of Pesticides and industrial chemicals in domestically produced food. To remove from commerce food containing residues of regulatory significance. In FY 01 there is an increased emphasis on dioxins.

5. PROGRAM JUSTIFICATION

The food supply requires monitoring for both pesticides and industrial chemicals. This is indicated by previous program results, by needs identified via EPA or other means, and by pesticide usage data.

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 survey). Districts are encouraged to utilize this time for special district-initiated surveys.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All foods consumed by human.	All human food codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

Pesticides and industrial chemicals.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Domestic Foods	Pesticides and Chemical Contaminants -04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04004A, D	[X] ORA [X] CENTER	25.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INV (hours)	3 DSCs *	3 DSCs EPAs	7 DSAs	7 DSAs EPA	7 DI/DSC Dioxins	DSAs Dioxins ***	7 DSAs (HOURS) ** MASS SPEC	3 DSCs SEAFOOD PEST (04004A)	7 DSAs SEAFOOD PEST (04004A)
	TOTAL FIELD	500	2300	(712)	2300	(712)	500	700	1835	175	175
	HEADQUARTERS										
	REGIONAL STAFF										
NE	NEW ENGLAND	11	51	(34)			34			7	
	NEW YORK	19	87	(14)			49			14	
	REGIONAL LAB				90				665		21
	WEAC										
	REGIONAL STAFF										
	BALTIMORE	8	35	(14)			44			21	
	CHICAGO	20	93	(12)			16			7	
	CINCINNATI	11	52	(14)			10				
CE	DETROIT	24	109	(22)			10				
	MINNEAPOLIS	50	231	(34)							
	NEW JERSEY	5	24	(24)						7	
	PHILADELPHIA	10	45	(24)			26			7	
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	12	56	(14)			39			7	
	FLORIDA	39	178	(56)			44			14	
	NEW ORLEANS	10	43	(16)			36			32	
	SAN JUAN									7	
	REGIONAL LAB				271						95
	REGIONAL STAFF										
	DALLAS	15	67	(18)			16			17	
	DENVER	30	140	(96)							
	KANSAS CITY	43	196	(22)	267		47				17
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB				365			700	1180		7
	REGIONAL STAFF										
PA	LOS ANGELES	53	242	(170)			45			17	
	SAN FRANCISCO	58	268	(44)			43			7	
	SEATTLE	82	383	(84)			41			11	
	PACIFIC REGIONAL LABORATORY- SW				646	(350)					24
	PACIFIC REGIONAL LABORATORY- NW				661	(362)					11
	HOURS PER OPERATION		2.2		4.7		3.5	10.0		2.2	4.7
	TOTAL HOURS	500	5060		10810		1750	7000	1845	385	823
	CONVERSION FACTOR	930	930		1180		930	1180	1180	930	1180
	TOTAL OPERATIONAL FTEs	0.54	5.44		9.16		1.88	5.93	1.56	0.41	0.70

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

* Approximately 712 samples for EPA's Food Quality Protection Act (FQPA) for organophosphates.

** DSA Hours: MASS SPEC in NRL & ARL

***Includes analyses of 200 of Total Diet Study sample homogenates.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Imported Foods	Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To determine incidence and levels of pesticides and industrial chemicals in imported food (including seafood and aquaculture products); and, to prevent importation of products failing to meet the requirements of the FD&C Act.

5. PROGRAM JUSTIFICATION

Imported food requires monitoring for the presence of both pesticides and industrial chemicals to enforce tolerances, regulatory limits, and other requirements of the FD&C Act. This is indicated by precious program results, by needs identified via EPA or other means, and by foreign pesticides usage information.

6. FIELD OBLIGATIONS

Emphasis on pesticide/commodity combinations with high exposure potentials in planning sampling for pesticides. Emphasis should be given on foods eaten by infants and children. Designation of a portion of each District's total resources which may be devoted to special assignments. (e.g. Center- directed surveys).

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

Pesticide and industrial chemicals.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Imported Foods	Pesticides and Chemical Contaminants - 04

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04016A	X ORA ___ CENTER	28.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY			4 ISCs	4 ISCs EPA **	8 ISAs	8 ISAs EPA *	4 ISCs SEAFOOD (PEST)	8 ISAs SEAFOOD (PEST)	
	TOTAL FIELD			4600	(288)	4600	(288)	300	300	
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND			131				31		
	NEW YORK			395	(55)			43		
	REGIONAL LAB					471			74	
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			116	(10)			10		
	CHICAGO			117	(20)					
	CINCINNATI			101						
	DETROIT			256	(17)			11		
	MINNEAPOLIS			103						
	NEW JERSEY									
	PHILADELPHIA			244	(34)					
	FORENSIC CHEM. CTR									
SW	REGIONAL STAFF									
	ATLANTA			103	(10)					
	FLORIDA			371	(31)			61		
	NEW ORLEANS			104						
	SAN JUAN			126						
	REGIONAL LAB					1080			71	
PA	REGIONAL STAFF									
	LOS ANGELES			253	(44)			68		
	SAN FRANCISCO			116	(10)			18		
	SEATTLE			239	(6)			35		
	PACIFIC REGIONAL LABORATORY-SW					2241	(152)		109	
	PACIFIC REGIONAL LABORATORY-NW					369	(136)		35	
	HOURS PER OPERATION			1.2		5.4		1.3	5.4	
	TOTAL HOURS			5520		24840		390	1620	
	CONVERSION FACTOR			930		1180		930	1180	
	TOTAL OPERATIONAL FTEs			5.94		21.1		0.42	1.4	

7. PERSONNEL TYPES REQUIRED — 8. WORK SCHEDULE

ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPECTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALYTICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

9. REMARKS

* Samples for EPA Food Quality Protection organaphasphate pesticide assignment (EPA ISAs split between PRN & PRS Labs) and EPA ISAs are included in ISAs

EPA ISCs are included in ISCs

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Seafood Chemotherapeutics Sampling Assignment	Pesticides and Chemical Contaminants

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

4. OBJECTIVES

To sample and analyze imported and domestically produced aquaculture products to obtain information on potential residues of illegal drugs and initiate administrative or regulatory actions against shipments found to contain illegal residues.

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.

6. FIELD OBLIGATIONS

Districts will collect domestic and import samples of products specified in the assignment.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	16

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

f. CHECK THE FOLLOWING ATTRIBUTES

Non-permitted ingredients, microbiological/contaminants, labeling warnings.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Seafood Chemotherapeutic Sampling Assignment	Pesticides and Chemical Contaminants -04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
0[illegible]18	[X] ORA [X] CENTER	3.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INV (hours)	4 ISCs	3 DSCs	7 ISAs	7 DSAs	7	7	3	7
	TOTAL FIELD		125	100	125	100				
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND		3	15						
	NEW YORK									
	REGIONAL LAB		10		13	15				
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI		6							
CE	DETROIT		22							
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA		30							
	NEW ORLEANS		2	40						
	SAN JUAN									
	REGIONAL LAB				32	40				
	REGIONAL STAFF									
	DALLAS			20						
	DENVER				28	30				
	KANSAS CITY			10						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES		52							
	SAN FRANCISCO									
	SEATTLE			15						
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW				52	15				
	HOURS PER OPERATION		2.0	4.0	16.0	16.0				
	TOTAL HOURS		250	400.0	2000	1600				
	CONVERSION FACTOR		930	930	1180	1180				
	TOTAL OPERATIONAL FTEs		0.27	0.43	1.69	1.36				

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Food. Foodware: (Domestic and Import)	Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To determine the incidence and levels of lead. cadmium and other toxic elements of significance and radionuclides in domestic. imported food and seafood and domestic and imported 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 and seafood; and domestic and imported foodware for the presence of toxic elements (i.e., lead, cadmium and other elements of significance).

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 are to be sampled and analyzed for the presence of toxic elements in accordance with instructions for this activity contained in the "Toxic Element" program. Analysis of additional elements of significance will be added as methodology becomes available.

Sample collections, analyses and other activities relating to domestic and imported foodware will continue as directed by the "Toxic Element" program.

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All human food products. Ceramic foodware.	02 - 41, 52A

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

f. CHECK THE FOLLOWING ATTRIBUTES

Lead, cadmium and other toxic elements as directed. DOMESTIC - tritium, ^{90}Sr & gamma ray emiters; IMPORTS: ^{134}Cs, ^{137}Cs and ^{90}Sr

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Radiochemical analysis capability. (Available only at WEAC.)
Graphite furnace atomic absorption with Zeeman background correction.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Foods (Domestic and Import)	Pesticides and Chemical Contaminants - 04

OGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019A	[X] ORA [X] CENTER	14.5 (8.1)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		2 INVESTI-GATIONS (Hours)	3 DISC NON SEAFOOD	8 DISA NON SEAFOOD	3 DSCs (Seafood) Trace Elements	7 DSAs (Seafood) Trace Elements	3 DISC SEAFOOD Trace Elements	8 DISA SEAFOOD Trace Elements	
	TOTAL FIELD			525	525	70	70	200	200	
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND			19		7		32		
	NEW YORK			105				34		
	REGIONAL LAB				124		7		66	
	WEAC									
	REGIONAL STAFF									
	BALTIMORE			15		7		16		
	CHICAGO			12						
	CINCINNATI									
CE	DETROIT			25						
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA			12						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA			13		7				
	FLORIDA			38		3		29		
	NEW ORLEANS					11				
	SAN JUAN									
	REGIONAL LAB				78		28		45	
	REGIONAL STAFF									
	DALLAS					4		11		
	DENVER									
	KANSAS CITY				211		4		11	
	SOUTHWEST IMPORT OPERATION			174						
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES			58		12		32		
	SAN FRANCISCO			26	112	7	31	14	78	
	SEATTLE			28		12		32		
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION				1.6	10.0	1.6	10.0	1.6	10.0	
TOTAL HOURS				840	5250	112	700	320	2000	
CONVERSION FACTOR				930	1180	930	1180	930	1180	
TOTAL OPERATIONAL FTEs				0.90	4.45	0.12	0.59	0.34	1.69	

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

* Area of emphasis for toxic elements in non-seafood products are foods manufactured in Asia, Eastern Europe, Central and South America, processed foods, and foods likely to be consumed by children.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Foodware (Domestic and Import)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019B	[X] ORA [ ] CENTER	(5.7)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		3 DSCs (Houseware) *	4 ISCs (Houseware)	5 FIELD EXAMS	6 IMPORT FIELD EXAMS	7 DSAs	8 ISAs		
	TOTAL FIELD		210	400	485	2750	210	400		
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND		18	13	41	87				
	NEW YORK		7	121	17	829				
	REGIONAL LAB						25	134		
	WEAC									
	REGIONAL STAFF									
	BALTIMORE			20	5	140				
	CHICAGO		4	24	9	164				
	CINCINNATI		47	8	109	57				
CE	DETROIT			8	2	29				
	MINNEAPOLIS		6		11	22				
	NEW JERSEY				5					
	PHILADELPHIA		6	12	4	82				
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		13	15	31	106				
	FLORIDA			8	2	51				
	NEW ORLEANS		14	20	33	141				
	SAN JUAN				2	9				
	REGIONAL LAB						80	75		
	REGIONAL STAFF									
SW	DALLAS				2					
	DENVER				3					
	KANSAS CITY		5		7		15	40		
	SOUTHWEST IMPORT OPERATION			47		321				
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES		39	72	90	494				
	SAN FRANCISCO		51	19	109	130	51	19		
	SEATTLE			13	3	88				
	PACIFIC REGIONAL LABORTORY-SW						39	119		
	PACIFIC REGIONAL LABORTORY-NW							13		
HOURS PER OPERATION			2.0	1.0	0.4	0.3	7.5	7.0		
TOTAL HOURS			420	400	194	825	1575	2800		
CONVERSION FACTOR			930	930	930	930	1180	1180		
TOTAL OPERATIONAL FTEs			0.45	0.43	0.21	0.89	1.33	2.37		

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

*DSCs should be collected at warehouses and retail level if samples collected during inspections do not meet obligations.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Radionuclides in Foods (Domestic and Import)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04019C	[X] ORA [X] CENTER	(0.7)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 Inspections	2 INV	3 DSCs	4 ISCs	5 Field Exams	6 Import Field Exams	7 DSAs	8 ISAs	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD			16	84			16	84	
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK				17					
	REGIONAL LAB									
	WEAC							16	84	
	REGIONAL STAFF									
	BALTIMORE				4					
	CHICAGO			4	3					
	CINCINNATI									
CE	DETROIT				4					
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA			4						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA				8					
	NEW ORLEANS			4						
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION				29					
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES				10					
	SAN FRANCISCO			4	4					
	SEATTLE				5					
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION			2.0	1.9			15.0	3.5	
	TOTAL HOURS			32	160			240	294	
	CONVERSION FACTOR			930	930			1180	1180	
	TOTAL OPERATIONAL FTEs			0.03	0.17			0.20	0.25	

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

CFSAN spreads DSCs based on location of nuclear power plants.
CFSAN will provide guidance for all assignments.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Total Diet Study	Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To determine the levels of occurrence and dietary intakes of selected pesticides, industrial chemicals and toxic elements by various age/sex groups through analyses of table-ready foods, to observe differences or trends in the intake of these chemicals, and to investigate unusual findings.

To monitor radionuclide levels in food.

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 of the National Nutrition Monitoring System (NNMS).

5. PROGRAM JUSTIFICATION

This 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 and selected nutrients, in addition to selected pesticides, industrial chemicals and toxic elements).

The current Selected Nutrients in Foods 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

The collection and analysis of four market baskets, each consisting of three separate samplings of 260 items, which are to be obtained simultaneously from three locales in the region, over a five week period.

KAN-DO will analyze Total Diet samples for selected pesticides, industrial chemicals and toxic elements. KAN-DO will analyze Total Diet samples for 12 nutrients identified in item 7f, below. The Atlanta Center for Nutrient Analysis (ACNA) will analyze Selected Total Diet samples from one market basket annually for folic acid. WEAC will analyze the first market basket for radionuclides.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Various Human Foods	All Human Food Codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

Pesticides, industrial chemicals, selected toxic elements. Calcium, phosphorus, iron, selenium, zinc, copper, magnesium, nickel, Manganese, potassium, sodium, iodine and water. ^{90}Sr, ^{106}Ru, ^{137}Cs, ^{131}I, ^{40}K.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Radiochemical analysis capability. (Available only at WEAC.)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Total Diet Study	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04839	[ ] ORA [X] CENTER	22.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLES COLLECTED (TOTAL DIET) *	2 DOMESTIC SAMPLE TO BE ANALYZED **	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) ***						
	TOTAL FIELD	60	1116							
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	5								
	NEW YORK	5								
	REGIONAL LAB									
	WEAC			1						
	REGIONAL STAFF									
	BALTIMORE	5								
	CHICAGO	5								
	CINCINNATI	5								
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA	5								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA	5								
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS	5								
	DENVER	5								
	KANSAS CITY	5	1116							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO	5								
	SEATTLE	5								
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION	23.0	20.1	2800						
	TOTAL HOURS	1380	22432	2800						
	CONVERSION FACTOR	930	1180	1180						
	TOTAL OPERATIONAL FTEs	1.48	19.01	2.37						

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH		INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/99	09/30/00
ANALYTICAL	10/15/99	09/30/00

9. REMARKS

* Each DSC represents a District's weekly collection of specified food items.

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

*** All TDS food items from one market basket analyzed by WEAC for selected radionuclides.

1. PROGRAM/ASSIGNMENT TITLE	2. PMS PROJECT NAME/NUMBER
Genetically Modified Corn Assignments	Pesticides and Contaminants – 04

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

4. OBJECTIVES

To collect and analyze corn and finished corn products for the presence of Cry9C, a protein added to corn seed. EPA has approved the use of Cry9C for animal use BUT NOT for human consumption.

5. PROGRAM JUSTIFICATION

Unapproved for human consumption, Cry9C protein has been found in human, corn-containing foods. These assignments are intended to find such genetically modified corn at corn processors and finishers that manufacture human, corn-containing foods.

6. FIELD OBLIGATIONS

Districts are instructed to collect 2 samples of corn meal from each firm designated in the assignments (CFSAN Field Assignments #01-05 and #01-09).

Districts are also instructed to collect 3-5 samples of finished corn-containing foods at each firm designated in assignment (CFSAN Field Assignments).

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)
Corn Meal and finished Corn Products	02 B [ ] [ ]

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Trait Bt9 Lateral Flow Test Kit and PCR Analysis

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Genetically Modified Corn Assignment	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
102	[ ] ORA [X] CENTER	2.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DSC *	DSC **	DSC ***		TEST KIT DSA %	PCR DSA	PROJECTED PCR DSA @		
	TOTAL FIELD	28	40	89		68	89	14		
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND			4						
	NEW YORK			7						
	REGIONAL LAB					13	30	3		
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		2	9						
	CHICAGO	9		6						
	CINCINNATI	2	4	3						
	DETROIT	2	2							
	MINNEAPOLIS		4	7						
	NEW JERSEY									
	PHILADELPHIA			10						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		4	8						
	FLORIDA			5						
	NEW ORLEANS		6	4						
	SAN JUAN		2							
	REGIONAL LAB					26	34	5		
SW	REGIONAL STAFF									
	DALLAS	3	4	8						
	DENVER			5						
	KANSAS CITY	8	4	5						
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL STAFF									
	LOS ANGELES	2		4						
	SAN FRANCISCO	2	4							
	SEATTLE		4	4						
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW					29	25	6		
	HOURS PER OPERATION	7.3	7.3	3.7		5.5	10.0	10.0		
	TOTAL HOURS	203	292	329		374.0	890.0	140.0		
	CONVERSION FACTOR	930	930	930		1180	1180	1180		
	TOTAL OPERATIONAL FTEs	0.22	0.31	0.35		0.32	0.75	0.12		

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

(*)Corn Meal, Assignment 01-05
(**) Corn Meal, Assignments 01-09
(***) Finished corn products, Assignment 01-06
(%) BT 9 Lateral flow test kit
(@) Projected PCR Analysis for Corn Meal Assignments 01- 05 and 01- 09
FTEs and DSAs are estimates based on FY' 99 & FY '00 FACTS accomplishment data.

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

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: N/A A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Science Advisors Research Associate Program (SARAP)	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04R813	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 (SARAP) SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION							
	TOTAL FIELD	1205								
	HEADQUARTERS									
NE	REGIONAL STAFF									
	BUFFALO									
	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									
	NASHVILLE									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB	1205								
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1205								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	1.00								

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL		
ANALYTICAL	10/1/00	09/30/01

9. REMARKS

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

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: N/A A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

OGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04R816	[X] ORA [ ] CENTER	5.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 DISTRICT RESEARCH (CHEM)	9 RESEARCH CENTER (CHEM)							
	TOTAL FIELD	350	5900							
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY	350	5900							
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
HOURS PER OPERATION										
TOTAL HOURS		350	5900							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		0.29	5.00							

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL		
ANALYTICAL	10/1/99	09/30/00

9. REMARKS

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

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

4. OBJECTIVES

Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations.

This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law.

It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.

5. PROGRAM JUSTIFICATION

Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.

6. FIELD OBLIGATIONS

Appropriate scientific analysis of official physical samples in support of Investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 04R838 or OCI PAC 04R831.

Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 04R838; Petition Validation, Methods Development, or Forensic Evaluation.

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

b. INSPECTION TYPE: N/A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04R838	[X] ORA [ ] CENTER	11.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION							
	TOTAL FIELD	1180	11800							
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR	1180	11800							
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1800	11800							
	CONVERSION FACTOR	1180	1180							
	TOTAL OPERATIONAL FTEs	1.00	10.00							

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE		
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL		
ANALYTICAL	10/1/00	09/30/01

9. REMARKS

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
ood and Cosmetics	Molecular Biology and Natural Toxins: Food and Cosmetics - 07

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		19.9	6.6		26.5	46.4	
1	Mycotoxins in Domestic Foods	07001	14.6			14.6	28.3	2-5
2	Mycotoxins in Imported Foods	07002		6.6		6.6	12.8	6-9
3	ORA/Center Directed Research Projects	07R816	5.3			5.3	5.3	10-11

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (202) 205-2262	Lorraine B. Jefferson (301)827-1631

FORM FDA 2622 (9/98)

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

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

4. OBJECTIVES

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

To remove from interstate commerce those foods which contain aflatoxins at level 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.

Fumonisins is a naturally occurring toxin metabolites produced by fungus which occurs ubiquitously on corn from around the world. world. Because of its potential carcinogenicity and its frequent occurence in corn based feeds and foods, its presence should be monitored, especially for incidence data.

Deoxynivelol (DON) is a trichothecene mycotoxin produced by several strains of *Fusarium*, which under certain climatic conditions, conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated acute ga gastrointestinal illness in humans in China and India. An advisory level of 1 ppm for DON in finished wheat products has been issued by FDA. There is a need for continuous monitoring of this toxin.

Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera *Aspergillis* and *Penicillium*. It is mainly a contaminant of 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 produced by several species of mold fungi including *Penicillium expansum*, the causal 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. In the U.S. there is need for more exposure data to assess the potential risk associated with the presence of this toxin in apple juice.

6. FIELD OBLIGATIONS

The field will conduct follow-up inspections, collect, and analyze samples of domestic products as directed by the Compliance Program.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Attachment "A" C.P. 7307.001 for list of Products.	02, 03, 05, 07, 09, 12, 13, 23, 24

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

f. CHECK THE FOLLOWING ATTRIBUTES

Aflatoxins, Fumonisins B_1 and B_2, Deoxynivalenol (DON), Ochratoxin A, and Patulin.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE
Mycotoxins in Domestic Foods

2. PFS PROJECT NAME/NUMBER
Molecular Biology and Natural Toxins:

3. PROGRAM/ASSIGNMENT CODE(S)
07001

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

5. OPERATIONAL FTE POSITIONS
14.6 (6.8)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY		3 DOMESTIC SAMPLE COLL AFLA	3 DOMESTIC SAMPLE COL FUM	3 DOMESTIC SAMPLE COL DON	3 DOMESTIC SAMPLE COL OCHRA	3 DOMESTIC SAMPLE COL PATULIN			9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		800	400	125	125	400			
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND		19	5		3	36			
	NEW YORK		25	8	12	6	32			
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE		35	10		6	21			
	CHICAGO		53	48	12	9	28			
	CINCINNATI		72	63	10	7	14			
CE	DETROIT		43	38	12	8	64			
	MINNEAPOLIS		29	15	22	14	17			
	NEW JERSEY		14	3		2	19			
	PHILADELPHIA		34	14	7	7	51			
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		113	28		11	6			
	FLORIDA		24	4	3	4	12			
SE	NEW ORLEANS		66	31	7	8	5			
	SAN JUAN		4	3	2		4			
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS		77	35	4	6	5			
	DENVER		10	5		3	3			
	KANSAS CITY		26	25	9	9	15			
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		48	18	5	5	12			
	SAN FRANCISCO		66	19	7	6	14			
	SEATTLE		42	28	13	11	42			
PA	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY- NW									
	HOURS PER OPERATION		3.4	3.4	3.4	3.4	3.4			
	TOTAL HOURS		2720	1360	425	425	1360			
	CONVERSION FACTOR		930	930	930	930	930			
	TOTAL OPERATIONAL FTEs		2.92	1.46	0.46	0.46	1.46			

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS
Hours per operation for ISAs is an average based on accomplishment data for all mycotoxins sample analysis.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001	[X] ORA [ ] CENTER	(7.8)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLE ANAL AFLA	7 DOMESTIC SAMPLE ANAL FUM	7 DOMESTIC SAMPLE ANAL DON	7 DOMESTIC SAMPLE ANAL OCHRA	7 DOMESTIC SAMPLE ANAL PATULIN				9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	800	400	125	125	400				
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB			31	31	173				
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB	800		56		136				
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY		400	13	72	23				
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PA	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY- NW			25	22	68				
	HOURS PER OPERATION	5.0	5.0	5.0	5.0	5.0				
	TOTAL HOURS	4000	2000	625	625	2000				
	CONVERSION FACTOR	1180	1180	1180	1180	1180				
		3.39	1.69	0.53	0.53	1.69				

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

Page 2 of 2

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

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

4. OBJECTIVES

To direct coverage of imported food products in order to determine their compliance with the FD&C Act and regulations promulgated under the Act in regards to mycotoxin contamination.

To determine the incidence and levels of aflatoxins, fumonisins, dexynivalenol (DON), ochratoxin, and patulin in specific imported foods.

5. PROGRAM JUSTIFICATION

This program monitors imported products known to be susceptible to aflatoxin contamination and prevents food found to be contaminated with aflatoxins above 20 ng/g from reaching consumer channels. It also gathers data on foods suspected of having the the potential for aflatoxin contamination.

Fumonisins B_1 and B_2 are naturally occurring toxin metabolites produced by fungus which occur ubiquitously on corn from around the the world. Because of its potential carcinogenicity and its frequent occurrence in corn based feeds and foods, their presence monitored specifically for incidence data.

Deoxynivelol (DON) is a trichothecene mycotoxin produced by several strains of *Fusarium*, which under certain climatic conditions, Conditions, invade certain grains in the field (particularly wheat). There have been reports of outbreaks of DON-associated acute Gastrointestinal illness in humans in China and India. An advisory level of 1 ppm for DON in finished wheat products has been Issued by FDA. There is a need for continuous monitoring of this toxin.

Ochratoxin A is a nephrotoxic metabolite produced by certain species of the genera *Aspergillis* and *Penicillium*. It is mainly a contaminant of 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 produced by several species of mold fungi including *Penicillium expansum*, the causal 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. In the U.S. there is need for more exposure data to assess the potential risk associated with the presence of this toxin in apple juice.

6. FIELD OBLIGATIONS

The field will collect and analyze samples of imported food products as directed by the Compliance Program. Some resources may be expended to develop a history on foods suspected of having the potential for mycotoxin contamination (i.e., sesame,poppy seeds, white pepper, nutmeg, figs, paprika, turmeric, and cinnamon) on a when encountered basis.

All samples designated for special surveillance coverage and fumonisin analysis will be sent to MAL.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Attachment "A" of CP 7307.002 for list of products	02, 03, 05, 07, 23, 24, 28

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

f. CHECK THE FOLLOWING ATTRIBUTES

Aflatoxins, Fumonisins B_1 and B_2, Deoxynivalenol (DON), Ochratoxin A, and Patulin.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07002	[X] ORA [ ] CENTER	6.6 (1.9)

6. REGION	DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL AFLATOXIN	4 IMPORT SAMPLE COLL PEANUT BUTTER	4 IMPORT SAMPLE COL FUMON	4 IMPORT SAMPLE COL DON	4 IMPORT SAMPLE COL OCHRA	4 IMPORT SAMPLE COL PATULIN	4 IMPORT SAMPLE COL SPECIAL SURV		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	500	(105)	200	80	80	200	40		
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	11			4		7			
	NEW YORK	136	(20)	39	28	20	79	16		
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	16	(4)		2		6			
	CHICAGO	11			5					
	CINCINNATI									
CE	DETROIT	79	(44)	42	11	8	23	4		
	MINNEAPOLIS	25			8	7				
	NEW JERSEY									
	PHILADELPHIA						11			
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	19	(10)		2		7			
	FLORIDA	12		9		8	8	4		
SE	NEW ORLEANS	3				8				
	SAN JUAN			25						
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT	31		63		8	34	4		
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	54		12	7	6	8	7		
PA	SAN FRANCISCO	26			3	7		5		
	SEATTLE	77	(27)	10	10	8	17			
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION	1.6		1.6	1.6	1.6	1.6	1.6		
	TOTAL HOURS	800		320	128	128	320	64		
	CONVERSION FACTOR	930		930	930	930	930	930		
	TOTAL OPERATIONAL FTEs	0.86		0.34	0.14	0.14	0.34	0.07		

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

The 105 peanut butter samples in parentheses are included in the ISCs for aflatoxins

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07002	[X] ORA [ ] CENTER	(4.7)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLE ANAL ALFA	8 IMPORT SAMPLE ANAL FUMON	8 IMPORT SAMPLE ANAL DON	8 IMPORT SAMPLE ANAL OCHRA	8 IMPORT SAMPLE ANAL PATULIN	8 IMPORT SAMPLE SPECIAL SURV			9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	500	200	80	80	200	40			
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	147		34	20	103				
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB	165		26	23	38	40			
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY	31	200		16	34				
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW	157		20	21	25				
	HOURS PER OPERATION	5.0	5.0	5.0	5.0	5.0	5.0			
	TOTAL HOURS	2500	1000	400	400	1000	200			
	CONVERSION FACTOR	1180	1180	1180	1180	1180	1180			
		2.12	0.85	0.34	0.34	0.85	0.17			

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

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

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
16	[X] ORA [ ] CENTER	5.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEMIST	RESEARCH CENTER RESEARCH MICRO					
	TOTAL FIELD	1550		4130	590					
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	500								
	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			3540						
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW	600								
	PACIFIC REGIONAL LABORTORY - NW	450		590	590					
	HOURS PER OPERATION									
	TOTAL HOURS	1550		4130	590					
	CONVERSION FACTOR	1205		1180	1180					
	TOTAL OPERATIONAL FTEs	1.28		3.50	0.50					

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL		
ANALYTICAL	10/15/2000	09/30/2001

9. REMARKS

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
and Cosmetics	Food and Color Additives Petition Review and Policy Development - 09

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL			7.0		7.0	13.6	
1	Imported Foods-Food and Color Additives	09006A,B		7.0		7.0	13.6	2-3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (202) 205-2262	Lorraine B. Jefferson (301)827-1631

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

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

4. OBJECTIVES

To direct coverage of imported food products in order to determine their compliance with the FD&C Act and regulations regulations promulgated under the Act.

5. PROGRAM JUSTIFICATION

Imported as well as domestic products must comply with the provisions of the FD&C Act and the regulations for food and color additives. The Imported Foods--Food and Color Additives Compliance Program directs sample collections and label/ record reviews of imported foods for unsafe food additives and non-permitted food/undeclared color additives to insure that these foods meet the requirements of the law.

6. FIELD OBLIGATIONS

The field is to collect and analyze samples of imported food products having a known potential for food and color additive violations.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

Food and color additives

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
A,B	[X] ORA [ ] CENTER	7.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2	4 ISCs COLOR ADDITIVIES	9 LABEL REVIEW COLOR ADDITIVES	8 ISAs COLOR ADDITIVES	4 ISCs FOOD ADDITIVES	9 LABEL REVIEW FOOD ADDITIVES	8 ISAs FOOD ADDITIVES		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		755	250	755	270	540	270		
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND		19			7	13			
	NEW YORK		171	63		61	123			
	REGIONAL LAB				227			85		
	WEAC									
	REGIONAL STAFF									
	BALTIMORE		25	8		9	18			
	CHICAGO		22	8		8	16			
	CINCINNATI									
CE	DETROIT		33	11		12	24			
	MINNEAPOLIS		12				10			
	NEW JERSEY									
	PHILADELPHIA		12	9		8	9			
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		19	9		11	9			
	FLORIDA		33	11		12	23			
	NEW ORLEANS		10				11			
	SAN JUAN									
	REGIONAL LAB				62			23		
	REGIONAL STAFF									
	DALLAS									
SW	DENVER				250			89		
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		250	82		89	178			
	REGIONAL LAB				67			20		
	REGIONAL STAFF									
	LOS ANGELES		79	26		28	56			
PA	SAN FRANCISCO		38	13	149	14	27	53		
	SEATTLE		32	10		11	23			
	PACIFIC REGIONAL LABORTORY- SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION		1.2	0.5	5.6	0.5	1.1	6.7		
	TOTAL HOURS		906	125	4228	135	594	1809		
	CONVERSION FACTOR		930	930	1180	930	930	1180		
	TOTAL OPERATIONAL FTEs		0.97	0.13	3.58	0.15	0.64	1.53		

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/2000	09/30/2001
ANALYTICAL	10/15/2000	09/30/2001

9. REMARKS

NOTE: Resources for Entry Review and Filer Evalution are planned under the Import Foods- General Program (03819 A,B,C).

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
d and Cosmetics	Technical Assistance: Food and Cosmetics - 18

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		90.7	0.2		90.9	177.4	
1	Retail Food Protection - Federal Program	18001	4.7			4.7	9.1	2/3
2	Retail Food Protection - State Program	18002	30.4			30.4	60.0	4/5
3	Milk Safety Program	18003	20.6			20.6	40.0	6/7
4	Molluscan Shellfish Evaluation	18004	13.4	0.2		13.6	26.4	8/9
5	Interstate Travel Program - Conveyances and Support Facilities	18029A-E	21.6			21.6	41.9	10/13

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
ld R. Roy (202) 205-4771	Marlene Garcia Swider, 301-827-1635

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Retail Food Protection - Federal Program	Technical Assistance: Food and Cosmetics - 18

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

4. OBJECTIVES

To assist federal agencies in achieving and maintaining acceptable levels of food safety in retail food operations under their direct or indirect responsibility or sponsorship by providing inspections, special investigations, complaint/illness investigations, sample collection, plan review, equipment evaluation, training and general technical assistance.

Note: Federal agencies include, but are not limited to, the Treasury/Secret Service, Office of Personnel Management, GSA, Interior/National Park Service, Justice/Bureau of Prisons, HHS (PHS, Office of Human Development which includes the Administration on Aging and the Administration on Children, Youth and Families' Head Start Bureau, and the Health Care Financing Administration), FDA, USDA and others.

To assist and cooperate with government agencies of other countries.

During FY 2001 and 2002, this program will address the list of "High Risk" foods as defined by CFSAN, as appropriate.

5. PROGRAM JUSTIFICATION

Services to all federal agencies are provided under authority of the Economy Act, as amended 31 USC 1535. Assistance to other countries is provided under authority of the Agricultural Trade Development and Assistance Act of 1954 (P.L. 83-480), as amended, and other appropriate authorities in the Public Health Service Act.

This program also fulfills agency responsibilities incurred under an ongoing interagency agreement with the General Services Administration. This interagency agreement is reviewed annually and updated as necessary.

6. FIELD OBLIGATIONS

Standardize FDA field investigators in the current Food Code. Provide HACCP training and technical assistance to FDA field investigators.

Conduct sanitation inspections for all designated federal food facilities. Conduct special investigations to assist the U.S. Secret Service or other agencies, as appropriate.

Submit GSA inspection forms to HFS-627 for technical review when a significant level of violations are encountered.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Foods	Inspections: 51 NY Samples: All Food Codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

Reduction in the occurrence of CDC Identified Risk factors associated with foodborne illness and national promotion of the Food Code Interventions.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Work assigned in this program is to be conducted by persons who are standardized in the application of the Food Code.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Retail Food Protection - Federal Program	Technical Assistance: Food and Comsmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
	[ ] ORA [X] CENTER	4.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	CONTINUED STANDS & CERTIFICATES (HOURS)	NEW STANDS & CERTIFICATES (HOURS)	GSA INSP *	OPM INSP	FDA FACILITIES				
	TOTAL FIELD	430	1920	450	2	6				
	HEADQUARTERS									
NE	REGIONAL STAFF	60	336							
	NEW ENGLAND			29						
	NEW YORK			8						
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	160	480		2					
	BALTIMORE			93		2				
	CHICAGO			6		2				
	CINCINNATI			14						
	DETROIT			6						
	MINNEAPOLIS			14						
	NEW JERSEY			3						
	PHILADELPHIA			18						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	70	384							
	ATLANTA			28						
	FLORIDA			21						
	NEW ORLEANS			24						
	SAN JUAN			4						
	REGIONAL LAB									
SW	REGIONAL STAFF	70	384							
	DALLAS			35		2				
	DENVER			35						
	KANSAS CITY			15						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	70	336							
	LOS ANGELES			25						
	SAN FRANCISCO			36						
	SEATTLE			36						
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION				5.6	5.6	5.6				
TOTAL HOURS		430	1920	2520	11.2	33.6				
CONVERSION FACTOR		1200	1200	930	930	930.0				
TOTAL OPERATIONAL FTEs		0.36	1.60	2.71	0.01	0.04				

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE		
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST			X	MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/1/2000	9/30/2001
ANALYTICAL	10/15/2000	9/30/2001

9. REMARKS

Work assigned in this program is to be conducted by persons standardized in the us of FDA Model Codes.

* The District assignments may change after the Memorandum of Understanding [MOU] negotiations with GSA are completed.

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

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

4. OBJECTIVES

To provide guidance, support, and assistance to the federal, state, tribal and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in food borne illnesses.

During FY 2001 and FY 2002, this program will address "High Risk" foods at retail as determined to be high priority by CFSAN. High risk foods such as soft cheeses, seafood products, eggs, produce, unpasteurized juices and others will all be addressed and state programs will be provided assistance.

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'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. Conduct periodic baseline and follow up surveys to measure conditions nationwide in selected retail food establishments. Promote the adoption of uniform retail program standards. Provide training on the provisions of he FDA Food Code, HACCP, Facility Plan Review, egg safety and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events. Including retail food safety. Conduct pilot programs to test new technology and innovative approaches to increase effectiveness. Participate in the FDA Retail Steering Committee, the National Conference for Food Protection and other conferences and industry events to share information and present FDA's position on issues concerning retail food protection. Maintain a cadre of trained FDA Retail Food Specialists.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Foods	Inspections: 51 NY

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

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

AM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18002	[X] ORA [ ] CENTER	30.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	TECHNICAL ASSISTANCE (Hours)	TRAINING (Hours)	NEW STDS & CERT *	SEMINARS (Hours)	PROMOTE UNIFORM NATIONAL STANDARDS (Hours)**	SPECIAL PROJECT (Hours)***	STEERING COMMITTEE (Hours)	RENEWAL STD (Hours)	CFP AND NFSS (Hours) ****
	TOTAL FIELD	14150	1900	5000	2150	9500	600	400	2200	570
	HEADQUARTERS									
NE	REGIONAL STAFF	2650	100	900	250	1300			350	100
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	4100	700	1400	500	2200			500	100
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	3000	250	700	400	1800			650	100
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF	2100	200	1000	500	2100	600	200	600	100
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	2300	650	1000	500	2100		200	100	170
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	14150	1900	5000	2150	9500	600	400	2200	570
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	11.79	1.58	4.17	1.79	7.92	0.50	0.33	1.83	0.48

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE				8. WORK SCHEDULE PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPECTIONAL	10/1/00	9/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL	10/15/00	9/30/01
	PHYSICIST			X	MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS * Hours allocated for Co-Team leaders to work with Steering Committee.

** Special Projects include preparatory activities for the 2002 Olympics.

Conference of Food Protection and National Food Safety System Workgroup.

*** Program time has been allocated for the Regional Food Specialists to provide technical assistance to the states in promoting egg safety safety (refrigeration and labeling). Time has also been provided for the Regional Food Safety Specialist in promoting adoption of the Food Code by state and local regulatory food agencies.

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

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

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Grade "A" Milk and Milk Products, Cheese, Butter, Dry Milk and Frozen Dessert	09, 13 & 14

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

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

GRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18003	[ ] ORA [X] CENTER	20.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANTS	CHECK RATINGS FARMS	SINGLE SERVICE AUDITS	CONTINUED STATE CERT. *	TECHNICAL ASSISTANCE HOURS	STATE EVALUATION REPORTS	CERTIFICATION **	HACCP Pilot Site Visits ***	HACCP Pilot Evaluation (Hours) ****
	TOTAL FIELD	216	292	118	(122)	8928	25	120	6	6
	HEADQUARTERS									
NE	REGIONAL STAFF	27	38	9	(22)	1225	4	14	1	1
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	97	142	49	(43)	2626	6	41	2	2
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	19	19	20	(16)	1576	5	18	1	1
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF	37	56	22	(21)	1925	5	22	1	1
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	36	37	18	(20)	1576	5	26	1	1
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	24.0	20.0	7.0			100	8	40	40
	TOTAL HOURS	5184	5840	826		8928	2500	960	240	240
	CONVERSION FACTOR	1200	1200	1200		1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	4.32	4.87	0.69		7.44	2.08	0.80	0.20	0.20

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST			X	MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/1/00	9/30/01
ANALYTICAL	10/15/00	9/30/01

9. REMARKS

*Continuous State Certifications listed by region; no separate block of time is necessary since these are in conjunction with check-ratings.

ification of State Milk Sample Surveillance Officers.

oint inspections with State officials at selective dairies to identify deficiencies.

****Time for writing reports and findings.

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

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

4. OBJECTIVES

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

Provide standardization, technical assistance, 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 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 National Shellfish Sanitation Program (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 enforcemer of appropriate public health controls. Oversee national standardization program for inspecting shellfish processing plants and Evaluating 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 attend the annual Interstate Shellfish Conference meeting and 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. Also, program time has been allocated for Regional Shellfish Specialists to work with ISSC in reviewing state monitoring programs for Vibrio parahaemolicicus and Vibrio Vulnificus (should theInterstate Shellfish Sanitation Conference adopt additional controls).

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fresh and fresh frozen molluscan shellfish	16, 52 B,Y

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
	[ ] ORA [X] CENTER	13.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION **	PATROL EVALUATION	PLANT EVAL	FOREIGN EVALUATIONS	STANDARD & TRAINING	NATIONAL & REGIONAL WORKSHOP *	TECHNICAL ASSISTANT (Hours)		
	TOTAL FIELD	176	21	522	3	30	26	4228		
	HEADQUARTERS									
NE	REGIONAL STAFF	50	5	120	1	6	6	720		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	37	4	123		7	6	920		
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	48	7	147	1	8	8	1718		
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF	6	1	43		4	2	320		
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	35	4	89	1	5	4	550		
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	20.0	40.0	8.0	200.0	64.0	40.0			
	TOTAL HOURS	3520	840	4176	600	1920	1040	4228		
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200		
	TOTAL OPERATIONAL FTEs	2.93	0.70	3.48	0.50	1.60	0.87	3.52		

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE				8. WORK SCHEDULE PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPECTIONAL	10/1/00	9/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL	10/15/00	9/30/01
	PHYSICIST			X	MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

* Program time has been allocated for each Regional Shellfish Specialist to attend the annual Interstate Shellfish Sanitation Conference meeting and 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.

** Program time has been allocated for Regional Shellfish Specialists to review state monitoring programs for Vibrio Parahemolyticus and Vibrio Vulnificus (should the ISSC adopt additional controls).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities	Technical Assistance: Food and Cosmetics - 18

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

4. OBJECTIVES

To investigate and identify insanitary conditions in conveyances and support facilities which are associated with passenger and crew food, water and waste operations, facilities, and construction; to initiate regulatory and administrative compliance actions based on the Acts and regulations enforced by FDA; to work cooperatively with the regulated industry, associations and others to promote voluntary compliance; to coordinate activities with Federal/State/Local authorities, and to the extent possible with foreign governments; to cooperate with Canada, CDC, DOT, and EPA in accordance with MOUs; and to perform other activities in support of a national/international program in Interstate Travel Program (ITP).

For FY 2001 special emphasis will be directed towards inspections of conveyances under construction, conveyance food establishments (caterers/catering points), and watering points. Special resources continue to be allocated to food establishment inspections to determine industry compliance with the new food safety initiatives contained in the 1999 Food Code.

5. PROGRAM JUSTIFICATION

This IT program directs agency efforts in fulfillment of DHHS functional redelegations to FDA under sections 311, 361 and 368 of the Public Health Service Act which relate to the law enforcement functions of FDA. The IT program provides the means for FDA to accomplish functional requirements for the protection of the health and well-being of passengers, crews and others from the sanitation associated hazards of food, water and waste product and services in conjunction with the operation of interstate and other regulated carrier conveyances and support facilities. In addition to PHS authorities, the Food, Drug and Cosmetic Act and other acts with their associated regulations provide for additional authority and other program requirements.

6. FIELD OBLIGATIONS

The field is to perform comprehensive inspections of "high risk foods" establishments (including HACCP) and investigations, to apply effective compliance measures and to perform other activities as necessary. The field will also establish and maintain support and expertise for a national ITP; cooperate with other agencies, groups and industry; and maintain interregional/district communications for activities such as the regulatory review of specifications; plan and follow-up work associated with interstate conveyances, support facilities, and equipment. These activities apply to certain exported and/or imported services, equipment and conveyances.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Foods, Water	Inspections/Investigations: Industry 51 All food codes, including water 29W (Y30).

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

f. CHECK THE FOLLOWING ATTRIBUTES

Samples: Food and water contamination, mostly microbiological.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

These field assignments will be conducted by persons annually standardized in the use of FDA's model codes and in accordance with established FDA procedures and the specific guidelines established for the IT Program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
A - E	[X] ORA [X] CENTER	(20.3) 21.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 CONVEY UNDER CONSTRUC INSPECT A	1 WATERING POINTS INSPECT B	1 CATERING POINTS INSPECT C	3 DSCs	7 DSAs MICRO	FOOD SAFETY INITIATIVE CONSULTATIONS (HOURS) **	2 INVEST (HOURS)	FOOD SAFETY MGMT SYS INITIATIVES (HOURS) *
	TOTAL FIELD	1894	(296)	(710)	(458)	51	51	345	1628	425
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	107	10	50	27	3		21	88	
	NEW YORK	108	6	15	70	2		10	67	75
	REGIONAL LAB						5	38		
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	107	25	38	12	3		8	106	75
	CHICAGO	67	6	20	16	2		13	72	
	CINCINNATI	80	17	32	9	2		11	77	
CE	DETROIT	42	4	9	8	2		7	51	
	MINNEAPOLIS	92	11	27	18	3		11	102	
	NEW JERSEY	63	10	29	9	2		10	59	
	PHILADELPHIA	63	10	23	8	2		5	68	
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	91	24	28	18	2		13	77	
SE	FLORIDA	122	23	53	34	3		5	81	
	NEW ORLEANS	135	30	73	9	4		30	115	
	SAN JUAN	22	0	17	3			5	18	
	REGIONAL LAB						18			
	REGIONAL STAFF									
	DALLAS	109	18	44	23	3		10	94	75
SW	DENVER	48	5	15	12	2		10	48	
	KANSAS CITY	76	11	22	23	2		17	67	
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB						7			
	REGIONAL STAFF									
	LOS ANGELES	175	34	70	28	5		27	159	
PA	SAN FRANCISCO	202	13	68	85	5		62	150	75
	SEATTLE	185	39	77	46	4		32	129	125
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW						14			
	HOURS PER OPERATION	8.4				4.2	9.8			
	TOTAL HOURS	15910				214	500	345	1628	425
	CONVERSION FACTOR	930				930	1180	930	930	930
	TOTAL OPERATIONAL FTEs	17.11				0.23	0.42	0.37	1.75	0.46

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE		
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/1/2000	9/30/2001
ANALYTICAL	10/15/2000	9/30/2001

ARKS

Inspections in Columns A, B, and C are included in Column 1.

* Includes time for continual use of HACCP principles by 4 additional FDA districts, and time given to SEA-DO for training others.

** Includes time for changes to the 1999 Food Code, further discussions of Interventions & Risk Factors, and meetings with the airlines to discuss Chapter 2 of the Food Code on Employee Health Issues.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
A - E	[X] [X] CENTER	(1.3)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ITP SPECIALIST TIME (HOURS) ****	NBA AUDIT (HOURS) ***	STEERING COMMITTEE (HOURS)						
	TOTAL FIELD	930	80	200						
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS		80							
	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			200						
	SEATTLE	930								
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	930	80	200						
	CONVERSION FACTOR	930	930	930						
	TOTAL OPERATIONAL FTEs	1.00	0.09	0.22						

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL								PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/1/2000	9/30/2001
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALYTICAL	10/15/2000	9/30/2001
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

*** Includes time for meetings with North West Airlines to determine restaurants involved with serving food to NBA teams, and audit inspection.

**** A national ITP Specialist in Seattle

Page 2 of 2

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME-NUMBER
Food and Cosmetics	Food Composition, Standards, Labeling and Economics - 21

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
	TOTAL		22.4	4.6		27.0	51.0	
1	Medical Foods - Domestic and Import	21002	3.0	0.6		3.6	7.0	2-3
2	Domestic NLEA, Nutrient Sample Analysis and General Food Labeling Program*	21005	3.4			3.4	6.6	4-7
3	Infant Formula Program	21006	2.8	0.5		3.3	6.4	8-9
4	Import NLEA, Nutrient Sample Analysis and General Food Labeling Program**	21007 *		3.0		3.0	5.8	10-11
5	Diet Supplements***	21008 **	9.0	0.5		9.5	18.4	12-13
6	Selected Nutrients in Food Survey	21839	2.8			2.8	5.4	14-15
7	ORA-Center Directed Research Projects	21R816	1.4			1.4	1.4	16-17

* Includes 21R829 (Health Fraud) and FPLA.

** 03R833, 99R833,21R824

*** Includes DISC and DISA FTEs.

CENTER PROJECT MANAGER-TELEPHONE	ORA PLANNER-TELEPHONE
Ronald R. Roy (202) 205-2262	Lorraine B. Jefferson, 301-827-1631

FORM FDA 2622 (9-98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Foods - Domestic and Import	Food Composition, Standards, Labeling and Economics - 21

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

4. OBJECTIVES

To obtain information regarding the manufacturing process and quality assurance programs employed by manufacturers of Medical Foods.

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 manufacture and/or importation of Medical Foods is rapidly increasing in the U.S. due to advances in nutritional science and the aging of the population. The products are often used for life support and are subject to compositional and microbiological errors (as evidenced by four infant deaths in 1986). However, as the products currently must conform only to those regulations dealing with general food safety and labeling, they have received little in-depth inspectional or analytical coverage. In addition to the infant deaths in 1986 related to use of medical foods, there have been a number of recalls of medical foods in recent years associated with significant compositional deviations and occurrences of underprocessing and potential microbiological hazard. There were some instances of contamination of medical foods which were deemed acute, life-threatening health hazards. Therefore, FDA plans to expand oversight activities in this area.

Medical foods are identified as "high risk" foods under the Center's Food Safety Initiaitves. Additional resources have been budgeted to allow annual inspections and sample collections from medical foods firms.

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. SRL Microbiology Branch will perform microbiological analyses.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Medical Foods	41, 54

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

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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
[X] ORA [X] CENTER

5. OPERATIONAL FTE POSITIONS
3.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DSAs MICRO	7 DSAs CHEM	8 ISAs CHEM	8 ISAs MICRO
	TOTAL FIELD	26		36	14		9	27	7	7
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	1		1						
	NEW YORK	1		2	1					
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1		2						
	CHICAGO	2		2						
	CINCINNATI	1		2	2					
CE	DETROIT	5		8						
	MINNEAPOLIS	7		8						
	NEW JERSEY	1		1						
	PHILADELPHIA	1		1						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA	1		1						
SE	NEW ORLEANS				3					
	SAN JUAN	1		2						
	REGIONAL LAB						9	27	7	7
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY	2		2						
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	1		2	4					
	SAN FRANCISCO	1		2	4					
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
HOURS PER OPERATION		30.0		4.4	2.5		30.0	75.0	75.0	30.0
TOTAL HOURS		780		158	35		270	2025	525	210
CONVERSION FACTOR		930		930	930		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.84		0.17	0.04		0.23	1.72	0.44	0.18

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS
CFSAN spreads inspections and DSCs.
ORA spreads import operations.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic NLEA. Nutrient Sample/Analysis and General Food Labeling Program	Food Composition. Standards. Labeling and Economics - 21

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

4. OBJECTIVES

To determine compliance with: (1) the nutrition labeling regulations as required under the Nutrition Labeling and Education Act (NLEA) of 1990: (2) the July 8. 1998 regulation that requires a warning statement on packaged fruit and vegetable juice products. (i.e.. juices and beverages containing juice) that have not been pasteurized or otherwise treated to prevent. reduce. or eliminate harmful bacteria: (3) FDA's notice to manufacturers regarding label declaration of allergenic substances in foods: and. (4) regulations promulgated under the FD&C Act for other mandatory label information.

5. PROGRAM JUSTIFICATION

The Federal Food, Drug and Cosmetic Act requires that certain label information appear on food labels. The NLEA requires nutrition labeling on most foods consumed in the United States. In addition, a regulation was published on July 8, 1998 that requires firms to place a warning label on packaged fruit and vegetable juice products that have not been pasteurized or treated in another way capable of preventing, reducing, or eliminating harmful bacteria.

On June 10, 1996, the FDA issued a notice to manufacturers requesting that they voluntarily declare ingredients that are known to cause allergic reactions in sensitive individuals. The FDA is currently reviewing labels on conventional foods that contain novel ingredients and that make claims on the label that affects the structure and/or function of the body. Continuous monitoring ensures Compliance with the regulations established under the FD&C Act and identifies potential problem areas related to foods.

6. FIELD OBLIGATIONS

Review of product labels for compliance with NLEA, the July 8, 1998, juice warning and notice regulation for juice products, and other mandatory label information. Districts should collect documentary samples of labels that appear to be violative.
Physical samples will be collected for subsequent 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 #4); and; (2) surveillance samples collected for general nutrient analyses.
Field Exams and sample collections to be conducted during inspections under the following compliance programs: 7303.803, 7303.803A,7303.037 and 7303.842.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All food products (except vitamins/minerals)	02-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

Label review and nutrient analysis as appropriate.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic NLEA, Nutrient Sample/Analysis and General Food Labeling Program	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21005 (Includes FPLA)	[X] ORA [ ] CENTER	3.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INV	3 DSCs COLL SURV *		5 FIELD EXAMS/ TESTS **	3 DOCUMENTARY SAMPLES ***		7 DOMESTIC SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD			100		3600	540		100	
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND			5		194	29			
	NEW YORK			5		188	28			
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE			4		141	21			
MA	CHICAGO			4		162	24			
	CINCINNATI			4		126	19			
	DETROIT			4		160	24			
	MINNEAPOLIS			6		212	32			
	NEW JERSEY			4		123	18			
	PHILADELPHIA			4		139	21			
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA			5		185	28			
	FLORIDA			5		157	24			
	NEW ORLEANS			6		202	30			
	SAN JUAN					44	7			
	REGIONAL LAB								100	
	REGIONAL STAFF									
SW	DALLAS			7		267	40			
	DENVER			4		129	19			
	KANSAS CITY			7		235	35			
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES			5		194	29			
	SAN FRANCISCO			10		350	53			
	SEATTLE			11		392	59			
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION			4.2		0.4	0.4		14.3	
	TOTAL HOURS			420		1440	216		1430	
	CONVERSION FACTOR			930		930	930		1180	
	TOTAL OPERATIONAL FTEs			0.45		1.55	0.23		1.21	

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL	10/15/00	09/30/01
	PHYSICIST			MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER	SHELLFISH SPEC		OTHER			

* Surveillance samples are to be collected according to CP 7321.005 & Attachment A.

** Compliance samples are to be collected, as necessary, for verification of appropriate label claims. CP: 7303.803, 7303.803A, 7303.037 and 7303.842 sample collections and field exams are to be conducted during inspections.

*** CFSAN planned 3600 field exams for major label violations (15% or 540 will result in documentary sample collections). Use PAC 21003 to report economic deception or food standard violations only .

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ATTACHMENT A

Domestic NLEA, Nutrient Sample Analysis and General Food Labeling Program (21005)
FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS - 21

SURVEILLANCE SAMPLE COLLECTION SCHEDULE (FY 2001)

YEAR/ MONTHS	00 OCT	00 NOV	00 DEC	2001 JAN	01 FEB	01 MAR	01 APR	01 MAY	01 JUN	01 JUL	01 AUG	01 SEP	TOTAL
DISTRICTS													
NEW ENGLAND					1		1		2		1		5
NEW YORK					1		1			2		1	5
BALTIMORE					1			2			1		4
CHICAGO								2		2			4
CINCINNATI						2			2				4
DETROIT						1			2		1		4
MINNEAPOLIS							2		2			2	6
NEW JERSEY						1		1		1		1	4
PHILADELPHIA						1			1		2		4
ATLANTA					1		1			1		2	5
FLORIDA					1		2			1		1	5
NEW ORLEANS						2			2		2		6
SAN JUAN													
DALLAS					2		2		2		1		7
DENVER						1		1		1		1	4
KANSAS CITY					2		1	1		2	1		7
SOUTHWEST IMPORT													
LOS ANGELES			1		1			2		1			5
SAN FRANCISCO			2			2		3		2		1	10
SEATTLE					2		3		3	2		1	11
TOTAL			3		12	10	13	12	16	15	9	10	100

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Infant Formula Program	Food Composition, Standards, Labeling and Economics - 21

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

4. OBJECTIVES

To ensure compliance with the Infant Formula Act and regulation promulgated thereunder by inspection of infant formula manufacturers 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.

6. FIELD OBLIGATIONS

Districts will conduct inspections and collect samples. SRL/ACNA will perform all nutrient analyses and label reviews. SRL/Microbiology Branch will perform microbial analyses.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Infant Formula and Nutrient Premixes	40C

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

Nutrients as per Infant Formula Act, Section 412. Micro exam for *Listeria monocytogenes, Salmonella, Clostridium perfringens, Staphylococcus aureus, Bacillus cereus, Escherichia coli,* Aerobic Plate Count (APC).

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Infant Formula Program	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
20162	[X] ORA [X] CENTER	3.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (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		30	(19)	(11)	19	11	8	8
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	1		2	(1)	(1)				
	NEW YORK	1								
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1		2	(2)					
	CHICAGO	1								
	CINCINNATI	3		2	(2)					
CE	DETROIT	4		8	(4)	(4)				
	MINNEAPOLIS	4		8	(4)	(4)				
	NEW JERSEY	2		2	(1)	(1)				
	PHILADELPHIA	1								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN								4	
	REGIONAL LAB						19	11		8
	REGIONAL STAFF									
	DALLAS								1	
	DENVER									
	KANSAS CITY	4		4	(4)					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	2		2	(1)	(1)			3	
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION	37.0		5.3			86.3	30.0	4.7	70.0
	TOTAL HOURS	888		159			1640	330	38	560
	CONVERSION FACTOR	930		930			1180	1180	930	1180
	TOTAL OPERATIONAL FTEs	0.95		0.17			1.39	0.28	0.04	0.47

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN	
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	
	PHYSICIST				MILK/FOOD SPEC			
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

* May also be used for microbiological analysis.
Numbers in parenthesis are included in DSCs
ORA spreads import operations

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program	Food Composition, Standards, Labeling and Economics - 21

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

4. OBJECTIVES

To determine compliance of imported food products with (1) the nutrition labeling regulations as required under the Nutrition Labeling and Education Act (NLEA); (2) the July 8, 1998 regulation that requires a warning statement on packaged fruit and vegetable juice products (i.e., juices and beverages containing juice) that have not been pasteurized or otherwise treated to prevent, reduce, or eliminate harmful bacteria; and (3) the regulations promulgated under the Fair Packaging and Labeling Act (FPLA) for other mandatory label information.

5. PROGRAM JUSTIFICATION

The Nutrition Labeling and Education Act (NLEA) of 1990, provided the FDA with specific authority to require nutrition labeling on most imported and domestic foods regulated by FDA. In addition, a regulation published on July 8, 1998 that requires firms to place a warning statement on packaged fruit and vegetable juice products that have not been pasteurized or treated in another way capable of preventing, reducing, or eliminating harmful bacteria. Continuous monitoring ensures compliance with FDA's regulations and increases the safety of the food supply, which is in the best interest of American consumers.

The objectives of this program will be fulfilled by:

1) reviewing the nutrition label and ensuring that all other mandatory labeling information is present on the label;
2) ensuring the packaged fruit and vegetable juice products that have not been pasteurized or otherwise treated to prevent, reduce, or eliminate harmful bacteria bear the required warning label statement; and
3) analyzing foods that contain nutrient content claims to determine compliance with the food labeling regulations.

6. FIELD OBLIGATIONS

Field obligations include sample collections, import field exams, label reviews and nutrient analysis of imported food samples. Sample collection should be equitably distributed across imported food codes.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All food products including packaged fruit and vegetable juice products.	02-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

Label review and nutrient analysis.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21007, 21R829 (Health Fraud) (Includes FPLA)	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED CHEM	9 IMPORT LABEL EXAMS *	7 DOMESTIC SAMPLES TO BE ANALYZED		9 OTHER OPERATIONS (Hours)
	TOTAL FIELD				910	125	4450			
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND				33		162			
	NEW YORK				183		896			
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE				27		130			
	CHICAGO				20		93			
	CINCINNATI									
CE	DETROIT				43		208			
	MINNEAPOLIS						52			
	NEW JERSEY									
	PHILADELPHIA				19		51			
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA				10		50			
	FLORIDA				66		322			
	NEW ORLEANS						25			
	SAN JUAN				13		38			
	REGIONAL LAB					125				
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION				302		1475			
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES				100		490			
	SAN FRANCISCO				46		223			
	SEATTLE				48		235			
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION				1.2	8.2	0.2			
	TOTAL HOURS				1092	1025	890			
	CONVERSION FACTOR				930	1180	930			
	TOTAL OPERATIONAL FTEs				1.17	0.87	0.96			

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

* Nutrition Labeling & Educational Act (NLEA) - to determine compliance with the nutrition Labeling regulations through import field exams, collections and inspections of labels on products bearing nutrition labeling.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Dietary Supplements	Food Composition, Standards, Labeling and Economics - 21

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

4. OBJECTIVES

To ensure compliance with the Dietary Supplement Health and Education Act and regulations promulgated thereunder by inspections of dietary supplement manufacturers and collections and analyses of dietary supplement samples.

Effective March 23, 1999, all non-exempt dietary supplements must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these new requirements will be determined by field exams and documentary sample collections conducted under the program.

5. PROGRAM JUSTIFICATION

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

The compliance program will provide coverage of Supplement Facts Labeling and other labeling of dietary supplements, including the requirement for unit-dose packaging for supplements containing 30mg or more of iron per unit and the Voluntary warning statement on stimulant laxative products.

During FY'01, the Center plans to issue a special assignment that will target raw material botanicals, both domestic and import, for sampling and analyses for heavy metals and/or pesticides. In addition, samples are set aside for coverage of Dissolution/disintegration testing of folic acid supplements.

6. FIELD OBLIGATIONS

Field obligations include inspections, sample collections, label reviews, and analyses of dietary ingredients in dietary supplements.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Dietary supplements	54

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

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Dietary Supplements	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21008	[X] ORA [X] CENTER	9.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 FIELD EXAMS	3 DOMESTIC SAMPLE COLL	4 DISC SAMPLE COLL	3 HQ INIT DOMESTIC SAMPLE COLL *	7 HQ INIT DOMESTIC SAMPLE ANALYZED *	7 DOMESTIC SAMPLES TO BE ANALYZED	8 DISAs	DSCs **
	TOTAL FIELD	80	700	100	25	225	225	100	25	230
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	2	18	3	3	6				6
	NEW YORK	9	78	10		25				25
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	2	18	3	5	6				6
	CHICAGO	2	18	3		6				6
	CINCINNATI	2	18	3		6				6
CE	DETROIT	2	18	3		6				6
	MINNEAPOLIS	4	35	5		11				12
	NEW JERSEY	9	78	10		25				25
	PHILADELPHIA	5	44	6	4	14				14
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	3	26	4		8				9
	FLORIDA	6	53	8	3	17				17
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB						225	100	25	
	REGIONAL STAFF									
	DALLAS	2	18	3	3	6				6
	DENVER	3	26	4		8				9
SW	KANSAS CITY	4	35	5		11				12
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	12	104	15	7	34				34
	SAN FRANCISCO	4	35	5		11				12
	SEATTLE	9	78	10		25				25
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
	HOURS PER OPERATION	17.5	0.5	4.2	4.2	4.2	20.0	20.0	20.0	0.4
	TOTAL HOURS	1400	350	420	105	945	4500	2000	500	92
	CONVERSION FACTOR	930	930	930	930	930	1180	1180	1180	930
	TOTAL OPERATIONAL FTEs	1.51	0.38	0.45	0.11	1.02	3.81	1.69	0.42	0.10

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

9. REMARKS

ORA spreads Domestic-Import Sample Collections (DISCs). CFSAN spreads the remaining operations. Field Exams and sample collections may be conducted at packers/repackers, distriubtors, or warehouses if the levels planned cannot be performed during the inspections.

* These samples are set aside for special, targeted assignments and the spread to districts is for planning purposes only. Final participating districts will be specified in assignments as issued. ** DSCs for reviewing documents only.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Selected Nutrients in Foods- Total Diet	Foods Composition Standard Labeling and Economics-21

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

KAN-DO will analyze Total Diet samples for the 12 nutrients identified below in 7F, and for water.
The Atlanta Center for Nutrient Analysis(ACNA) will analyze selected Total Diet study food items from one market basket annually for folic acid

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)
Various foods as required by the Total Diet Studies Program	37,40

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Selected Nutrient in Foods Survey - Total Diet	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21839	[ ] ORA [X] CENTER	2.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 WHARF EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM *	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO**	
	TOTAL FIELD							1036	168	
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB								168	
	REGIONAL STAFF									
	DALLAS									
	DENVER									
SW	KANSAS CITY							1036		
	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	7.0	
	TOTAL HOURS							2072	1176	
	CONVERSION FACTOR							1180	1180	
	TOTAL OPERATIONAL FTEs							1.76	1.00	

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC-TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL	10/15/00	09/30/01
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

* Represents total number of assays to be analyzed.

** Folic Acid for one market basket consisting of 168 Food items.

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

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: N/A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
21R816	[X] ORA [ ] CENTER	1.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH (CHEM)	RESEARCH CENTER (CHEM)							
	TOTAL FIELD	500	1180							
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	500								
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY- NW		1180							
	HOURS PER OPERATION									
	TOTAL HOURS	500	1180							
	CONVERSION FACTOR	1205	1180							
	TOTAL OPERATIONAL FTEs	0.41	1.00							

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC-TIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL	10/15/00	09/30/01
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
ood and Cosmetics	Colors and Cosmetics Technology - 29

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		3.5	2.9		6.4	12.4	
1	Cosmetics - Domestic and Import	29001, 29002,	3.5	2.9		6.4	12.4	2-3
		29F099*						
	*Includes 29R833, 99R833,29R824							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ronald R. Roy (202) 205-2262	Lorraine B. Jefferson (301)827-1631

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics; Domestic and Import	Colors and Cosmetics Technology - 29

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

4. OBJECTIVES

Issuance of center-initiated assignments to address specific problems or areas of concern for both domestic and imported cosmetics.

5. PROGRAM JUSTIFICATION

Congress appropriated $2.5 million in the FY 99 budget for the agency to use to assure that consumers are protected from unsafe cosmetics; particularly those presenting a microbiological risk.

6. FIELD OBLIGATIONS

As directed in special assignments, districts will review and screen entry documents for imported cosmetics, inspect domestic firms, collect and analyze samples for non-permitted ingredients and microbiological contamination. All servicing laboratories will conduct label reviews for declaration of ingredients, warning statements, and directions for use as required by 21 CFR Part 700.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

Non-permitted ingredients, microbiological/contaminants, labeling warnings.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

RAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
,29002,29R833,99R833,29R824	[X] ORA [ ] CENTER	6.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REV HOURS OP 14 29R833 *	2	9 IMPORT LABEL EXAMS	4 IMPORT SAMPLE COLL PHYSICAL	8 IMPORT SAMPLE ANALYSIS (MICRO)	1 INSPECTION	3 DOMESTIC SAMPLE COLL	8 DOMESTIC SAMPLE ANALYSIS (MICRO) **		
	TOTAL FIELD	700		700	125	125	100	75	75		
	HEADQUARTERS										
	REGIONAL STAFF										
NE	NEW ENGLAND	7		6			5	5			
	NEW YORK	167		278	51		7	5			
	REGIONAL LAB					51			10		
	WEAC										
	REGIONAL STAFF										
	BALTIMORE	15		18	5						
	CHICAGO	16		9			9	7			
	CINCINNATI	26		17	3		5	4			
CE	DETROIT	23		69	12		5	4			
	MINNEAPOLIS	4					8	6			
	NEW JERSEY						9	7			
	PHILADELPHIA	10		27	5						
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	17		21	6		7	5			
	FLORIDA	50		42	8		7	5			
	NEW ORLEANS	22		7							
	SAN JUAN	26		7			2				
	REGIONAL LAB					27			21		
	REGIONAL STAFF										
	DALLAS						9	7			
SW	DENVER					7			12		
	KANSAS CITY						7	5			
	SOUTHWEST IMPORT DISTRICT	70		39	7						
	REGIONAL LAB					12			17		
	REGIONAL STAFF										
	LOS ANGELES	194		86	15		15	10			
	SAN FRANCISCO	31		24	4	13	5	5	5		
	SEATTLE	22		50	9						
PA	PACIFIC REGIONAL LABORTORY-SW					15			10		
	PACIFIC REGIONAL LABORTORY-NW										
	HOURS PER OPERATION			0.4	1.3	17.6	18.2	5.5	17.6		
	TOTAL HOURS	700		280	163	2200	1820	413	1320		
	CONVERSION FACTOR	1200		930	930	1180	930	930	1180		
	TOTAL OPERATIONAL FTEs	0.58		0.30	0.17	1.86	1.96	0.44	1.12		

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-		
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN	TIONAL	10/1/2000	09/30/2001
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-	10/15/2000	09/30/2001
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL		

9. REMARKS

For PAC 29001-CFSAN may continue to issue special assigments during the course of the year to address specific problems; however, routine coverage of the domestic cosmetic industries should be conducted in accordance with the guidance in the compliance program.

* Filer Evaluation hours (99R833) and Follow-up to Refusal (29R824) are included in Entry Review Hours.

Compliance Program- All servicing laboratories will conduct label reviews for declaration of ingredients, warning statements, and directions for use quired by 21 CFR Part 700.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2001

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	111.0	2.5	8.0	121.5	219.2	5.3	10.5	235.0
41	THERAPEUTIC PRODUCTS	20.0		1.0	21.0	39.9		1.0	40.9
42	BLOOD AND BLOOD PRODUCTS	82.7	2.5	4.2	89.4	166.5	5.3	6.2	178.0
45	VACCINES AND ALLERGENIC PRODUCTS	8.3		2.8	11.1	12.8		3.3	16.1

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
logics	Therapeutic Products - 41

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		20.0		1.0	21.0	40.9	
1	Licensed Therapeutic Drug Products (Core)	41001,A	2.5 2.5		1.0	3.5 3.5	3.5	2-3
	(Field Investigations)		0.3			0.3	0.7	
2	Tissue Establishments	41002	9.3			9.3	19.8	4/5
3	Bioresearch Monitoring Programs *		7.9			7.9	16.9	
	Good Laboratoy Practices	41808	*			*		6/11
	(Nonclinical Labs)							
	Institutional Review Board	41809	*			*		
	Sponsors, Contract Research Organizations,	41810	(1.5)			(1.5)		
	and Monitors							
	Clinical Investigators	41811	(6.4)			(6.4)		
	* See 2621a for details							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Elaine Knowles Cole, 301 827-6220	Harriet Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Therapeutic Drug Products (Post-Market)	Therapeutic Products - 41

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

4. OBJECTIVES

To ensure the safety and effectiveness of licensed thereapeutic drug products, through inspections, the conditions under which a particular class of biological therapeutic drug products, well characterized bio-technology product, 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

Licensed Therapeutic Drug Products are: (1) therapeutic synthetic peptides of 40 or fewer amino acids; (2) therapeutic DNA plasmid products; (3) monoclonal antibodies for in vivo use; (4) therapeutic recombinant DNA-derived products 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 asses the adequacy of all significant processes and systems. These should be performed on **at least a Biennial Basis**. Inspections will be conducted as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Therapeutic Drug Products (Post-Market)	Therapeutic Products - 41

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
01, A Domestic & Foreign *	[X] ORA [ ] CENTER	3.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS DOMESTIC *	1 INSPECTIONS FOREIGN *	1 INVESTIGATIONS	1	5	6	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	10	4	273						
	HEADQUARTERS	10	4							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY			69						
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA			68						
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			68						
	SAN FRANCISCO			68						
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	RACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	227.5	227.5							
	TOTAL HOURS	2275	910	273						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	2.50	1.00	0.30						

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-		
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN	TIONAL	10/01/00	09/30/01
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC	X	CORE TEAM BIOL	ANALY-		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL		

MARKS

41001 GMP Inspections, 41001A Pre-Licensed Inspections All inspections will be performed by Core Team Biologics.
No separate resources are planned for Pre-License Inspections (41001A), Use above resources as needed.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Tissue Establishments	Therapeutic Products - 41

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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 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 [X] BY CENTER [ ] BY BOTH

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Tissue Establishments	Therapeutic Products - 41

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
.002	[X] ORA [ ] CENTER	9.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (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	**165**	**254**							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	4	6							
	NEW YORK	12	18							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	14	22							
	CHICAGO	6	9							
	CINCINNATI	10	15							
	DETROIT	7	11							
	MINNEAPOLIS	6	9							
	NEW JERSEY	3	5							
	PHILADELPHIA	6	9							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	7	11							
	FLORIDA	6	9							
	NEW ORLEANS	9	14							
	SAN JUAN	1	2							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	14	22							
	DENVER	5	8							
	KANSAS CITY	12	18							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	30	46							
	SAN FRANCISCO	6	9							
	SEATTLE	7	11							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	49.7								
	TOTAL HOURS	8201	254							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTES	9.01	0.28							

7. PERSONNEL TYPES REQUIRED

	ANALYTICAL				INVESTIGATIVE		
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

REMARKS

Please use "HT" as the establishment-type code for Tissue Establishments.

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practice (Nonclinical Laboratory) (PDUFA)	Therapeutic Products - 41

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

4. OBJECTIVES

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.

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Institutional Review Board (PDUFA)	Therapeutic Products - 41

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

4. OBJECTIVES

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).

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Sponsors, Contract Research Organizations, and Monitors (PDUFA)	Therapeutic Products - 41

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Clinical Investigators (PDUFA)	Therapeutic Products - 41

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

4. OBJECTIVES

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

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

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor-Monitors, Clinical Investigators (PDUFA)	Therapeutic Products - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41808, 41809, 41810, 41811	[X] ORA [ ] CENTER	7.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS *	1 INSPECTIONS Clin Invest	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	21	55							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	1	2							
	NEW YORK	1	2							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1	5							
	CHICAGO	1	2							
	CINCINNATI	1	2							
	DETROIT	1	3							
	MINNEAPOLIS	1	3							
	NEW JERSEY	1	1							
	PHILADELPHIA	1	4							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	1	4							
	FLORIDA	3	2							
	NEW ORLEANS	3	3							
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	1	6							
	DENVER		2							
	KANSAS CITY		3							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2	7							
	SAN FRANCISCO		2							
	SEATTLE	2	2							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	65.0	105.9							
	TOTAL HOURS	1365	5825							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTES	1.50	6.40							

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

9. REMARKS

* Resources for PACs 41808, 41809 and 41810 are planned under 41810. Report Accomplishments under appropriate PAC.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
ologics	Blood and Blood Products - 42

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		82.7	2.5	4.1	89.3	178.0	
1	Inspection of Licensed and Unlicensed	42001ABCDE,	58.1		0.9	59.0	125.9	2-3
	Blood Banks	42R825						
	(National Experts)		2.4		0.1	2.5	2.5	
	Inspection of Unlicensed Blood Banks							
	Inspection of Licensed Blood Banks							
	Inspection of Donor Centers							
	Inspection of Reference Laboratories							
	Inspection of Plasma Brokers							
	Inspection of Blood Product Contractors							
2	Inspection of Source Plasma Establishments	42002	11.7			11.7	24.9	4/5
3	Inspection of Plasma Derivatives of							
	Human Origin (Core Team Biologics)	42006,A	2.8		1.1	3.9	3.9	6/7
	(Field)		0.7			0.7	1.5	
4	Examination of Blood & Blood Components	42007, 42R833,		2.5		2.5	5.3	8/9
	Offered for Import	42R824,99R833						
5	Inspection of Licensed Viral Marker Test Kits	42008,A	3.0		1.0	4.0	4.0	10/11
	(Core Team Biologics)							
6	Bioresearch Monitoring Programs *		1.0		1.0	2.0	4.2	12/15
	Institutional Review Board	42809	*			*		
	Sponsors, Contract Research Organizations,	42810	*			*		
	and Monitors							
	Clinical Investigators	42811	(1.0)		(0.8)	(1.8)		
	Field (GLPs & Clin Investigators) **	41808, 41811			(0.2)	(0.2)		
	National Experts (GLPs & Clin Investigators)	42808, 42811						
		45808, 45811						
7	Inspection of Medical Device Manufacturers	42830L,C	2.5			2.5	5.3	16/17
8	ORA/Center Directed Research Project	42R816	0.5			0.5	0.5	18/19
	* All resources planned under 42811							
	** Resources cover PPS 41, 42, 45							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Elaine Knowles Cole, 301 827-6220	Harriet Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed and Unlicensed Blood Banks	Blood and Blood Products - 42

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Blood and Blood Products	55, 57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign)	Blood and Blood Products - 42

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42001,A,B,C,D,E 42R825	[X] ORA [ ] CENTER	61.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS *	2 DOMESTIC INV (Hours)	3 DOMESTIC SAMPLE COLL	1 FOREIGN BLOOD BANK INSPECTIONS	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	1484	1936		34					
	HEADQUARTERS	60			3					
	REGIONAL STAFF									
NE	NEW ENGLAND	75	81		3					
	NEW YORK	71	77							
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	92	499		6					
	CHICAGO	70	76		3					
	CINCINNATI	62	67							
CE	DETROIT	76	82							
	MINNEAPOLIS	64	69							
	NEW JERSEY	33	36		3					
	PHILADELPHIA	76	82							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	76	82		3					
SE	FLORIDA	108	116							
	NEW ORLEANS	101	109		3					
	SAN JUAN	15	16		1					
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	123	131		3					
SW	DENVER	47	51							
	KANSAS CITY	87	94		3					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	98	106							
PA	SAN FRANCISCO	66	71							
	SEATTLE	84	91		3					
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		35.8			27.5					
TOTAL HOURS		53127	1936		935					
CONVERSION FACTOR		910	910		910					
TOTAL OPERATIONAL FTEs		58.38	2.13		1.03					

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALYTICAL		
	PHYSICIST				MILK/FOOD SPEC	X	TEAM BIOLOGICS			
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

. REMARKS

* Time is for all facilities listed in the current compliance program and follow up time as needed.
Domestic Inspectional module of 35.8 represents an average of PACs 42001,A,B,C and 42R825 (FY98 & FY99).
Use Operational Code 11 for Foreign Inspections.
The National Expert time planned above may be used for other Biologics programs as needed.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Source Plasma Establishments	Blood and Blood Products - 42

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

The collection of Source Plasma as source material for further manufacturing into products used in the prevention and treatment of disease is of immeasurable value to the Consumer.

Through this program the Agency can accomplish its objectives of donor protection and product safety, purity, and potency.

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Source Plasma Establishments	Blood and Blood Products - 42

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42002	[X] ORA [ ] CENTER	11.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS *	2 INVESTIGATIONS (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	286	500	43						
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	6	10	1						
	NEW YORK	3	5							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	7	12	1						
	CHICAGO	6	10	1						
	CINCINNATI	18	31	3						
	DETROIT	19	33	3						
	MINNEAPOLIS	18	31	3						
	NEW JERSEY	2	3							
	PHILADELPHIA	14	24	2						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	25	45	4						
	FLORIDA	13	23	2						
	NEW ORLEANS	30	53	5						
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	38	67	5						
	DENVER	16	28	2						
	KANSAS CITY	20	35	3						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	24	43	4						
	SAN FRANCISCO	9	16	1						
	SEATTLE	18	31	3						
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	34.2		8.5						
	TOTAL HOURS	9781	500	366						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATION FTEs	10.75	0.55	0.40						

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC	X	TEAM BIOLOGICS
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

REMARKS

* Time is for all inspections, including follow-up inspections.

The inspectional module of 34.2 represents an average of PAC 42002 accomplishments for FY98 & FY99.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Plasma Derivatives of Human Origin	Blood and Blood Products - 42

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Plasma Derivatives of Human Origin	Blood and Blood Products - 42

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42006, A Domestic & Foreign *	[X] ORA [ ] CENTER	4.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPECT-IONS	1 FOREIGN LICENSED INSPECT-IONS	3 DOMESTIC SAMPLE COLL	2 DOMESTIC INVESTI-GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	14	6		637					
	HEADQUARTERS	14	6							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO				295					
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS				114					
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				114					
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES				114					
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	180.0	171.4							
	TOTAL HOURS	2520	1028		637					
	CONVERSION FACTOR	910	910		910					
	OPERATIONAL FTEs	2.77	1.13		0.70					

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC	X	CORE TEAM BIOL
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

REMARKS

* All inspections will be conducted by Core Team Biologics.

42006 GMP Inspections; 42006A Pre-Licensed Inspections Report foreign inspections under Operation Code 11.

All resources are planned under Licensed Inspections, these resources may be used for pre-licensed inspections.

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] POGRAM 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)	d. INDUSTRY/PRODUCT CODE(S)
Blood and Blood Components	57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42007, 42R833, 42R824, 99R833	[X] ORA [ ] CENTER	2.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 IMPORT ENTRY REVIEW 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		3000							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		110							
	NEW YORK		529							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		44							
	CHICAGO		127							
	CINCINNATI		66							
	DETROIT		54							
	MINNEAPOLIS		30							
	NEW JERSEY									
	PHILADELPHIA		112							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		13							
	FLORIDA		26							
	NEW ORLEANS		745							
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		231							
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES		533							
	SAN FRANCISCO		35							
	SEATTLE		345							
	PACIFIC REGIONAL LAB - NW									
	PACIFIC REGIONAL LAB - SW									
	HOURS PER OPERATION									
	TOTAL HOURS		3000							
	CONVERSION FACTOR		1200							
	TOTAL OPERATION FTES		2.50							

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

Resources are for: 42R833 Entry Review; 42R824 Follow-Up to Refusals; 99R833 Filer Evaluation; and Label Exams/Reviews as needed (Report Hours under PAC 42007).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Viral Marker Test Kits (Inspections of In Vitro Diagnostic Product Manufactures)	Blood and Blood Products - 42

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

4. OBJECTIVES

To evaluate the manufacturing processes 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 Part 809), Biologics regulations (21 CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
In Vitro Diagnostic Products accordance with the stated objective.	55, 57, 65 & 81 (Device Categories)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Viral Marker Test Kits	Blood and Blood Products - 42

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42008, A Domestic & Foreign *	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 Post-Licensed DOMESTIC INSPECTIONS	1 Post-Licensed FOREIGN INSPECTIONS	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	12	4							
	HEADQUARTERS	12	4							
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		228.0	228.0							
TOTAL HOURS		2736	912							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		3.01	1.00							

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC	X	CORE TEAM BIOL
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPEC-	10/01/00	09/30/01
ANALY- TICAL		

REMARKS

All inspections will be performed by Core Team Biologics.

No Resources are planned for 42008A, use above resources if there are any Pre-License Inspections.

* 42008 GMP Inspections, 42008A Pre-License Inspections

Report Foreign Inspections under the Operation Code 11.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Institutional Review Board (PDUFA)	Blood and Blood Products - 42

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

4. OBJECTIVES

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).

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Sponsors, Contract Research Organizations, and Monitors (PDUFA)	Blood and Blood Products - 42

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Clinical Investigators (PDUFA)	Blood and Blood Products - 42

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

4. OBJECTIVES

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

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

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
IRBs, Sponsors-Monitors, Clinical Investigators (PDUFA Domestic and Foreign)	Blood and Blood Products - 42

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
309-IRBs, 42810-Spon./Monitor, 42811- Clinical Investigators	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS (IRBs, SPON/MON CIs)	1 FOREIGN BIMO INSPECTIONS (GLPs, CIs)	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	14	12							
	HEADQUARTERS		2							
	REGIONAL STAFF									
NE	NEW ENGLAND	1								
	NEW YORK	1	1							
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE		1							
	CHICAGO									
	CINCINNATI									
CE	DETROIT	1								
	MINNEAPOLIS		1							
	NEW JERSEY		1							
	PHILADELPHIA	2								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	2								
SE	FLORIDA	2	1							
	NEW ORLEANS	1	1							
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS		1							
	DENVER		1							
	SOUTHWEST IMPORT DISTRICT									
	KANSAS CITY									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	3								
	SAN FRANCISCO	1	1							
	SEATTLE		1							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	65.0	75.0							
	TOTAL HOURS	910	900							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	1.00	0.99							

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

Resources are planned under Clinical Investigators. Operations are to be conducted only when assignments are received from CBER. See individual assignments from CBER for appropriate reporting PAC.
Report Foreign Inspections under Operation Code 11.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers (Biologics)	Blood and Blood Products - 42

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

4. OBJECTIVES

To evaluate the manufacturing processes for those medical devices and in-vitro diagnostic products which were transferred to the Center for Biologics Evaluation and Research (CBER) under the 4/1/82 Working Relationships Agreement with CDRH.

5. PROGRAM JUSTIFICATION

As a result of the 4/1/82 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 7382.830. Report findings/observations to the Center for Biologics Evaluation and Research (CBER). Recommend/initiate Regulatory follow-up consistent with the compliance program guidance and Agency policy.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All devices in the product categories transferred to CBER	65 & 81 (Device Categories)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers (Biologics)	Blood and Blood Products - 42

ROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
2830 L, C	[X] ORA [ ] CENTER	2.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	36	204							
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	2	11							
	NEW YORK	4	23							
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	4	22							
	CHICAGO	4	23							
	CINCINNATI	1	6							
CE	DETROIT	1	6							
	MINNEAPOLIS									
	NEW JERSEY	2	11							
	PHILADELPHIA	1	6							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA	3	17							
	NEW ORLEANS	1	6							
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	3	17							
SW	DENVER									
	KANSAS CITY	2	11							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3	17							
PA	SAN FRANCISCO	3	17							
	SEATTLE	2	11							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		57.6								
TOTAL HOURS		2074	204							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		2.28	0.22							

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

MARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Blood and Blood Products - 42

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Blood and Blood Products - 42

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
2R816	[X] ORA [ ] CENTER	0.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (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	603								
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	603								
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS	603								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.50								

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALYTICAL	10/15/00	09/30/01
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
logics	Vaccines and Allergenic Products - 45

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		8.4		2.8	11.2	16.1	
1	Licensed Allergenic Products (Core)	45001,A	1.0		0.5	1.5	1.5	2-3
	(Field Joint Pre-License Inspections)		0.5		0.5	1.0	2.0	
	(Field Investigations)		0.2			0.2	0.4	
2	Licensed Vaccine Products (Core)	45002, A	3.5		1.8	5.3	5.3	4-5
	(Field Investigations)		0.3			0.3	0.7	
3	Bioresearch Monitoring Programs *		2.9			2.9	6.2	6-9
	Institutional Review Board	45809	*					
	Sponsors, Contract Research Organizations,	45810	*					
	and Monitors							
	Clinical Investigators	45811	(2.9)			(2.9)		

* All resources planned under 45811

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Elaine Knowles Cole, 301 827-6220	Harriet Gerber, 301-827-1630

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Allergenic Products	Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Allergenic Products (Post-Market & Pre-License)	Vaccines and Allergenic Products - 45

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
001, A Domestic/Foreign * & Joint Pre-License **	[X] ORA [ ] CENTER	2.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 * DOMESTIC INSPECTIONS	1 * FOREIGN INSPECTIONS	1 ** PRE-LICENSE INSPECTIONS DOMESTIC	1 ** PRE-LICENSE INSPECTIONS FOREIGN	2 INVESTIGATIONS (HOURS)	6 IMPORT FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	5	2	12	5	182				
	HEADQUARTERS	5	2							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK			1		91				
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO			1	2					
	CINCINNATI									
	DETROIT			1						
	MINNEAPOLIS									
	NEW JERSEY			1						
	PHILADELPHIA			1						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA			1		91				
	FLORIDA			1						
	NEW ORLEANS			1						
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS				3					
	DENVER			1						
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			3						
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	182.0	228.0	37.9	91.0					
	TOTAL HOURS	910	456	455	455	182				
	CONVERSION FACTOR	910	910	910	910	910				
	TOTAL OPERATIONAL FTEs	1.00	0.50	0.50	0.50	0.20				

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC	X	TEAM BIOL	ANALYTICAL		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

45001 GMP Inspection, 45001A Pre-License Inspections Inspections conducted by Team Biologics.
No resources are planned for PAC 45001A.

** Resources are for Joint Pre-Licensed Inspections with CBER for any Biologics Program 41, 42, 45
Report inspection hours under appropriate PAC. Report Foreign Inspections under Operation Code 11.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Vaccine Products	Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

To ensure the safety and effectiveness of licensed vaccines by determining that they are manufactured in compliance with current Good Manufacturing Practice regulations and that they comply with standards and commitments made in license applications and/or supplements.
To encourage voluntary compliance by identifying practices which establish and implement programs.
To 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: [ ] BY DISTRICT OFFICE [ ] BY CENTER [ ] BY BOTH

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Vaccine Products (Post-Market)	Vaccines and Allergenic Products - 45

OGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
J02, A Domestic/Foreign *	[X] ORA [ ] CENTER	5.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 * DOMESTIC INSPECTIONS	1 * FOREIGN INSPECTIONS	2 INVESTIGATIONS DOMESTIC (HOURS)	3 DOMESTIC SAMPLE COLL	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	32	17	273						
	HEADQUARTERS	32	17							
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK			91						
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT			91						
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA			91						
	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	97.5	97.5							
	TOTAL HOURS	3120	1658	273						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	3.43	1.82	0.30						

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-		
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN	TIONAL	10/01/00	09/30/01
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC	X	CORE TEAM BIOL	ANALY-		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL		

MARKS

5002 GMP Inspection, 45002A Pre-License Inspections (No planned resources for Pre-License Inspections)
Core Team Biologics (42 INSP Planned) Breakdown of Domestic & Foreign Inspections is: 28 Domestic & 14 Foreign.
National Experts (7 INSP Planned) Breakdown of Domestic & Foreign Inspections is: 4 Domestic & 3 Foreign.
Report inspection hours under appropriate PAC. Report Foreign Inspections under Operation Code 11.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Institutional Review Board (PDUFA)	Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

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).

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Sponsors, Contract Research Organizations, and Monitors (PDUFA)	Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Clinical Investigators (PDUFA)	Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

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

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

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

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
IRBs, Sponsors-Monitors, Clinical Investigators (PDUFA)	Vaccines and Allergenic Products - 45

OGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
809 IRBs, 45810 Spon/ Mon., 45811 Clin Invest	[X] ORA [ ] CENTER	2.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY (SPECIALIZED)	1 INSPECTIONS *	2 INVESTIGATIONS (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	28								
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	7								
	NEW YORK	2								
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	3								
	CHICAGO	2								
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY	2								
	PHILADELPHIA	2								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	1								
	FLORIDA	1								
	NEW ORLEANS	1								
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER	1								
	KANSAS CITY	1								
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3								
PA	SAN FRANCISCO	1								
	SEATTLE	1								
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	94.0								
	TOTAL HOURS	2632								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTEs	2.89								

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

MARKS

* All resources are planned under 45811, Clinical Investigators. Report Accomplishment hours under Appropriate PAC.

CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2001

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	273.5	31.0	52.8	357.3	577.1	67.8	112.1	757
46	NEW DRUG EVALUATION	37.5		18.8	56.3	81.6		39.8	121.4
48	BIORESEARCH MONITORING HUMAN DRUGS	47.3		6.9	54.2	101.6		14.7	116.3
52	GENERIC DRUG EVALUATION	37.4		10.6	48.0	81.0		22.5	103.5
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	6.3		1.7	8.0	13.7		3.4	17.1
56	DRUG QUALITY ASSURANCE	131.5	31.0	14.8	177.3	269.8	67.8	31.7	369.3
63	HEALTH FRAUD: HUMAN DRUGS	13.5			13.5	29.4			29.4

Note: Supported FTEs includes Operational (Workplan) and Program Direction & Assistance (Non-Workplan) positions

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	New Drug Evaluation - 46

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs DOMESTIC	IMPORT	FOREIGN	TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
	TOTAL		37.5		18.8	56.3	121.4	
1	NDA Pre-Approval Inspections/Investigations	46832/B/C	37.5			37.5	81.6	2-3
	Methods Validation - Domestic (PDUFA)							
2	NDA Pre-Approval Inspections/Investigations	46832/B/C *			18.8	18.8	39.8	6-7
	Methods Validation - Foreign (PDUFA)							
	* 1 Fte National exports unsupported							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Joseph Famulare, HFD-320; (301) 594-0093	Joel A. Turner 301-827-1636

FORM FDA 2622 (9/98)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/ Investigations	New Drug Evaluation - 46

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

4. OBJECTIVES

To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS

Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive Drugs	All Human Drug Codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive Drugs	All Human Drug Codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Inv. Methods Validation-Domestic (PDUFA)	New Drug Evaluation - 46

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832, 46832B, 46832C	[X] ORA [ ] CENTER	37.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDAs TO INSPECT (Domestic) *	1 CHEMIST INSPECT (HOURS) (Domestic) **	2 INVESTI-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	5 FIELD EXAMS\ TESTS	7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	7 DSAs METH. VALID. (MICRO) ****	7 METH. VALID. RADPHARM TRANSDERM. ***** (chem) (Hours)	7 DSAs (METH.) (VALID) CHEM ******
	TOTAL FIELD	190	3000	350	30		30	6	2380	190
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	11		20	2					
	NEW YORK	18		33	3					
	REGIONAL LAB		800				13	1		19
	WEAC								1180	
	REGIONAL STAFF									
	BALTIMORE	6		11	1					
	CHICAGO	10		18	2					
	CINCINNATI	9		17	1					
CE	DETROIT	6	100	11	1					
	MINNEAPOLIS	2		4						
	NEW JERSEY	27		50	4					
	PHILADELPHIA	16	600	29	3				1200	65
	FORENSIC CHEM. CTR		200				17			
	REGIONAL STAFF									
	ATLANTA	16		29	3					
SE	FLORIDA	2		4						
	NEW ORLEANS	5		9	1					
	SAN JUAN	27	375	50	4					66
	REGIONAL LAB		275							19
	REGIONAL STAFF									
	DALLAS	7		13	1					
SW	DENVER	3	100	6				5		
	KANSAS CITY	8	100	15	1					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	11		20	2					
PA	SAN FRANCISCO	4		7	1					
	SEATTLE	2		4						
	PACIFIC REGIONAL LAB - SW									3
	PACIFIC REGIONAL LAB - NW		450							18
	HOURS PER OPERATION	65.0			8.0		50.0	105.0		105.0
	TOTAL HOURS	12350	3000	350	240		1500	630	2380	19950
	CONVERSION FACTOR	910	1180	910	910		1180	1180	1180	1180
	TOTAL OPERATIONAL FTES	13.57	2.54	0.38	0.26		1.27	0.53	2.02	16.91

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL	10/15/00	09/30/01

REMARKS

* An estimated 190 NDAs require Methods Validation @ approx. 105 Hours. ** Includes Microbiologists on inspections.
*** NRL analyzes profile DSCs in NE & SE Regions. FCC analyzes profile DSCs in CE, SW AND PA Regions.
**** Micro Meth. Val.105 hrs NRL; 525 HRS DEN LAB ***** Radpharm 1180 Hrs WEAC; 1200 Hrs Phi-lab
Transdermal testing ****** Meth. Valid DSAs : See Servicing Laboratory Table Appendix III.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/ Investigations - Foreign	New Drug Evaluation - 46

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

4. OBJECTIVES

To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS

Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive Drugs	All Human Drug Codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations Methods Validation) - Foreign (PDUFA)	New Drug Evaluation - 46

PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832, 46832B, 46832C	[X] ORA [ ] CENTER	18.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FOREIGN	1 CHEMIST INSPS (Hours) FOREIGN **	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL ***	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLES ANALYSES PROFILE (CHEM) ****	8 IMPORT SAMPLES ANALYSES METH. VAL. (Chem) ****	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	199	4500		90			80	10	
	HEADQUARTERS	16								
	REGIONAL STAFF									
NE	NEW ENGLAND	11			6					
	NEW YORK	15			8					
	REGIONAL LAB		900					80	10	
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	10			5					
	CHICAGO	10			5					
	CINCINNATI	8			4					
CE	DETROIT	6			3					
	MINNEAPOLIS	2			1					
	NEW JERSEY	26			11					
	PHILADELPHIA	12	1750		6					
	FORENSIC CHEM. CTR		225							
	REGIONAL STAFF									
	ATLANTA	16			8					
	FLORIDA	3			2					
SE	NEW ORLEANS	2			1					
	SAN JUAN	26	400		11					
	REGIONAL LAB		375							
	REGIONAL STAFF									
	DALLAS	6			3					
SW	DENVER	3	200		2					
	KANSAS CITY	8	250		4					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	11			6					
PA	SAN FRANCISCO	6			3					
	SEATTLE	2			1					
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW		400							
	HOURS PER OPERATION	55.0			3.0			30.0	75.0	
	TOTAL HOURS	10945	4500		270			2400	750	
	CONVERSION FACTOR	910	1180		910			1180	1180	
	TOTAL OPERATIONAL FTEs	12.03	3.81		0.30			2.03	0.64	

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALYTICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

*** Report as follows: Insps./Chem on Insps under new foreign operation code 11 Pac Code 46832;**
M. Valid.-46832; Profile ISCs & ISAs -46832B; Biotest ISCs & ISAs (not planned) if collected -46832C.
** Includes microbiologists on inspections. *** Samples are collected at foreign manufacturers.
**** NRL analyzes all Profile ISCs and meth. valid. ISAs.

PROJECT SUMMARY SHEET

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

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		47.3		6.9	54.2	116.3	
1	In Vivo Bioequivalence	48001,48001A	4.0			4.0	8.8	2/3
	Foreign Inspections (In Vivo Bioequivalence,				6.9	6.9	14.4	4/5
	GLPs, Clinicial Investigators)							
	(National Experts)				(0.3)	(0.3)	0.3	
2	Good Laboratory Practices (Non-clinical Lab)	48808	6.0			6.0	11.3	6/7
	(National Experts)		(0.8)			(0.8)	0.8	
3	Institutional Review Board	48809	9.8			9.8	21.3	8-11
	Radioactive Drug Research Committee	48809A*	0.3			0.3	0.7	
	*(48809A planned under 48809)							
4	Sponsors, Contract Research Organizations,	48810	3.8			3.8	8.3	12/13
	and Monitors							
5	Clinical Investigators	48811	23.4			23.4	49.9	14/15
	(National Experts)		(0.5)			(0.5)	0.5	

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Stan Woollen, 301 594-0020	Anitia T. McCurdy, 301-827-1632

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

Conduct the inspections and forward the reports directly to the Division of Scientific Investigations, CDER.

7a. ESTABLISHMENTS TO BE SELECTED [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence (Pre-Approval)	Bioresearch Monitoring: Human Drugs - 48

GRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
01 (ANDAs) 48001A (NDAs)	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDA INSPECTIONS	1 NDA INSPECTIONS	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	40	3							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK	4	1							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	7								
	CHICAGO	1								
	CINCINNATI	3								
	DETROIT	2								
	MINNEAPOLIS	4								
	NEW JERSEY	1								
	PHILADELPHIA	4	1							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	4	1							
	FLORIDA	1								
	NEW ORLEANS									
	SAN JUAN	1								
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3								
	DENVER									
	KANSAS CITY	1								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3								
	SAN FRANCISCO	1								
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	86.0	86.0							
	TOTAL HOURS	3440	258							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	3.78	0.28							

7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPECTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

gnments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification for ated assignments.

An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 95%, PDUFA 48001A (NDA) 5%.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

To determine through audit procedures whether: (a) bioequivalence data, (b) non-clinical laboratory study data, and (c) clinical data are substantiated by on-site documentation, are valid, scientifically accurate and the studies were conducted according to appropriate regulations.

GLP inspections in foreign laboratories may also provide an assessment of the effectiveness of an existing Memorandum of Understanding with that named nation.

5. PROGRAM JUSTIFICATION

An increasing number of bioequivalence studies are conducted by contract laboratories, private and university affiliated, located in Canada and Europe. In addition, large numbers of animal studies (GLP) and clinical studies are conducted in Europe and other foreign countries. Serious problems associated with lack of adherence to protocols, lack of and inadequate record keeping, inadequate and inaccurate analytical procedures, and fraud have been documented in such studies. These studies are required for drug approval in the United States.

6. FIELD OBLIGATIONS

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

7a. ESTABLISHMENTS TO BE SELECTED: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60/61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48001,A NDA &, ANDA *	[X] ORA [ ] CENTER	6.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDA INSPECTIONS PDUFA	1 ANDA INSPECTIONS	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	90	10							
	HEADQUARTERS	3								
	REGIONAL STAFF									
NE	NEW ENGLAND	6								
	NEW YORK	4								
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	6								
	CHICAGO	5	2							
	CINCINNATI	5								
CE	DETROIT	5								
	MINNEAPOLIS	2								
	NEW JERSEY	3	1							
	PHILADELPHIA	4	2							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	10								
	FLORIDA	10	2							
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	5								
SW	DENVER	2								
	KANSAS CITY	4	1							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	4								
PA	SAN FRANCISCO	4								
	SEATTLE	8	2							
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	60.0	91.0							
	TOTAL HOURS	5400	910							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	5.93	1.00							

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

9. REMARKS

* Planned inspections include: In Vivo Bioequivalence, Clinical Investigators, GLPs (PDUFA).
HIGH PRIORITY inspections when the data have been submitted in a NDA.
** Report hours used under appropriate PAC. Report foreign inspections under the operation code 11.
An estimate of percentage of time: PDUFA (NDA) 85% and Non-PDUFA, Pre-Approval (ANDA) 15%.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practice (Nonclinical Laboratory)	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. ESTABLISHMENTS TO BE SELECTED: [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60/61

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

f. CHECK THE FOLLOWING ATTRIBUTES

Presence and concentration of test article feed mixture used in the study audited. CDER will specify in the assignment when samples samples are to be collected and analyzed.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Use methodology prescribed in protocol or actually used in nonclinical laboratory.

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

GRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
08	[X] ORA [ ] CENTER	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (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	65								
	HEADQUARTERS	9								
NE	REGIONAL STAFF									
	NEW ENGLAND	3								
	NEW YORK	4								
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	5								
	CHICAGO	2								
	CINCINNATI	3								
	DETROIT	4								
	MINNEAPOLIS	1								
	NEW JERSEY	10								
	PHILADELPHIA	5								
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	3								
	FLORIDA									
	NEW ORLEANS	1								
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3								
	DENVER	3								
	KANSAS CITY	2								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2								
	SAN FRANCISCO	4								
	SEATTLE	1								
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	84.3								
	TOTAL HOURS	5480								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTEs	6.02								

7. PERSONNEL TYPES REQUIRED

ANALYTICAL				INVESTIGATIVE			
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT
	PHYSICIST				MILK/FOOD SPEC		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER

8. WORK SCHEDULE

PERSON TYPE	BEGIN	END
INSPECTIONAL	10/01/00	09/30/01
ANALYTICAL		

9. REMARKS

sources planned for inspections may also be used for DSCs.
signments issued by the Center will contain designations for coverage under PDUFA when assignments identify data audits of studies submitted in NDAs.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Institutional Review Board	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

To assure the quality and integrity of institutional review boards (21 CFR 56, 21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

Conduct inspections of IRBs which may be evaluation of human drugs studies and forward the reports to the Division of Scientific Investigations, CDER.

Assist in presentation of IRB workshops.

7a. ESTABLISHMENTS TO BE SELECTED [ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	60/61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING