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WORKPLAN SUMMARY / COMBINED OPERATIONS  
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	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>FIELD TOTAL</b>	<b>2963</b>	<b>83.94</b>	<b>37</b>	<b>66.83</b>	<b>1718</b>	<b>7.96</b>	<b>4966</b>	<b>10.84</b>	<b>927</b>	<b>0.94</b>
<b>FOOD SAFETY/COS</b>	<b>856</b>	<b>16.50</b>	<b>37</b>	<b>41.83</b>	<b>870</b>	<b>3.91</b>	<b>4756</b>	<b>10.32</b>	<b>748</b>	<b>0.34</b>
03	646	13.13	37	39.70	132	0.75	2635	6.32	0	0.00
04	0	0.00	0	0.27	400	1.70	1574	3.07	7	0.01
07	0	0.00	0	0.00	212	0.89	201	0.42	0	0.00
09	0	0.00	0	0.30	0	0.00	300	0.44	0	0.00
18	142	1.78	0	0.00	9	0.04	0	0.00	0	0.00
21	54	1.34	0	1.39	109	0.50	34	0.05	741	0.33
29	14	0.25	0	0.16	8	0.04	12	0.02	0	0.00
<b>BIOLOGICS</b>	<b>366</b>	<b>17.25</b>	<b>0</b>	<b>0.82</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	111	4.99	0	0.00	0	0.00	0	0.00	0	0.00
42	241	10.93	0	0.72	0	0.00	0	0.00	0	0.00
45	14	1.33	0	0.10	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>399</b>	<b>24.87</b>	<b>0</b>	<b>2.55</b>	<b>165</b>	<b>0.89</b>	<b>29</b>	<b>0.09</b>	<b>0</b>	<b>0.00</b>
46	13	0.63	0	0.00	1	0.01	0	0.00	0	0.00
48	99	8.98	0	0.00	0	0.00	0	0.00	0	0.00
52	14	0.71	0	0.25	9	0.05	21	0.07	0	0.00
53	10	0.70	0	0.00	0	0.00	0	0.00	0	0.00
56	254	13.53	0	2.05	150	0.82	8	0.02	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	9	0.34	0	0.24	5	0.02	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>992</b>	<b>10.89</b>	<b>0</b>	<b>3.16</b>	<b>675</b>	<b>3.10</b>	<b>31</b>	<b>0.08</b>	<b>0</b>	<b>0.00</b>
68	26	1.55	0	0.00	0	0.00	0	0.00	0	0.00
71	966	9.34	0	3.16	675	3.10	31	0.08	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>350</b>	<b>14.43</b>	<b>0</b>	<b>18.48</b>	<b>8</b>	<b>0.05</b>	<b>150</b>	<b>0.35</b>	<b>179</b>	<b>0.60</b>
81	2	0.03	0	0.01	0	0.00	0	0.00	0	0.00
82	149	8.91	0	14.55	7	0.05	150	0.35	0	0.00
83	60	4.31	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	122	0.85	0	0.90	0	0.00	0	0.00	0	0.00
86	17	0.32	0	3.01	1	0.00	0	0.00	179	0.60

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	6		7		8		9		10	
	OPRNS	OPR FTE'S								
<b>FIELD TOTAL</b>	0	0.32	6661	75.28	4829	45.63	424	28.34	133	7.42
<b>FOOD SAFETY/COS</b>	0	0.32	5585	56.19	4681	44.67	424	20.34	21	0.66
03	0	0.32	360	9.25	2456	22.52	0	2.87	21	0.66
04	0	0.00	3885	41.82	1597	17.07	0	6.78	0	0.00
07	0	0.00	269	1.37	261	1.55	0	0.10	0	0.00
09	0	0.00	0	0.00	343	3.13	0	0.00	0	0.00
18	0	0.00	14	0.10	0	0.00	213	10.32	0	0.00
21	0	0.00	1040	3.35	0	0.00	211	0.27	0	0.00
29	0	0.00	17	0.31	24	0.40	0	0.00	0	0.00
<b>BIOLOGICS</b>	0	0.00	0	0.00	0	0.00	0	0.00	3	0.13
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	0.00	3	0.13
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	0	0.00	141	8.82	4	0.13	0	0.20	67	3.82
46	0	0.00	0	1.26	0	0.00	0	0.00	30	1.64
48	0	0.00	0	0.00	0	0.00	0	0.00	6	0.51
52	0	0.00	0	0.62	0	0.00	0	0.00	6	0.32
53	0	0.00	0	0.00	0	0.00	0	0.00	4	0.25
56	0	0.00	138	6.89	4	0.13	0	0.20	21	1.11
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	3	0.05	0	0.00	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	0	0.00	925	9.74	144	0.83	0	5.30	5	0.42
68	0	0.00	0	0.18	0	0.00	0	0.00	4	0.36
71	0	0.00	925	9.56	144	0.83	0	5.30	1	0.06
<b>DEVICES &amp; RAD H</b>	0	0.00	10	0.53	0	0.00	0	2.50	37	2.39
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	0	0.00	10	0.53	0	0.00	0	0.00	24	1.64
83	0	0.00	0	0.00	0	0.00	0	0.00	11	0.61
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	0	0.00	0	0.00	0	0.00	0	1.06	0	0.00
86	0	0.00	0	0.00	0	0.00	0	1.44	2	0.14

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	Total	
	OPR FTE'S	PERSNHRS
<b>FIELD TOTAL</b>	327.49	352214.30
<b>FOOD SAFETY/COS</b>	195.07	217223.70
03	95.52	102572.20
04	70.71	82322.80
07	4.33	4811.00
09	3.87	4396.00
18	12.24	14208.00
21	7.23	7634.50
29	1.18	1279.20
<b>BIOLOGICS</b>	18.19	17282.10
41	4.99	4741.90
42	11.77	11183.20
45	1.43	1357.00
<b>HUMAN DRUGS</b>	41.37	40442.70
46	3.54	3362.00
48	9.48	9007.70
52	2.00	1906.00
53	0.95	900.00
56	24.75	24638.00
61	0.00	0.00
63	0.65	629.00
88	0.00	0.00
<b>ANIMAL D &amp; F</b>	33.53	35239.30
68	2.09	1988.00
71	31.44	33251.30
<b>DEVICES &amp; RAD H</b>	39.33	42026.50
81	0.05	42.00
82	26.02	27978.90
83	4.93	4680.00
84	0.00	0.00
85	2.82	3273.00
86	5.52	6052.60







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	1		2		3		4		5	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>FIELD TOTAL</b>	<b>4497</b>	<b>132.23</b>	<b>181</b>	<b>91.18</b>	<b>2225</b>	<b>9.92</b>	<b>7465</b>	<b>18.10</b>	<b>1503</b>	<b>1.21</b>
<b>FOOD SAFETY/COS</b>	<b>2451</b>	<b>46.71</b>	<b>181</b>	<b>72.79</b>	<b>1657</b>	<b>7.02</b>	<b>7052</b>	<b>17.06</b>	<b>1345</b>	<b>0.60</b>
03	1837	37.67	181	69.67	401	2.05	5472	13.58	0	0.00
04	0	0.00	0	0.84	848	3.21	1074	2.60	8	0.01
07	0	0.00	0	0.00	199	0.84	179	0.38	0	0.00
09	0	0.00	0	0.22	0	0.00	226	0.33	0	0.00
18	524	7.01	0	0.15	34	0.14	0	0.00	0	0.00
21	69	1.66	0	1.61	163	0.73	63	0.11	1337	0.59
29	21	0.38	0	0.30	12	0.06	38	0.06	0	0.00
<b>BIOLOGICS</b>	<b>349</b>	<b>16.61</b>	<b>0</b>	<b>1.31</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	126	5.77	0	0.00	0	0.00	0	0.00	0	0.00
42	214	9.99	0	1.21	0	0.00	0	0.00	0	0.00
45	9	0.86	0	0.10	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>440</b>	<b>26.89</b>	<b>0</b>	<b>6.53</b>	<b>195</b>	<b>1.00</b>	<b>37</b>	<b>0.11</b>	<b>0</b>	<b>0.00</b>
46	19	0.92	0	0.00	3	0.02	0	0.00	0	0.00
48	104	9.50	0	0.00	0	0.00	0	0.00	0	0.00
52	29	1.47	0	0.35	20	0.11	21	0.07	0	0.00
53	18	1.25	0	0.00	0	0.00	0	0.00	0	0.00
56	248	13.20	0	5.28	124	0.68	16	0.05	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	22	0.55	0	0.91	48	0.20	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>625</b>	<b>9.34</b>	<b>0</b>	<b>4.38</b>	<b>351</b>	<b>1.75</b>	<b>111</b>	<b>0.29</b>	<b>0</b>	<b>0.00</b>
68	7	0.43	0	0.00	0	0.00	0	0.00	0	0.00
71	618	8.91	0	4.38	351	1.75	111	0.29	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>632</b>	<b>32.68</b>	<b>0</b>	<b>6.18</b>	<b>22</b>	<b>0.15</b>	<b>265</b>	<b>0.64</b>	<b>158</b>	<b>0.61</b>
81	4	0.07	0	0.00	0	0.00	0	0.00	0	0.00
82	417	23.55	0	2.73	21	0.15	265	0.64	0	0.00
83	119	7.83	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	46	0.32	0	1.23	0	0.00	0	0.00	0	0.00
86	46	0.91	0	2.22	1	0.00	0	0.00	158	0.61

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	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>FIELD TOTAL</b>	<b>0</b>	<b>1.12</b>	<b>1859</b>	<b>29.31</b>	<b>9894</b>	<b>80.70</b>	<b>580</b>	<b>32.35</b>	<b>167</b>	<b>9.25</b>
<b>FOOD SAFETY/COS</b>	<b>0</b>	<b>1.12</b>	<b>1377</b>	<b>19.26</b>	<b>9348</b>	<b>74.82</b>	<b>580</b>	<b>28.43</b>	<b>27</b>	<b>0.85</b>
03	0	1.12	575	14.25	7149	52.85	0	12.76	27	0.85
04	0	0.00	684	4.20	1770	18.30	0	1.25	0	0.00
07	0	0.00	72	0.37	163	0.97	0	1.00	0	0.00
09	0	0.00	0	0.00	226	2.07	0	0.00	0	0.00
18	0	0.00	34	0.23	0	0.00	218	11.88	0	0.00
21	0	0.00	0	0.00	0	0.00	362	1.54	0	0.00
29	0	0.00	12	0.22	40	0.64	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>3</b>	<b>0.13</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	0.00	3	0.13
45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>0</b>	<b>0.00</b>	<b>138</b>	<b>7.46</b>	<b>67</b>	<b>1.50</b>	<b>0</b>	<b>0.31</b>	<b>60</b>	<b>3.45</b>
46	0	0.00	0	0.92	0	0.00	0	0.00	27	1.48
48	0	0.00	0	0.00	0	0.00	0	0.00	6	0.52
52	0	0.00	0	0.50	0	0.00	0	0.00	6	0.32
53	0	0.00	0	0.00	0	0.00	0	0.00	3	0.19
56	0	0.00	114	5.63	67	1.50	0	0.31	18	0.95
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	24	0.41	0	0.00	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>0</b>	<b>0.00</b>	<b>344</b>	<b>2.59</b>	<b>165</b>	<b>0.90</b>	<b>0</b>	<b>1.01</b>	<b>5</b>	<b>0.42</b>
68	0	0.00	0	0.03	0	0.00	0	0.00	4	0.36
71	0	0.00	344	2.56	165	0.90	0	1.01	1	0.06
<b>DEVICES &amp; RAD H</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>314</b>	<b>3.48</b>	<b>0</b>	<b>2.60</b>	<b>72</b>	<b>4.41</b>
81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
82	0	0.00	0	0.00	314	3.48	0	0.00	51	3.49
83	0	0.00	0	0.00	0	0.00	0	0.00	15	0.75
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	0	0.00	0	0.00	0	0.00	0	0.98	4	0.03
86	0	0.00	0	0.00	0	0.00	0	1.62	2	0.14

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	Total	
	OPR FTE'S	PERSNHRS
<b>FIELD TOTAL</b>	<b>405.38</b>	<b>424786.80</b>
<b>FOOD SAFETY/COS</b>	<b>268.65</b>	<b>289559.80</b>
03	204.80	218982.80
04	30.40	34367.40
07	3.55	3907.00
09	2.62	2961.40
18	19.42	21436.00
21	6.23	6148.40
29	1.64	1756.80
<b>BIOLOGICS</b>	<b>18.04</b>	<b>17139.90</b>
41	5.77	5477.40
42	11.32	10758.00
45	0.95	904.50
<b>HUMAN DRUGS</b>	<b>47.24</b>	<b>46350.50</b>
46	3.34	3169.00
48	10.03	9524.60
52	2.80	2661.00
53	1.44	1368.00
56	27.58	27574.90
61	0.00	0.00
63	2.06	2053.00
88	0.00	0.00
<b>ANIMAL D &amp; F</b>	<b>20.68</b>	<b>21132.60</b>
68	0.82	780.90
71	19.86	20351.70
<b>DEVICES &amp; RAD H</b>	<b>50.76</b>	<b>50604.00</b>
81	0.07	64.00
82	34.04	33629.20
83	8.58	8153.00
84	0.00	0.00
85	2.56	2976.00
86	5.51	5781.80

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TOTAL FIELD	1 DOMESTIC INSPECTIONS		2 INVESTIGATIONS		3 DOM SAMPL COLL		4 IMP SAMPL COLL		5 FIELD EXAM/TESTS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>FIELD TOTAL</b>	<b>19687</b>	<b>592.02</b>	<b>600</b>	<b>365.23</b>	<b>9641</b>	<b>44.81</b>	<b>26160</b>	<b>61.00</b>	<b>5859</b>	<b>5.58</b>
<b>FOOD SAFETY/COS</b>	<b>8849</b>	<b>168.50</b>	<b>600</b>	<b>255.36</b>	<b>6102</b>	<b>27.29</b>	<b>24481</b>	<b>56.66</b>	<b>4925</b>	<b>2.18</b>
03	6900	140.63	600	243.21	1442	7.59	16700	41.01	0	0.00
04	0	0.00	0	2.63	2836	11.77	5494	11.76	25	0.02
07	0	0.00	0	0.00	1000	4.21	664	1.40	0	0.00
09	0	0.00	0	1.14	0	0.00	1175	1.73	0	0.00
18	1555	18.62	0	0.53	100	0.42	0	0.00	0	0.00
21	294	7.46	0	6.66	664	3.02	218	0.40	4900	2.16
29	100	1.79	0	1.18	60	0.28	230	0.36	0	0.00
<b>BIOLOGICS</b>	<b>1930</b>	<b>95.29</b>	<b>0</b>	<b>7.71</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>
41	547	24.93	0	0.00	0	0.00	0	0.00	0	0.00
42	1307	62.22	0	7.10	0	0.00	0	0.00	0	0.00
45	76	8.14	0	0.61	0	0.00	0	0.00	0	0.00
<b>HUMAN DRUGS</b>	<b>2686</b>	<b>162.13</b>	<b>0</b>	<b>37.35</b>	<b>1285</b>	<b>6.83</b>	<b>258</b>	<b>0.78</b>	<b>0</b>	<b>0.00</b>
46	120	5.81	0	0.00	30	0.15	0	0.00	0	0.00
48	511	46.33	0	0.00	0	0.00	0	0.00	0	0.00
52	132	6.67	0	1.90	91	0.48	140	0.44	0	0.00
53	122	8.48	0	0.00	0	0.00	0	0.00	0	0.00
56	1693	91.31	0	31.95	1046	5.70	118	0.34	0	0.00
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	108	3.54	0	3.50	118	0.50	0	0.00	0	0.00
88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>3790</b>	<b>45.15</b>	<b>0</b>	<b>20.19</b>	<b>2177</b>	<b>10.15</b>	<b>620</b>	<b>1.63</b>	<b>0</b>	<b>0.00</b>
68	79	4.74	0	0.00	0	0.00	0	0.00	0	0.00
71	3711	40.42	0	20.19	2177	10.15	620	1.63	0	0.00
<b>DEVICES &amp; RAD H</b>	<b>2432</b>	<b>120.94</b>	<b>0</b>	<b>44.62</b>	<b>77</b>	<b>0.54</b>	<b>801</b>	<b>1.93</b>	<b>934</b>	<b>3.40</b>
81	21	0.36	0	0.03	3	0.03	0	0.00	0	0.00
82	1464	83.10	0	28.96	69	0.49	801	1.93	0	0.00
83	466	31.57	0	0.00	0	0.00	0	0.00	0	0.00
84	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
85	327	2.30	0	6.15	0	0.00	0	0.00	0	0.00
86	154	3.61	0	9.47	5	0.02	0	0.00	934	3.40

WORKPLAN SUMMARY / COMBINED OPERATIONS  
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TOTAL FIELD	6		7		8		9		10	
	IMPORT FIELD EXAMS		DOM SAMPL ANALYSIS		IMP SAMPL ANALYSIS		MISC		FOREIGN INSPECTIONS	
	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S	OPRNS	OPR FTE'S
<b>FIELD TOTAL</b>	<b>0</b>	<b>3.37</b>	<b>12690</b>	<b>233.08</b>	<b>27617</b>	<b>250.33</b>	<b>2485</b>	<b>136.44</b>	<b>956</b>	<b>55.46</b>
<b>FOOD SAFETY/COS</b>	<b>0</b>	<b>3.37</b>	<b>9641</b>	<b>127.20</b>	<b>25936</b>	<b>229.96</b>	<b>2485</b>	<b>98.78</b>	<b>150</b>	<b>4.73</b>
03	0	3.37	1802	41.62	17905	145.07	0	25.50	150	4.73
04	0	0.00	5315	65.27	5744	62.06	0	10.48	0	0.00
07	0	0.00	1000	5.09	664	3.94	0	4.50	0	0.00
09	0	0.00	0	0.00	1175	10.75	0	0.00	0	0.00
18	0	0.00	100	0.68	0	0.00	1340	55.72	0	0.00
21	0	0.00	1364	13.45	218	4.49	1145	2.60	0	0.00
29	0	0.00	60	1.09	230	3.65	0	0.00	0	0.00
<b>BIOLOGICS</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>0.00</b>	<b>0</b>	<b>2.50</b>	<b>29</b>	<b>4.58</b>
41	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	0	0.00	0	0.00	0	0.00	0	2.50	22	2.61
45	0	0.00	0	0.00	0	0.00	0	0.00	7	1.96
<b>HUMAN DRUGS</b>	<b>0</b>	<b>0.00</b>	<b>1144</b>	<b>81.81</b>	<b>260</b>	<b>5.87</b>	<b>0</b>	<b>3.06</b>	<b>446</b>	<b>25.18</b>
46	0	0.00	30	7.16	0	0.00	0	0.00	192	10.51
48	0	0.00	0	0.00	0	0.00	0	0.00	35	2.98
52	0	0.00	90	7.05	140	2.67	0	0.00	42	2.21
53	0	0.00	0	0.00	0	0.00	0	0.00	16	1.01
56	0	0.00	965	54.60	120	3.20	0	3.06	161	8.48
61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
63	0	0.00	59	1.00	0	0.00	0	0.00	0	0.00
88	0	0.00	0	12.00	0	0.00	0	0.00	0	0.00
<b>ANIMAL D &amp; F</b>	<b>0</b>	<b>0.00</b>	<b>1740</b>	<b>17.94</b>	<b>620</b>	<b>3.51</b>	<b>0</b>	<b>10.48</b>	<b>25</b>	<b>2.08</b>
68	0	0.00	0	0.30	0	0.00	0	0.00	20	1.79
71	0	0.00	1740	17.64	620	3.51	0	10.48	5	0.29
<b>DEVICES &amp; RAD H</b>	<b>0</b>	<b>0.00</b>	<b>165</b>	<b>6.14</b>	<b>801</b>	<b>10.99</b>	<b>0</b>	<b>21.61</b>	<b>306</b>	<b>18.89</b>
81	0	0.00	3	0.08	0	0.00	0	0.00	0	0.00
82	0	0.00	60	2.90	801	10.99	0	2.34	200	13.69
83	0	0.00	0	0.00	0	0.00	0	0.00	64	3.43
84	0	0.00	0	0.00	0	0.00	0	4.72	0	0.00
85	0	0.00	0	0.00	0	0.00	0	6.03	14	0.10
86	0	0.00	102	3.15	0	0.00	0	8.52	28	1.68

WORKPLAN SUMMARY / COMBINED OPERATIONS  
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	OPR FTE'S	PERSNHR
<b>FIELD TOTAL</b>	<b>1747.32</b>	<b>1833195.00</b>
<b>FOOD SAFETY/COS</b>	<b>974.02</b>	<b>1055965.40</b>
03	652.73	693613.50
04	163.99	187898.10
07	19.13	21296.00
09	13.62	15412.00
18	75.96	86141.50
21	40.23	42571.80
29	8.36	9032.50
<b>BIOLOGICS</b>	<b>110.08</b>	<b>104566.90</b>
41	24.93	23687.10
42	74.43	70712.90
45	10.71	10166.90
<b>HUMAN DRUGS</b>	<b>323.02</b>	<b>324076.40</b>
46	23.63	22746.00
48	49.31	46843.40
52	21.42	21666.00
53	9.49	9012.00
56	198.64	201312.00
61	0.00	0.00
63	8.53	8337.00
88	12.00	14160.00
<b>ANIMAL D &amp; F</b>	<b>111.14</b>	<b>114042.10</b>
68	6.83	6484.00
71	104.32	107558.10
<b>DEVICES &amp; RAD H</b>	<b>229.05</b>	<b>234544.20</b>
81	0.50	489.90
82	144.40	146281.60
83	35.00	33253.70
84	4.72	5570.00
85	14.58	16951.00
86	29.85	31998.00

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# FY 2008

## PART III - PROGRAM FORECASTS



**DEPT OF HEALTH & HUMAN SERVICES**



**FOOD & DRUG ADMINISTRATION**

**PROGRAM PLANNING & WORKFORCE**

**MANAGEMENT BRANCH**

**ORA/ORM/DPEM**

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**PART III**  
**RESOURCE SUMMARY BY PROGRAM CATEGORY**  
**FY 2008**

	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
	DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
<b>TOTAL ALL PROGRAMS</b>	1072.1	605.9	69.3	1747.3	1904.0	1073.2	122.8	3100.0
FOOD AND COSMETICS	459.7	508.8	5.7	974.2	817.9	901.0	10.1	1729.0
BIOLOGICS	103.0	2.5	4.5	110.0	182.7	4.4	7.9	195.0
HUMAN DRUGS	253.7	30.5	38.8	323.0	450.1	54.1	68.8	573.0
ANIMAL DRUGS AND FEEDS	90.3	18.7	2.1	111.1	160.1	33.2	3.7	197.0
MEDICAL DEVICES AND RADIOLOGICAL HEALTH	165.4	45.4	18.2	229.0	293.2	80.5	32.3	406.0

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
RESOURCE SUMMARY  
FY 2008**

October 1, 2007

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	459.7	508.8	5.7	974.2	817.9	901.0	10.1	1729.0
03	FOODBORNE BIOLOGICAL HAZARDS	247.3	399.7	5.7	652.7	441.4	706.1	10.1	1157.6
04	PESTICIDES AND CHEMICAL CONTAMINANTS	89.1	75.0		164.1	157.5	134.2		291.7
07	MOLECULAR BIOLOGY AND NATURAL TOXINS	13.8	5.3		19.1	24.6	9.4		34.0
09	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		13.6		13.6		24.2		24.2
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	76.0			76.0	135.1			135.1
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	30.3	10.0		40.3	53.6	17.9		71.5
29	COLOR AND COSMETICS TECHNOLOGY	3.2	5.2		8.4	5.7	9.2		14.9



1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low-Acid Canned Foods, CP 7303.003		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
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.  (b)(2) & (b)(7)(E)			
5. PROGRAM JUSTIFICATION Acidified and Low-Acid Canned Foods continue to be the source of sporadic problems from improper processing (e.g., under-processing, inadequate pH or Aw control, leakage). Inspections of foreign firms have shown many firms (and their products) to be out of compliance with 21 CFR Parts 108, 113 and 114.  The number of foreign AF/LACF firms submitting registrations has been increasing significantly each year. As in FY 07, the number of planned hours for Import Field Exams will remain at 3200 and the number of Import Sample Collections will remain at 1400.			
6. FIELD OBLIGATIONS The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements.  All import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 5.4.1.4 for additional information on Food and Cosmetic Defense Activities.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		NA <input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		NA <input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) Refer to Compliance Program (7303.003)		d. INDUSTRY/PRODUCT CODE (S) 03-04, 09, 12-18, 20-25, 27, 29, 30-31, 33-41	
e. EXAM TYPE		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES pH, water activity, salinity, soluble solids.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low Acid Canned Foods			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03003, 03003A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 14.8			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2	4	4	4	8	8	
			IMPORT FIELD EXAMS (Hours) *	IMPORT SAMPLE COLLECTION	IMPORT SAMPLE COLL. MICRO GUIDANCE	IMPORT SAMPLE COLL. CHEM GUIDANCE	IMPORT SAMPLES TO BE ANALYZED MICRO **	IMPORT SAMPLES TO BE ANALYZED CHEM **	
	TOTAL FIELD		3200	1400	1230	170	1230	170	
	HEADQUARTERS		(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)	(b)(2) & (b)(7)(E)
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
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				1.8			7.0	10.0	
TOTAL HOURS			3200	2520			8610	1700	
CONVERSION FACTOR			950	950			1180	1180	
TOTAL OPERATIONAL FTEs			3.37	2.65			7.30	1.44	
9. REMARKS									
<p>* Workload : Spreads for Field Exams and Import Sample Collections were determined by CFSAN using previous planned and accomplished data for each district and ORADSS line entry data for LACF, Acidified and aseptic foods. Field Exam hours are for field exams as required by the District to cover program priorities. Each field exam is estimated to take one hour.</p> <p>Import Field Exams, are to routinely include: verification that the imported product is the same as declared (reconciliation exam); an assessment of security concerns related to labeling &amp; source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns. These activities are to be reported as a single Import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up, report the CT exam under the CT PAC (03R845, 04R845 etc.). See IOM Section 5.4.1.4 for additional information on Food &amp; Cosmetic activities.</p> <p>(b)(2) &amp; (b)(7)(E)</p> <p>Surveillance activities under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program unless otherwise directed.</p> <p>** NOTE: SWID SAMPLES COLLECTED FROM TX &amp; NM ARE SENT TO ARL. SWID SAMPLES COLLECTED FROM CA &amp; AZ ARE SENT TO PRS.</p>									

1. PROGRAM/ASSIGNMENT TITLE Domestic and Imported Cheese and Cheese Products 03037		2. PMS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03			
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT					
4. OBJECTIVES To conduct inspections of domestic soft cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered.					
5. PROGRAM JUSTIFICATION Cheese and cheese products have been demonstrated to contain pathogenic microorganisms and to cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.					
6. FIELD OBLIGATIONS The field is requested to conduct inspections of domestic cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings. The field is also requested to conduct sample collections and analyses of imported cheese focusing on soft cheese as high priority. Refer to the guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections.  As in FY 07: High Risk firms whose last inspection was NAI may be placed on a 3-year inspection frequency. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.  <b>NOTE: (For specialized micro testing below, see compliance program or contact DFS for additional details)</b> DEN will perform Salmonella serotyping for isolates originating from the following labs: DEN, SAN, PRL-SW, PRL-NW. ARL will perform Salmonella serotyping for isolates originating from all labs: ARL, SRL, NRL					
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Hard and Soft Cheeses		d. INDUSTRY/PRODUCT CODE(S) 12			
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)		
f. CHECK THE FOLLOWING ATTRIBUTES <u>Salmonella</u> , <u>Listeria</u> , <u>E. coli</u> , <u>Enterotoxigenic E. Coli (ETEC)</u> , <u>Enterohemorrhagic E. Coli EHEC 0157:H7</u> - <u>S. Aureus</u> , And Phosphatase and Filth					
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.					

1. PROGRAM/ASSIGNMENT TITLE Domestic and Imported Cheese and Cheese Products			2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03														
3. PROGRAM/ASSIGNMENT CODE(S) 03037, 03037B, 03037D			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 24.1										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S (1)	2 INVEST I G A T I O N S (Hours) (3)	3 DOMESTIC SAMPLE COLLECTION (2)	4 IMPORT SAMPLE COLL MICRO (5)	IMPORT SAMPLE COLL CHEM GUIDANCE	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	8 IMPORT SAMPLES TO BE ANALYZED CHEM FILTH (6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (7)								
	TOTAL FIELD	300	350	300	700	75	300	75	700								
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)												
NE	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
SW	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
PA	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
HOURS PER OPERATION										17.0		4.0	2.0		18.0	6.1	18.0
TOTAL HOURS										5100	350	1200	1400		5400	458	12600
CONVERSION FACTOR										950	950	950	950		1180	1180	1180
TOTAL OPERATIONAL FTEs										5.37	0.37	1.26	1.47		4.58	0.39	10.68

9. REMARKS

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

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

(3) INVESTIGATION HOURS DISTRIBUTED BY CFSAN. TIME IS PROVIDED FOR ASSIGNMENTS TO COVER THE INVESTIGATION OF RAW MILK CHEESES.

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low-Acid Canned Foods, CP 7303.803A,		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine if the firms comply with 21 <u>CFR</u> , Part 108, 113 and 114 and other requirements of the FD&C Act. To perform annual inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods.  A continued priority will remain with out-of-compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Firms who have been in compliance are on a 3-year inspection cycle. Please refer to the compliance program for guidance.			
5. PROGRAM JUSTIFICATION <u>Low-Acid Canned Foods</u> : Inspections conducted in prior year's programs have demonstrated that the degree of compliance with Low-acid canned food regulations relate directly to the degree of freedom from hazard to consumers found in the food produced. High risk industry segments, identified under previous programs, as well as re-inspection of the remaining portions of the industry are needed to establish and maintain compliance with the low-acid canned food regulations.  <u>Acidified Foods</u> : To improve the acidified food industry's degree of freedom from public health hazard and their degree of compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas which need emphasis in future programs.			
6. FIELD OBLIGATIONS Firms in compliance and that have not registered new products nor significantly changed a current process, may be inspected on a 3-year frequency. Special situation firms are to be inspected according to the guidance in the compliance program (see program). It is estimated that 400 FDA inspections are needed to fulfill program obligations FY 08. State contract inspections are to be used to increase firm coverage under this program.  State inspections may be conducted in addition to the number of inspections assigned per district. Resources include coverage of food security issues (see IOM) at domestic processors.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT (S) See Compliance Program		d. INDUSTRY/PRODUCT CODE(S) 16, 20-22, 24-25, 27, 35, 37, 38, 40-41	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified and Low Acid Canned Food				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03					
3. PROGRAM/ASSIGNMENT CODE(S) 03803A (2)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 16.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	4	4	4	7	7	9
		INSP CTIONS (1) (3)	INVEST IGATIONS (HOURS) (1)	DOMESTIC SAMPLE COLLECTION (1) (5)	DOMESTIC SAMPLE COLLECTION MICRO GUIDANCE	DOMESTIC SAMPLE COLLECTION CHEM GUIDANCE	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	BETTER PROCESS- ING SCHOOL (Training Hours) (4)
	TOTAL FIELD	400	400	200	180	20	20	180	950
	HEADQUARTERS	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		27.0		6.0			14.0	14.0	
TOTAL HOURS		10800	400	1200			280	2520	950
CONVERSION FACTOR		950	950	950			1180	1180	950
TOTAL OPERATIONAL FTEs		11.37	0.42	1.26			0.24	2.14	1.00

9. REMARKS

(1) Source of workload: Inspections, Investigation Hours and DSC's provided by CFSAN. Resource distribution based on CFSAN's LACF database as of 3/2007.

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

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety 03803		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE	<input type="checkbox"/> PROGRAM <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act. The top program priority for FY 2008 remains to inspect all high-risk firms annually.  Ample resources have been provided to cover the full high-risk inventory covered by this program as well as to accomplish other program objectives (see compliance program). Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate district, will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program. Resources from this program may be directed to monitor chicken eggs for <i>Salmonella</i> Enteritidis and for follow-up Assignments. Also, resources needed for inspections of domestic firms for FDA E.U. certification will be taken from this program. Food security issues are to be covered during all inspections (See IOM).			
5. PROGRAM JUSTIFICATION  Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibilities of assuring that manufacturers produce these products under current Good Manufacturing Practices.			
6. FIELD OBLIGATIONS  To conduct domestic inspections, focusing on high-risk firms and allergen firms with additional program resources to provide coverage with the priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk, allergen, and other firms. Sample collections will typically be "for cause," i.e., no surveillance sampling is to be conducted. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations. Only those "for cause" collections needed to support regulatory inspections are to be conducted. Currently, allergen surveillance inspections are on hold pending finalization of the Agency's allergen enforcement strategy. The field may do "for cause" allergen inspections as needed, but only proceed with surveillance inspections when new allergen guidance is issued by CFSAN. <b>NOTE:</b> Confirmation tests for <i>Clostridium botulinum</i> , <i>Yersinia enterocolitica</i> will be split between SRL & Pacific Regional Laboratory-NW. SRL will be the confirmation servicing laboratory for NE, CE, & SE Regions. Pacific Regional Laboratory-NW will be the confirmation servicing laboratory for SW & PA Regions.  Surveillance activities planned under this program may be pro-rated by enforcement initiatives agreed upon by ORA & CFSAN. Such activities will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATE <input type="checkbox"/> DIRECTED
c. PRODUCT (S) All Food Products (Except 12 & 16)		d. INDUSTRY/PRODUCT CODE (S) 02-11, 13-15, 17-41, 45-46, 50	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES Filth, Decomposition and Microbiological Contamination (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

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1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03										
3. PROGRAM/ASSIGNMENT CODE(S) 03803, B, C, D, E; 04803; 09803E,F (2) (5) (8)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 96.3				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS INCLUDING HIGH RISK (1) (3) (6)	1 NON CLINICAL GLP INSPEC- TIONS (4)	4 INVESTI- GATIONS (HOURS) INCLUDES NATL EXPERTS (1)	3 DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL MICRO GUIDANCE	DOMESTIC SAMPLE COLL CHEM GUIDANCE	DSAs MICRO SALMONELLA SEROTYPING (HOURS) (6)	DOMESTIC SAMPLES TO BE ANALYZED MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	FOOD SAFETY METHOD VALIDATION MICRO (HRS) (7)	FOOD SAFETY METHOD VALIDATION CHEM (HRS) (7)
	TOTAL FIELD	4000	10	13860	400	240	160	1180	240	160	1500	1500
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	NEW ENGLAND	(b)(2) & (b)(7)(E)										
	NEW YORK	(b)(2) & (b)(7)(E)										
	REGIONAL LAB WEAC	(b)(2) & (b)(7)(E)										
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	BALTIMORE	(b)(2) & (b)(7)(E)										
	CHICAGO	(b)(2) & (b)(7)(E)										
	CINCINNATI	(b)(2) & (b)(7)(E)										
	DETROIT	(b)(2) & (b)(7)(E)										
	MINNEAPOLIS	(b)(2) & (b)(7)(E)										
	NEW JERSEY	(b)(2) & (b)(7)(E)										
	PHILADELPHIA FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)										
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	ATLANTA	(b)(2) & (b)(7)(E)										
	FLORIDA	(b)(2) & (b)(7)(E)										
	NEW ORLEANS SAN JUAN REGIONAL LAB	(b)(2) & (b)(7)(E)										
SW	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	DALLAS	(b)(2) & (b)(7)(E)										
	DENVER	(b)(2) & (b)(7)(E)										
	KANSAS CITY	(b)(2) & (b)(7)(E)										
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2) & (b)(7)(E)										
PA	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	LOS ANGELES	(b)(2) & (b)(7)(E)										
	SAN FRANCISCO	(b)(2) & (b)(7)(E)										
	SEATTLE	(b)(2) & (b)(7)(E)										
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)										
HOURS PER OPERATION		17.0			6.0				12.0	12.0		
TOTAL HOURS		68000		13860	2400			1180	2880	1920	1500	1500
CONVERSION FACTOR		950		950	950			1180	1180	1180	1180	1180
OPERATIONAL FTEs		71.58		14.59	2.53			1.00	2.44	1.63	1.27	1.27

7. REMARKS

(1) FY 2008 100% INSP, DSC, and Investigations based on: OEI of firms flagged as High Risk in FACTS less firms with only industry code 12, 16, or 51 as of December 14, 2006. Includes time for National Experts (3 FTEs). Resources have been allocated for 4000 total inspections. High Risk and GLP firms are included in this total number. Some of the inspectional & analytical resources planned may be directed for Allergen Work, once an Allergen Program or Assignment is issued by CFSAN.

(2) Resources for 04803 and 09803E,F are included. Resources for audits are under State Contracts Program, 03R843.

(3) Allergen Inspections may be assigned upon the issuance of an Allergen Program for FY08.  
 \* Do Not Initiate Surveillance (Allergen) Inspections until a New Allergen Program is issued.  
 \* Report Allergen inspections under PAC 03803E. "For Cause" Allergen Inspections are to be conducted as needed.

(4) Non-Clinical Good Laboratory Practice Inspections: CFSAN will contact affected Districts to arrange inspections during the course of the year.

(5) Assignments for sprout producers and egg farms, if needed in FY 08, will be taken from this Program.

(6) Salmonella Serotyping: Samples generated from NRL, SRL & ARL go to ARL; Samples generated from other labs go to Denver.

(7) Food Safety Method Validation for CHEM and MICRO: Resources are Pro-Rated based on the CHEM and MICRO Labs in the ORA Field Workplan Lab Servicing Table.

(8) Non Seafood Inspections for EU and Chilean Certification will be handled by CFSAN Assignment and counted against the inspectional obligations of this program.

1. PROGRAM/ASSIGNMENT TITLE Import Foods – General 03819		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.			
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.			
6. FIELD OBLIGATIONS To conduct activities directed by CFSAN, identified through program guidance, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth disease vector, or decomposition.  Districts should emphasize priority products from the compliance program. The Compliance Program prioritizes high risk products (raw produce, RTE foods, ice cream products, dried milk products, tahini, sesame seed and halva candy, bush meat, baked goods, custard or cream-filled (egg containing), and BSE at-risk products), imported foods of regional significance, foods with a high frequency of contamination with filth which presents a public health hazard, and foods subject to decomposition which presents a public health hazard. Districts should deemphasize coverage of products that are not consistent with the Compliance Program priorities. (b)(2) & (b)(7)(E)  (b)(2) & (b)(7)(E) See full program for additional details. Coverage of imported dried milk products from MOU & non-MOU countries report under Import Foods - General PAC. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.  <b>NOTE TO LABS: (see compliance program or contact DFS for additional details)</b> DEN will perform Salmonella antibiotic resistance testing. Salmonella Isolates from NRL, SRL and ARL will be serotyped in ARL. Salmonella Isolates from SAN, PRL-NW, PRL-SW and DEN will be serotyped in DEN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		NA	<input type="checkbox"/> BY DISTRICT OFFICE
			<input type="checkbox"/> BY CENTER
			<input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		NA	<input type="checkbox"/> COMPREHENSIVE
			<input type="checkbox"/> ABBREVIATED
			<input type="checkbox"/> DIRECTED
c. PRODUCT(S) All Food Products (except seafood and cheese)		d. INDUSTRY/PRODUCT CODE(S) 02-09, 13-15, 17-41	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
		<input checked="" type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)
f. CHECK THE FOLLOWING ATTRIBUTES Microbiological Contamination, Filth, and Decomposition (See Compliance Program)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

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1. PROGRAM/ASSIGNMENT TITLE Import Foods General				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03						
3. PROGRAM/ASSIGNMENT CODE(S) 03819A,B,C (03R833/99R/833/03R824)(1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 267.1			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HRS  OPR 14 03R833 (2)	2 PRIOR NOTICE REVIEW HOURS  OPR 14 03R833 (5)	2 INVESTI- GATION HOURS  (3)	4 IMPORT SAMPLE COLL  PHYSICAL	4 IMPORT SAMPLE COLL MICRO GUIDANCE	4 IMPORT SAMPLE COLL CHEM GUIDANCE	5 IMPORT SAMPLES TO BE ANALYZED MICRO	8 IMPORT SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED SALM RESIST (Hours) (4)
	TOTAL FIELD	101000	30000	82380	7750	5080	2670	5080	2670	1180
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2)	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)	
NE	REGIONAL STAFF				& (b)					
	NEW ENGLAND				(7)(E)					
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION					2.2			8.2	7.5	
TOTAL HOURS		101000	30000	82380	17050			41656	20025	1180
CONVERSION FACTOR		1200	1200	950	950			1180	1180	1180
OPERATIONAL FTEs		84.17	25.00	86.72	17.95			35.30	16.97	1.00

7. REMARKS

- (1) Resources in this program can be used to report Import Food activities under the following PAC codes: 03R833- Import/Entry Review hours; 99R833 - Evaluation hours; R824 - Follow-up-to-Refusal.
- (2) Import Entry Review Hours: resources for these activities cover all Import Food programs.
- (3) Investigation hours: resources are for Import Field Exams, Import Filer Evaluations, Follow-up to refusals (marking and tracking the disposition of detained lots) and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Note: Additional time for Import Field Exams under investigation hours is planned in the Import LACF, Import Seafood and Toxic Elements Program.
- ALL IMPORT FIELD EXAMS ARE TO ROUTINELY INCLUDE THE FOLLOWING:**
- (a) VERIFICATION THAT THE IMPORTED PRODUCT IS THE SAME AS THAT WHICH WAS DECLARED (RECONCILIATION EXAM);
  - (b) AN ASSESSMENT OF SECURITY CONCERNS RELATED TO LABELING AND SOURCE COUNTRY (INCLUDING CONTAINER INTEGRITY, SIGNS OF INTENTIONAL ADULTERATION, ETC.);
  - (c) TRADITIONAL SAFETY CONCERNS.
- THESE ACTIVITIES ARE TO BE REPORTED AS A SINGLE IMPORT FIELD EXAM UNDER THIS COMPLIANCE PROGRAM AND PAC. ONLY ONE EXAM SHOULD BE REPORTED PER LINE ENTRY. ONLY IN THE EVENT OF A PRE-DETERMINED "FOR CAUSE" CT EXAM, OR IN THE EVENT CT SUSPICIONS ARE RAISED CONDUCTING ROUTINE FOLLOW-UP, SHOULD AN ADDITIONAL EXAM AND TIME BE REPORTED UNDER THE CT PAC (03R845, 04R845 ETC.). SEE IOM SECTION 5.4.1.4 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES.
- (4) Denver Laboratory: Salmonella Resistance
- (5) Resources in headquarters for review of prior notices at the Prior Notice Center.
- NOTE: Please review the latest program sampling priorities available at CFSAN OC Intranet site.

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program (03842)		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the Act.			
5. PROGRAM JUSTIFICATION  FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices, the Seafood HACCP Regulation, and the FD&C Act.			
6. FIELD OBLIGATIONS  Starting in FY08 High Risk Potential Products (HRPP) processors whose last inspection was NAI, can be considered for a 2-year inspection cycle. An exception would be if the firm added a new high risk seafood product to their line since the last inspection.  <b>HACCP verification samples are not to be routinely collected.</b>  Sample collections and analyses are to be made only for cause or as part of a CFSAN issued assignment. It is important that products be analyzed for the health hazard as identified in the HACCP guide – i.e., raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw Seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw.  There are obligations to provide the states with standards and instructions for sampling/analyzing for PSP/ASP in seafood.  Note: Animal confirmation tests for PSP, NSP, ciguatera toxin and botulinum toxins will be done at ARL for all regions.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE		<input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Domestic Fish and Fishery Products		d. INDUSTRY/PRODUCT CODE(S) 16	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING		<input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify) (PSP, ASP, Standards, Economic Deception, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fisheries Products Hazards & Controls guidance manual (most recent edition) for hazards associated with each specific seafood product.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03										
3. PROGRAM/ASSIGNMENT CODE(S) 03842, B, C, D, H (1)			4. WORK ALLOCATION PLANNED BY ORA <input checked="" type="checkbox"/> CENTER							5. OPERATIONAL FTE POSITIONS 56.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	3	3	7	7	7	7	9	
		INSPECTIONS INCLUDING HIGH RISK (4) (5)	DOMESTIC SAMPLES COLL VIBRIO ASSIGNMENT (7)	DOMESTIC SAMPLES COLL (3) (5)	DOMESTIC SAMPLES COLL MICRO GUIDANCE	DOMESTIC SAMPLES COLL CHEM GUIDANCE	DSA VIBRIO ASSIGNMENT (7)	DSA ORGANO EXAMS (Hours) (2)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (7)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (7)	EU CERTIFICATION (HOURS) (6)	
TOTAL FIELD		1900	12	280	210	70	72	400	70	210	1860	
HEADQUARTERS		(b)(2) & (b)(7)(E)										
NE	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
	REGIONAL STAFF											
SE	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
	REGIONAL LAB											
SW	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
PA	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
PACIFIC REGIONAL LABORATORY-SW												
PACIFIC REGIONAL LABORATORY-NW												
HOURS PER OPERATION		23.0	5.0	5.0			45.0		13.0	17.0		
TOTAL HOURS		43700	60	1400			3240	400	910	3570	1860	
CONVERSION FACTOR		950	950	950			1180	1180	1180	1180	950	
TOTAL OPERATIONAL FTEs		46.00	0.06	1.47			2.75	0.34	0.77	3.03	1.96	

9. REMARKS

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

(2) ORGANOLEPTIC NATIONAL EXPERT

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

(4) IN FY 08 HIGH RISK POTENTIAL PRODUCTS (HRPP) PROCESSORS WHOSE LAST TWO INSPECTIONS WERE NAI, CAN BE CONSIDERED FOR A 2-YEAR INSPECTION CYCLE UNLESS THE FIRM HAS ADDED A NEW HIGH RISK SEAFOOD PRODUCT TO THEIR LINE.

**SOURCE OF SEAFOOD WORKLOAD:**

(5) OEI OF SEAFOOD FIRMS FLAGGED IN FACTS AS HIGH RISK EXCLUDING FIRMS WITH INDUSTRY CODE 12 AS OF DECEMBER 14, 2006. INSPECTIONS AND DSCs BASED ON OEI.

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

(7) THE MAJORITY OF THE SAMPLES FOR THE SPECIAL VIBRIO ASSIGNMENT WILL BE COLLECTED BY AND PAID FOR BY STATE REPRESENTATIVES OF ISSC. THERE WILL BE 108 SAMPLES COLLECTED/ANALYZED BUT 1/3 OF THE ANALYSIS WILL BE DONE BY THE GULF COAST SEAFOOD LABORATORY. DFS ASSIGNED THE LABORATORY DISTRIBUTION.

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program 03844	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP Regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and regulations promulgated under the Act.	
5. PROGRAM JUSTIFICATION Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP Regulation.	
6. FIELD OBLIGATIONS The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. It is equally important that products be analyzed for the health hazard as identified in the HACCP Guide. Raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw.  HACCP trained investigators, will review importers' written verification procedures, product specifications and affirmative step documents, which demonstrate that the foreign processors' product was produced under HACCP, food safety hazards prevention program. Inspectional priorities should be based on those listed in the current compliance program.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives or other special assignments agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.  NOTE: Animal confirmation tests for PSP, NSP, ciguatera toxin and botulinum toxins will be done at ARL for all regions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) (PSP, ASP, Standards, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fisheries Products Hazards & Controls Guidance Manual (most recent edition) for hazards associated with Each specific seafood product.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  See Compliance Program.	

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Products						2. PFS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03				
3. PROGRAM/ASSIGNMENT CODE(S) 03844B, C, D, H; 07844: 09844E,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 83.4				
R E G I O N	5. DISTRICT/ SPECIALIZED LABORATORY	1 IMPORTER INSP + 03844H (1)	4 IMPORT SAMPLE COLL PHYSICAL (2)/(6)	4 IMPORT SAMPLE COLL BIORG GUIDANCE	4 IMPORT SAMPLE COLL CHEM GUIDANCE	9 INVESTIGATION HOURS (3)	8 ISAs ORGANO ANALYSES (Hours) (5)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (4)/(6)	8 IMPORT SAMPLES TO BE ANALYZED MICRO (4)/(6)	
	TOTAL FIELD	500	6400	4480	3050	950	1180	3050	4480	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	CE									REGIONAL STAFF
										BALTIMORE
										CHICAGO
										CINCINNATI
DETROIT										
MINNEAPOLIS										
NEW JERSEY										
PHILADELPHIA										
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION	16.0	2.6					5.3	11.0		
TOTAL HOURS	8000	16840			950	1180	18165	49280		
CONVERSION FACTOR	950	950			950	1180	1180	1180		
TOTAL OPERATIONAL FTEs	8.42	17.52			1.00	1.00	13.70	41.76		

9. REMARKS

(1) FY 2008 : IMPORTER INSPECTIONS: BASED ON OASIS CONSIGNEE DATA. PER CFSAN, INSPECTIONS OF IMPORTERS ARE TO ASCERTAIN THAT THE IMPORTER HAS COMPLIED WITH SEAFOOD HACCP REGULATIONS (NOT TO PERFORM FILER INSPECTIONS).

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

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

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

THESE ACTIVITIES ARE TO BE REPORTED AS A SINGLE IMPORT FIELD EXAM UNDER THIS COMPLIANCE PROGRAM AND PAC. ONLY ONE EXAM SHOULD BE REPORTED PER LINE ENTRY. ONLY IN THE EVENT OF A PRE-DETERMINED "FOR CAUSE" CT EXAM, OR IN THE EVENT CT SUSPICIONS ARE RAISED CONDUCTING ROUTINE FOLLOW-UP, SHOULD AN ADDITIONAL EXAM AND TIME BE REPORTED UNDER THE CT PAC (03R845, 04R845 ETC.). SEE IOM SECTION 5.4.1.4 FOR ADDITIONAL INFORMATION ON FOOD AND COSMETIC DEFENSE ACTIVITIES.

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

(5) ORGANOLEPTIC NATIONAL EXPERT

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03													
3. PROGRAM/ASSIGNMENT CODE(S) 03847H, 03847 (1)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.4										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTIONS (2)	4 DOMESTIC SAMPLE COLLECTION (3)	DOMESTIC SAMPLE COLLECTION CHEM GUIDE ONLY	DOMESTIC SAMPLE COLLECTION MICRO GUIDE ONLY	7 DOMESTIC SAMPLES ANALYZED CHEM	7 DOMESTIC SAMPLES ANALYZED MICRO	1 IMPORTER INSPECTIONS (4)	9 OTHER OPERATIONS (Hours)								
	TOTAL FIELD		300	100	25	75	25	75	100								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
SAN FRANCISCO																	
SEATTLE																	
PACIFIC REGIONAL LABORATORY-SW																	
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										20.0	5.0			11.0	15.0	13.0	
TOTAL HOURS										6000	500			275	1125	1300	
CONVERSION FACTOR										950	950			1180	1180	950	
TOTAL OPERATIONAL FTEs										6.32	0.53			0.23	0.95	1.37	

9. REMARKS

(1) Additional related PAC's: 03847, 04847H, 07847H, 09847H, 21847H. 03847 would be used for general sanitation issues (non-HACCP) and the "H" PACs for HACCP verification samples and the HACCP component of inspection. Non "H" PACs would be used for "For Cause" samples and filth/sanitation component of inspection.

(2) Per CFSAN, Domestic Inspections based on OEI juice processor data as of FY 2007. State inspections may be conducted in addition to the number of inspections assigned per district (PAC 03S004). Resources have been added to cover food security issues at all domestic processor inspections. Inspectional priority is as follows: firms associated with recent outbreaks, unpasteurized juice firms, firms whose previous inspections were OAI, and firms that have not yet been inspected.

(3) Per CFSAN, DSC resources have been provided for anticipated "for cause" and "verification" samples (pending issuance of revised compliance program).

(4) Per CFSAN, Importer inspections based on ORADSS data as of FY 2007 (physical location of juice importers). Please refer to the list of juice importers distributed by the program monitor and follow the same inspectional priority.

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

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments 03F098 (Domestic), 03F100 (Import)		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES  To collect and analyze selected food commodities of domestic and foreign origin for pathogenic microorganisms as needed and directed by CFSAN assignments.			
5. PROGRAM JUSTIFICATION  The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens have reached an unacceptably high level in the U.S. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it.			
6. FIELD OBLIGATIONS  To collect samples and perform analyses as specified in the FY 08 produce assignments issued by CFSAN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		NA <input type="checkbox"/>	BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH <input checked="" type="checkbox"/>
b. INSPECTION TYPE:		NA <input type="checkbox"/>	COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED <input checked="" type="checkbox"/>
c. PRODUCT(S) Fresh fruits and vegetables as specified in the assignment.		d. INDUSTRY/PRODUCT CODE(S) 20-22, 24-25	
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )			
f. CHECK THE FOLLOWING ATTRIBUTES Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

2008 ORA WORKPLAN

OCTOBER 1, 2007

1. PROGRAM/ASSIGNMENT TITLE Import and Domestic Micro Assignments				2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03				
3. PROGRAM/ASSIGNMENT CODE(S) 03F098 ( Import) 03F100 (Domestic)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 22.1		
REGION	DISTRICT/SPECIALIZED LABORATORY	INVESTIGATIONS (HOURS)	DOMESTIC SAMPLE COLLECTION *	IMPORT SAMPLE COLLECTION	DOMESTIC SAMPLE ANALYSIS MICRO	IMPORT SAMPLE ANALYSIS MICRO	OTHER OPERATIONS (Hours)	
	TOTAL FIELD	1100	150	450	450	450		
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)						
	REGIONAL STAFF	(b)(2) & (b)(7)(E)						
	NEW ENGLAND	(b)(2) & (b)(7)(E)						
	NEW YORK	(b)(2) & (b)(7)(E)						
	REGIONAL LAB	(b)(2) & (b)(7)(E)						
CE	WEAC	(b)(2) & (b)(7)(E)						
	REGIONAL STAFF	(b)(2) & (b)(7)(E)						
	BALTIMORE	(b)(2) & (b)(7)(E)						
	CHICAGO	(b)(2) & (b)(7)(E)						
	CINCINNATI	(b)(2) & (b)(7)(E)						
	DETROIT	(b)(2) & (b)(7)(E)						
	MINNEAPOLIS	(b)(2) & (b)(7)(E)						
	NEW JERSEY	(b)(2) & (b)(7)(E)						
SE	PHILADELPHIA	(b)(2) & (b)(7)(E)						
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)						
	REGIONAL STAFF	(b)(2) & (b)(7)(E)						
	ATLANTA	(b)(2) & (b)(7)(E)						
	FLORIDA	(b)(2) & (b)(7)(E)						
SW	NEW ORLEANS	(b)(2) & (b)(7)(E)						
	SAN JUAN	(b)(2) & (b)(7)(E)						
	REGIONAL LAB	(b)(2) & (b)(7)(E)						
	REGIONAL STAFF	(b)(2) & (b)(7)(E)						
	DALLAS	(b)(2) & (b)(7)(E)						
PA	DENVER	(b)(2) & (b)(7)(E)						
	KANSAS CITY	(b)(2) & (b)(7)(E)						
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)						
	REGIONAL LAB	(b)(2) & (b)(7)(E)						
	REGIONAL STAFF	(b)(2) & (b)(7)(E)						
	LOS ANGELES	(b)(2) & (b)(7)(E)						
SEATTLE	(b)(2) & (b)(7)(E)							
PACIFIC REGIONAL LABORATORY-SW	(b)(2) & (b)(7)(E)							
PACIFIC REGIONAL LABORATORY-NW	(b)(2) & (b)(7)(E)							
HOURS PER OPERATION			3.0	3.0	25.0	25.0		
TOTAL HOURS		1100	450	1350	11250	11250		
CONVERSION FACTOR		950	950	950	1180	1180		
TOTAL OPERATIONAL FTEs		1.16	0.47	1.42	9.53	9.53		

9. REMARKS

CFSAN will work with ORA to determine how resources will be allocated in FY 2008. Assignments will be issued by CFSAN for the collection of cantaloupe, green onions, tomatoes, loose-leaf lettuce, spinach, cilantro, basil, parsley.  
 Note: SWID samples collected from TX & NM are sent to ARL. SWID samples collected from CA & AZ are sent to DEN.  
 Resource distribution per CFSAN.  
 \* In FY 2008 an additional 300 domestic samples will be collected under state contracts.  
 Domestic and Import Sample Analysis based on Domestic and Import Sample collection(s) and Laboratory Servicing Table.

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments 03R233		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, will take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety.			
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to food borne illness, due to the presence of microbial pathogens have reached an unacceptably high level in the U.S. To the best of our knowledge, approximately half of the foods that have been associated with food borne illness have been imported. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. An important aspect of this new initiative is to increase our knowledge of the conditions under which a variety of foods are manufactured in foreign countries.			
6. FIELD OBLIGATIONS ORA/DFI shall assist CFSAN by reviewing imported food entry and compliance data to assist in determining the countries and firms whose inspections would be of greatest value to the Agency.  ORA/DFI shall plan inspections of foreign firms recommended by CFSAN in so far as contacting the firms and foreign governments and working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN review and classification. The Investigator shall prepare and, after obtaining any CFSAN team member concurrence, submit the entire original EIR to the Manufacturing and Storage Adulteration Branch no later than 30 days following the trip. Submit individual EIRs as they are completed. Don't delay until all EIRs from a particular trip are completed; rather submit each EIR individually as they are completed due to workflow issues. Prioritize submission of EIRs based on classification (i.e., OAI and VAI before NAI).  In FY 08, 100 foreign inspections of food firms are planned. On a "for cause" basis as needed, additional inspections may be requested by CFSAN, such as those needed to follow-up on food borne outbreaks.  <b>PAC REPORTING INSTRUCTIONS:</b> All CFSAN foreign inspection time is planned under PAC 03R233. Report accomplishments against PAC 03R233, using the Foreign Inspection Operation Code 11.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection outbreaks, infant formulas, seafood, cheese, etc.		d. INDUSTRY/PRODUCT CODE(S) 02-50, 54	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING	<input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES Check appropriate domestic compliance program for details.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Resources for samples collected as part of infant formula or medical food foreign inspections are planned under those programs.			

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections/Assessments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R233	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	2 INVESTIG- ATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) *					9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>150</b>		<b>950</b>					
	HEADQUARTERS	(b)(2) &		(b)(2) & (b)					
NE	REGIONAL STAFF	(b)(7)(E)		(7)(E)					
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	30.0							
	TOTAL HOURS	4500		950					
	CONVERSION FACTOR	950		950					
	TOTAL OPERATIONAL FTEs	4.74		1.00					

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

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





1. PROGRAM/ASSIGNMENT TITLE Contract Management 03R843		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT By DFRS			
4. OBJECTIVES To conduct an effective state contract inspection program, augmenting regulatory inspections conducted by Agency investigators. To perform audits of inspections by states that are under contract to FDA to conduct food inspections.			
5. PROGRAM JUSTIFICATION Over 8000 food inspections are anticipated to be contracted out in FY 08 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.			
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the district. Inspections should be planned by the field. <b>Report under Operation Code 13 (Domestic Investigation). Audits are not considered inspections.</b>			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED Audits
c. PRODUCT(S) All Food Products		d. INDUSTRY/PRODUCT CODE(S) 02-41, 45-46, 50	
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )      Audits of State Contract Food Inspections.			
f. CHECK THE FOLLOWING ATTRIBUTES  Follow DFRS guidance.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Contract Management		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03							
3. PROGRAM/ASSIGNMENT CODE(S) 03R843		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 8.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	9 CONTRACT MANAGE- MENT HOURS							
	TOTAL FIELD	(1) 7600							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS		7600							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		8.00							

9. REMARKS

(1) Time planned for contract management includes resources to conduct audits. Allocation of planned hours for contract activities is based on a two year average of time reported into FACTS by operational employees under PAC 03R843 during the period July 1, 2005 to June 30, 2007.

Note: Non-operational FTEs (i.e. supervisors) should not report contract management time. Time spent on contract management should only be reported by operational FTEs.

1. PROGRAM/ASSIGNMENT TITLE Food Defense 03R845      FY 2008	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards
3. PROGRAM TYPE: NA <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENTS & Preparedness Activities	
4. OBJECTIVES To maintain food defense preparedness by means of joint CFSAN/ORA field assignments, FDA collection and analysis of proficiency samples for the Food Emergency Response Network, providing resources for general laboratory preparedness activities including instrument, reagent, and standards maintenance, and related activities. Maintain and expand food defense alertness to the food industry.	
5. PROGRAM JUSTIFICATION A secure food supply is considered part of the nation's infrastructure. FDA, along with other federal Agencies, is responsible for responding to threats to the security of the food supply. The resources and activities planned under this program will help the Agency maintain a necessary state of readiness to respond to threats and activities planned for periods of heightened alert, as well as initiate and/or maintain food defense alertness to expanding industry groups.	
6. FIELD OBLIGATIONS Actual emergency and code-red alert status activities, when needed, will be directed jointly by CFSAN and ORA, and the Field will be instructed on planned work that will be halted. Food defense assignments, cleared by CFSAN and ORA, are to be carried out expeditiously.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All food products.	d. INDUSTRY/PRODUCT CODE(S) All food industry/product codes.
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify)    All food security examinations	
f. CHECK THE FOLLOWING ATTRIBUTES . To be directed by assignment and protocols jointly developed by CFSAN and ORA.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING To be directed by assignment and protocols jointly developed by CFSAN and ORA.	





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

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 59.7 (32.3)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs		DSCs DIOXINS	DSAs DIOXINS	DSAs DIOXINS	DSCs SEAFOOD	DSAs SEAFOOD
	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)				
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY- SW									
	PACIFIC REGIONAL LABORATORY- NW									
HOURS PER OPERATION			3.0	6.5		4.0	20.0	11.6	3.0	6.5
TOTAL HOURS		1100	4200	9100		3000	15000	2691	300	650
CONVERSION FACTOR		950	950	1180		950	1180	1180	950	1180
TOTAL OPERATIONAL FTEs		1.16	4.42	7.71		3.16	12.71	2.28	0.32	0.55

7. REMARKS  
 CFSAN will issue biannual Dioxin Schedule.  
 DSC Seafoods: See compliance program for collection details.  
 \*Includes 232 Total Diet Study samples homogenates.

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1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04			
3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS (27.4)		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY			ISCs	ISAs	ISCs SEAFOOD	ISAs SEAFOOD
	TOTAL FIELD			3000	3000	300	300
	HEADQUARTERS			(b)(2) & (b)(7)(E)			
	REGIONAL STAFF						
NE	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB WEAC						
MA	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			1.6	7.8	1.6	7.8
	TOTAL HOURS			4800	23400	480	2340
	CONVERSION FACTOR			950	1180	950	1180
	TOTAL OPERATIONAL FTEs			5.05	19.83	0.51	1.98
9. REMARKS ISC Seafoods: See compliance program for collection details ISAs: Planned numbers based on SWID sending 40% of ISAs to ARL and 60% of ISAs to PRL-SW.							

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Chemotherapeutics in Seafood	<b>2. PPS PROJECT NAME/NUMBER</b> Pesticides and Chemical Contaminants - 04
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To sample and analyze selected import and domestic aquaculture seafood products. To determine the presence of unapproved chemical compounds such as drugs or antifungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.	
<b>5. PROGRAM JUSTIFICATION</b>  Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the U.S. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.	
<b>6. FIELD OBLIGATIONS</b> Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 08 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or additional validated methods are ready to implement.  As a budget relief, two agent analyses may be run per sample provided the second agent is one of interest for that product. Please refer to the FY 08 Collection Schedule and Compliance Program (both when issued) for species to collect, assigned servicing laboratories, and agents of interest.  Individual subsample analyses will only be required for samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining samples will be a composite of 12 sub-samples. Please refer to the FY 08 Collection Schedule for additional collection instructions when issued.  Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Seafood Products	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 16
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )    Label Review	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Unapproved drugs per the Compliance Program and the Collection Schedule.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood	2. PPS PROJECT NAME/NUMBER Pesticides and chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04018	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 32.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLL	IMPORT SAMPLE ANALYSIS	ISAs NITRO- FURANS	ISAs INDIVIDUAL SUBS	ISAs COMPOSITES	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE ANALYSIS	DSAs INDIVIDUAL SUBS	DSAs COMPOSITES	DSAs NITRO- FURANS																																																		
	<b>TOTAL FIELD</b>	1000	1000	250	215	335	100	100	35	65	30																																																		
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																																																											
	REGIONAL STAFF																																																												
	NEW ENGLAND																																																												
	NEW YORK																																																												
	REGIONAL LAB																																																												
	WEAC																																																												
CE	REGIONAL STAFF																																																												
	BALTIMORE																																																												
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	CINCINNATI																																																												
	DETROIT																																																												
	MINNEAPOLIS																																																												
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	PHILADELPHIA																																																												
	FORENSIC CHEM. CTR																																																												
SE	REGIONAL STAFF																																																												
	ATLANTA																																																												
	FLORIDA																																																												
	NEW ORLEANS																																																												
	SAN JUAN																																																												
	REGIONAL LAB																																																												
SW	REGIONAL STAFF																																																												
	DALLAS																																																												
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	SOUTHWEST IMPORT DISTRICT																																																												
	REGIONAL LAB																																																												
PA	REGIONAL STAFF																																																												
	LOS ANGELES																																																												
	SAN FRANCISCO																																																												
	SEATTLE																																																												
	PACIFIC REGIONAL LAB - SW																																																												
	PACIFIC REGIONAL LAB - NW																																																												
	<b>HOURS PER OPERATION</b>																																																			2.5	24.0	30.0			5.0	24.0			30.0
	<b>TOTAL HOURS</b>																																																			2500	24000	7500			500	2400			900
	<b>CONVERSION FACTOR</b>																																																			950	1180	1180			950	1180			1180
	<b>OPERATIONAL FTEs</b>																																																			2.63	20.34	6.36			0.53	2.03			0.76

**7. REMARKS**

CFSAN spread the number of sample collections per district based on ORADSS line entry data and domestic OEI data. DFS spread the laboratory analyses. Individual sub sample analyses will be for Chloramphenicol and Nitrofurans samples. All remaining residue analyses will be a composite of 12 subsamples. The analytical module is a Field Wide Average, based on number of total samples planned for individual subsample analysis and for composite analysis. Refer to the FY08 Collection Schedule (when issued) for specific commodities to collect. Domestic samples can be collected as D/I samples if a district cannot meet sample obligations with OEI firms, or if samples are being collected fresh. The import sample collection and analytical numbers are based on most samples being analyzed for two chemotherapeutic agents.

Because of limitations in the FACTS Reporting System, the analytical accomplished operations will only be one half of the agents analyzed. It is very important that samples only be analyzed for the chemotherapeutic agents listed in the Annual Sampling Plan. Specifically, all catfish and related species are only to be analyzed for in this priority: Nitrofurans, Malachite Green, Fluoroquinolones, and then Quinolones. Crabmeat and Crawfish are to be analyzed for Chloramphenicol. Shrimp are to be analyzed for Nitrofurans, Chloramphenicol, Fluoroquinolones, and Quinolones. Tilapia is to be analyzed for Methyltestosterone, Malachite Green, and Fluoroquinolones.

\* Import Samples for Nitrofurans include 125 Basa/Catfish samples and 125 Shrimp samples.  
 \*\* Domestic Samples for Nitrofurans include 20 catfish and 10 shrimp samples

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic)		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES  To determine the incidence and levels of lead, cadmium, mercury and other toxic elements of significance and radionuclides in domestic imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in foodware.			
5. PROGRAM JUSTIFICATION  Historical evidence mandates the continued monitoring of domestic and imported food (including seafood) and foodware for the presence of toxic elements (i.e. lead, cadmium, and mercury).  The continuing monitoring of radionuclides in foods is necessary to guard against any dangerous level of radiochemical contamination of domestic and imported foods. Also, this monitoring will provide continuing background data to identify any upward trend in tritium, gamma-ray emitters and Sr levels.			
6. FIELD OBLIGATIONS  Foods that may be significant sources of lead in children are Mexican candy, chocolate/cocoa, and seafood. These products are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" program and assignments (to be issued). Planned assignments include mercury in specific seafood species. CFSAN will issue collection schedules and direct other FY 08 food work.  Import field exams should be focused upon (b)(2) & (b)(7)(E) Sample collections and analyses of domestic and imported foodware will continue as directed by the "Toxic Element" program. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides. The program should be maintained to keep expertise and proficiency in this area. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) 02-41, 52A	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Specify)			
f. CHECK THE FOLLOWING ATTRIBUTES Lead, cadmium, mercury and other toxic elements as directed. Domestic - tritium, 90 Sr & gamma ray emitters; IMPORTS; 134 Cs, 137 Cs, 90 Sr			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Radiochemical analysis capability. (Available only at WEAC). Graphite furnace atomic absorption with Zeeman background correction.			

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)					2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04														
3. PROGRAM/ASSIGNMENT CODE(S) 04019A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 19.0 (9.0)													
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSC NON- SEAFOOD	ISC NON- SEAFOOD	DSA NON- SEAFOOD	ISA NON- SEAFOOD	DSCs SEAFOOD	DSAs SEAFOOD	DSC MERCURY IN SEAFOOD	DSA MERCURY IN SEAFOOD	ISC SEAFOOD									
	<b>TOTAL FIELD</b>	100	280	100	280	100	100	100	100	170									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
REGIONAL LAB																			
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
REGIONAL LAB																			
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORTORY - SW																		
PACIFIC REGIONAL LABORTORY - NW																			
HOURS PER OPERATION											3.5	1.8	12.0	14.0	4.5	12.0	4.5	12.0	4.5
TOTAL HOURS											350	504	1200	3920	450	1200	450	1200	765
CONVERSION FACTOR											950	950	1180	1180	950	1180	950	1180	950
TOTAL OPERATIONAL FTEs											0.37	0.53	1.02	3.32	0.47	1.02	0.47	1.02	0.81
7. REMARKS Both Seafood and Non-Seafood Domestic and Import Sample Collections: CFSAN will issue collection schedules.																			

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1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04			
3. PROGRAM/ASSIGNMENT CODE(S) 04019A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (5.4)	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISA SEAFOOD	DISC MERCURY IN TUNA *	DISA MERCURY IN TUNA *		DISC MERCURY IN SEAFOOD *	DISA MERCURY IN SEAFOOD *
	TOTAL FIELD	170	75	75		135	135
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN REGIONAL LAB						
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LABORTORY - SW PACIFIC REGIONAL LABORTORY - NW						
HOURS PER OPERATION		14.0	3.5	14.0		4.5	14.0
TOTAL HOURS		2380	263	1050		608	1890
CONVERSION FACTOR		1180	950	1180		950	1180
TOTAL OPERATIONAL FTEs		2.02	0.28	0.89		0.64	1.60
7. REMARKS * To be issued as CFSAN Field Assignment.							

1. PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foodware (Domestic and Import)			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04				
3. PROGRAM/ASSIGNMENT CODE(S) 04019B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (3.7)	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DSCs (Houseware)	4 ISCs (Houseware)	5 DOMESTIC FIELD EXAMS	6 IMPORT INV HOURS	7 DSAs	8 ISAs
	TOTAL FIELD	10	200	25	1400	10	200
HEADQUARTERS		(b)(2) & (b)(7)(E)					
NE	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
	FORENSIC CHEM. CTR						
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	REGIONAL LAB						
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LABORTORY-SW						
PACIFIC REGIONAL LABORTORY-NW							
HOURS PER OPERATION		3.5	1.8	0.7		10.0	10.0
TOTAL HOURS		35	360	18	1400	100	2000
CONVERSION FACTOR		950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		0.04	0.38	0.02	1.47	0.08	1.69

7. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Radionuclides in Foods (Domestic and Import)				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3. PROGRAM/ASSIGNMENT CODE(S) 04019C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (0.8)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Inspections	2 INV	3 DSC	4 ISC	5 Field Exams	6 Import Field Exams	7 DSAs	8 ISAs	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD			16	84			16	84	
NE	HEADQUARTERS			(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY-SW									
	PACIFIC REGIONAL LABORTORY-NW									
HOURS PER OPERATION				2.5	1.7			15.0	6.0	
TOTAL HOURS				40	143			240	504	
CONVERSION FACTOR				950	950			1180	1180	
TOTAL OPERATIONAL FTEs				0.04	0.15			0.20	0.43	

7. REMARKS

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Total Diet Study	<b>2. PPS PROJECT NAME/NUMBER</b> Pesticides and Chemical Contaminants - 04
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex groups through analyses of table-ready foods. In addition, to observe differences or trends in the intake of these chemicals and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.	
<b>5. PROGRAM JUSTIFICATION</b>  The continuing study has provided valuable information on dietary intakes of residues and nutrients and has often been used to gauge intakes in ready-to-eat foods. EPA relies on the data for hazard assessment in special review and other proceedings. Portions of the Total Diet samples are used for other analysis (e.g., radionuclides, selected nutrients, pesticides, industrial chemicals, and toxic elements). Additionally, selected Total Diet Study foods are analyzed for dioxins under the pesticide program.	
<b>6. FIELD OBLIGATIONS</b> The collection and analysis of four market baskets each consisting of three separate samplings of 284 food items are to be collected from three locales in the region over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, and toxic elements. WEAC will analyze all foods from one market basket for radionuclides.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Various Human Foods	<b>d. INDUSTRY/PRODUCT CODE(S)</b> All Human Food Codes
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) Radiochemical Analysis	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04				
3. PROGRAM/ASSIGNMENT CODE(S) 04839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 23.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DSCs (TOTAL) (DIET)  (1)	2 DOMESTIC SAMPLE TO BE ANALYZED  (2)	7 TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) (3)				
	<b>TOTAL FIELD</b>	60	1136	1				
	HEADQUARTERS	(b)(2) & (b)(7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
SE	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORTORY-SW							
	PACIFIC REGIONAL LABORTORY-NW							
	<b>HOURS PER OPERATION</b>	26.0	20.1	2800.0				
	<b>TOTAL HOURS</b>	1560	22834	2800				
	<b>CONVERSION FACTOR</b>	950	1180	1180				
	<b>TOTAL OPERATIONAL FTEs</b>	1.64	19.35	2.37				

7. REMARKS

(1) Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over five week period and involves 3 separate districts. Four market baskets are planned annually.

(2) Represents the total number of food items analyzed for various attributes.

(3) All TDS food items from one market basket analyzed by WEAC for selected radionuclides.



1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04						
3. PROGRAM/ASSIGNMENT CODE(S) 04F800 (*)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 7.8			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		DSA PERCHLORATE IN FOODS TDS SAMPLES **	DSC FURAN IN FOODS	DSA FURAN IN FOODS	ISC CONTAMINANTS IN HONEY	ISA CONTAMINANTS IN HONEY	ISC/DISC PES & TE DIETARY SUPPL		ISA/DISA PES & TE DIETARY SUPPL ***
	TOTAL FIELD		1140	100	100	100	100	150		150
	HEADQUARTERS		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
NE	REGIONAL STAFF		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	NEW ENGLAND		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	NEW YORK		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL LAB		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	WEAC		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
CE	REGIONAL STAFF		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	BALTIMORE		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	CHICAGO		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	CINCINNATI		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	DETROIT		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	MINNEAPOLIS		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	NEW JERSEY		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	PHILADELPHIA		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
FORENSIC CHEM. CTR		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)	
SE	REGIONAL STAFF		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	ATLANTA		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	FLORIDA		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	NEW ORLEANS		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	SAN JUAN		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
SW	REGIONAL LAB		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL STAFF		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	DALLAS		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	DENVER		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	KANSAS CITY		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	SOUTHWEST IMPORT DISTRICT		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
PA	REGIONAL LAB		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	REGIONAL STAFF		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	LOS ANGELES		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	SAN FRANCISCO		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	SEATTLE		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
	PACIFIC REGIONAL LABORATORY- SW		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)
PACIFIC REGIONAL LABORATORY- NW		(b)(2) & (b)(7)(E)							(b)(2) & (b)(7)(E)	
HOURS PER OPERATION			3.0	3.0	3.0	3.0	6.5	3.0		24.0
TOTAL HOURS			3420	300	300	300	650	450		3600
CONVERSION FACTOR			1180	950	1180	950	1180	950		1180
TOTAL OPERATIONAL FTEs			2.90	0.31	0.25	0.31	0.55	0.47		3.05
7. REMARKS * Pac code is for planning purpose only. When reporting into FACTS, use the appropriate pac code that was given in the assignment. **All TDS foods and all baby food add-ons from all 4 TDS Market Baskets will be analyzed for perchlorate. *** The Analytical module includes resources for both Pesticides and Toxic Elements Collections for Perchlorate and Dietary Supplements will be directed by CFSAN field assignments. Contaminants in honey include chloroamphenicol (See Import Bulletin) and CFSAN assignment.										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Methods Validation/Development Program	<b>2. PPS PROJECT NAME/NUMBER</b> Pesticides and Chemical Contaminants - 04
<b>3. PROGRAM TYPE:</b> <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  Develop new and/or improved methodology in support of regulatory analysis.	
<b>5. PROGRAM JUSTIFICATION</b>  Validated analytical methods are essential to support enforcement activities.	
<b>6. FIELD OBLIGATIONS</b>  Conduct activities under this program as directed by the Division of Field Science.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b>
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04							
3. PROGRAM/ASSIGNMENT CODE(S) 04R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)							
	TOTAL FIELD	5395	5900							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		5395	5900							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		4.48	5.00							

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04							
3. PROGRAM/ASSIGNMENT CODE(S) 04R838			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		9 FORENSIC SAMPLE ANALYSIS (CHEM)	9 FORENSIC EVALUATION						
	TOTAL FIELD		1205	13255						
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SW	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
PA	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
KANSAS CITY										
SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB										
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORTORY - SW										
PACIFIC REGIONAL LABORTORY - NW										
HOURS PER OPERATION										
TOTAL HOURS			1205	13255						
CONVERSION FACTOR			1205	1205						
TOTAL OPERATIONAL FTEs			1.00	11.00						

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



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

1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods					2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07					
3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DOMESTIC)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS Total (14.6) 9.3			
R E G I O N	6.	3	3	3	3	3	7	7	7	7
	DISTRICT/ SPECIALIZED LABORATORY	DSCs AFLA- TOXIN	DSCs FUMON- ISON	DSCs DON	DSCs OCHRA TOXIN	DSCs PATULIN	ALL DOMESTIC SAMPLE ANALYSES	DSAs AFLA- TOXIN	DSAs FUMON- ISON	DSAs DON
<b>TOTAL FIELD</b>		465	190	145	60	140	1000	465	190	145
(b)(2) & (b)(7)(E)										
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		4.0	4.0	4.0	4.0	4.0	6.0			
TOTAL HOURS		1880	760	580	240	580	6000			
CONVERSION FACTOR		950	950	950	950	950	1180			
TOTAL OPERATION FTEs		1.96	0.80	0.61	0.25	0.59	5.08			
7. REMARKS										
Report all Domestic and Import Operations under PAC 07001.										



1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 3	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3. PROGRAM/ASSIGNMENT CODE(S) 07001 (ISAs)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	8	8	8	8	8	8	8	8	9
		ALL IMPORT SAMPLE ANALYSES	ISAs AFLA TOXIN	ISAs FUMON- ISON	ISAs DON	ISAs OCHRA TOXIN	ISAs PATULIN	ISAs SPECIAL SURVEY	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERAT- IONS (HOURS)
	TOTAL FIELD	664	284	90	90	40	140	20		
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	7.0								
	TOTAL HOURS	4648								
	CONVERSION FACTOR	1180								
	TOTAL OPERATION FTEs	3.94								

7. REMARKS

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Methods Validation/Development Program	<b>2. PPS PROJECT NAME/NUMBER</b> Molecular Biology and Natural Toxins - 07
<b>3. PROGRAM TYPE:</b> <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  Develop new and/or improved methodology in support of regulatory analysis.	
<b>5. PROGRAM JUSTIFICATION</b>  Validated analytical methods are essential to support enforcement activities.	
<b>6. FIELD OBLIGATIONS</b>  Conduct activities under this program as directed by the Division of Field Science.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b>
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program				2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07						
3. PROGRAM/ASSIGNMENT CODE(S) 07R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)						
	TOTAL FIELD	600	4130	590						
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		600	4130	590						
CONVERSION FACTOR		1205	1180	1180						
TOTAL OPERATIONAL FTEs		0.50	3.50	0.50						

9. REMARKS

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



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

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives				2. PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09			
3. PROGRAM/ASSIGNMENT CODE(S) 09006A (Foods), 09006B (Colors)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 13.6	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	4 ISCs FOOD ADDITIVES	8 ISAs FOOD ADDITIVES	4 ISCs COLOR ADDITIVES	8 ISAs COLOR ADDITIVES	9 IMPORT INVESTIGATIONS (HOURS)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	310	310	865	865	1087	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)	
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
WEAC							
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
SEATTLE							
PACIFIC REGIONAL LAB - SW							
PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		1.4	13.0	1.4	10.0		
TOTAL HOURS		434	4030	1211	8650	1087	
CONVERSION FACTOR		950	1180	950	1180	950	
OPERATIONAL FTEs		0.46	3.42	1.27	7.33	1.14	

7. REMARKS

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

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

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



1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To provide guidance, support, and assistance to the federal, state, tribal, and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in foodborne illnesses. This program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, National Food Safety needs at retail level, CFSAN directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.	
5. PROGRAM JUSTIFICATION  There are more than 3,000 federal, tribal, state, and local regulatory food control agencies which together represent the regulatory resource through which federal food policy is implemented at the retail level. This segment totals more than one million commercial and institutional food establishments, locations, and operations.  Each year the Centers for Disease Control and Prevention's Annual Report shows that a major percentage of foodborne outbreaks, where mishandling of food is implicated, occur in retail food establishments. Therefore, an important part of FDA's mission is to provide assistance to federal, tribal, state, and local regulatory agencies with control over this segment of the food industry.	
6. FIELD OBLIGATIONS Provide technical assistance to federal, tribal, state, and local regulatory food agencies. Provide technical assistance to CFSAN and Headquarters in the preparation of position papers. Conduct periodic baseline and follow-up studies to measure trends on the occurrence of foodborne illness risk factors nationwide in selected food service and retail food establishment. Promote the adoption of retail program standards. Provide training on the provisions of FDA Food Code, HACCP, Facility Plan Review, the Egg Rule, and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events impacting retail food safety. Participate in the FDA Retail Food Steering Committee, the National Conference for Food Protection committees, and other conferences and industry events to share information and present FDA's position on issues concerning retail food protection. Specialists will participate in the National Team Workgroups. These workgroups will address issues which include Voluntary National Retail Food Regulatory Program Standards, standardization procedures, prestandardization workshops, HACCP, and Retail Specialist certification, etc. Maintain a cadre of trained FDA Food Specialists.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Foods	d. INDUSTRY/PRODUCT CODE(S) Inspections: 51 NY
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> ) N/A	
f. CHECK THE FOLLOWING ATTRIBUTES Reduction in the occurrence of CDC identified risk factors associated with foodborne illness in retail establishments and national promotion of Food Code Interventions.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Work assigned in this program is to be conducted by persons who are Center standardized in the application of the relevant retail Food Code provisions and related program documents.	

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18						
3. PROGRAM/ASSIGNMENT CODE(S) 18002		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 23.0 (20.5)				
REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL/FOOD PROGRAM STANDARDS BASELINE SUPPORT (1)	STANDARD- IZATION (ITP CDC IHS, STATE AND LOCAL) (2)	RE-STANDARD- IZATION (ITP, STATE AND LOCAL) (3)	FDA FOOD- BORNE ILLNESS RISK FACTOR STUDY (4)	TEAM LEADERS SC/NATIONAL (5)	NATL TEAM WORK GROUP (6)	REGIONAL SEMINARS (7)	TRAINING WORKSHOPS PRE-STANDARD- IZATION TRAINING (8)	TECHNICAL ASSISTANCE (9)
	TOTAL FIELD	6700	1488	2848	3400	1200	2760	1150	1610	3454
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	NEW ENGLAND	(b)(2) & (b)(7)(E)								
	NEW YORK	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
CE	WEAC	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	BALTIMORE	(b)(2) & (b)(7)(E)								
	CHICAGO	(b)(2) & (b)(7)(E)								
	CINCINNATI	(b)(2) & (b)(7)(E)								
	DETROIT	(b)(2) & (b)(7)(E)								
	MINNEAPOLIS	(b)(2) & (b)(7)(E)								
	NEW JERSEY	(b)(2) & (b)(7)(E)								
SE	PHILADELPHIA	(b)(2) & (b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	ATLANTA	(b)(2) & (b)(7)(E)								
	FLORIDA	(b)(2) & (b)(7)(E)								
SW	NEW ORLEANS	(b)(2) & (b)(7)(E)								
	SAN JUAN	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
	DALLAS	(b)(2) & (b)(7)(E)								
PA	DENVER	(b)(2) & (b)(7)(E)								
	KANSAS CITY	(b)(2) & (b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)								
	REGIONAL LAB	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF	(b)(2) & (b)(7)(E)								
PA	LOS ANGELES	(b)(2) & (b)(7)(E)								
	SAN FRANCISCO	(b)(2) & (b)(7)(E)								
	SEATTLE	(b)(2) & (b)(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2) & (b)(7)(E)								
	PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)								
HOURS PER OPERATION										
TOTAL HOURS		6700	1488	2848	3400	1200	2760	1150	1610	3454
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		5.58	1.24	2.37	2.83	1.00	2.30	0.96	1.34	2.88

7. REMARKS:

Report Counter Terrorism work performed only under 18R845.

(1) Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards. Contact with jurisdictions to assist them with completing their self assessments, strategic plans, and verification audits performed directly by the FDA Food Specialists.

(2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting risk-based inspections. Continued support of the ITP Program. FDA Food Specialists will be standardizing a few ITP Associate Standards.

(3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections. Also included is the re-standardization of FDA Food Specialists by their respective Regional Associate Standard. The joint inspections required in the re-standardization process may be completed in one fiscal year or spread out over a three year period.

(4) Allocation of time to work with the 2008 Risk Factor Study Design Work Group for the FDA Foodborne Illness Risk Factor Study and to collect data, data entry, quality assurance, and data analysis.

(5) Time allocated for team leaders of the National Retail Food Team Steering Committee for retail food program planning, development, coordination.

(6) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards, and initiatives of national importance. Includes attendance and active participation in team conference calls and face -to-face meetings/planning sessions.

(7) Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the annual Regional Retail Food Seminars.

(8) Includes training workshops not limited to Food Code courses, pre-standardization workshops, HACCP workshops, and other identified training topics. Also includes time for the Specialists' to prepare candidates for standardization, as well as, the presentation and training sessions given to stakeholders groups via conference calls, seminars, conferences, web meetings, or other means.

(9) Includes technical assistance and consultation to enrolled state and local jurisdictions performing self-assessments and developing strategic plans using the Program Standards as the foundation for enhancing the effectiveness of their retail food programs. Also includes interpretations and consultations on the Food Code and other food safety issues. Also includes planning and field activities related to food safety and security events working in conjunction with other federal agencies.

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1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18							
3. PROGRAM/ASSIGNMENT CODE(S) 18002		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS (2.5)	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CONFERENCE FOR FOOD PRO- TECTION ACTIVITIES (10)	FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (11)						
	TOTAL FIELD	2070	920						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
SE	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
SW	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
REGIONAL STAFF									
LOS ANGELES									
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION									
TOTAL HOURS		2070	920						
CONVERSION FACTOR		1200	1200						
TOTAL OPERATIONAL FTEs		1.73	0.77						
7. REMARKS:									
<p>(10) Includes all committee work for the Conference for Food Protection and preliminary work on issues/position paper development for 2008 CFP.</p> <p>(11) Time allocated for the presentation and distribution of FDA materials related to food defense, such as guidance document, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures", to state and local regulatory agencies and industry. Includes counter-terrorism presentations at seminars, meetings, conferences, etc. Also includes Specialists' activities related to CFSAN priority assignments in response to national food safety needs.</p>									

1. PROGRAM/ASSIGNMENT TITLE (NCIMS)Milk Safety Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To implement FDA's responsibility under the Public Health Service Act, 42 USC 214; 42 USC 243; and 42 USC 246a and the Memorandum of Understanding between FDA and the National Conference on Interstate Milk Shipments. This responsibility includes all Grade "A" dairy products processing plants, and all dairy farms supplying raw milk to these plants.	
5. PROGRAM JUSTIFICATION  This program will promote a uniform, safe, and wholesome supply of Grade "A" Milk and Milk products throughout the U.S. This program enables FDA to exert influence on the application of Uniform Sanitary Standards for Grade "A" Milk produced in the U.S. This program provides a mechanism for reciprocity between states, thereby eliminating the need for costly <i>duplicative inspection</i> across jurisdictional lines. Without this program, FDA would have direct responsibility for inspecting all Grade "A" Milk products moving in Interstate commerce. This program also provides a mechanism for promoting greater sanitation uniformity of all dairy products. Due to the increasing consumer interest in chemical contaminants in the food supply, the perception and the potential for animal drug residues in milk and dairy products has become an important issue. This program will place additional emphasis toward continuous vigilance in maintaining a safe wholesome milk supply that is free of illegal animal drug residues.	
6. FIELD OBLIGATIONS To promote the adoption, implementation and enforcement of the uniform technical guidelines, administrative procedures and regulatory standards provided in the Pasteurized Milk Ordinance (PMO) and related documents through provision of technical assistance and consultation; conduct check ratings of IMS listed shippers and audits of listed single service facilities; participation in regional seminars, state workshops and other training courses and evaluate state programs to measure effectiveness in maintaining adequate level of conformity with the PMO and related documents.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Grade "A" Milk and Milk Products, (Cheese, Butter, Dry Milk and Frozen Dessert - when produced in IMS Plants)	d. INDUSTRY/PRODUCT CODE(S) 09, 13, 14
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES  <u>Listeria</u> , <u>Yersinia</u> , <u>Salmonella</u> , <u>Coliform</u> 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 (NCIMS) Milk Safety Program	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM/ASSIGNMENT CODE(S)  18003	4. WORK ALLOCATION PLANNED BY  <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS  20.3 (18.3)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATINGS PLANT <sup>1</sup>	CHECK RATINGS TRANSFER AND RECEIVING <sup>1</sup>	CHECK RATING BTU <sup>1</sup>	SINGLE SERVICE AUDITS <sup>1</sup>	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICA- TION <sup>2</sup>	TECHNICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATION <sup>3</sup>	STATE MILK SAMPLING SURVEILLANCE OFFICER INITIAL CONT <sup>2</sup>	NATIONAL STEERING TEAM MEETING CONFERENCE CALLS/TEAM LEADER <sup>4</sup>
	TOTAL FIELD	154	44	287	72	43	51	17	51	32
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	24.0	12.0	20.0	8.0	40.0	100.0	120.0	24.0	40.0
	TOTAL HOURS	3696	528	5740	576	1720	5100	2040	1224	1280
	CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
	TOTAL OPERATIONAL FTEs	3.08	0.44	4.78	0.48	1.43	4.25	1.70	1.02	1.07

7. REMARKS:

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

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

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

4/ Activities Include the National Steering Team Meetings and conference calls and time for team leader activities ( 2 RMSs with an additional 240 hours each identified).

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1. PROGRAM/ASSIGNMENT TITLE  
(NCIMS) Milk Safety Program

2. PPS PROJECT NAME/NUMBER  
Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)  
18003

4. WORK ALLOCATION PLANNED BY  
 ORA  CENTER

OPERATIONAL FTE POSITIONS  
(2.0)

R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	RMS <sup>5</sup> STANDARDI- ZATION	Food Defense <sup>6</sup> COORDINATION	TRAINING GIVEN <sup>7</sup>								
	TOTAL FIELD	7	20	20								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
WEAC												
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
SEATTLE												
PACIFIC REGIONAL LAB - SW												
PACIFIC REGIONAL LAB - NW												
HOURS PER OPERATION				50.0	25.0	80.0						
TOTAL HOURS				350	500	1600						
CONVERSION FACTOR				1200	1200	1200						
TOTAL OPERATIONAL FTEs				0.29	0.42	1.33						

5/ Activities include the Re-standardization (Group Field Exercise) of the RMS

6/ Includes time for presentation and distribution of the food defense preventive measures guidance document for dairy products to the state regulatory agencies during check ratings routine field work and state program assessments. Presentations may be made at regional seminars or local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of food defense activities and field activities related to food defense. Report time against PAC 18R845.

7/ Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops.

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

1. PROGRAM/ASSIGNMENT TITLE <b>Molluscan Shellfish Evaluation</b>		2. PPS PROJECT NAME/NUMBER <b>Technical Assistance: Food and Cosmetics - 18</b>										
3. PROGRAM/ASSIGNMENT CODE(S) <b>18004</b>		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS <b>12.0 (10.7)</b>				
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	GROWING AREA EVALUATION (1)	PATROL EVALUATION (2)	VIBRIO SPECIES MANAGEMENT (HOURS) (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	TRAINING WORKSHOPS (7)	PLANT EVALUATION (8)			STANDARDIZATION & RE-STAN- DARDIZATION (9)
	TOTAL FIELD	195	15	610	1908	6	2	13	244			14
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF	(b)(2) & (b)(7)(E)										
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
CE	WEAC											
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
SE	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
HOURS PER OPERATION		20.0	80.0		200.0	400.0	50.0	8.0			40.0	
TOTAL HOURS		3900	1200	610	1908	1200	800	650	1952		600	
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200		1200	
TOTAL OPERATIONAL FTEs		3.25	1.00	0.51	1.59	1.00	0.67	0.54	1.63		0.50	

7. REMARKS:

(1) Time is allocated for planning, field evaluations, file reviews (Comprehensive Growing Area Sanitary Surveys, Triennial Evaluations and Annual Updates), growing area data reviews and report writing to determine state program conformity to the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The overwhelming majority of shellfish related illnesses have been attributed to shellfish contamination due to conditions in the shellfish growing areas.

(2) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity to the requirements of the NSSP MO. Illnesses and outbreaks have been attributed to the illegal harvest of shellfish from closed waters.

(3) Activities include technical assistance, education, and evaluation of state shellfish programs *Vibrio vulnificus* and *vibrio parahaemolyticus* and management programs.

(4) Includes interpretations and consultation on NSSP MO requirements related to program administration, risk management, laboratory, shellfish growing areas, shell stock relaying, shellfish aquaculture, shellfish wet storage and depuration, patrol, shellfish harvest and transportation, HACCP, and general sanitation in processing plants.

(5) Activities include planning, field evaluations, file reviews, and report writing for countries with MOUs with the FDA. Current MOU countries include Canada, Chile, South Korea Mexico, and New Zealand.

(6) Includes time for shellfish program planning, development and coordination responsibilities assigned to two specialists selected as team representatives of the Regional Shellfish Specialists' team.

(7) Includes training workshops coordinated and delivered by the specialists, including but not limited to basic shellfish plant and program courses applied concepts for shellfish growing areas courses and HACCP workshops.

(8) Includes time for planning, field evaluations of processing plants, file reviews, and final report writing to determine state conformity with the NSSP MO. Plant evaluations include a full evaluation of HACCP, including plan implementation and adherence to the sanitation requirements of the NSSP MO.

(9) Standardization conducted every 5 years for all FDA and state standardization officers. Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs.

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1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18										
3. PROGRAM/ASSIGNMENT CODE(S) 18004		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/>						5. OPERATIONAL FTE POSITIONS (1.3)				
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM WORKSHOP (10)	CENTER INITIA- TIVES/LAB (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE COORDINATION (13)	ISSC COMMITTEE (14)						
	TOTAL FIELD	12	4	12	12	12						
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
CE	WEAC											
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
SE	PHILADELPHIA											
	FORENSIC CHEM. CTR											
	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
SW	NEW ORLEANS											
	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF											
PA	DALLAS											
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
TOTAL	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW											
	PACIFIC REGIONAL LAB - NW											
	HOURS PER OPERATION	30.0	80.0	40.0	15.0	20.0						
	TOTAL HOURS	360	320	480	180	240						
	CONVERSION FACTOR	1200	1200	1200	1200	1200						
	TOTAL OPERATIONAL FTE	0.30	0.27	0.40	0.15	0.20						

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Interstate Travel Program - Conveyances and Support Facilities	<b>2. PPS PROJECT NAME/NUMBER</b> Technical Assistance: Food and Cosmetics - 18
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> <p>To inspect and investigate passenger conveyances and their support facilities based on the Public Health Service Act, the Food Drug and Cosmetic Act (the Act), regulations, program guidance, Food Code, and in cooperation with the regulated industry and cooperating third party organizations. Also to identify risk factors related to environmental conditions or management practices that may lead to foodborne, waterborne illnesses, and the transmission of communicable diseases. The program includes administrative compliance and regulatory actions as appropriate to ensure conformance with the public health principles embodied in the Acts and their regulations. The goals of the program are to cooperate with the regulated industry, trade associations, and others to promote voluntary compliance, coordinate activities with FAA, CDC, DOT, EPA, Department of Homeland Security (USCG, TSA) and other domestic and foreign government health officials as much as possible to enhance the protection of the traveling public and crew of conveyances under construction and in operation and at related watering points, caterers, commissaries and servicing areas for conveyances.</p>	
<b>5. PROGRAM JUSTIFICATION</b> <p>This program directs Agency efforts in fulfilling Public Health Service Act responsibilities delegated to the Commissioner of Food and Drugs [21 CFR 5.10(a)(2) and (4)]. Sections 311, 361, and 368 of the Act address federal-state cooperation, the controls of communicable disease, and penalties of noncompliance. The Agency also bases the Interstate Travel Program, in part, on provisions of the Federal Food, Drug and Cosmetic Act and related regulations.</p>	
<b>6. FIELD OBLIGATIONS</b> <p>The field is to perform the operations assigned in the Workplan, conduct comprehensive inspections of "high risk" food operations, initiate administrative or regulatory actions as needed to ensure compliance, establish and maintain technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication between CFSAN and ORA Headquarters regarding significant program issues and activities. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.</p>	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Human food, water, and waste; conveyance environmental conditions	<b>d. INDUSTRY/PRODUCT CODE(S)</b> Inspections/Investigations: Industry 51, All food codes including water 29W (Y30).
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Food and water surveillance and contamination, mostly microbiological.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> Catering point inspections will be conducted by persons standardized in the use of FDA's Food Code and procedures established for the Interstate Travel Program.	

1. PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18																	
3. PROGRAM/ASSIGNMENT CODE(S) 18029 A - F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 20.7													
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY		INSP CTIONS	CONVEY UNDER CONSTRUCTION HOURS (*)	WATERING POINTS INSP (A)	CATERING POINTS INSP (B) (**)	VESSELS INSP (C) (***)	DSCs	DSAs MICRO	INV (HOURS)	RE- ENGINEERING COMMITTEE (HOURS) (****)									
	TOTAL FIELD		1555	1360	(669)	(494)	(311)	100	100	500	400									
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)																	
	REGIONAL STAFF																			
	NEW ENGLAND																			
	NEW YORK																			
	REGIONAL LAB																			
	WEAC																			
CE	REGIONAL STAFF																			
	BALTIMORE																			
	CHICAGO																			
	CINCINNATI																			
	DETROIT																			
	MINNEAPOLIS																			
	NEW JERSEY																			
	PHILADELPHIA																			
	FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																			
	ATLANTA																			
	FLORIDA																			
	NEW ORLEANS																			
	SAN JUAN																			
SW	REGIONAL LAB																			
	REGIONAL STAFF																			
	DALLAS																			
	DENVER																			
	KANSAS CITY																			
PA	SOUTHWEST IMPORT DISTRICT																			
	REGIONAL LAB																			
	REGIONAL STAFF																			
	LOS ANGELES																			
	SAN FRANCISCO																			
	SEATTLE																			
PACIFIC REGIONAL LAB - SW																				
PACIFIC REGIONAL LAB - NW																				
HOURS PER OPERATION												10.5					4.0	8.0		
TOTAL HOURS												16328	1360				400	800	500	400
CONVERSION FACTOR												950	950				950	1180	950	950
TOTAL OPERATIONAL FTEs												17.19	1.43				0.42	0.68	0.53	0.42

7. REMARKS:

Inspections in Columns A-C are included in Column 1. The additional inspections can be used on other establishments under the program. Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B. (\*\*\*)Catering Point Insp. (B) is High Risk Priority and some potential Food Allergen firms identified by the District. DSCs should be randomly collected from on-board conveyances water systems outlets ex. faucets, as close to the water holding tank as possible. (\*)Time for Conveyance under Construction- time to be used for plan review, meetings, and final inspections. It includes galleys in DAL, LOS and Aircraft/Vessels in SAN & SEA. (\*\*\*) Vessels with food and water on board. (b)(2) & (b)(7)(E) Districts should use INV hours to correct OEI, coordinate with other federal agencies and other 3RD parties within the district. (\*\*\*\*) Re-engineering Committee hours are for NYK, CIN, FLA, DAL, LOS, SEA and DIB, SEA-DO will take the lead to increase the effectiveness of the program.



1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES  To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods.			
5. PROGRAM JUSTIFICATION  Medical foods are formulated to be consumed or administered interally under the supervision of a physician and are intended for specific dietary management of specific disease or condition for which distinctive nutritional requirements, based on recognized scientific principles established by medical evaluation. The products are often used for life support and are subject to compositional errors and microbiological errors. In addition to four infant deaths in 1986, there have been a number of medical food recalls associated with compositional deviations and under processing.  Medical foods are identified as "high-risk" foods under the Center's Food Safety Initiatives. Firms producing Oral Rehydration Solutions (ORS) will continue to be inspected annually. All other medical food firms will be inspected every two years unless the last inspection was classified as VAI or OAI or unless other factors warrant annual inspection. Foreign inspections of medical foods are planned under PAC 03R833. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03819. Resources are planned in this program for collection and analyses of samples collected from these imported lots.			
6. FIELD OBLIGATIONS Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food security issues are to be covered during all inspections.  CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: N/A <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Medical Foods		d. INDUSTRY/PRODUCT CODE(S) 41G[] [] Use appropriate product identification number	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) Label Review			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , and Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

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

7. REMARKS

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

ORA spreads import operations.

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

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

\*\*May be used for microbiological analysis.

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis and General Food Labeling Program		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES  To determine the compliance of domestic and imported food product labels with regulations promulgated under the Federal Food, Drug and Cosmetic Act, including the Nutrition Labeling and Education Act (NLEA) and the Food Allergen Labeling and Consumer Protection Act (FALCPA). This objective is to be accomplished by reviewing labels of domestic and imported food products and by collecting compliance and surveillance samples for label review and analyses to assure: (1) that the nutrition label is in compliance with the regulations in Title 21 Code of Federal Regulations 101.9; (2) that labeled nutrient content and health claims are made in a manner that complies with applicable regulations; (3) that the label complies with FALCPA; and (4) that all labels include all required label elements.			
5. PROGRAM JUSTIFICATION  Two new labeling requirements related to public health and safety went into effect on January 1, 2006. All domestic and imported foods labeled on or after January 1, 2006 must disclose the presence of any ingredient that is or contains protein derived from one of the 8 major food allergens so that individuals with allergies will be able to easily identify the presence of substances that they must avoid. In addition, most food products entering interstate commerce on or after January 1, 2006 must list trans fat in the nutrition label. The FD&C Act also mandates other required label information and valid nutrient content and health claims provide useful information that assists consumers in selecting foods that promote good health and weight management. Continuous monitoring of food labels is necessary to ensure that consumers are provided with truthful information that they need to select foods that are appropriate for their specific dietary needs and health maintenance.			
6. FIELD OBLIGATIONS Districts will review import and domestic product labels for compliance with FALCPA, NLEA, and other mandatory label requirements by conducting field exams. Districts will collect labels that do not appear to comply with FDA's food labeling laws and regulations for review by the district's compliance branch. Physical samples will be collected for lab analyses as follows: (1) compliance samples that do not appear to qualify for labeled health or nutrient content claims (see C.P. Area of Emphasis #2); and (2) surveillance samples collected for general nutrient analyses (see C.P. Area of Emphasis #6). Prior to collecting labels for trans fat and allergens, contact CFSAN. Domestic Field Exams and sample collections to be conducted during inspections under the following compliance programs: 7303.803, 7303.803A, 7303.037, 7303.842, and 7303.847. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed. For all import field exams, see note under "Remarks" section on the 2621a for this program.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All food products (except vitamins/minerals)		d. INDUSTRY/PRODUCT CODE(S) 02-41	
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) Label Reviews			
f. CHECK THE FOLLOWING ATTRIBUTES Label review and nutrient analyses as appropriate, focus should be given to allergen and trans fat labeling.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  Samples for nutrient analyses to be sent to SRL/ACNA. See compliance program for details.			

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21005, 03R833, 99R833 21R824, 21R829(Health Fraud)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.3			
R E G I O N	6.	1	2	3	4	5	6	7	8	
	DISTRICT/ SPECIALIZED LABORATORY	DSC	DSCs (DOCUMENTARY)	DSCs (PHYSICAL)	DSAs	DOMESTIC FIELD EXAMS **	ISCs (PHYSICAL) OASIS #51 (SEE REMARKS) ****	ISAs	IMPORT INV HOURS (SEE REMARKS) ***	ISCs (PAPER) OASIS #41 (SEE REMARKS) *****
	TOTAL FIELD	340	240	100	100	4000	125	125	2225	785
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORTORY - SW									
	PACIFIC REGIONAL LABORTORY - NW									
	HOURS PER OPERATION	4.2			19.0	0.4	1.2	10.0		1.2
	TOTAL HOURS	1428			1900	1600	150	1250	2225	942
	CONVERSION FACTOR	950			1180	950	950	1180	950	950
	TOTAL OPERATIONAL FTEs	1.50			1.61	1.68	0.16	1.06	2.34	0.99

7. REMARKS

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

\*\*Domestic operations to be conducted during inspections conducted under CP 7303.803,7303.803A,7303.037, 7303.842 and 7303.847. Districts should report time spent reviewing labels that does not result in a collection.

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

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

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

All import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc); and safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under CT PAC (03R845, 04R845, etc.) See IOM Section 5.4.1.4 for additional information on Food and Cosmetic Security Activities.

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

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

1. PROGRAM/ASSIGNMENT TITLE Infant Formula -Domestic and Import					2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21														
3. PROGRAM/ASSIGNMENT CODE(S) 21006			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.4													
R E G I O N	6.	1	2	3	3	3	7	7	4	8									
	DISTRICT/ SPECIALIZED LABORATORY	INSP CTIONS	INVEST GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	IMPORT SAMPLES COLL *	IMPORT SAMPLES TO BE ANALYZED CHEM **									
	TOTAL FIELD	22	200	30	20	10	20	10	15	15									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
PA	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORTORY-SW																		
	PACIFIC REGIONAL LABORTORY-NW																		
HOURS PER OPERATION											42.0		5.3			100.0	120.0	5.0	100.0
TOTAL HOURS											924	200	159			2000	1200	75	1500
CONVERSION FACTOR											950	950	950			1180	1180	950	1180
TOTAL OPERATIONAL FTEs											0.97	0.21	0.17			1.69	1.02	0.08	1.27
7. REMARKS																			
<p>CFSAN spreads inspections and DSCs, CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.</p> <p>ORA spreads import operations</p> <p>* Includes samples resulting from import entry review as well as samples collected during foreign inspections.</p> <p>Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819)</p> <p>** May also be used for microbiological analysis.</p>																			

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

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21008, 21R829 (Health Fraud)	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.9 (13.7)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	DOMESTIC FIELD EXAMS	DOMESTIC SAMPLE COLL. *	DOMESTIC SAMPLES TO BE ANALYZED	HQ INIT DOMESTIC SAMPLE COLL.	HQ INIT DOMESTIC SAMPLE ANALYZED CHEM				INV HOURS
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)									(b)(2) &
	REGIONAL STAFF	(b)(2) & (b)(7)(E)									(b)(7)(E)
	NEW ENGLAND	(b)(2) & (b)(7)(E)									
	NEW YORK	(b)(2) & (b)(7)(E)									
	REGIONAL LAB	(b)(2) & (b)(7)(E)									
	WEAC	(b)(2) & (b)(7)(E)									
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)									
	BALTIMORE	(b)(2) & (b)(7)(E)									
	CHICAGO	(b)(2) & (b)(7)(E)									
	CINCINNATI	(b)(2) & (b)(7)(E)									
	DETROIT	(b)(2) & (b)(7)(E)									
	MINNEAPOLIS	(b)(2) & (b)(7)(E)									
	NEW JERSEY	(b)(2) & (b)(7)(E)									
	PHILADELPHIA	(b)(2) & (b)(7)(E)									
SE	FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF	(b)(2) & (b)(7)(E)									
	ATLANTA	(b)(2) & (b)(7)(E)									
	FLORIDA	(b)(2) & (b)(7)(E)									
	NEW ORLEANS	(b)(2) & (b)(7)(E)									
SW	SAN JUAN	(b)(2) & (b)(7)(E)									
	REGIONAL LAB	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF	(b)(2) & (b)(7)(E)									
	DALLAS	(b)(2) & (b)(7)(E)									
	DENVER	(b)(2) & (b)(7)(E)									
PA	KANSAS CITY	(b)(2) & (b)(7)(E)									
	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)									
	REGIONAL LAB	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF	(b)(2) & (b)(7)(E)									
	LOS ANGELES	(b)(2) & (b)(7)(E)									
	SAN FRANCISCO	(b)(2) & (b)(7)(E)									
	SEATTLE	(b)(2) & (b)(7)(E)									
	PACIFIC REGIONAL LABORTORY-SW	(b)(2) & (b)(7)(E)									
	PACIFIC REGIONAL LABORTORY-NW	(b)(2) & (b)(7)(E)									
HOURS PER OPERATION		22.0	0.5	4.2	25.0	4.2	25.0				
TOTAL HOURS		5500	450	840	2500	210	1250				3000
CONVERSION FACTOR		950	950	950	1180	950	1180				950
TOTAL OPERATIONAL FTEs		5.79	0.47	0.88	2.12	0.22	1.06				3.18

7. REMARKS

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

Investigational hours are planned primarily for CFSAN directed assignments.

Import resources planned in page 2.

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

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1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21008, 21R829 (Health Fraud)	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (3.2)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	ISC PAPER OASIS #41	ISC PHYSICAL	IMPORT INV HOURS	ISA PHYSICAL CHEM				
	<b>TOTAL FIELD</b>	360	70	900	70				
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	1.6	1.6		25.0				
	TOTAL HOURS	576	112	900	1750				
	CONVERSION FACTOR	950	950	950	1180				
	TOTAL OPERATIONAL FTEs	0.61	0.12	0.95	1.48				

7. REMARKS

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

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

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Selected Nutrients in Food Survey -Total Diet	<b>2. PPS PROJECT NAME/NUMBER</b> Food Composition Standard Labeling and Economics-21
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To 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.	
<b>5. PROGRAM JUSTIFICATION</b>  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.	
<b>6. FIELD OBLIGATIONS</b> KAN-DO will analyze Total Diet Study foods from all market baskets for 12 nutrients identified below in 7F , and all TDS foods from one market basket annually for moisture.  Note: In FY 07 folic acid analysis by the Atlanta Center for Nutrient Analysis (ACNA) was cancelled.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Various foods as required by the Total Diet Studies Program	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 37, 40
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> ) Label Review	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>  Calcium, phosphorus, iron, selenium, zinc, copper, magnesium, manganese, nickel, potassium, sodium, iodine and water.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrient in Foods Survey - Total Diet				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21					
3. PROGRAM/ASSIGNMENT CODE(S) 21839			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.4		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 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							1040	
NE	HEADQUARTERS							(b)(2) & (b)(7)(E)	
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORTORY-SW								
	PACIFIC REGIONAL LABORTORY-NW								
	HOURS PER OPERATION							3.8	
	TOTAL HOURS							3952	
	CONVERSION FACTOR							1180	
	TOTAL OPERATIONAL FTEs							3.35	

7. REMARKS

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Methods Validation/Development Program	<b>2. PPS PROJECT NAME/NUMBER</b> Food Composition, Standards, Labeling and Economics - 21
<b>3. PROGRAM TYPE:</b> <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  Develop new and/or improved methodology in support of regulatory analysis.	
<b>5. PROGRAM JUSTIFICATION</b>  Validated analytical methods are essential to support enforcement activities.	
<b>6. FIELD OBLIGATIONS</b>  Conduct activities under this program as directed by the Division of Field Science.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b>
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	APPLIED TECHNOLOGY CENTER CHEM (Hours)								
	TOTAL FIELD	1180								
	HEADQUARTERS	(b)(2) &								
	REGIONAL STAFF	(b)(7)(E)								
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION										
TOTAL HOURS			1180							
CONVERSION FACTOR			1180							
TOTAL OPERATIONAL FTEs			1.00							

9. REMARKS

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



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

1. PROGRAM/ASSIGNMENT TITLE <b>Cosmetics: Domestic and Imports</b>	2. PPS PROJECT NAME/NUMBER <b>Colors and Cosmetics Technology - 29</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>29001, 29R833, 29R824, 99R833</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>8.4</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECTI- ONS	2 DOMESTIC INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT INVESTI- GATIONS (HOURS)		4 IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	8 IMPORT SAMPLE ANALYSIS (CHEM)	8 IMPORT SAMPLE ANALYSIS (MICRO)
		<b>TOTAL FIELD</b>	<b>100</b>		<b>60</b>	<b>60</b>	<b>1121</b>		<b>230</b>	<b>115</b>
	HEADQUARTERS	(b)(2) &		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	17.0		4.4	21.5			1.5	16.0	21.5
	TOTAL HOURS	1700		264	1290	1121		345	1840	2473
	CONVERSION FACTOR	950		950	1180	950		950	1180	1180
	OPERATIONAL FTEs	1.79		0.28	1.09	1.18		0.36	1.56	2.10

7. REMARKS

\* Import Investigation Hour Resources cover: Entry Review Hours, Import Investigation, and time for 700 Import Label Reviews.

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

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

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

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2008**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	103.0	2.5	4.5	110.0	182.7	4.4	7.9	195.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	24.9			24.9	44.1			44.1
42	BLOOD AND BLOOD PRODUCTS	69.3	2.5	2.6	74.4	122.9	4.4	4.6	131.9
45	VACCINES AND ALLERGENIC PRODUCTS	8.8		1.9	10.7	15.7		3.3	19.0

# PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY  Biologics		2. PPS PROJECT NAME/NUMBER  Human Cellular, Tissue and Gene Therapeutics - 41						
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		24.9			24.9	44.1	
1	Tissue Establishments	41002B,C,D	19.5			19.5	34.5	2/3
2	Bioresearch Monitoring Programs *		5.4			5.4	9.6	4/5
	Good Laboratory Practices (Nonclinical Labs)	41808	*			*		
	Institutional Review Board	41809	*			*		
	Sponsors, Contract Research Organizations, and Monitors	41810	*			*		
	Clinical Investigators *	41811	(5.4)			(5.4)	(9.6)	
	* All resources planned under PAC 41811.							

CENTER PROJECT MANAGER/TELEPHONE  
Anita Richardson, 301 827-6220

ORA PLANNER/TELEPHONE  
Harriet R. Gerber, 301-827-1630



1. PROGRAM/ASSIGNMENT TITLE Inspection of Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps)      Inspection of Tissue Establishments	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41002B, C, D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 CBER PRIORITY ESTAB *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>472</b>	<b>(113)</b>							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	39.3								
	TOTAL HOURS	18550								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	19.53								

9. REMARKS

\* Refer to CBER's 7-17-07 Memo for inspectional priorities.

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

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

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

Personnel Types Required: Investigator

<b>1. PROGRAM/ASSIGNMENT TITLE</b> GLPs (Nonclin. Lab), IRBs, Spon/Mon/CROs, Clinical Investigators (PDUFA)	<b>2. PPS PROJECT NAME/NUMBER</b> Human Cellular, Tissue and Gene Therapies - 41
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  <p><b>GLP:</b> To assure compliance with GLP regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.</p> <p><b>IRB:</b> To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).</p> <p><b>Spon/Mon/CROs:</b> To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.</p> <p><b>Clin. Investigators:</b> To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).</p>	
<b>5. PROGRAM JUSTIFICATION</b>  <p><b>GLP:</b> Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.</p> <p><b>IRB:</b> Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.</p> <p><b>Spon/Mon/CROs:</b> Sections of the FD &amp; C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.</p> <p><b>Clin. Investigators:</b> The Kefauver Harris amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.</p>	
<b>6. FIELD OBLIGATIONS</b>  <p><b>GLP:</b> Conduct inspections and forward report(s) to the assigning office in CBER.</p> <p><b>IRB:</b> Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office.</p> <p><b>Spon/Mon/CROs:</b> Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office.</p> <p><b>Clin. Investigators:</b> Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.</p>	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Biologics	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 57 / 99 99 is used for products n.e.c.
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>  	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>  	

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue & Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41808-GLP, 41809-IRB, 41810-Spon/ Mon/CROs, 41811 Clinical Investigator*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>75</b>								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	68.5								
	TOTAL HOURS	5138								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	5.41								

9. REMARKS

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

Personnel Types Required: Investigator



1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations: (a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products: (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products: (b) Licensed Blood Donor Centers which collect blood and ship to the Licensed Blood Banks of which they are a part; (c) Laboratories that perform testing on blood products and donors, e.g. donor screening for communicable disease agents (HIV 1 and 2, Hepatitis B and C, HTLV I and II, syphilis) and supplemental testing on reactive tests (HIV Western Blot, HCV RIBA). (d) Laboratories that perform quality control testing for licensed blood establishments, e.g., platelet q.c. GMP evaluation to determine the level of competency and adherence to contractual agreements with the licensed establishments.	
5. PROGRAM JUSTIFICATION  Blood and Blood Products are vitally important products in medical treatment. Monitoring the collection of whole blood and the processing, manufacturing, and preparation of products derived from human blood assures consumer protection from defective products which may endanger public health.	
6. FIELD OBLIGATIONS  ORA will perform the inspections, prepare and submit the certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed. Training of field personnel will be coordinated with CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Blood and Blood Products	d. INDUSTRY/PRODUCT CODE(S) 55, 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign) *				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42						
3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G 42R825			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 53.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSP - TIONS	1	2 DOMESTIC INVESTI- GATIONS (Hours) **	1 FOREIGN BLOOD BANK INSP - TIONS ***	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDIN- ATION (Hours)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	1060		2469	12			2375		
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF	(7)(E)						(7)(E)		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		42.5			40.0					
TOTAL HOURS		45050		2469	480			2375		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		47.42		2.60	0.51			2.50		

7. REMARKS

\* All listed resources are planned under PAC 42001F. Resources cover all facilities listed in current compliance program. Pre-License Inspections for PPS 41, 42, 45 and Field Investigation Hours are not planned separately. Use above resources for these as needed, at district discretion.  
**For Inspection Risk Based Approach, Refer to CBER's July 17, 2007 Memo,  
 Subject: HCT/P, Blood Bank, and Source Plasma Inspection Priorities for FY08.**

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

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

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

Personnel Types Required: Investigator, National Experts

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42002F,G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L	4 I M P O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours)		
	TOTAL FIELD	182	1330									
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
	CE			REGIONAL STAFF								
				BALTIMORE								
				CHICAGO								
				CINCINNATI								
				DETROIT								
				MINNEAPOLIS								
				NEW JERSEY								
				PHILADELPHIA								
	SE			FORENSIC CHEM. CTR								
				REGIONAL STAFF								
				ATLANTA								
				FLORIDA								
				NEW ORLEANS								
	SW			SAN JUAN								
REGIONAL LAB												
REGIONAL STAFF												
DALLAS												
DENVER												
KANSAS CITY												
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LAB - SW											
	PACIFIC REGIONAL LAB - NW											
	HOURS PER OPERATION	41.8										
	TOTAL HOURS	7608	1330									
	CONVERSION FACTOR	950	950									
	TOTAL OPERATION FTEs	8.01	1.40									

7. REMARKS

The above resources are planned under PAC 42002F, use resources as needed to accomplish this compliance program. Resources may be used for Domestic/Foreign/Follow-up Inspections/Investigations, DSCs as needed. Report operations under appropriate PAC and Operation Code.

Refer to CBER Memo of July 17, 2007 for inspection priorities.

Personnel Types Required: Investigator, Team Biologics

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

1. PROGRAM/ASSIGNMENT TITLE <b>Examination of Biological Products Offered for Import</b>					2. PPS PROJECT NAME/NUMBER <b>Blood and Blood Products - 42</b>					
3. PROGRAM/ASSIGNMENT CODE(S) 42007, 42R833, 42R824, 99R833 41R824, 45R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 IMPORT INVESTIG- ATION HOURS	3 DOMESTIC INVESTIG- ATIONS (HOURS)	4 IMPORT INVESTIG- ATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>		<b>2375</b>							
NE	HEADQUARTERS		(b)(2) & (b)(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION										
TOTAL HOURS			2375							
CONVERSION FACTOR			950							
TOTAL OPERATION FTES			2.50							
<p>9. REMARKS</p> <p>ALL Resources are planned under PAC 42007, as Import Investigation Hours. Report Accomplishments under Appropriate PAC and Operation. Planned Resources are to Cover ALL Import Operations: 42R833 Entry Review; 41R824, 42R824, 45R824 Follow-Up to Refusals; 99R833 Filer Evaluation, Import Investigation Hours, and any inspections needed for PAC 42007.</p> <p>Note: C.P. 7342.007 Addendum "Imported Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" provides product specific guidance.</p> <p>Personnel Types Required: Investigator</p>										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspections of Licensed Viral Marker Test Kits (Inspections of In Vitro Diagnostic Product Manufacturers)	<b>2. PPS PROJECT NAME/NUMBER</b> Blood and Blood Products - 42
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To evaluate the manufacturing process for licensed <i>in vitro</i> diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including the Quality System regulations (21 CFR 820), <i>In Vitro</i> Diagnostic Products regulations (21 CFR 809), Biologics regulations (21CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.	
<b>5. PROGRAM JUSTIFICATION</b>  <i>In Vitro</i> Diagnostic Kits are important tools in medical treatment and blood and plasma donor screening. This program enables the Agency to continue to protect the public health by assuring safety, purity, potency, and efficacy of these products.	
<b>6. FIELD OBLIGATIONS</b>  Conduct <b>comprehensive inspections</b> that assess the adequacy of all significant processes and systems. These inspections should be performed on <b>at least a Biennial Basis</b> . Inspections will be conducted by a Team Biologics Core Team member and may include a district representative and / or a Product Specialist from CBER.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> <i>In Vitro</i> Diagnostic Products accordance with the stated objective.	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 55, 57, 65 & 81 (Device Categories)
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )    Device Specific	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Viral Marker Test Kits				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42						
3. PROGRAM/ASSIGNMENT CODE(S) 42008, A Domestic & Foreign *		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 Post-Licensed DOMESTIC INSP CTIONS	1 Post-Licensed FOREIGN INSP CTIONS	3 DOMESTIC INV (Hours)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	10	3	570						
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		125.0	185.0							
TOTAL HOURS		1250	555	570						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.32	0.58	0.60						
7. REMARKS  * 42008 GMP Inspections, 42008A Pre-License Inspections All inspections will be performed by Core Team Biologics. No separate resources are planned for 42008A, use above resources as needed. Report accomplishments under appropriate operation code and PAC.  Field Investigation Hours may be used for any Core Team Program.  Personnel Types Required: Investigator, Core Team Biologics										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	<b>2. PPS PROJECT NAME/NUMBER</b> Blood and Blood Products - 42
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  <p><b>IRBs:</b> To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).</p> <p><b>Spon./Mon./CROs:</b> To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.</p> <p><b>Clin. Investigators:</b> To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).</p>	
<b>5. PROGRAM JUSTIFICATION</b>  <p><b>IRBs:</b> Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of biological products are protected.</p> <p><b>Spon./Mon./CROs:</b> Sections of the FD &amp; C Act and the Public Health Service Act require the submission of reliable, accurate. clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.</p> <p><b>Clin. Investigators:</b> The Kefauver Harris amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.</p>	
<b>6. FIELD OBLIGATIONS</b>  <p><b>IRBs:</b> Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office.</p> <p><b>Spon./Mon./CROs:</b> Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office.</p> <p><b>Clin. Investigators:</b> Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.</p>	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Biologics	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 57 / 99 99 is used for products n.e.c.
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE  
 IRBs, Sponsor/Monitor/Contract Research Organizations,  
 Clinical Investigators (PDUFA Domestic & Foreign)

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

3. PROGRAM/ASSIGNMENT CODE(S)  
 42809-IRB, 42810-Spon/Monitor/CROs,  
 42811 Clinical Investigator \*

4. WORK ALLOCATION PLANNED BY  
 ORA  CENTER

5. OPERATIONAL FTE POSITIONS  
 3.5

REGION	DISTRICT/SPECIALIZED LABORATORY	INSPECTIONS	DOMESTIC INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>37</b>								
NE	HEADQUARTERS	(b)(2) &								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	89.9								
	TOTAL HOURS	3326								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	3.50								

9. REMARKS

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

Personnel Types Required: Investigator

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	9								
NE	HEADQUARTERS	(b)(2) &								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		52.8								
TOTAL HOURS		475								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.50								

7. REMARKS

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

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

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

Personnel Types Required: Investigator



1. PROGRAM/ASSIGNMENT TITLE Inspection of Plasma Derivatives of Human Origin	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42848A, F, G; 41848A, F, G Domestic & Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPECT- IONS	1 FOREIGN LICENSED INSPECT- IONS	3 DOMESTIC SAMPLE COLL	2 DOMESTIC INVESTI- GATIONS (Hours)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	9	7							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		155.8	206.8							
TOTAL HOURS		1402	1448							
CONVERSION FACTOR		950	950							
OPERATIONAL FTEs		1.48	1.52							

7. REMARKS

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

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

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



<b>1. PROGRAM/ASSIGNMENT TITLE</b> IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	<b>2. PPS PROJECT NAME/NUMBER</b> Vaccines and Allergenic Products - 45
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  <b>IRBs:</b> To ensure the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).  <b>Spon./Mon./CROs:</b> To assess the adherence of sponsors, contract research organizations, and monitors to the current regulations (21 CFR 312) and their oversight of clinical studies.  <b>Clin. Investigators:</b> To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).	
<b>5. PROGRAM JUSTIFICATION</b>  <b>IRBs:</b> Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.  <b>Spon./Mon./CROs:</b> Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.  <b>Clin. Investigators:</b> The Kefauver Harris amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.	
<b>6. FIELD OBLIGATIONS</b>  <b>IRBs:</b> Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office. <b>Spon./Mon./CROs:</b> Conducts inspections as assigned by CBER and forward the report(s) to the appropriate office. <b>Clin. Investigators:</b> Conducts inspections as assigned by CBER and forward the reports including recommendations for compliance follow-up as needed.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Biologics	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 57 / 99    99 is used for products n.e.c.
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING  <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45					
3. PROGRAM/ASSIGNMENT CODE(S) 45809 IRBs, 45810 Spon/Mon/CROs, 45811 Clinical Investigators			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	SPECIALIZED									
	<b>TOTAL FIELD</b>	<b>63</b>								
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT OPERATION REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		90.5								
TOTAL HOURS		5702								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		6.00								
7. REMARKS  * Resources for PACs 45809, 45810, and 45811 are planned under PAC 45811 Clinical Investigators. Use above resources for Foreign Inspections as needed. Inspections are to be conducted only when assignments are received from CBER. Report accomplishment hours under appropriate PAC. Report Foreign Inspections under Operation Code 11.										
Personnel Types Required: Investigator										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspection of Licensed Allergenic Products PACs 45848A,F,G	<b>2. PPS PROJECT NAME/NUMBER</b> Vaccines and Allergenic Products - 45
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which licensed allergenic products and unlicensed allergenic source materials are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, standards and commitments made in license applications and/or supplements, and applicable regulations.	
<b>5. PROGRAM JUSTIFICATION</b>  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.	
<b>6. FIELD OBLIGATIONS</b>  ORA will perform single, <b>inspections</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Biologics	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 57
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products (Post-Market & Pre-License)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45848A,F,G Domestic/Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 *	1 *	2	3	4	6	7	8	9
		DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	DOMESTIC INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	5	1							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		108.0	125.0							
TOTAL HOURS		540	125							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.57	0.13							

7. REMARKS

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspection of Licensed Vaccine Products PACs 45848B,C,D	<b>2. PPS PROJECT NAME/NUMBER</b> Vaccines and Allergenic Products - 45
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b>  To ensure the safety and effectiveness of biological products by determining through inspections, the conditions under which vaccines are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, Standards and commitments made in license applications and/or supplements, and applicable regulations.	
<b>5. PROGRAM JUSTIFICATION</b>  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.	
<b>6. FIELD OBLIGATIONS</b>  ORA will perform single, <b>inspections</b> that assess the adequacy of all significant processes and systems. These inspections should be performed on <b>at least a Biennial Basis</b> . Inspections will be conducted by a Team Biologics Core Team Member and may include a district representative and/or a Product Specialist from CBER.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Biologics	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 57
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>  	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>  	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic/Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	5	6	7	8	9	
		DOMESTIC INSP CTIONS	FOREIGN INSP CTIONS	DOMESTIC INVESTI- GATIONS (Hours)	DOMESTIC INVESTI- GATIONS (HOURS)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	8	6	570							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	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		186.3	290.0								
TOTAL HOURS		1490	1740	570							
CONVERSION FACTOR		950	950	950							
TOTAL OPERATIONAL FTEs		1.57	1.83	0.60							

7. REMARKS

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

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

**CENTER FOR DRUG EVALUATION AND RESEARCH  
 RESOURCE SUMMARY  
 FY 2008 ORA WORKPLAN  
 October 1, 2007**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES	PROGRAM FTES			TOTAL PROGRAM FTES
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	253.7	30.5	38.8	323.0	450.1	54.1	68.8	573.0
46	NEW DRUG EVALUATION	9.6		14.0	23.6	17.0		24.8	41.8
48	BIORESEARCH MONITORING HUMAN DRUGS	46.3		3.0	49.3	82.1		5.3	87.4
52	GENERIC DRUG EVALUATION	13.1		8.3	21.4	23.2		14.7	37.9
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	8.5		1.0	9.5	15.1		1.8	16.9
56	DRUG QUALITY ASSURANCE	155.7	30.5	12.5	198.7	276.3	54.1	22.2	352.6
63	UNAPPROVED AND MISBRANDED DRUGS	8.5			8.5	15.1			15.1
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0	21.3			21.3



## FY 2008

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

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations Domestic (PDUFA)		2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46				
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46832M <input checked="" type="checkbox"/>		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.6	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDAs TO INSPECT	1 CHEMIST INSPECT (HOURS)	3 DOMESTIC SAMPLE COLL	7 DSAs PROFILE (Hours) **	
	TOTAL FIELD	120	2272	30	30	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	REGIONAL STAFF					
	NEW ENGLAND					
	NEW YORK					
	REGIONAL LAB					
	WEAC					
CE	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
	PHILADELPHIA					
FORENSIC CHEM. CTR						
SE	REGIONAL STAFF					
	ATLANTA					
	FLORIDA					
	NEW ORLEANS					
	SAN JUAN					
	REGIONAL LAB					
SW	REGIONAL STAFF					
	DALLAS					
	DENVER					
	KANSAS CITY					
	SOUTHWEST IMPORT DISTRICT					
PA	REGIONAL LAB					
	REGIONAL STAFF					
	LOS ANGELES					
	SAN FRANCISCO					
	SEATTLE					
	PACIFIC REGIONAL LAB - SW					
PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		46.0		5.0	50.0	
TOTAL HOURS		5520	2272	150	1500	
CONVERSION FACTOR		950	950	950	1180	
TOTAL OPERATIONAL FTES		5.81	2.39	0.16	1.27	

7. REMARKS  
 \* Includes Microbiologists on Inspections.  
 \*\* NRL analyzes profile DSCs in NE & SE Regions. FCC analyzes profile DSCs in CE, SW and PA Regions.  
 46832M Therapeutic Biologics Products PAC- Resources under 56002M.

**FY 2008**

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

1. PROGRAM/ASSIGNMENT TITLE <b>NDA Pre-Approval Inspections/Investigations                  - Foreign (PDUFA)</b>	2. PPS PROJECT NAME/NUMBER <b>New Drug Evaluation - 46</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46832D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 14.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S ++	1 CHEMIST INSP S (Hours)  **						9 O T H E R O P E R A T I O N S (Hours)	
	<b>TOTAL FIELD</b>	<b>192</b>	<b>3325</b>							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	52.0								
	TOTAL HOURS	9984	3325							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	10.51	3.50							

7. REMARKS

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

\*\* Includes microbiologists on inspections.

++ Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).



**FY 2008**

<p>1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (PDUFA)</p>	<p>2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48</p>
<p>3. PROGRAM TYPE:    <input checked="" type="checkbox"/> COMPLIANCE PROGRAM    <input type="checkbox"/> PROGRAM CIRCULAR    <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES</p> <p>Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.</p>	
<p>5. PROGRAM JUSTIFICATION</p> <p>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.</p>	
<p>6. FIELD OBLIGATIONS</p> <p>Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</p> <p align="center"> <input type="checkbox"/> BY DISTRICT OFFICE                      <input checked="" type="checkbox"/> BY CENTER                      <input type="checkbox"/> BY BOTH         </p>	
<p>b. INSPECTION TYPE:    <input checked="" type="checkbox"/> COMPREHENSIVE                      <input type="checkbox"/> ABBREVIATED                      <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) Human Drugs</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 60, 61</p>
<p>e. EXAM TYPE:    <input type="checkbox"/> CHEMICAL                      <input type="checkbox"/> MICROBIOLOGICAL                      <input type="checkbox"/> PHYSICAL                      <input type="checkbox"/> ENGINEERING</p> <p>                         <input type="checkbox"/> MICROANALYTICAL                      <input type="checkbox"/> OTHERS (<i>Specify</i>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (Pre-Approval)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSP ECTI ONS D O M E S T I C	1 48001A NDA INSP ECTI ONS (P D U F A) D O M E S T I C						
	TOTAL FIELD	34	39						
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB (SW)								
	PACIFIC REGIONAL LAB (NW)								
	HOURS PER OPERATION	70.0	85.0						
	TOTAL HOURS	2380	3315						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	2.51	3.49						

7. REMARKS

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

An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 48%, PDUFA 48001A (NDA) 52%.

Personnel Types Required: Investigator

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

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)		2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48811; 48001D,E; 48811D NDA &, ANDA *		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 3.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSP CTIONS (PDUFA)	1 FOREIGN 48001 ANDA INSP CTIONS (PRE-APPR)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9
	TOTAL FIELD	20	15					
	HEADQUARTERS	(b)(2) & (b)(7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB (SW)							
	PACIFIC REGIONAL LAB (NW)							
	HOURS PER OPERATION	78.0	85.0					
	TOTAL HOURS	1560	1275					
	CONVERSION FACTOR	950	950					
	TOTAL OPERATIONAL FTEs	1.64	1.34					

7. REMARKS

\* Planned inspections include: 48001,A In Vivo Bioequivalence, 48811 Clinical Investigators, 48808 GLPs (PDUFA), PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence, and 48811D PEPFAR Clinical Investigator.

Report Inspections under Appropriate PAC, Foreign Inspections under Operation Code 11.

HIGH PRIORITY for NDA inspections.

\*\* President's Emergency Plan for AIDS Relief (PEPFAR):  
48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator.  
NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001.  
We are not planning separate PEPFAR work.

Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs.  
Data audit under PEPFAR will be verified by on site inspections.

Personnel Types Required: Investigator, National Expert

**FY 2008**

<p>1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Nonclinical Laboratory)</p>	<p>2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48</p>
<p>3. PROGRAM TYPE:    <input checked="" type="checkbox"/> COMPLIANCE PROGRAM        <input type="checkbox"/> PROGRAM CIRCULAR        <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES</p> <p>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.</p>	
<p>5. PROGRAM JUSTIFICATION</p> <p>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.</p>	
<p>6. FIELD OBLIGATIONS</p> <p>Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</p> <p align="center"> <input type="checkbox"/> BY DISTRICT OFFICE                      <input checked="" type="checkbox"/> BY CENTER                      <input type="checkbox"/> BY BOTH </p>	
<p>b. INSPECTION TYPE:        <input checked="" type="checkbox"/> COMPREHENSIVE                      <input type="checkbox"/> ABBREVIATED                      <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) Human Drugs</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 60 , 61</p>
<p>e. EXAM TYPE:        <input type="checkbox"/> CHEMICAL                      <input type="checkbox"/> MICROBIOLOGICAL                      <input type="checkbox"/> PHYSICAL                      <input type="checkbox"/> ENGINEERING</p> <p align="center"> <input type="checkbox"/> MICROANALYTICAL                      <input type="checkbox"/> OTHERS (<i>Specify</i>) </p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

**FY 2008**

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

<p>1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, &amp; Monitors</p>	<p>2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48</p>
<p>3. PROGRAM TYPE:    <input checked="" type="checkbox"/> COMPLIANCE PROGRAM        <input type="checkbox"/> PROGRAM CIRCULAR        <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES</p> <p>To assure adherence by sponsors, contract research organizations, and monitors to the regulations (21 CFR 312) and to assess their interaction with clinical investigators and the sponsors development of safety and efficacy data in NDAs.</p>	
<p>5. PROGRAM JUSTIFICATION</p> <p>Sections of the FD&amp;C Act and the Public Health Service Act require the submission of data to FDA ensuring the safety of human drugs, as well as the filing of an Investigational New Drug Application and New Drug Applications. An inspectional program is required to assess compliance with current regulations.</p>	
<p>6. FIELD OBLIGATIONS</p> <p>Conduct inspections of sponsors, contract research organizations, and monitors for the IND/NDAs identified in the assignments. Forward reports directly to the Division of Scientific Investigations, CDER, for final classification, including District recommendations for compliance follow-up.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</p> <p style="text-align: center;"> <input type="checkbox"/> BY DISTRICT OFFICE                      <input checked="" type="checkbox"/> BY CENTER                      <input type="checkbox"/> BY BOTH         </p>	
<p>b. INSPECTION TYPE:    <input checked="" type="checkbox"/> COMPREHENSIVE                      <input type="checkbox"/> ABBREVIATED                      <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) Human Drugs</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 60 , 61</p>
<p>e. EXAM TYPE:    <input type="checkbox"/> CHEMICAL                      <input type="checkbox"/> MICROBIOLOGICAL                      <input type="checkbox"/> PHYSICAL                      <input type="checkbox"/> ENGINEERING</p> <p style="margin-left: 20px;"> <input type="checkbox"/> MICROANALYTICAL                      <input type="checkbox"/> OTHERS (<i>Specify</i>)         </p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To assess through audit procedures whether data submitted to FDA in a specific study are substantiated by source documents and whether clinical investigators have complied with regulations (21 CFR 312).	
5. PROGRAM JUSTIFICATION  Clinical data are submitted to FDA in support of a marketing permit (IND, NDA). The clinical studies that generated the data are evaluated for accuracy, completeness, and regulatory compliance.	
6. FIELD OBLIGATIONS  Conduct inspections and forward EIRs directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <div style="display: flex; justify-content: space-around;"> <span><input type="checkbox"/> BY DISTRICT OFFICE</span> <span><input checked="" type="checkbox"/> BY CENTER</span> <span><input type="checkbox"/> BY BOTH</span> </div>	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED.	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60 , 61
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors; Clinical Investigators (PDUFA)						2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48			
3. PROGRAM/ASSIGNMENT CODE(S) 48808, 48809, 48809A, 48810, 48811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 40.3			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 GLP INSP EC- TIONS 48808	2 NAT'L EXPERT INVESTI- GATIONS (Hours) 48808 - GLP	1 * IRB INSP ECTIONS 48809, 48809A §	1 SPONSOR, CRO, MONITORS INSP ECTIONS 48810 **	1 CLINICAL INVESTI- GATORS INSP ECTIONS 48811	2 NAT'L EXPERT INVESTI- GATIONS (Hours) 48811 - Cl ***		
	<b>TOTAL FIELD</b>		<b>39</b>	<b>380</b>	<b>85</b>	<b>32</b>	<b>282</b>	<b>333</b>	
HEADQUARTERS		(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		87.8		56.0	90.0	94.1			
TOTAL HOURS		3424	380	4760	2880	26536	333		
CONVERSION FACTOR		950	950	950	950	950	950		
TOTAL OPERATIONAL FTEs		3.60	0.40	5.01	3.03	27.93	0.35		
9. REMARKS									
48808:									
Resources planned for Inspections may also be used for DSCs.									
Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER. CDER assignments, i.e. Directed Inspections, cover studies associated with IND's and NDA's.									
Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-5).									
* Institutional Review Board									
** Sponsors, Contract Research Organizations, and Monitors									
*** Clinical Investigators									
§48809A: Resources for the Radioactive Drug Research Committee (RDRC, PAC 48809A) are not planned, please use above resources as needed.									
Personnel Types Required: Investigator, National Expert									



**FY 2008**

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

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Inv. - Domestic	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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PROGRAM/ASSIGNMENT CODE(S) 52832, B, C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAs TO INSPECT	1 CHEMIST INSPECT. (Hours)	2 DOMESTIC INVEST (Hours)	3 DOMESTIC SAMPLE COLL **		7 DOMESTIC SAMPLE ANALYSES PROFILE (Hours) **	7 BIOTEST (Chem) ***		
	<b>TOTAL FIELD</b>	132	1900	855	91		45	45		
	HEADQUARTERS	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	NEW ENGLAND	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	NEW YORK	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	REGIONAL LAB	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	WEAC	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	BALTIMORE	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	CHICAGO	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	CINCINNATI	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	DETROIT	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	MINNEAPOLIS	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	NEW JERSEY	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	PHILADELPHIA	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)				
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	ATLANTA	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	FLORIDA	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	NEW ORLEANS	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	SAN JUAN	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	REGIONAL STAFF	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	DALLAS	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	DENVER	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	KANSAS CITY	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
PA	SOUTHWEST IMPORT DISTRICT	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	REGIONAL LAB	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	REGIONAL STAFF	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	LOS ANGELES	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	SAN FRANCISCO	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	SEATTLE	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	PACIFIC REGIONAL LAB - SW	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)					(b)(2) & (b)(7)(E)			
	HOURS PER OPERATION	48.0			5.0		50.0	30.0		
	TOTAL HOURS	6336	1900	855	455		2250	1350		
	CONVERSION FACTOR	950	950	950	950		1180	1180		
	TOTAL OPERATIONAL FTEs	6.67	2.00	0.90	0.48		1.91	1.14		

7. REMARKS

\*Includes microbiologists on inspections. \*\*Time for handling of profile samples.  
 \*\*\* NRL-analyzes profile/biotest DSCs collected in NE & SE Region;  
 FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.

**FY 2008**

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

ANDA Pre - Approval Inspections/Investigations - Foreign				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52				
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B, 52832C, 52832E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 8.3		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS * (Foreign) **	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS	5 IMPORT SAMPLE COLL ***	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****	
	<b>TOTAL FIELD</b>	42	1900	950	140	70	70	
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	NEW ENGLAND	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	NEW YORK	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	REGIONAL LAB	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	WEAC	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
CE	REGIONAL STAFF	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	BALTIMORE	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	CHICAGO	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	CINCINNATI	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	DETROIT	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	MINNEAPOLIS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	NEW JERSEY	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	PHILADELPHIA	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
FORENSIC CHEM. CTR	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)				
SE	REGIONAL STAFF	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	ATLANTA	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	FLORIDA	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	NEW ORLEANS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	SAN JUAN	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
SW	REGIONAL LAB	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	REGIONAL STAFF	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	DALLAS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	DENVER	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	KANSAS CITY	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
PA	Southwest Import District	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	REGIONAL LAB	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	REGIONAL STAFF	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	LOS ANGELES	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	SAN FRANCISCO	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	SEATTLE	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	PACIFIC REGIONAL LAB - SW	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	PACIFIC REGIONAL LAB - NW	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	HOURS PER OPERATION	50.0			3.0	30.0	15.0	
	TOTAL HOURS	2100	1900	950	420	2100	1050	
	CONVERSION FACTOR	950	950	950	950	1180	1180	
	TOTAL OPERATIONAL FTEs	2.21	2.00	1.00	0.44	1.78	0.89	
7. REMARKS * Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832; ++ PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).  Profile ISCs & ISAs -52832B; Biotest ISCs & ISAs under PAC 52832C. ** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers. **** NRL analyzes all Profile/Biotest ISCs and methods development ISAs.								



## FY 2008

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

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations		2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53								
3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B *		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 9.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN	2 INVESTI- GATION	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 MISC. HOURS
	TOTAL FIELD	122	16							
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION		66.0	60.0							
TOTAL HOURS		8052	960							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		8.48	1.01							

7. REMARKS

\*Report both Domestic and Foreign inspections under 53001A for Center-Initiated and 53001B for District-Initiated. Domestic inspections are spread by CDER HFD-332 based upon where inspections are likely to occur. Numbers for domestic inspections may change slightly pending CDER assignment. Foreign inspections are spread by ORA/DFI.



**FY 2008**

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

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832, 56R359, 56002M*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 106.0
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	3	3	3	7	7
		INSPECTIONS	INVESTIGATIONS (Hours)	CHEMIST ON INSPECTIONS (Hours)	MICRO ON INSPECTIONS (Hours)	DOMESTIC SAMPLE COLL **	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	DOMESTIC SAMPLES TO BE ANALYZED (MICRO)
	<b>TOTAL FIELD</b>	<b>1377</b>	<b>2850</b>	<b>10450</b>	<b>1995</b>	<b>350</b>	<b>229</b>	<b>40</b>	<b>229</b>	<b>40</b>
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	55.0				5.0			38.0	28.0
	TOTAL HOURS	75735	2850	10450	1995	1750			8702	1120
	CONVERSION FACTOR	950	950	950	950	950			1180	1180
	TOTAL OPERATIONAL FTEs	79.72	3.00	11.00	2.10	1.84			7.37	0.95

7 REMARKS  
 \* Hours for certification audits or general investigations as needed by the District.  
 (b)(2) & (b)(7)(E)  
 Gas firms are under a separate worksheet 56-5 . \*\* DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.

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

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1. PROGRAM/ASSIGNMENT TITLE DRUG Process Inspections- Domestic (Gas Manufacturer)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS  MEDICAL GAS	2 INVESTI- GATION Hours	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLE ANALYSES	8 IMPORT SAMPLES ANALYSES	9 MISC. HOURS
	<b>TOTAL FIELD</b>	<b>127</b>							
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	CE		REGIONAL STAFF						
BALTIMORE									
CHICAGO									
CINCINNATI									
DETROIT									
MINNEAPOLIS									
NEW JERSEY									
PHILADELPHIA									
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
HOURS PER OPERATION		30.0							
TOTAL HOURS		3810							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		4.01							

9. REMARKS  
 \* Total number of planned gas inspections in the Program for FY 2008.  
 (b)(2) & (b)(7)(E)

## FY 2008

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

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002,A,B,C,D,E,F 56832	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **							
	<b>TOTAL FIELD</b>	<b>161</b>	<b>3800</b>							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		50.0								
TOTAL HOURS		8050	3800							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		8.47	4.00							

7. REMARKS  
 \* Foreign inspections (DPI) are planned under 56002 and should be reported under operation 11 PACs 56002A, B, C, D, E, F, 56832. \*\* Time planned in this column may be used by chemists or microbiologists.

**FY 2008**

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

FY 2008 ORA Workplan

October 1, 2007

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
PROGRAM/ASSIGNMENT CODE(S) 56008A, C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.7		
R E G I O N	6.	2	3	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	7	7	7	
	DISTRICT/ SPECIALIZED LABORATORY	INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLLECTIONS			DOMESTIC SAMPLES ANALYZED (CHEM)	DOMESTIC SAMPLES ANALYZED (MICRO)	METHODS DEVELOPMENT HOURS (Chem)	
	TOTAL FIELD	950	632	510	122	510	122	3615	
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)			
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
HOURS PER OPERATION			5.5			36.3	22.0		
TOTAL HOURS		950	3476			18513	2684	3615	
CONVERSION FACTOR		950	950			1180	1180	1180	
TOTAL OPERATIONAL FTEs		1.00	3.66			15.69	2.27	3.06	
9. REMARKS									
<div style="border: 1px solid black; width: 20px; height: 10px; display: inline-block; vertical-align: middle;"></div> The shaded area breaks out the sample collections and is only a guideline for Districts.									

**[This Page Left Intentionally Blank]**

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56					
3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 30.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGATIONS HOURS **		MAIL/ COURIERS REVIEWS INV HOURS	4 IMPORT SAMPLE COLLECT- IONS *	8 IMPORT SAMPLES ANALYZED APIs CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	10992	6650		10260	118	60	60
NE	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
SE	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
SW	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
PA	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
LOS ANGELES								
SAN FRANCISCO								
SEATTLE								
PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION						2.7	38.0	25.0
TOTAL HOURS		10992	6650		10260	319	2280	1500
CONVERSION FACTOR		1200	950		950	950	1180	1180
TOTAL OPERATIONAL FTEs		9.16	7.00		10.80	0.34	1.93	1.27

7. REMARKS  
 \* Reporting Guidance:  
 - Import Entry Reviews (electronic and manual-- operation code 14) PAC 56R833;  
 - Filer Evaluations (operation code 95) PAC 99R833;  
 - Follow-Up to Refusals 56R824, 63R824  
  
 - Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001, 63002;  
 - Report finished dosage form drugs and APIs collected at the site of entry under 56008H.  
  
 \*\* Import investigation hours are for field exams, filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.  
 Use CT PAC 56R845 only when specific CT work is performed.

**FY 2008**

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

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56						
3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL				7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)		
	<b>TOTAL FIELD</b>	<b>112</b>		<b>30</b>				<b>30</b>		
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
NE	REGIONAL STAFF	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	25.0		4.0				35.0		
	TOTAL HOURS	2800		120				1050		
	CONVERSION FACTOR	950		950				1180		
	TOTAL OPERATIONAL FTEs	2.95		0.13				0.89		
7. REMARKS										

**FY 2008**

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

