

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) 45002, A Domestic/Foreign * 45R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.7
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R E G I O N	6.	1	1	2	3	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	INVESTI- GATIONS DOMESTIC (HOURS)	CT 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>	<b>10</b>	<b>3</b>	<b>273</b>	<b>500</b>					
NE	HEADQUARTERS	10	3							
	REGIONAL STAFF									
	NEW ENGLAND				100					
	NEW YORK			91	100					
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE				100					
	CHICAGO									
	CINCINNATI									
	DETROIT			91	100					
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR			91	100					
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		259.6	166.0							
TOTAL HOURS		2596	498	273	500					
CONVERSION FACTOR		910	910	910	500					
TOTAL OPERATIONAL FTEs		2.85	0.55	0.30	1.00					

7. PERSONNEL TYPES REQUIRED										
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP TIONAL	10/01/02	09/30/03	
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL			
PHYSICIST				MILK/FOOD SPEC	X	CORE TEAM BIOL				
ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				

9. REMARKS  
 \* 45002 GMP Inspection, 45002A Pre-License Inspections All inspections will be performed by Core Team Biologics.  
 No separate resources are planned for 45002A, use above resources as needed.  
 Use CT PAC ONLY when specific CT Work is performed, otherwise use related program PAC's.

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board (PDUFA)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by institutional review boards (21 CFR 56, 21 CFR 50).	
5. PROGRAM JUSTIFICATION Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.	
6. FIELD OBLIGATIONS Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products n.e.c.
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	



1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).	
5. PROGRAM JUSTIFICATION The Kefauver Harris amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.	
6. FIELD OBLIGATIONS Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products n.e.c.
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

FY 2003 ORA WORKPLANNING SHEET

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsors-Monitors, Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45					
3. PROGRAM/ASSIGNMENT CODE(S) 45809 IRBs, 45810 Spon/Mon, 45811 Clin. Invest.			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.9				
R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY  SPECIALIZED	INSP EC T I O N S	INVEST I G A T I O N S (HOURS)	DOMESTIC S A M P L E C O L L	I M P O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	I M P O R T F I E L D E X A M S	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	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	O T H E R O P E R A T I O N S (Hours)
<b>TOTAL FIELD</b>		<b>49</b>								
N E	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2								
	NEW YORK	2								
	REGIONAL LAB									
C E	WEAC									
	REGIONAL STAFF									
	BALTIMORE	8								
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY	2								
PHILADELPHIA	8									
S E	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA	4								
	NEW ORLEANS									
S W	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2								
	DENVER	5								
P A	KANSAS CITY	4								
	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
P A	LOS ANGELES	8								
	SAN FRANCISCO	4								
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		72.4								
TOTAL HOURS		3548								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		3.90								
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL			INVESTIGATIVE				PERSON TYPE	BEGIN	END	
CHEMIST	PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC-TIONAL	10/01/02	09/30/03			
MICROBIOLOGIST	BIO. SCIENCE TECH		INSPECTOR	VETERINARIAN	ANALY-TICAL					
ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT						
PHYSICIST			MILK/FOOD SPEC							
ENTOMOLOGIST	OTHER		SHELLFISH SPEC	OTHER						
9. REMARKS * All resources are planned under 45811, Clinical Investigators. Report Accomplishment hours under Appropriate PAC.										

**CENTER FOR DRUG EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2003 ORA WORKPLAN/BULLETIN-1  
January 15, 2003**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	318.7	57.7	52.1	428.5	629.9	93.2	101.9	825
46	NEW DRUG EVALUATION	26.0		16.2	42.2	50.9		31.7	82.6
48	BIORESEARCH MONITORING HUMAN DRUGS	50.2		3.9	54.1	98.3		7.6	105.9
52	GENERIC DRUG EVALUATION	43.4		14.6	58.0	84.9		28.6	113.5
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	15.3		1.7	17.0	29.9		3.3	33.2
56	DRUG QUALITY ASSURANCE	167.3	57.7	15.7	240.7	333.6	93.2	30.7	457.5
61	OTC DRUG EVALUATION	1.0			1.0	1.9			1.9
63	HEALTH FRAUD: HUMAN DRUGS	10.5			10.5	20.6			20.6
88	INTERAGENCY COOPERATIVE ACTIVITIES	5.0			5.0	9.8			9.8

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



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

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1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Inv. Methods Validation-Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 23.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	5	7	7	7	7
		NDA TO INSPECT (Domestic) *	CHEMIST INSPECT (Hours) (Domestic) **	INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	DSAs METH. VALID. (MICRO) ****	METH. VALID. RADPHARM TRANSDERM. ***** (chem) (Hours)	DSAs (METH.) (VALID) CHEM *****
	TOTAL FIELD	140	2311		30		30	6	2380	89
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	7			2					
	NEW YORK	12			2					
	REGIONAL LAB		617				12	1		
	WEAC								1180	
CE	REGIONAL STAFF									
	BALTIMORE	4			1					
	CHICAGO	8			1					
	CINCINNATI	4			1					
	DETROIT	7	77		2					
	MINNEAPOLIS	4			1					
	NEW JERSEY	18			4					
	PHILADELPHIA	14	462		3				1200	36
	FORENSIC CHEM. CTR		154				18			
SE	REGIONAL STAFF									
	ATLANTA	11			2					
	FLORIDA	3			1					
	NEW ORLEANS	3			1					
	SAN JUAN	18	289		4					33
	REGIONAL LAB		212							15
SW	REGIONAL STAFF									
	DALLAS	5			1					
	DENVER	5	77		1			5		
	KANSAS CITY	7	77		1					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	6			1					
	SAN FRANCISCO	3			1					
	SEATTLE	1								
	PACIFIC REGIONAL LAB - SW		173							5
	PACIFIC REGIONAL LAB - NW		173							
	HOURS PER OPERATION	56.0			3.0		50.0	105.0		105.0
	TOTAL HOURS	7840	2311		90		1500	630	2380	9345
	CONVERSION FACTOR	910	910		910		1180	1180	1180	1180
	TOTAL OPERATIONAL FTES	8.62	2.54		0.10		1.27	0.53	2.02	7.92

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC- TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

9. REMARKS  
 \* An estimated 75% of NDAs require Methods Validation @ approx. 105 Hours. \*\* Includes Microbiologists on Inspections.  
 \*\*\* NRL analyzes profile DSCs in NE & SE Regions. FCC analyzes profile DSCs in CE, SW AND PA Regions.  
 \*\*\*\* Micro Meth. Val.105 hrs NRL; 525 HRS DEN LAB \*\*\*\*\* Radpharm 1180 Hrs WEAC; 1200 Hrs Phi-lab  
 Transdermal testing \*\*\*\*\* Meth. Valid DSAs : See Servicing Laboratory Table Appendix III.

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



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1. PROGRAM/ASSIGNMENT TITLE NDA Counter Terrorism	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46R845 *	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.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	O T H E R O P E R A T I O N S (Hours)
	TOTAL FIELD		1500							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		73							
	NEW YORK		129							
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		40							
	CHICAGO		81							
	CINCINNATI		40							
	DETROIT		73							
	MINNEAPOLIS		40							
	NEW JERSEY		194							
	PHILADELPHIA		153							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		121							
	FLORIDA		32							
	NEW ORLEANS		40							
	SAN JUAN		194							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		48							
	DENVER		48							
	KANSAS CITY		81							
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		65							
	SAN FRANCISCO		40							
	SEATTLE		8							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS		1500							
	CONVERSION FACTOR		500							
	TOTAL OPERATIONAL FTEs		3.00							

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
 Use CT PAC 46R845 ONLY when specific CT work is performed,  
 otherwise use related Program PAC's e.g. 46832.  
 Hours spread in same porportion to planned domestic inspections in 46832.



1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.	
5. PROGRAM JUSTIFICATION Bioequivalence studies are conducted mainly by private and university affiliated contract laboratories. Previous inspections noted deviations from protocols, poor recordkeeping, inadequate controls over test subjects, poor analytical procedures and fraud. Results of bioequivalence inspections have a direct relationship to approvability of NDA and ANDA applications.	
6. FIELD OBLIGATIONS Conduct the inspections and forward the reports directly to the Division of Scientific Investigations, CDER.	
7a. ESTABLISHMENTS TO BE SELECTED <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 In Vivo Bioequivalence (Pre-Approval)				2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDA INSP EC- TIONS	1 NDA INSP EC- TIONS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	35	7							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK	3	1							
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	6	1							
	CHICAGO	1								
	CINCINNATI	2	2							
	DETROIT	2								
	MINNEAPOLIS	1								
	NEW JERSEY	1								
	PHILADELPHIA	1								
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2	1							
	FLORIDA	3	1							
	NEW ORLEANS									
	SAN JUAN	1								
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	4	1							
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	2								
	SAN FRANCISCO	5								
	SEATTLE	1								
	PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		86.0	86.0							
TOTAL HOURS		3010	602							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		3.31	0.66							
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY- TICAL		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification for related assignments. An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 95%, PDUFA 48001A (NDA) 5%.										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Foreign Inspections (48001/A)-FY 2003	<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> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> Conduct the inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.	
<b>7a. ESTABLISHMENTS TO BE SELECTED:</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>	

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 NDA &, ANDA *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDA INSP EC- TION S PDUFA	1 ANDA INSP EC- TION S	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>	44	10							
	HEADQUARTERS	3								
NE	REGIONAL STAFF									
	NEW ENGLAND	3								
	NEW YORK	2								
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3								
	CHICAGO	1	2							
	CINCINNATI	2								
	DETROIT	2								
	MINNEAPOLIS	1								
	NEW JERSEY	1	1							
	PHILADELPHIA	2	2							
FORENSIC CHEM. CTR										
SW	REGIONAL STAFF									
	ATLANTA	4								
	FLORIDA	5	2							
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS	2								
	DENVER	1								
	KANSAS CITY	2	1							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2								
	SAN FRANCISCO	3								
	SEATTLE	5	2							
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		60.0	91.0							
TOTAL HOURS		2640	910							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		2.93	1.00							
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC- TION AL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY- TICAL		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS *All Foreign Inspections are planned in PPS 48 under PAC 48001 * Report In Vivo Bioequivalence(48001, 48001A), Clinical Investigators(48811), and GLPs(48808 and PDUFA) under their respective PACs. ** Report hours used under appropriate PAC. Report foreign inspections under the operation code 11.										

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Nonclinical Laboratory)	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 assure compliance with current Good Laboratory Practice Regulations (21 CFR 58) by nonclinical laboratories and to assure validity of data through associated data audits.	
5. PROGRAM JUSTIFICATION Animal Studies are vital prerequisites to human clinical trials of drugs and other FDA regulated products. Past experience has shown serious deficiencies in the conduct of nonclinical laboratories in recordkeeping, adherence to study protocol, and in some cases fraudulent practices.	
6. FIELD OBLIGATIONS Conduct the inspections and forward EIRs directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. ESTABLISHMENTS TO BE SELECTED: <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 Presence and concentration of test article feed mixture used in the study audited. CDER will specify in the assignment when samples are to be collected and analyzed.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Use methodology prescribed in protocol or actually used in nonclinical laboratory.	

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48					
3. PROGRAM/ASSIGNMENT CODE(S) 48808			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 National Experts INV HRS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	52	590							
NE	HEADQUARTERS		590							
	REGIONAL STAFF									
	NEW ENGLAND	4								
	NEW YORK	3								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	5								
	CHICAGO	2								
	CINCINNATI	4								
	DETROIT	4								
	MINNEAPOLIS	1								
	NEW JERSEY	7								
	PHILADELPHIA	3								
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2								
	FLORIDA	1								
	NEW ORLEANS	1								
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	2								
	DENVER	2								
	KANSAS CITY	2								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3								
	SAN FRANCISCO	3								
	SEATTLE	3								
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		84.3								
TOTAL HOURS		4384	590							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		4.82	0.65							
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03	
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY TICAL			
PHYSICIST				MILK/FOOD SPEC						
ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS										
Resources planned for inspections may also be used for DSCs. Assignments issued by the Center will contain designations for coverage under PDUFA when assignments identify data audits of studies submitted in NDAs.										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Institutional Review Board (48809)-FY 2003	<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> To assure the quality and integrity of institutional review boards (21 CFR 56, 21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.	
<b>5. PROGRAM JUSTIFICATION</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>6. FIELD OBLIGATIONS</b> Conduct inspections of IRBs which may be evaluation of human drugs studies and forward the reports to the Division of Scientific Investigations, CDER.  Assist in presentation of IRB workshops.	
<b>7a. ESTABLISHMENTS TO BE SELECTED</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>	

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board (PDUFA) Radioactive Drug Research Committee (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S)  48809	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS  11.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 IRB INSPECTIONS	1 RDRC INSPECTIONS						
	<b>TOTAL FIELD</b>	<b>198</b>							
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	15							
	NEW YORK	14							
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	19							
	CHICAGO	14							
	CINCINNATI	12							
	DETROIT	12							
	MINNEAPOLIS	14							
	NEW JERSEY	5							
	PHILADELPHIA	4							
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	13							
	FLORIDA	15							
	NEW ORLEANS	5							
	SAN JUAN	2							
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS	10							
	DENVER	1							
	KANSAS CITY	7							
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	19							
	SAN FRANCISCO	12							
	SEATTLE	5							
	PACIFIC REGIONAL LAB (SW)								
PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	51.0							
	TOTAL HOURS	10098							
	CONVERSION FACTOR	910							
	TOTAL OPERATIONAL FTES	11.10							

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
 Resources in the Radioactive Drug Research Committee (RDRC, PAC 48809A) have been collapsed into the Institutional Review Board (IRB, PAC 48809) program.

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

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations and Monitors (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48					
3. PROGRAM/ASSIGNMENT CODE(S) 48810			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.9			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY	1 I N S P E C T I O N S	2 I N V E S T 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)
	<b>TOTAL FIELD</b>	<b>32</b>								
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	2								
	NEW YORK	4								
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1								
	CHICAGO	1								
	CINCINNATI	1								
	DETROIT	1								
	MINNEAPOLIS	1								
	NEW JERSEY	3								
	PHILADELPHIA	3								
	FORENSIC CHEM. CTR									
SW	REGIONAL STAFF									
	ATLANTA	1								
	FLORIDA	1								
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS	3								
	DENVER									
	KANSAS CITY	2								
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	5								
	SAN FRANCISCO	3								
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		82.0								
TOTAL HOURS		2624								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTES		2.88								
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC-TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY-TICAL		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators	2. PMS 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 records and whether clinical investigators have complied with regulations (21 CFR 312).	
5. PROGRAM JUSTIFICATION Clinical studies necessary for FDA evaluation of new drug applications are assessed for scientific accuracy, veracity, and regulatory compliance. Past experience has demonstrated deficiencies ranging from carelessness to fraudulent submissions.	
6. FIELD OBLIGATIONS Conduct the inspections and forward EIRs directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. ESTABLISHMENTS TO BE SELECTED <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 Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48					
3. PROGRAM/ASSIGNMENT CODE(S) 48811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 26.8				
R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC TIONS	National Experts INV HRS	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
TOTAL FIELD		344	280							
HEADQUARTERS			280							
NE	REGIONAL STAFF									
	NEW ENGLAND		19							
	NEW YORK		13							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		21							
	CHICAGO		12							
	CINCINNATI		22							
	DETROIT		8							
	MINNEAPOLIS		12							
	NEW JERSEY		6							
	PHILADELPHIA		17							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		28							
	FLORIDA		33							
	NEW ORLEANS		18							
	SAN JUAN		1							
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS		40							
	DENVER		11							
	KANSAS CITY		23							
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES		35							
	SAN FRANCISCO		10							
	SEATTLE		15							
	PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		70.0								
TOTAL HOURS		24080	280							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		26.46	0.31							
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		INSP EC TIONAL	10/01/02	09/30/03	
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR					VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	ANALY TICAL			
	PHYSICIST				MILK/FOOD SPEC					NAT'L EXPERT
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC					OTHER
9. REMARKS										



1. PROGRAM/ASSIGNMENT TITLE New Drug (Prescription) Not Covered by Approved NDAs	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  To establish uniform procedures for removal from the market of all prescription drug products described by FDA to be new drugs not covered by approved New Drug Applications; complete Category VII of Compliance Policy Guide (CPG) 7132c.02 which are not in the earlier categories of this CPG; and any drug products in prior categories remaining for regulatory action.	
5. PROGRAM JUSTIFICATION  The Drug Amendments of 1962 to the FD&C Act require that all marketed drug products be safe and effective. Judge June L. Green of the U.S. District Court for the District of Columbia ruled (July 29, 1975) that an approved new drug application for prescription drugs which the FDA has previously declared to be a new drug within the meaning of 21 USA 321(p) is required in order for the drug product to be introduced into interstate commerce. Therefore, those without approved applications must be withdrawn from the market. This compliance program is responsive to this mandate.	
6. FIELD OBLIGATIONS  -Assign District Coordinator, whose name shall be supplied to HFD-310. -Identify all drug products which require regulatory letters and prepare such letters to be signed by the District Director. -Maintain records of all activities under this program, including a list of drug products voluntarily removed from the market in compliance with the warning letters, products removed by recall, etc. -Initiate regulatory actions, where appropriate, to assure compliance with program. Submit monthly report to HFD-310.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Prescription Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, and 60-66
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Not Covered by Approved NDAs					2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52					
3. PROGRAM/ASSIGNMENT CODE(S) 52002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL.	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 TRAINING (Hours)
	<b>TOTAL FIELD</b>		<b>50</b>	<b>1500</b>	<b>40</b>					
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3	83	2						100
	NEW YORK	6	176	5						214
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	2	59	2						71
	CHICAGO	2	69	2						83
	CINCINNATI	1	39	1						48
	DETROIT	2	69	2						83
	MINNEAPOLIS	1	25	1						30
	NEW JERSEY	7	210	4						256
	PHILADELPHIA	3	93	2						113
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	4	113	3						137
	FLORIDA	2	59	2						71
	NEW ORLEANS	1	25	1						30
	SAN JUAN	8	225	5						274
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	1	34	1						42
	DENVER	1	39	1						48
	KANSAS CITY	2	69	2						83
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2	69	2						83
	SAN FRANCISCO	1	39	1						48
	SEATTLE	1	5	1						6
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		30.0		5.0						
TOTAL HOURS		1500	1500	200						1820
CONVERSION FACTOR		910	910	910						910
TOTAL OPERATIONAL FTEs		1.65	1.65	0.22						2.00
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
CHEMIST	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03		
MICROBIOLOGIST	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN					
ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03		
PHYSICIST			MILK/FOOD SPEC							
ENTOMOLOGIST	OTHER		SHELLFISH SPEC		OTHER					
9. REMARKS										

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

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

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1. PROGRAM/ASSIGNMENT TITLE ANDA Pre - Approval Inspections/Inv. Methods Validation - Domestic					2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52					
3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 34.9				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	3	7	7	7	9
		ANDAs TO INSPECT Domestic *	CHEMIST INSPECT. (Hours) **	NEW HIRE INVESTIGATOR INV. Hrs. ON INSPECTIONS DOMESTIC	DOMESTIC SAMPLE COLL ***	PROFILE/ PORTION OF DSCs FOR DDA ***	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ****	DOMESTIC SAMPLE ANALYSES BIOTEST (Chem) ****	DSAs (METH) (VALID) (Chem) (Hours) *	TRAINING HOURS
TOTAL FIELD		150	2311	1000	150	(50)	50	50	145	2640
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	4		26	4					70
	NEW YORK	23		151	23					405
	REGIONAL LAB		775				19	19	30	
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	8		53	8					141
	CHICAGO	10		66	10					176
	CINCINNATI	5		33	5					88
	DETROIT	6	154	40	6				19	106
	MINNEAPOLIS	3		20	3					53
	NEW JERSEY	24		158	24					422
	PHILADELPHIA	14	538	92	14				40	246
	FORENSIC CHEM. CTR		154				31	31		
SE	REGIONAL STAFF									
	ATLANTA	9		59	9					158
	FLORIDA	5		33	5					88
	NEW ORLEANS	3		20	3					53
	SAN JUAN	14	116	92	14				13	246
	REGIONAL LAB		193						18	
SW	REGIONAL STAFF									
	DALLAS	2		19	2					35
	DENVER	3	73	20	3				13	53
	KANSAS CITY	8	77	53	8					141
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	7		46	7					123
	SAN FRANCISCO	2	77	19	2					36
	SEATTLE									
	PACIFIC REGIONAL LAB- SW		77						5	
	PACIFIC REGIONAL LAB - NW		77						7	
HOURS PER OPERATION		65.0			3.0		50.0	30.0	105.0	
TOTAL HOURS		9750	2311	1000	450		2500	1500	15225	2640
CONVERSION FACTOR		910	910	500	910		1180	1180	1180	910
TOTAL OPERATIONAL FTEs		10.71	2.54	2.00	0.49		2.12	1.27	12.90	2.90
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
* An estimated 75% of ANDAs will require methods validation @ 105 hours each.										
**Includes microbiologists on inspections. *** DSCs for profile/biotest analyses.										
Includes 50 Profile DSCs to be analyzed by DDA (HFH-300). **** NRL-analyzes profile/biotest DSCs collected in NE & SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.										

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

ANDA Pre - Approval Inspections/Investigations (Methods Validation) - Foreign					2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52					
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B ,52832C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	3	5	6	8	8	8
		INSP CTIONS (Foreign)	CHEMIST INSP. (Hours) (Foreign) **	NEW HIRE INVESTIGATORS INVEST. HRS. ON INSPS. (FOREIGN)	IMPORT SAMPLE COLL ***	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	IMPORT SAMPLE ANALYSES PROFILE (Chem) ****	IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****	IMPORT SAMPLE ANALYSES METH. VALID. ****
	TOTAL FIELD	80	1771	2000	140			70	70	15
NE	HEADQUARTERS	7								
	REGIONAL STAFF									
	NEW ENGLAND	3		82	5					
	NEW YORK	9		247	18					
	REGIONAL LAB WEAC		386					70	70	15
CE	REGIONAL STAFF									
	BALTIMORE	3		82	5					
	CHICAGO	3		82	7					
	CINCINNATI	3		82	5					
	DETROIT	5	169	137	9					
	MINNEAPOLIS	1		27	3					
	NEW JERSEY	12		329	28					
	PHILADELPHIA FORENSIC CHEM. CTR	3	539	82	6					
SE	REGIONAL STAFF									
	ATLANTA	4		110	7					
	FLORIDA	3		82	5					
	NEW ORLEANS	2		55	4					
	SAN JUAN REGIONAL LAB	5	184	138	8					
SW	REGIONAL STAFF									
	DALLAS	2		55	5					
	DENVER	3	77	82	5					
	KANSAS CITY	5		137	5					
	Southwest Import District REGIONAL LAB		77							
PA	REGIONAL STAFF									
	LOS ANGELES	5		137	10					
	SAN FRANCISCO	1		27	2					
	SEATTLE	1		27	3					
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW		77 131							
HOURS PER OPERATION		55.0			3.0			30.0	15.0	50.0
TOTAL HOURS		4400	1771	2000	420			2100	1050	750
CONVERSION FACTOR		910	910	500	910			1180	1180	1180
TOTAL OPERATIONAL FTEs		4.84	1.95	4.00	0.46			1.78	0.89	0.64
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
* Report as follow: Insp./Chem on Insp. under new foreign operation code 11 Pac Code 52832; Meth. Valid. under PAC 52832; Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C. ** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers. **** NRL analyzes all Profile/Biotest ISCs and methods Validation ISAs.										

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1. PROGRAM/ASSIGNMENT TITLE ANDA Counter Terrorism					2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52						
3. PROGRAM/ASSIGNMENT CODE(S) 52R845			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 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>				<b>1500</b>						
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND			40							
	NEW YORK			230							
	REGIONAL LAB WEAC										
CE	REGIONAL STAFF										
	BALTIMORE			80							
	CHICAGO			100							
	CINCINNATI			50							
	DETROIT			60							
	MINNEAPOLIS			30							
	NEW JERSEY			240							
	PHILADELPHIA			140							
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA			90							
	FLORIDA			50							
	NEW ORLEANS			30							
	SAN JUAN			140							
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS			20							
	DENVER			30							
	KANSAS CITY			80							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES			70							
	SAN FRANCISCO			20							
	SEATTLE										
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION											
TOTAL HOURS				1500							
CONVERSION FACTOR				500							
TOTAL OPERATIONAL FTEs				3.00							
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03	
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03	
	PHYSICIST				MILK/FOOD SPEC						
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS Use CT PAC 52R845 ONLY when specific CT work is performed, otherwise use related Program PAC's e.g. 52832 Hours spread in same porportion to planned domestic inspections in 52832.											



<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 ADR reporting requirements of 21 CFR 310.305 ,314.80 and 318.98. Regulatory and/or administrative follow-up will be coordinated between the field and headquarters in cases where significant violations of reporting regulations or deficiencies in following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by responsible parties, including applicants, manufacturers, packers and distributors.	
<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 ADR information is essential to the safety evaluation of marketed drug products. It enables FDA to act when information concerning the use and safety of marketed drug products suggests that new labeling, market withdrawal or other action is required.	
<b>6. FIELD OBLIGATIONS</b> Conduct inspections and forward reports directly to the Division of Prescription Drug Compliance and Surveillance/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up. Issue regulatory letters as approved by DPDCS. Notify DPDCS of findings from other inspectional program activities which are relevant to ADR reporting.	
<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 type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.0				
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		1 INSPEC- TIONS  DOMESTIC	1 INSPEC- TIONS  FOREIGN	2 MEDICAL ERRORS 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 MEDICAL ERRORS training (Hours)
	TOTAL FIELD		85	26	1500						2730
NE	HEADQUARTERS			5							
	REGIONAL STAFF										
	NEW ENGLAND		3	1	83						152
	NEW YORK		5	2	176						321
	REGIONAL LAB WEAC										
CE	REGIONAL STAFF										
	BALTIMORE		4	1	59						107
	CHICAGO		5	1	69						125
	CINCINNATI		1	1	39						71
	DETROIT			1	69						125
	MINNEAPOLIS		1		25						45
	NEW JERSEY		15	2	210						384
	PHILADELPHIA		8	1	93						170
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA		7	1	113						205
	FLORIDA		5	1	59						107
	NEW ORLEANS				25						45
	SAN JUAN		2	2	225						410
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS		1	2	34						62
	DENVER		1	1	39						71
	KANSAS CITY		3	1	69						125
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES		10	2	69						125
	SAN FRANCISCO		10	1	39						71
SEATTLE		4		5						9	
PACIFIC REGIONAL LAB - NW											
PACIFIC REGIONAL LAB - SW											
HOURS PER OPERATION			67.0	60.0							
TOTAL HOURS			5695	1560	1500						2730
CONVERSION FACTOR			910	910	500						910
TOTAL OPERATIONAL FTEs			6.26	1.7	3.0						3.0
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE				
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END		
	CHEMIST		PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03	
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL			
	PHYSICIST				MILK/FOOD SPEC						
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS											
*Report both Domestic and Foreign inspections under 53001A for Center-Initiated and 53001B for District -Initiated. <b>Foreign inspections must be reported under foreign operation code 11.</b>											

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1. PROGRAM/ASSIGNMENT TITLE Epidemiology Counter Terrorism	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidimiology:Human Drugs
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3. PROGRAM/ASSIGNMENT CODE(S) 53R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 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)
	<b>TOTAL FIELD</b>		<b>1500</b>							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		83							
	NEW YORK		176							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		59							
	CHICAGO		69							
	CINCINNATI		39							
	DETROIT		69							
	MINNEAPOLIS		25							
	NEW JERSEY		211							
	PHILADELPHIA		93							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		112							
	FLORIDA		59							
	NEW ORLEANS		25							
	SAN JUAN		225							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		34							
	DENVER		39							
	KANSAS CITY		69							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES		69							
	SAN FRANCISCO		39							
	SEATTLE		5							
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION										
TOTAL HOURS			1500							
CONVERSION FACTOR			500							
TOTAL OPERATIONAL FTEs			3.00							

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
Use CT PAC 53R845 ONLY when specific CT work is performed, otherwise use related Program PAC's e.g. 53001A,B.



1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  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.	
5. PROGRAM JUSTIFICATION  The Drug Process Inspections program is FDA's primary means for evaluating the conditions under which drug products are manufactured, tested, packaged and held.	
6. FIELD OBLIGATIONS  The field will conduct drug process inspections and maintain profiles or other monitoring systems which will insure that each drug firm receives the biennial inspection coverage provided for in the inspectional strategy.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66
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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

Drug Process Inspections - Domestic					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 105.8(99.0)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS NON GAS *	CDER IDENTIFIED HIGH RISK FIRMS **	1 CHEMISTS INSP- CTIONS HOURS	1 MICRO INSP- CTIONS (Hours)	3 DOMESTIC SAMPLE COLL **	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	9 Training CERTIFICATION HOURS ***	9 Training POST APPROVAL AUDIT HOURS ****
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	58	(32)			20			171	102
	NEW YORK	107	(29)			35			310	213
	REGIONAL LAB WEAC			1222	462		21	11		
CE	REGIONAL STAFF									
	BALTIMORE	38	(5)			13			106	71
	CHICAGO	72	(12)			24			194	82
	CINCINNATI	42	(5)			14			158	47
	DETROIT	50	(19)	701		17	21		160	82
	MINNEAPOLIS	41	(11)			14			150	29
	NEW JERSEY	150	(32)			51			307	254
	PHILADELPHIA FORENSIC CHEM. CTR	69	(23)	2168		23	37		169	111
SE	REGIONAL STAFF									
	ATLANTA	67	(34)			23			217	135
	FLORIDA	55	(19)			19			193	70
	NEW ORLEANS	38	(17)			13			142	28
	SAN JUAN	83	(29)	960		27	10		213	272
	REGIONAL LAB			615	616		21	18		
SW	REGIONAL STAFF									
	DALLAS	61	(25)			21			240	41
	DENVER	43	(17)	615	75	15	21	6	199	46
	KANSAS CITY	59	(15)	528		20			192	83
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	100	(32)			34			300	83
	SAN FRANCISCO	30	(9)		385	10		5	140	45
	SEATTLE	22	(7)			7			79	26
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW			90 675				19		
HOURS PER OPERATION		58.0				4.0	39.0	21.0		
TOTAL HOURS		68730		7594	1538	1600	5850	840	3640	1820
CONVERSION FACTOR		910		910	910	910	1180	1180	910	910
TOTAL OPERATIONAL FTEs		75.53		8.35	1.69	1.76	4.96	0.71	4.00	2.00
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
*General Stratification for non-gas firms- Rx manufs.& control labs every 2 yrs.; non-rx manufs. every 3 yrs; repacker/reblabler every 4 yrs.										
** HIGH Risk RX drugs, sterile drugs new registerants identified by CDER for performance goal. Subset of 1st column.										
Gas firms are under a separate worksheet 56-5 . ** DSCs not analyzed are doc. samples. Training/Cert. Audit hrs report under 56002.										
****Report post approval audit invest.hrs. under 46843. See 56R845 for additional resources if not used for CT.										

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1. PROGRAM/ASSIGNMENT TITLE <b>DRUG Process Inspections- Domestic (Gas Manufacturer)</b>				2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>						
3. PROGRAM/ASSIGNMENT CODE(S) <b>56002E</b>			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS <b>(6.8)</b>			
R E G I O N	6.	1		3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	PLANNED INSPECTIONS MEDICAL GAS	FIRMS WITH MULTIPLE GAS PRODUCTS TO INSPECT	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLE ANALYSES	IMPORT SAMPLES ANALYSES	TRAINING
	<b>TOTAL FIELD</b>	<b>175</b>	<b>(97)</b>							<b>1820</b>
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	13	(8)							135
	NEW YORK	8	(7)							83
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	8	(4)							83
	CHICAGO	8	(4)							83
	CINCINNATI	13	(8)							135
	DETROIT	11	(5)							114
	MINNEAPOLIS	7	(4)							73
	NEW JERSEY	5	(3)							52
	PHILADELPHIA	13	(7)							135
FORENSIC CHEM. CTR										
	REGIONAL STAFF									
	ATLANTA	12	(6)							125
	FLORIDA	9	(6)							94
	NEW ORLEANS	13	(7)							135
	SAN JUAN	1	(1)							10
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	16	(8)							166
	DENVER	4	(2)							42
	KANSAS CITY	12	(6)							125
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	9	(6)							94
	SAN FRANCISCO	5	(2)							52
SEATTLE	8	(3)							84	
	PACIFIC REGIONAL-SW									
	PACIFIC REGIONAL-NW									
	HOURS PER OPERATION	25.0								
	TOTAL HOURS	4375								1820
	CONVERSION FACTOR	910								910
	TOTAL OPERATIONAL FTEs	4.81								2.00
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
* Total number of planned gas inspections in the Program for 2003. Resources are targeted for 50 % of the inventory of known medical gas firms with multiple products. Remaining resources are spread based on the inventory of single product gas manufacturers. It is expected that some coverage of the medical gas inventory will be accomplished through outsourcing.										

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections/Equivalence Evaluations	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  Non-MRA 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.  To implement the US-EC Mutual Recognition Agreement, Pharmaceutical Annex as published in Federal Register of November 18, 1998. During the transition or confidence building period of the MRA, FDA needs to undertake a number of operations to assess the equivalence of the EC and the 15 Member States of the EU as it relates to good manufacturing practice inspections and the resultant establishment inspection reports. FDA also needs to prepare for and participate in the EU's evaluation of the US system.	
5. PROGRAM JUSTIFICATION  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.  The Food and Drug Administration Modernization Act of 1997 modified Section 803 of the Food Drug and Cosmetic Act to require the Secretary to provide support to the Office of the United States Trade Representative to move toward the acceptance of mutual regulation of good manufacturing practices between the EU and the US.	
6. FIELD OBLIGATIONS  For Non-MRA work, the field will conduct drug process inspections and maintain profiles of foreign drug manufacturers. For the MRA, ORA will participate in the assessment of the EU and the EU's evaluation of the US system. Operational personnel will be used to review the other parties legal and regulatory system for pharmaceutical good manufacturing practice inspection and report preparation. This will involve a review of all documents relating to laws, regulations, procedures, etc.; on-site system evaluations of the regulatory authorities inspectional and analytical systems; and, verifications of the proper implementation of those requirements through audit inspections. Workplan allocations were modeled after the ranking of obligations for the domestic industry.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

FY 2003 ORA Workplan

July 1, 2002

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections/ Equivalence Evaluations	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 , 56R841 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **	1 MRA INSPS. FOR Invest- igators ***	1 MRA INSP. HRS. FOR Chemists/ Microbiols. ** ***	9 MRA Invest- igator OTHER OPERATIONS HRS. ***	9 MRA Chemists/ Microbiols. OTHER OPERATIONS HRS. ***
	<b>TOTAL FIELD</b>	<b>116</b>	<b>3646</b>	<b>6</b>	<b>336</b>	<b>2002</b>	<b>1062</b>
NE	HEADQUARTERS	6				760	
	REGIONAL STAFF						
	NEW ENGLAND	5					
	NEW YORK	9		2		162	
	REGIONAL LAB		260		112		302
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE	4					
	CHICAGO	9				336	
	CINCINNATI	2					
	DETROIT	8					
	MINNEAPOLIS	3					
	NEW JERSEY	10		2		260	
PHILADELPHIA	7	1315		112	260	202	
SE	FORENSIC CHEM. CTR		120				
	REGIONAL STAFF						
	ATLANTA	6					
	FLORIDA	4					
	NEW ORLEANS	4					
SW	SAN JUAN	9	539				
	REGIONAL LAB		347		112		152
	REGIONAL STAFF						
	DALLAS	5		2		112	
	DENVER	3	327				104
PA	KANSAS CITY	10	385			112	
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB		78				
	REGIONAL STAFF						
	LOS ANGELES	7					
PA	SAN FRANCISCO	4					
	SEATTLE	1					
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW		275				302
HOURS PER OPERATION		60		86			
TOTAL HOURS		6960	3646	516	336	2002	1062
CONVERSION FACTOR		910	910	910	910	910	1180
TOTAL OPERATIONAL FTEs		7.65	4.01	0.57	0.37	2.20	0.90

7. PERSONNEL TYPES REQUIRED						8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END
<input checked="" type="checkbox"/>	CHEMIST		<input checked="" type="checkbox"/>	INVESTIGATOR		INSPEC- TIONAL	10/01/02	09/30/03
<input checked="" type="checkbox"/>	MICROBIOLOGIST			INSPECTOR				
	ENGINEER(ANALYST)			ENGINEER (INV)	<input checked="" type="checkbox"/>	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST			OTHER				

9. REMARKS  
 \* Foreign inspections (DPI) are now planned under 56002 and should be reported under operation 11 PACs 56002A, B, C, D, E, F, 56832. \*\* Time planned in these columns may be used by chemists or microbiologists. \*\*\* Report Equivalence Evaluations under PAC 56R841 to include on site inspectional audits and technical assistance at foreign facilities by FDA personnel; and management of internal audits at U.S. facilities by the European Union.

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES  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 toward 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.			
5. PROGRAM JUSTIFICATION  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.			
6. FIELD OBLIGATIONS  To collect samples and perform laboratory examinations. Upon assignment form CDER, conduct inspections to obtain specific information, such as analytical results, production data, and formulation.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56 and 60-66	
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 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.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008A, C, D, G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 17.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	7	7	7	7	7	7
		INVEST- IGATIONS *	CHEM ON INVEST. (Hours)	DOMESTIC SAMPLES ANALYZED STERILITY *****	Domestic SAMPLES ANALYZED (Chem) Hours **	DOMESTIC SAMPLES ANALYZED (Chem) (WEAC) ***	DOMESTIC SAMPLES ANALYZED (Micro) (WEAC) ***	DOMESTIC SAMPLES ANALYZED (Chem) (FCC) ****	DOMESTIC SAMPLES ANALYZED (Chem) (NRL) *****
	<b>TOTAL FIELD</b>	<b>350</b>	<b>318</b>	<b>81</b>	<b>434</b>	<b>25</b>	<b>10</b>	<b>5</b>	<b>38</b>
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	19							
	NEW YORK	40							
	REGIONAL LAB			31					38
	WEAC		318			25	10		
CE	REGIONAL STAFF								
	BALTIMORE	14							
	CHICAGO	16							
	CINCINNATI	9							
	DETROIT	16							
	MINNEAPOLIS	7							
	NEW JERSEY	40							
	PHILADELPHIA	22				56			
	FORENSIC CHEM. CTR								5
SE	REGIONAL STAFF								
	ATLANTA	26							
	FLORIDA	14							
	NEW ORLEANS	9							
	SAN JUAN	50				57			
	REGIONAL LAB				57				
SW	REGIONAL STAFF								
	DALLAS	8							
	DENVER	9		20		74			
	KANSAS CITY	16				40			
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES	16							
	SAN FRANCISCO	10		30					
	SEATTLE	9							
	PACIFIC REGIONAL LAB - SW					70			
	PACIFIC REGIONAL LAB - NW				80				
HOURS PER OPERATION				25	30.0	36.0	24.0	230.0	50.0
TOTAL HOURS		350	318	2025	13020	900	240	1150	1900
CONVERSION FACTOR		910	910	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.38	0.35	1.72	11.03	0.76	0.20	0.97	1.61

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
 \* A Block of investigational hours are planned for inspections/domestic sample collections as needed.  
 \*\* DSAs analytical module may vary per drug product.\*\*\* Radioactive drugs-approx 10 of the 25 DSAs (Chem) tested for micro.  
 \*\*\*\*\* Counterfeit bulk drug analysis. \*\*\*\*\* Quality test bulk drug analysis. \*\*\*\*\* Sterility - testing.  
 Report ISCs and ISAs of finished dosage forms under 56008H.

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 47.7 (21.1)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2 IMPORT ENTRY REVIEW HOURS OPER 14	2 IMPORT FILER EVAL. HOURS OPER 95	2 REFUSAL Follow-Up HOURS	9 IMPORT LABEL EXAMS	9 TRAINING IMPORT ALERT 66-66 HOURS	6 IMPORT FIELD EXAMS	4 IMPORT SAMPLE COLLECT- IONS	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD		17100	1130	360	1125	1820	1600	60	60
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		450	47	8	25	37	32	2	
	NEW YORK		5100	191	80	387	626	550	20	
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		450	43	40	28	45	40	2	
	CHICAGO		850	55	8	57	92	81	3	
	CINCINNATI		550	31	8	46	74	65	2	
	DETROIT		950	35	8	80	130	114	4	
	MINNEAPOLIS		200	28	8	6	11	9		
	NEW JERSEY									
	PHILADELPHIA		650	22	8	43	69	60	2	
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		600	72	8	43	70	62	2	
	FLORIDA		575	84	8	34	55	49	2	
	NEW ORLEANS		2950	32	8	151	245	215	8	
	SAN JUAN		550	10	64	29	48	42	2	
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
SOUTHWEST IMPORT DISTRICT		1100	229	32	62	101	89	3		
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		1200	133	24	80	130	114	4	
	SAN FRANCISCO		425	57	16	24	39	35	2	
	SEATTLE		500	61	32	30	48	43	2	
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW									60	
HOURS PER OPERATION					1.0		0.3	2.0	25.0	
TOTAL HOURS		17100	1130	360	1125	1820	480	120	1500	
CONVERSION FACTOR		1200	910	910	910	910	910	910	1180	
TOTAL OPERATIONAL FTEs		14.25	1.24	0.40	1.24	2.00	0.53	0.13	1.27	
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC- TIONAL	10/01/02	09/30/03	
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03	
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER				
9. REMARKS										
* PAC Reporting: Entry Reviews 56R833 (electronic and manual); Filer Evaluations 99R833; Follow-Up to Refusals 56R824, 63R824; Import Label Reviews, Import Field Exams and Import Alert Hours under PACs 52002, 56008H, 56014/A, 63001; Note: Additional resources planned for imports under 56R845 Counter-terrorism.										

FY 2003 ORA Workplan

July 1, 2002

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Active Pharmaceutical Ingredients (Domestic Import)				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56008J, 56008K *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (26.6)			
R E G I O N	6.	2	3	7	7	9			
	DISTRICT/ SPECIALIZED LABORATORY	INV. HOURS FOR IMPORTERS	DOMESTIC IMPORT SAMPLE COLLECTIONS QUALITY	DOMESTIC IMPORT ANALYSES CHEM HRS. QUALITY (CENTER)	DOMESTIC IMPORT ANALYSES CHEM FINGERPRT.	TRAINING DOMESTIC IMPORT INVEST. HOURS			
	<b>TOTAL FIELD</b>	<b>3730</b>	<b>90</b>	<b>80</b>	<b>51</b>	<b>5460</b>			
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND		3			270			
	NEW YORK	1400	21			1365			
	REGIONAL LAB			54	20				
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE		3			270			
	CHICAGO	500	6			270			
	CINCINNATI		9			270			
	DETROIT	300							
	MINNEAPOLIS								
	NEW JERSEY		9			1385			
	PHILADELPHIA	230	15			270			
FORENSIC CHEM. CTR					24				
SE	REGIONAL STAFF								
	ATLANTA		6						
	FLORIDA	100	3			270			
	NEW ORLEANS	500	3						
	SAN JUAN	500	9		7	910			
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY		3						
	SOUTHWEST IMPORT DISTRICT	200							
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL STAFF								
	LOS ANGELES					180			
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW				26				
HOURS PER OPERATION			4.0	90.0	231.0				
TOTAL HOURS		3730	360	7200	11781	5460			
CONVERSION FACTOR		910	910	1180	1180	910			
TOTAL OPERATIONAL FTEs		4.10	0.40	6.10	9.98	6.00			
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR		
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN	INSPEC-TIONAL 10/01/02      09/30/03	
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL 10/15/02      09/30/03	
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		
9. REMARKS									
* Report BULK DISCs and DISAs from domestic manufacturers as follows: Quality 56008J; Fingerprinting 56008K.									
<b>ALL RESOURCES IN PROGRAM ARE FOR THE API SURVEY.</b>									
<b>ALL API COLLECTIONS SHOULD BE REPORTED UNDER THIS PAC.</b>									
Some sample collections to be analyzed by St. Louis Lab. Some samples will be analyzed for both quality and fingerprinting.									

1. PROGRAM/ASSIGNMENT TITLE Methods Validation Assessment	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To validate selected proposed or official compendial methods identified by Compendial Operations Branch, Center for Drug Evaluation and Research (CDER).	
5. PROGRAM JUSTIFICATION In order to assure the proposals made by the USPC in the Pharmacopeial Forum or official in the USP/NF are suitable for Regulatory purposes and applicable to multi-source drug products, a limited validation will be conducted.	
6. FIELD OBLIGATIONS Collect samples (when requested by CDER) and validate proposed or official methods.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, 60-66
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	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation Assessment					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56020/56020A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 1.0				
R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	METHODS V A L I D A T I O N (Hours) C H E M
	<b>TOTAL FIELD</b>			50						933
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			3						
	NEW YORK			6						
	REGIONAL LAB WEAC									105
CE	REGIONAL STAFF									
	BALTIMORE			2						
	CHICAGO			2						
	CINCINNATI			1						
	DETROIT			2						
	MINNEAPOLIS			1						
	NEW JERSEY			7						
	PHILADELPHIA FORENSIC CHEM. CTR			3						295
SE	REGIONAL STAFF									
	ATLANTA			4						
	FLORIDA			2						
	NEW ORLEANS			1						
	SAN JUAN REGIONAL LAB			8						79 88
SW	REGIONAL STAFF									
	DALLAS			1						
	DENVER			1						133
	KANSAS CITY			2						88
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			2						
	SAN FRANCISCO			1						
	SEATTLE			1						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									44 101
HOURS PER OPERATION				4.0						
TOTAL HOURS				200						933
CONVERSION FACTOR				910						1180
TOTAL OPERATIONAL FTEs				0.22						0.79
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System - DQRS NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
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.	
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.	
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.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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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 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D (Chem)	IMP O R T S A M P L E S T O B E A N A L Y Z E D	T R A I N I N G (Hours)
	TOTAL FIELD	100	200	40				30		910
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	5	10	2						46
	NEW YORK	8	18	4						82
	REGIONAL LAB							5		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	3	6	1						25
	CHICAGO	5	10	2						45
	CINCINNATI	4	7	1						33
	DETROIT	5	10	2				4		43
	MINNEAPOLIS	5	9	2						41
	NEW JERSEY	8	15	3						69
	PHILADELPHIA	5	9	2				5		41
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	7	14	3						63
	FLORIDA	6	11	2						52
	NEW ORLEANS	4	8	2						36
	SAN JUAN	4	9	2				3		40
REGIONAL LAB							4			
SW	REGIONAL STAFF									
	DALLAS	7	13	3						61
	DENVER	3	7	1				5		31
	KANSAS CITY	5	11	2						48
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	10	22	4						100
	SAN FRANCISCO	4	7	1						33
	SEATTLE	2	4	1						21
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW							4			
HOURS PER OPERATION		25.0		4.0				35.0		
TOTAL HOURS		2500	200	160				1050		910
CONVERSION FACTOR		910	910	910				1180		910
TOTAL OPERATIONAL FTEs		2.75	0.22	0.18				0.89		1.00

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR			
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN	INSPEC TIONAL		
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	10/01/02	09/30/03	
	PHYSICIST				MILK/FOOD SPEC			ANALY TICAL	10/15/02	09/30/03
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
Note: Not all samples collected will be analyzed. Samples not analyzed are documentary samples.

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Monitor, investigate and take regulatory action, (including working jointly with state regulatory officials), on complaints involving pharmacy compounded drug products and pharmacy compounding operations that are in violation of applicable sections of the Federal Food, Drug, and Cosmetic Act (the Act).	
5. PROGRAM JUSTIFICATION While the pharmacy compounding law section 503A of the Act was recently struck down by the courts, the agency is still engaged In determining whether or not a pharmacy compounder and its compounded drug products comply with all other applicable sections of the Act. It continues to be FDA's policy to ensure the continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevents manufacturing under the guise of compounding. The agency needs to investigate pharmacy-compounding reports of illnesses associated with compounded drug products. In those cases where it is determined that exercising the agency's enforcement discretion in regard to pharmacy compounding is not warranted , the agency will consider regulatory action, where necessary, to address applicable violations of the Act.	
6. FIELD OBLIGATIONS Districts will conduct inspections and investigations, collect evidence, samples and develop cases in accordance with Assignments from HFD-330.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56 and 60-66
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	

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56D015 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	TRAINING (Hours)
	TOTAL FIELD		910							910
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			31						31
	NEW YORK			50						50
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE			42						42
	CHICAGO			31						31
	CINCINNATI			48						48
	DETROIT			41						41
	MINNEAPOLIS			37						37
	NEW JERSEY			26						26
	PHILADELPHIA			38						38
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA			62						62
	FLORIDA			70						70
	NEW ORLEANS			69						69
	SAN JUAN			80						80
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS			84						84
	DENVER			27						27
	KANSAS CITY			45						45
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			52						52
	SAN FRANCISCO			39						39
	SEATTLE			38						38
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS			910						910
	CONVERSION FACTOR			910						910
	TOTAL OPERATIONAL FTEs			1.00						1.00

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST	PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC TIONAL	10/01/02	09/30/03	
	MICROBIOLOGIST	BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN				
	ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03	
	PHYSICIST			MILK/FOOD SPEC					
	ENTOMOLOGIST	OTHER		SHELLFISH SPEC	OTHER				

9. REMARKS  
 \*A block of hours is planned for pharmacy compounding assignments. Please report under correct operation.  
 Block of hours includes sample collections and analyses if appropriate (DSAs and ISAs to Den Lab).  
 Import operations for compounding; time is planned under 56008H and reported as 56D015. Problem area Flags (PAFs)  
 have been added to FACTs for sample collections/analyses. DRT - Drug product Testing, DRA - Drug Ingredient Analysis

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Research	
6. FIELD OBLIGATIONS Accomplishment of goals of the individual research projects identified in Part IIA of the workplan. All research will be distributed in-house and/or published in the referred scientific literature.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS							
	<b>TOTAL FIELD</b>	<b>5414</b>							
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB	1800							
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT	602							
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA	1807							
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS	1205							
	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								
	TOTAL HOURS	5414							
	CONVERSION FACTOR	1205							
	TOTAL OPERATIONAL FTEs	4.49							

7. PERSONNEL TYPES REQUIRED						8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR			
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)			
	PHYSICIST				MILK/FOOD SPEC			
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC			
					RRHR	INSPEC- TIONAL		
					VETERINARIAN			
					NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03

9. REMARKS  
Additional research will be assigned later in the fiscal year.



1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R838, 56R831	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION																		
	TOTAL FIELD		10820																	
NE	HEADQUARTERS																			
	REGIONAL STAFF																			
	NEW ENGLAND																			
	NEW YORK																			
	REGIONAL LAB WEAC																			
CE	REGIONAL STAFF																			
	BALTIMORE																			
	CHICAGO																			
	CINCINNATI																			
	DETROIT																			
	MINNEAPOLIS																			
	NEW JERSEY																			
	PHILADELPHIA FORENSIC CHEM. CTR		10820																	
SE	REGIONAL STAFF																			
	ATLANTA																			
	FLORIDA																			
	NEW ORLEANS																			
	SAN JUAN REGIONAL LAB																			
SW	REGIONAL STAFF																			
	DALLAS																			
	DENVER																			
	KANSAS CITY																			
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB																			
PA	REGIONAL STAFF																			
	LOS ANGELES																			
	SAN FRANCISCO																			
	SEATTLE																			
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW																			
HOURS PER OPERATION																				
TOTAL HOURS			10820																	
CONVERSION FACTOR			1205																	
TOTAL OPERATIONAL FTEs			8.98																	

7. PERSONNEL TYPES REQUIRED										8. WORK SCHEDULE		
ANALYTICAL					INVESTIGATIVE					PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR		INSPEC- TIONAL			
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN					
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		ANALY- TICAL	10/15/02	09/30/03	
	PHYSICIST				MILK/FOOD SPEC							
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER					

9. REMARKS  
 The hours planned above are estimates. Report Forensic activities under the appropriate PAC 56R838; PODs operation code 03, Petition Evaluation, Methods Development or Forensic Evaluation (Forensic Evaluation added in FY1999); PODs operation 41 or 43 domestic or import sample analysis, PAC 56R838 or OCI PAC 56R831. Additional reporting instructions will appear in the Data Codes Manual.

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1. PROGRAM/ASSIGNMENT TITLE Counter Terrorism Initiative (CTI)					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56					
3. PROGRAM/ASSIGNMENT CODE(S) 56R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 33.0			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	2 DOMESTIC INVEST. HRS. ASSIGNED TO POSITION	2 OTHER DOMESTIC INVEST. (Hours)	2 IMPORT INVEST. HRS. ASSIGNED TO POSITION	2 OTHER IMPORT INVEST. (HOURS)	3 DOMESTIC SAMPLE COLLECTIONS	6 IMPORT SAMPLE COLLECTIONS	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM	9 OTHER OPERATIONS (Hours)
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		359		50	2	4			
	NEW YORK	500	569		300	4	13			
	REGIONAL LAB							6	17	
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		228		50	2	4			
	CHICAGO		407		150	3	9			
	CINCINNATI		332		75	2	4			
	DETROIT		336		200	2	10	7	20	
	MINNEAPOLIS		316		50	2	1			
	NEW JERSEY	500	643			4				
PHILADELPHIA		356		75	2	4	10	12		
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	500	451		75	4	5			
	FLORIDA		408		75	2	4			
	NEW ORLEANS	500	298		250	3	10			
	SAN JUAN		262		50	2	4			
REGIONAL LAB							11	23		
SW	REGIONAL STAFF									
	DALLAS		504			3				
	DENVER		419			2		7	10	
	KANSAS CITY		404			2				
	SOUTHWEST IMPORT DISTRICT			500	150		10			
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	500	803		150	5	10			
	SAN FRANCISCO		290		50	2	4			
	SEATTLE		165		50	2	4			
	PACIFIC REGIONAL LAB - SW							7	14	
PACIFIC REGIONAL LAB - NW							2	4		
HOURS PER OPERATION						4.0	2.0	25.0	25.0	
TOTAL HOURS		2500	7550	500	1800	200	200	1250	2500	
CONVERSION FACTOR		500	500	500	500	500	500	500	500	
TOTAL OPERATIONAL FTEs		5.00	15.10	1.00	3.60	0.40	0.40	2.50	5.00	
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP CTIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
Use CT PAC 56R845 Only when specific CT work is performed, otherwise use related Program PAC's e.g. 56002, 56008H. Domestic resources spread on inventory of establishment type M,R,Y,C; Import resources spread using import entries. Domestic resources may be used to conduct additional drug Process Inspections. Import investigation hours may be used for entry review, filer evaluation, field exams etc.										



1. PROGRAM/ASSIGNMENT TITLE OTC Drug Monograph Implementation	2. PPS PROJECT NAME/NUMBER Over-the Counter Drug Evaluation -61
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To identify and evaluate OTC drug products and to assure their compliance as related specific OTC drug monographs or other regulations.	
5. PROGRAM JUSTIFICATION The Kefauver-Harris Amendments passed by Congress in 1962 included a requirement that all drugs be proven effective and safe. In the Federal Register of January 5, 1972, (37 FR 85)), the Commissioner announced a proposed review of the safety, Effectiveness, and labeling of all OTC drugs by independent advisory panels. The end result of the review is the publication of final monographs ( in 21 CFR Part 330 through Part 358) which established conditions under which various OTC drugs can be Generally recognized as safe and effective and not misbranded (monograph conditions), and regulations (in 21 CFR Part 310) which Establish conditions under which OTC drug products are not generally recognized as safe and effective or are misbranded.	
6. FIELD OBLIGATIONS Field conducts inspections, collect samples, analyze samples, evaluates product labeling and conducts follow-up activities as set forth in the general compliance program and program circulars and responds to specific requests or recommendations from the Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs-non-rx	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, and 60-66
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

FY 2003 ORA WORKPLAN

July 1, 2002

1. PROGRAM/ASSIGNMENT TITLE OTC Drug Monograph Implementation	2. PPS PROJECT NAME/NUMBER Over-the-Counter Drug Evaluation - 61
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3. PROGRAM/ASSIGNMENT CODE(S) 61003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours)
	TOTAL FIELD	20	150	15				15		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	2	1						
	NEW YORK	3		2						
	REGIONAL LAB							2		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1	9							
	CHICAGO									
	CINCINNATI	1		1						
	DETROIT	1		1						
	MINNEAPOLIS	1	3	1						
	NEW JERSEY	1		1						
SE	PHILADELPHIA		16					5		
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		1							
	FLORIDA	3	13	2						
SW	NEW ORLEANS									
	SAN JUAN	1	2	1				1		
	REGIONAL LAB							2		
	REGIONAL STAFF									
	DALLAS	3	7	2						
PA	DENVER		1					2		
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	3	93	2						
	SAN FRANCISCO	1	3	1						
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW							3		
HOURS PER OPERATION		25.0		4.0				20.0		
TOTAL HOURS		500	150	60				300		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.55	0.16	0.07				0.25		

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
\* Not all samples collected will require analysis; most will be collected for documentary and label review.



1. PROGRAM/ASSIGNMENT TITLE Fraudulent Drugs	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs -63
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To detect, investigate and take action against fraudulent drug products which present the public with direct and indirect health hazard and economic fraud.	
5. PROGRAM JUSTIFICATION The activity is FDA's control strategy for combating the deceptive and misleading promotion of fraudulent drug products.	
6. FIELD OBLIGATIONS Conduct surveillance, investigations and compliance follow-up of drugs identified as fraudulent.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, and 60-66
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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Fraudulent Drugs					2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs-63						
3. PROGRAM/ASSIGNMENT CODE(S) 63001			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1 INSP EC T I O N S	2 INVEST I G A T I O N S (Hours)	3 DOMESTIC 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 C H E M	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			30	510	100				47	
N E	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND		1	23	5						
	NEW YORK		3	60	10						
	REGIONAL LAB								5		
C E	WEAC										
	REGIONAL STAFF										
	BALTIMORE		1	50	5						
	CHICAGO		1	22	1						
	CINCINNATI		1	5	3						
	DETROIT		1	5	4				2		
	MINNEAPOLIS		2	24	6						
	NEW JERSEY		1	7	2						
S E	PHILADELPHIA			2	1				9		
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA			2	1						
	FLORIDA		5	53	16						
	NEW ORLEANS		1	5	3						
S W	SAN JUAN										
	REGIONAL LAB								10		
	REGIONAL STAFF										
	DALLAS		1	17	2						
	DENVER		2		6					4	
P A	KANSAS CITY		1	13	4				2		
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
P A	LOS ANGELES		5	144	17						
	SAN FRANCISCO		2	36	6						
	SEATTLE		2	42	8						
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW								15		
HOURS PER OPERATION			26.0		4.0				17.0		
TOTAL HOURS			780	510	400				799		
CONVERSION FACTOR			910	910	910				1180		
TOTAL OPERATIONAL FTEs			0.86	0.56	0.44				0.68		
7. PERSONNEL TYPES REQUIRED									8. WORK SCHEDULE		
ANALYTICAL						INVESTIGATIVE			PERSON TYPE	BEGIN	END
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03	
<input checked="" type="checkbox"/>	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY T I C A L	10/15/02	09/30/03	
	PHYSICIST				MILK/FOOD SPEC						
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS * Not all samples collected will require analysis; most will be collected for documentary and label review.											

1. PROGRAM/ASSIGNMENT TITLE Internet Drug Sales	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs -63
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Monitoring, investigating and taking regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal pharmacy operations off-shore associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases in an effort to Protect the public from fraudulent drug products.	
5. PROGRAM JUSTIFICATION FDA has received several hundred complaints associated with the Internet, and has located over 200 web sites engaged in either illegal promotion sales and distribution activities. With increased interest in the use of the Internet by consumers, physicians, pharmacists, manufacturers, distribution/wholesalers, FDA must monitor and investigate allegations of wrong doing to determine those activities that violate the law and jeopardize the public health.	
6. FIELD OBLIGATIONS Districts will conduct inspections and investigations, collect evidence, samples and develop case in accordance with assignments from HFD-310 and HFD-330.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, and 60-66
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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Internet Drug Sales	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63D012, 63D013, 63D014	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	TRAINING (Hours)
	<b>TOTAL FIELD</b>		<b>3640</b>							<b>910</b>
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		141							35
	NEW YORK		809							232
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		83							21
	CHICAGO		18							5
	CINCINNATI									
	DETROIT		220							42
	MINNEAPOLIS		87							22
	NEW JERSEY		100							30
	PHILADELPHIA		199							50
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		202							51
	FLORIDA		262							66
	NEW ORLEANS		30							10
	SAN JUAN		85							20
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		192							48
	DENVER		339							85
	KANSAS CITY		50							10
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		579							122
	SAN FRANCISCO		161							40
	SEATTLE		83							21
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS		3640							910
	CONVERSION FACTOR		910							910
	TOTAL OPERATIONAL FTEs		4.00							1.0

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
 A block of hours is planned for monitoring drugs sold over the internet without a RX, unapproved or fraudulent.  
 \* Please report under correct operation; Report internet activities as follows; RX Drugs-- 63D012; OTC Drugs-- 63D013;  
 63D014 GHB/GBL/GD. Problem area Flags (PAFs) have been added to FACTs  
 for sample collections/analyses as follows: DRT - Drug Product Testing; DRA - Drug Ingredient Analysis.

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b Health Fraud Counter Terrorism	2. PPS PROJECT NAME/NUMBER Health Fraud:Human Drugs-63
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3. PROGRAM/ASSIGNMENT CODE(S) 63R845	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	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>		<b>1500</b>							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			58						
	NEW YORK			164						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			90						
	CHICAGO			57						
	CINCINNATI			37						
	DETROIT			37						
	MINNEAPOLIS			90						
	NEW JERSEY			39						
	PHILADELPHIA			10						
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA			10						
	FLORIDA			217						
	NEW ORLEANS			37						
	SAN JUAN			10						
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS			51						
	DENVER			62						
	KANSAS CITY			15						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			300						
	SAN FRANCISCO			104						
	SEATTLE			112						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION										
TOTAL HOURS				1500						
CONVERSION FACTOR				500						
TOTAL OPERATIONAL FTEs				3.00						

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
 Use CT PAC 63R845 ONLY when specific CT work is performed,  
 otherwise use related Program PAC's e.g. 63001  
 Hours spread in same porportion to planned domestic inspections/invs. in 63001.



1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects		2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88	
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To develop an effective program for extending the shelf Life of about-to expire drugs and medical devices.			
5. PROGRAM JUSTIFICATION Congress has placed a high priority on maintaining the military in a state of readiness. This includes purchasing and storing for contingency use sufficient quantities of medical products needed to sustain our military forces under wartime conditions. This project is established to assist DOD in reducing the cost of replacement stocks as the stockpiled materials expire.			
6. FIELD OBLIGATIONS Selected laboratories, on assignment from MPQAS.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		<input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:		<input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56, and 60-66	
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			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Environmental chambers used to stress drug products.			

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects					2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88					
3. PROGRAM/ASSIGNMENT CODE(S) *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.0				
R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED (Chem) Hours	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
TOTAL FIELD								5900		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT							3540		
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA							1180		
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN							1180		
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB-SW									
	PACIFIC REGIONAL LAB-NW									
HOURS PER OPERATION										
TOTAL HOURS								5900		
CONVERSION FACTOR								1180		
TOTAL OPERATIONAL FTEs								5.00		
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSP EC T I O N A L		
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY TICAL	10/15/02	09/30/03
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
Five FTEs are now assigned to this Program using dollars reimbursed by DOD. See Data Codes Manual for appropriate project reporting PACs.										

**CENTER FOR VETERINARY MEDICINE  
RESOURCE SUMMARY**

**FY 2003/BULLETIN-1**

January 15, 2004

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES	SUPPORTED FTES			TOTAL SUPPORTED FTES
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	115.5	36.0	2.4	153.9	202.3	66.7	4.3	280.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	12.4		2.0	14.4	22.3		3.6	29.6
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	103.1	36.0	0.4	139.6	180.0	66.7	0.7	250.4

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



1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities to fulfill their NADA commitments to manufacture, process, and pack new animal drugs that are safe and effective for their intended use.  Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION Domestic and foreign plant inspections are necessary to determine whether the establishment can produce the new animal drug in accordance with current good manufacturing practice regulations and comply with the commitments in the NADA. Inspections will be issued by assignment. Priority will be specified by CVM.  Outcome: Reduce new animal drug development and review time.	
6. FIELD OBLIGATIONS The Field will conduct NADA Pre-Approval Inspections at domestic and foreign plants in accordance with the assignment. Establishment inspection reports will be submitted to the New Animal Drug Evaluation (NADE) Program Manager (HFV-142) according to the procedures outlined for field reporting requirements in the compliance program.  Field laboratories on an assignment basis will validate methodology submitted with NADAs.	
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) Animal Drugs, Type A Medicated Feed Articles	d. INDUSTRY/PRODUCT CODE(S) 56, 67, 68
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 Petition validation work.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68						
3. PROGRAM/ASSIGNMENT CODE(S) 68001			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 INSP EC T I O N S	1 INSP EC T I O N S (Foreign) ***	1 INSP EC T I O N S (Chemist) Hours **	3 DOMESTIC SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	7 METHODS VALID Chem Hours *	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		67	50	599	40			40	1148
NE	HEADQUARTERS			1						
	REGIONAL STAFF									
	NEW ENGLAND	3	2			2				
	NEW YORK	4	3			3				
	REGIONAL LAB			67				5	129	
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	4	2			2				
	CHICAGO	3	2			2				
	CINCINNATI	2	1							
	DETROIT	3	1			3				
	MINNEAPOLIS	5	2			3				
	NEW JERSEY	5	3			3				
	PHILADELPHIA	3	2			2				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	4	4			2				
	FLORIDA	2	2							
	NEW ORLEANS	2	1							
	SAN JUAN	3	5			3				
REGIONAL LAB			101				5	194		
SW	REGIONAL STAFF									
	DALLAS	5	3			5				
	DENVER	3	3						133	
	KANSAS CITY	9	10	328		4		21	495	
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB			26				3	50		
PA	REGIONAL STAFF									
	LOS ANGELES	4	2			2				
	SAN FRANCISCO	3	1			3				
	SEATTLE					1				
	PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)			77				6	147		
HOURS PER OPERATION		60.3	40.0			3.0		19.4		
TOTAL HOURS		4040	2000	599		123		776	1148	
CONVERSION FACTOR		1000	1000	1180		1000		1180	1180	
TOTAL OPERATIONAL FTEs		4.04	2.00	0.51		0.12		0.66	0.97	
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/1/2002	9/30/2003
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/2002	9/30/2003
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
* Methods validation by assignment.										
** Analyst will participate on inspections as necessary.										
*** Foreign inspections spread by DEIO/ITOB. Use new Operation Code 11 to report foreign inspections.										

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-clinical Laboratory)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections of facilities and non-clinical laboratories engaged in the collection of data to determine whether the GLP regulations (21 CFR 58) are followed. To take appropriate action whenever a situation involving a serious violation of the GLPs is encountered or when fraud or other deliberate falsifications of test data has occurred.  Improve compliance review process by reducing BIMO backlogs by 2%.	
5. PROGRAM JUSTIFICATION FDA requires that extensive animal and other types of testing be carried out before approving new animal drug applications or animal food petitions. The FDA's reliance on the basic accuracy of data submitted is essential to the review and approval of Agency-regulated products. The submission of faulty, erroneous, or distorted data increases the potential for wrong decisions and makes it difficult, if not impossible, to draw conclusions regarding the health hazards of the tested product.  Outcome: Assure data integrity and reduce drug development time.  !!	
6. FIELD OBLIGATIONS ORA will perform the inspections and submit EIRs in accordance with established procedures set forth in the basic compliance program 7348.808.	
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) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 68 or 69
e. EXAM TYPE:    N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Sponsors, Contract Research Organizations, and Monitors	<b>2. PPS PROJECT NAME/NUMBER</b> Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
<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 assure the adherence of sponsors, contract research organizations and monitors to the clinical monitoring regulations specific s (21 CFR 511.1 (b)) and to evaluate representative clinical investigators utilized by the sponsor with regard to their adherence to applicable regulations.  Improve the compliance review by reducing the BIMO backlogs by 2%.	
<b>5. PROGRAM JUSTIFICATION</b> As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. Part of this comprehensive program was directed to sponsors, monitors, and clinical investigators under the above stated objective.  Outcome: Assure data integrity and reduce drug development time.	
<b>6. FIELD OBLIGATIONS</b> Conduct inspections of sponsors, contract research organizations, and monitors, identified by the Center in accordance with the guidance set forth in the basic compliance program 7348.810.	
<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> Animal Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 68 or 69
<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 GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)					2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68					
3. PROGRAM/ASSIGNMENT CODE(S) 68808, 68810, 68811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.1			
R E G I O N	6.	1	1	1	3	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	68808 INSPEC- TIONS (GLPs) (SPON/MON) *	INSPEC- TIONS	68811 INSPEC- TIONS (CLINICAL INVEST)	DOMESTIC 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>50</b>		<b>71</b>	<b>15</b>			<b>15</b>		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2		1	1					
	NEW YORK	2		4	1					
	REGIONAL LAB							2		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	2		2						
	CHICAGO	1		1						
	CINCINNATI	3		2	1					
	DETROIT	6		5	2					
	MINNEAPOLIS	2		3						
	NEW JERSEY	5		1	2					
SE	PHILADELPHIA	3		1						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	3		11	1					
	FLORIDA			4						
SW	NEW ORLEANS	3		4						
	SAN JUAN									
	REGIONAL LAB							3		
	REGIONAL STAFF									
	DALLAS	1		10	1					
PA	DENVER	7		6	2			2		
	KANSAS CITY	9		7	3			5		
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB							2		
PA	LOS ANGELES			2						
	SAN FRANCISCO	1		4	1					
	SEATTLE			3						
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)							1		
HOURS PER OPERATION		58.3		41.0	3.0			19.4		
TOTAL HOURS		2915		2911	45			291		
CONVERSION FACTOR		1000		1000	1000			1180		
TOTAL OPERATIONAL FTEs		2.92		2.91	0.05			0.25		
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR	X	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS * Resources for 68808 and 68810 are planned under 68808. Report inspections conducted under the appropriate PAC. Inspections are to be conducted only when assignments are received from CVM. Domestic Sample Collections are assigned by CVM and collected during the GLP inspections.										



1. PROGRAM/ASSIGNMENT TITLE Drug Process and New Animal Drug Inspections/Type A Medicated Articles		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71	
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21CFR 211 for Dosage form products and 21 CFR 226 for Type A Medicated Articles. To obtain accurate listing and labeling information for veterinary drug establishments. To check and verify the existence and scope of stability testing programs, protocols and commitments, and the validity of storage conditions, testing criteria and methodology together with reporting of results in the Drug Experience Report (DER) as specified in the approval New Animal Drug Application (NADA).  Reduce by 5% the number of non-compliant (OAI-classified inspections) firms making animal drugs.			
5. PROGRAM JUSTIFICATION Section 510(h) of the Act obligates the Agency to inspect (pursuant to 704 of the Act) drug establishments required to register with FDA. In addition, it is one of the primary purposes of establishment inspections to assure that the drug product is being manufactured, processed, controlled, etc. under the same conditions as approved and that it maintains the same stability profile as originally demonstrated.  Outcome: Ensure the marketing of safe and effective animal drugs.			
6. FIELD OBLIGATIONS The field will conduct CGMP inspections of registered animal drug establishments. Top priority will be given to establishments which manufacture sterile products.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.		d. INDUSTRY/PRODUCT CODE(S) 54, 56, 67, 68	
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 Sterility, purity, identity, potency, decomposition			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A			

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1. PROGRAM/ASSIGNMENT TITLE Drug Process and New Animal Drug Inspections/Type A Medicated Articles				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71001/A/B. 71005/A, 71R841			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.6			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		1	1	1	2	3	7	7	9
			INSPEC-TIONS	INSPEC-TIONS (Hours)	INSPEC-TIONS (Foreign)	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED (Chem)	DOMESTIC SAMPLES TO BE ANALYZED (Micro)	OTHER OPERATIONS (Hours)
<b>TOTAL FIELD</b>			<b>196</b>	<b>110</b>	<b>10</b>	<b>435</b>	<b>165</b>	<b>113</b>	<b>39</b>	
NE	HEADQUARTERS			110	1					
	REGIONAL STAFF									
	NEW ENGLAND		7			16	6			
	NEW YORK		7		1	16	7			
	REGIONAL LAB							9	3	
CE	REGIONAL STAFF									
	BALTIMORE		7			16	6			
	CHICAGO		15		1	33	13			
	CINCINNATI		10			22	8			
	DETROIT		6			13	5			
	MINNEAPOLIS		20		1	46	17			
	NEW JERSEY		16		2	36	14			
	PHILADELPHIA		10		1	22	9			
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		11			24	9			
	FLORIDA		7			16	6			
	NEW ORLEANS		5			11	4			
	SAN JUAN		3			7	3			
SW	REGIONAL LAB						41	13		
	REGIONAL STAFF									
	DALLAS		15		1	33	13			
	DENVER		5			11	4		18	
	KANSAS CITY		34		2	79	29	53		
	SOUTHWEST IMPORT DISTRICT							3	2	
PA	REGIONAL STAFF									
	LOS ANGELES		7			16	6			
	SAN FRANCISCO		6			14	6		3	
	SEATTLE		5			11	4			
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)							11		
HOURS PER OPERATION			43.4		40.0		4.0	18.4	21.1	
TOTAL HOURS			8506	110	400	435	660	2079	823	
CONVERSION FACTOR			1000	1000	1000	1000	1000	1180	1180	
TOTAL OPERATIONAL FTEs			8.51	0.11	0.40	0.44	0.66	1.76	0.70	
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
<input checked="" type="checkbox"/>	CHEMIST	<input checked="" type="checkbox"/>	PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR	<input type="checkbox"/>	RRHR	INSPEC-TIONAL	10/1/2002	9/30/2003
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR	<input type="checkbox"/>	VETERINARIAN			
<input type="checkbox"/>	ENGINEER(ANALYST)	<input type="checkbox"/>	ENGINEER TECH	<input type="checkbox"/>	ENGINEER (INV)	<input checked="" type="checkbox"/>	NAT'L EXPERT	ANALY-TICAL	10/15/2002	9/30/2003
<input type="checkbox"/>	PHYSICIST	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	OTHER			
<input type="checkbox"/>	ENTOMOLOGIST	<input type="checkbox"/>	OTHER	<input type="checkbox"/>		<input type="checkbox"/>	OTHER			
9. REMARKS Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples. Investigational or official samples should be collected as appropriate. Type A Medicated Articles program (71005/A is now under 71001; continue to report work to PAC 71005/A. For district servicing laboratory see Servicing Laboratory Table.										

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT
4. OBJECTIVES To monitor domestic and imported animal feed and feed ingredients to prevent widespread contamination of the nation's food supply.  Increase the number of cooperative activities related to this program.			
5. PROGRAM JUSTIFICATION The use of contaminated feed ingredients* has resulted in adulterated animal feeds and in economic losses to producers and processors when food-producing animals consume adulterated feeds.  A hazard to human health may result from subsequent deposition of residues in meat, poultry, eggs, fish and dairy products. These foods constitute a significant portion of the human diet.  Outcome: Prevention or containment of a potential human or animal health hazard.			
6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis.  Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities.  Anticipate inspection of renderers based on the BSE regulation.			
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) Complete animal feeds and feed ingredients.		d. INDUSTRY/PRODUCT CODE(S) 69-72	
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 *Mycotoxins, Pesticides, Industrial Chemicals, Metals and Microbiologicals			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A			

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1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants - DOMESTIC				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-E, 71R845 *(99R833, 71R833, 71R824)							5. OPERATIONAL FTE POSITIONS			
<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER							TOTAL	31.6		
							DOMESTIC	21.6		
							IMPORT	10.0		
R E G I O N	6.	3				7	7	7	7	9
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLES COLL				DOMESTIC SAMPLES ANALYSIS  Myc 71003C	DOMESTIC SAMPLES ANALYSIS  Micro 71003E	DOMESTIC SAMPLES ANALYSIS  Chem 71003A	DOMESTIC SAMPLES ANALYSIS  Dioxin 71003G	PROGRAM TRAINING
TOTAL FIELD		1050				250	200	500	100	9500
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	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		3.6				7.7	7.7	7.9	24.0	
TOTAL HOURS		3780				1925	1540	3950	2400	9500
CONVERSION FACTOR		1000				1180	1180	1180	1180	1000
TOTAL OPERATIONAL FTEs		3.78				1.63	1.31	3.35	2.03	9.50
7 PERSONNEL TYPES REQUIRED							8 WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST	X	PYS. SCIENC	X	INVESTIGATOR	RRHR	INSPECTIONAL	10/1/2002	9/30/2003	
X	MICROBIOLOGIST	X	BIO. SCIENC	X	INSPECTOR	VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER T		ENGINEER (INV)	NAT'L EXPERT	ANALYTICAL	10/15/2002	9/30/2003	
	PHYSICIST			X	CT CSO					
	ENTOMOLOGIST	X	CT CHEM			OTHER				
9 REMARKS										
NOTE: Domestic sample collections for "Micro" include an assignment to collect rendered feed ingredients to be sent to CVM lab for antimicrobial resistance analysis. USE CT PAC 71R845 ONLY WHEN SPECIFIC CT WORK IS PERFORMED, OTHERWISE USE THE PROGRAM PACS. Note: Continued on Page 71-7										

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-5				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71					
3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-E, 71R845 *(99R833, 71R833, 71R824)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 10.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		CT IMPORT ENTRY REVW HRS	CT IMPORT SAMPLE COLL	CT IMPORT FIELD EXAM	CT IMPORT SAMPLE ANALYZED CHEM	CT IMPORT SAMPLE ANALYZED MYCO		
	<b>TOTAL FIELD</b>		3110	175	500	100	75		
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND		124	77	120				
	NEW YORK								
	REGIONAL LAB WEAC					45			
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI		342	9	50				
	DETROIT		187	15	119				
	MINNEAPOLIS		205	19	25				
	NEW JERSEY								
	PHILADELPHIA		32	2	11				
FORENSIC CHEM. CTR									
SW	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB						5		
PA	REGIONAL STAFF								
	DALLAS								
	DENVER						17		
	KANSAS CITY						11		
	SOUTHWEST IMPORT DISTRICT		1162	29	170				
PA	REGIONAL LAB						9	7	
	REGIONAL STAFF								
	LOS ANGELES		498						
	SAN FRANCISCO		31	2	5				
	SEATTLE		529	22					
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)						13	68	
HOURS PER OPERATION				2.0	1.0	5.8	5.8		
TOTAL HOURS			3110	350	500	580	435		
CONVERSION FACTOR			500	500	500	500	500		
TOTAL OPERATIONAL FTEs			6.22	0.70	1.00	1.16	0.87		
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/1/2002 9/30/2003
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)				
	PHYSICIST			X	CT CSO			ANALY- TICAL	10/15/2002 9/30/2003
	ENTOMOLOGIST	X	CT CHEM				OTHER		
9. REMARKS									
USE CT PAC 71R845 ONLY WHEN SPECIFIC CT WORK IS PERFORMED, OTHERWISE USE THE PROGRAM PACS.									

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturers	2. PMS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine compliance with GMP elements of registered establishments producing medicated feeds. To determine whether a firm has the appropriate approved applications to make medicated feeds. To initiate appropriate administrative and/or regulatory action.  Reduce by 5% the number of non-compliant (OAI-classified inspections) firms making animal feeds.	
5. PROGRAM JUSTIFICATION Under Sec. 510(h) of the Act, the Agency is obligated to inspect registered medicated feed establishments.  Outcome: Ensure the marketing of safe and effective animal feeds.	
6. FIELD OBLIGATIONS To conduct inspections of registered medicated feed establishments and State audit inspections as needed. Districts will collect and analyze samples when appropriate. Field will coordinate federal/state operations. Anticipate inspection of feed mills, medicated and non-medicated to support the BSE regulation.	
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) Medicated Feeds	d. INDUSTRY/PRODUCT CODE(S) 69
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input 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 Drug analyses (potency) and drug contamination	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71				
3. PROGRAM/ASSIGNMENT CODE(S) 71004/A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.6			
R E G I O N	6	1	2			3	7	7	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S M E D I C A T E D F E E D E S T A B S	INSP EC T I O N S M E D I C A T E D F E E D E S T A B S (Hours)			D O M E S T I C S A M P L E S C O L L	D O M E S T I C S A M P L E S A N A L Y Z E D  (Micro)	D O M E S T I C S A M P L E S A N A L Y Z E D  (Chem)	O T H E R O P E R A T I O N S  (Hours)
<b>TOTAL FIELD</b>		245	75			100	30	30	
N E	HEADQUARTERS		75						
	REGIONAL STAFF								
	NEW ENGLAND	6				2			
	NEW YORK	2				2			
	REGIONAL LAB WEAC								
C E	REGIONAL STAFF								
	BALTIMORE	6				2			
	CHICAGO	3				2			
	CINCINNATI	3				2			
	DETROIT	1							
	MINNEAPOLIS	13				5			
	NEW JERSEY								
	PHILADELPHIA	2							
	FORENSIC CHEM. CTR								
S E	REGIONAL STAFF								
	ATLANTA	5				2			
	FLORIDA	6				2			
	NEW ORLEANS	35				13			
	SAN JUAN	9				4			
S W	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS	56				22			
	DENVER	11				6	30	30	
	KANSAS CITY	45				17			
P A	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	8				3			
	SAN FRANCISCO	24				10			
	SEATTLE	10				4			
PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		14.0				4.0	32.7	34.0	
TOTAL HOURS		3430	75			400	981	1020	
CONVERSION FACTOR		1000	1000			1000	1180	1180	
TOTAL OPERATIONAL FTEs		3.43	0.08			0.40	0.83	0.86	
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR		INSP EC T I O N A L	10/1/2002	9/30/2003
<input checked="" type="checkbox"/>	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		ANALY TICAL	10/15/2002	9/30/2003
	PHYSICIST		CT CSO		MILK/FOOD SPEC				
	ENTOMOLOGIST		CT CHEM		SHELLFISH SPEC	OTHER			
9. REMARKS									
* Inspections include 29 contract audit inspections.									
Some inspection time may be used as investigation time where appropriate.									
Non-potency feed sample analysis should be charged to 71003 A/E. Some samples collected are documentary.									
Inspections for Chi-DO and Cin-DO are audit inspection.									
<b>USE CT PAC 71R845 ONLY WHEN SPECIFIC CT WORK IS PERFORMED, OTHERWISE USE THE PROGRAM PACS.</b>									

1. PROGRAM/ASSIGNMENT TITLE Illegal Drug Residues in Meat and Poultry	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct follow-up investigations/inspections when illegal residues are reported to FDA by the USDA's Food Safety and Inspection Service. To initiate regulatory sanctions against those persistently causing residues.  Reduce future residues in edible animal tissues by increasing by 2% the number of follow-up investigations in violative tissue residues in targeted food producing animals. FDA will be partners with FSIS/HACCP on the environment, educational initiatives, and, as necessary, regulatory actions.	
5. PROGRAM JUSTIFICATION FDA is charged with the responsibility to ensure that food is free of adulterants which may render it injurious to health. FDA conducts investigations as a follow-up to USDA residue findings in meat and poultry to identify the source of adulteration and take corrective action to prevent it from re-occurring. This a cooperative program involving FDA, USDA, EPA, and a number of state governments.  Outcome: To provide a safe human food supply.	
6. FIELD OBLIGATIONS To conduct investigations or inspections in accordance with the compliance program requirements based on the Memoranda of Understanding between FDA, USDA and EPA. See CPG 7155a.19. Coordinate state activities with states having MOUs, informal and formal agreements or contracts with FDA to conduct inspections of first time violators.  Anticipate inspection of producers to support the BSE regulation.	
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) Meat and Poultry, Animal Feeds and Drugs	d. INDUSTRY/PRODUCT CODE(S) 17, 67, 68, and 69
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 Tissue Sample analysis by Denver laboratory when required, including confirmation on USDA CAST samples.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM/ASSIGNMENT CODE(S) 71006	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 16.3	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS					7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)		
	TOTAL FIELD	480					1801	1560		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	18								
	NEW YORK	40								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	17								
	CHICAGO	12								
	CINCINNATI	23								
	DETROIT	32								
	MINNEAPOLIS	44								
	NEW JERSEY	3								
	PHILADELPHIA	49								
SE	REGIONAL STAFF									
	ATLANTA	12								
	FLORIDA	5								
	NEW ORLEANS	8								
	SAN JUAN	11								
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	27								
	DENVER	20					1801	1560		
	KANSAS CITY	14								
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	42								
	SAN FRANCISCO	68								
SEATTLE	35									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	28.0								
	TOTAL HOURS	13440					1801	1560		
	CONVERSION FACTOR	1000					1180	1180		
	TOTAL OPERATIONAL FTEs	13.44					1.53	1.32		

7. PERSONNEL TYPES REQUIRED						8. WORK SCHEDULE					
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END			
<input checked="" type="checkbox"/>	CHEMIST		<input checked="" type="checkbox"/>	PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/1/2002	9/30/2003
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/2002	9/30/2003	
	PHYSICIST				MILK/FOOD SPEC		CT CSO				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				

9. REMARKS  
 Planned analytical time may be converted to methods development per CVM's concurrence. Methods development work will be assigned by CVM.

**USE CT PAC 71R845 ONLY WHEN SPECIFIC CT WORK IS PERFORMED, OTHERWISE USE THE PROGRAM PACS.**

1. PROGRAM/ASSIGNMENT TITLE National Drug Residue Milk Monitoring Program	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine if animal drug residues are present in milk and that farmers, distributors, and veterinarians comply with the Federal Food, Drug, and Cosmetic Act regulations and applicable policies.  Improve milk residue surveillance by increasing the number of antibiotics in the test battery as new methods are developed.	
5. PROGRAM JUSTIFICATION The National Drug Residue Milk Monitoring Program will provide indications of drug residues in milk and the extent of compliance with federal regulations. The results will help in the design of future education and compliance efforts for use by federal, state and local authorities. This initiative will enhance the NCIM and industry residue testing program and provide information on which to focus regulatory priorities.  Outcome: To provide a safe human food supply.	
6. FIELD OBLIGATIONS This is a joint FDA/State effort in collecting and analyzing samples for the presence of gentamicin, ivermectin, chloroulon, novobiocin, and beta-lactams. Follow-up visits/collections/inspections are anticipated by states and FDA for samples found with detectable residues.	
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) Grade "A" Milk/Non Grade "A" Milk	d. INDUSTRY/PRODUCT CODE(S) 9
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 Samples will be analyzed for eight sulfonamides, three tetracyclines, beta-lactams, novobiocin and chloramphenicol.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE National Drug Residue Milk Monitoring Program					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S)  71008			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS  1.4					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1  INSP EC T I O N S	2  INVE ST I G A T I O N S  (Hours)	3  D O M E S T I C  S A M P L E  C O L L	4  I M P O R T  S A M P L E  C O L L	5  F I E L D  E X A M S/  T E S T S	6  I M P O R T  F I E L D  E X A M S	7  D O M E S T I C  S A M P L E S  T O B E  A N A L Y Z E D  M i c r o	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	9  O T H E R  O P E R A T I O N S  (Hours)
	<b>TOTAL FIELD</b>					<b>200</b>				<b>400</b>	
N E	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND				6						
	NEW YORK				6						
	REGIONAL LAB										
WEAC											
C E	REGIONAL STAFF										
	BALTIMORE				20						
	CHICAGO				6						
	CINCINNATI				11						
	DETROIT				9						
	MINNEAPOLIS				20						
	NEW JERSEY				4						
	PHILADELPHIA				8						
	FORENSIC CHEM. CTR										
S E	REGIONAL STAFF										
	ATLANTA				5						
	FLORIDA				6						
	NEW ORLEANS				10						
	REGIONAL LAB										
S W	REGIONAL STAFF										
	DALLAS				12						
	DENVER				21				400		
	KANSAS CITY				18						
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
P A	REGIONAL STAFF										
	LOS ANGELES				3						
	SAN FRANCISCO				12						
	SEATTLE				23						
	PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)											
HOURS PER OPERATION					1.5				3.2		
TOTAL HOURS					300				1286		
CONVERSION FACTOR					1000				1180		
TOTAL OPERATIONAL FTEs					0.30				1.09		
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END	
	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/1/2002	9/30/2003	
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/2002	9/30/2003	
	PHYSICIST				MILK/FOOD SPEC						
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS											
The investigation hours may be used for follow-up activities/sample collections as needed.											
The National Milk Monitoring Program is a joint effort between CFSAN and CVM. Resources planned represent CVM's requirements under this program.											

1. PROGRAM/ASSIGNMENT TITLE BSE/Ruminant Feed Ban Inspections	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To enhance the FDA's uniformity in inspection and compliance of firms subject to the regulation prohibiting the utilization of specified animal proteins in ruminant feeds. 21 CFR 589.2000.  To ensure that specified animal proteins do not enter the U.S. from BSE-at-risk countries.	
5. PROGRAM JUSTIFICATION  Bovine Spongiform Encephalopathy (BSE) is the bovine form of a group of uniformly fatal neurological diseases known as Transmissible Spongiform Encephalopathies (TSEs). BSE appears to be spread through the feeding of infected material to cattle. BSE is a public health issue for the U.S. This disease has been linked to the human TSE know as variant Creutzfeldt-Jakob Disease (vCJD), presumably through people consuming ruminant tissues infected with the BSE agent. In addition, BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected.  Outcome: To prevent the establishment and amplification of BSE through feed in the United States.	
6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. All firms that handle animal feed and feed ingredients containing ruminant-based material are the subject of this program.  To provide guidance concerning the importation of animal feeds and feed ingredients from BSE at-risk countries, in accordance With Import Alert #99-25.  Field activities will cover the assessment of all aspects of animal feed and feed ingredient manufacture and distribution, as Described by the ruminant feed ban regulation, 21 CFR 589.2000.	
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) Animal feeds and feed ingredients.	d. INDUSTRY/PRODUCT CODE(S) 67-72
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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A	





1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71				
3. PROGRAM/ASSIGNMENT CODE(S) 71R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.6			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEM (Hours)				
	TOTAL FIELD		760		5900				
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER		760		4720				
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE				1180				
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)								
HOURS PER OPERATION									
TOTAL HOURS			760		5900				
CONVERSION FACTOR			1205		1180				
TOTAL OPERATIONAL FTEs			0.63		5.00				
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		INSPEC-TIONAL		
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)				
	PHYSICIST				MILK/FOOD SPEC		ANALY-TICAL	10/15/02	09/30/03
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC				
9. REMARKS									

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

4. OBJECTIVES

To analyze domestic and imported animal feed and feed ingredients in support of criminal investigations. Prevent widespread abuses by nation's food suppliers.

5. PROGRAM JUSTIFICATION

6. FIELD OBLIGATIONS

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

b. INSPECTION TYPE: N/A  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71	
3. PROGRAM/ASSIGNMENT CODE(S)  71R838, 71R831	4. WORK ALLOCATION PLANNED BY  <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS  0.7

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	<b>TOTAL FIELD</b>	<b>875</b>								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR	875								
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION									
	TOTAL HOURS	875								
	CONVERSION FACTOR	1180								
	TOTAL OPERATIONAL FTEs	0.74								

7. PERSONNEL TYPES REQUIRED						8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH	INVESTIGATOR	RRHR	INSPEC- TIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST	<input checked="" type="checkbox"/>	RESEARCH CHEMIST	SHELLFISH SPEC	OTHER			

9. REMARKS

3. PROGRAM TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES  
Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.

5. PROGRAM JUSTIFICATION  
A number of potential or emerging problems which cannot be predicted must be handled. The resources for these Center initiated assignments are planned under this umbrella program.

6. FIELD OBLIGATIONS  
Conduct inspections, investigations, sample collections and analyses as directed by Center assignments.

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

b. INSPECTION TYPE: N/A  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
All veterinary products

d. INDUSTRY/PRODUCT CODE(S)  
54, 56, 67-72

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING  
N/A

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71V800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.3					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI- GATIONS  (Hours)									
	<b>TOTAL FIELD</b>	<b>2300</b>									
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	71									
	NEW YORK	76									
	REGIONAL LAB WEAC										
CE	REGIONAL STAFF										
	BALTIMORE	81									
	CHICAGO	95									
	CINCINNATI	71									
	DETROIT	145									
	MINNEAPOLIS	232									
	NEW JERSEY										
	PHILADELPHIA	90									
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA	220									
	FLORIDA	51									
	NEW ORLEANS	93									
	SAN JUAN	59									
REGIONAL LAB											
SW	REGIONAL STAFF										
	DALLAS	244									
	DENVER	95									
	KANSAS CITY	435									
	SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB											
PA	REGIONAL STAFF										
	LOS ANGELES	73									
	SAN FRANCISCO	76									
	SEATTLE	93									
	PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)											
HOURS PER OPERATION											
TOTAL HOURS		2300									
CONVERSION FACTOR		1000									
TOTAL OPERATIONAL FTEs		2.30									
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE				
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END		
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR				
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN		10/01/02	09/30/03	
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT				
	PHYSICIST				MILK/FOOD SPEC				10/15/02	09/30/03	
	ENTOMOLOGIST		RESEARCH CHEMIST		SHELLFISH SPEC		OTHER				
9. REMARKS											

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
RESOURCE SUMMARY  
FY 2003**

FY 2003 ORA WORKPLAN

June 17, 2002

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>189.8</b>	<b>38.6</b>	<b>20.9</b>	<b>249.3</b>	<b>388.4</b>	<b>69.6</b>	<b>43.0</b>	<b>501.0</b>
81	POSTMARKET ASSURANCE: DEVICES	1.5			1.5	3.3			3.3
82	COMPLIANCE: DEVICES	105.3	33.8	14.1	153.2	217.7	62.3	28.2	308.2
83	PRODUCT EVALUATION: DEVICES	26.0		4.7	30.7	56.4		10.2	66.6
84	SCIENCE: DEVICES	8.6			8.6	10.6			10.6
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	17.9		0.1	18.0	36.7		0.3	37.0
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	30.5	4.8	2.0	37.3	63.7	7.3	4.3	75.3



1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Rapidly identify immediate hazards to health.  Identify significant problems by analyzing recurring problems and performing trends analysis.  Provide data on complaints, significant problems and potential hazards so that corrective action can be initiated for hazardous products in the marketplace.	
5. PROGRAM JUSTIFICATION Early detection of device problems is necessary to protect the public from health hazards. Reports of device defects are often the first warning of manufacturing or other problems. When the Center receives notices from manufacturers that a device has been associated with a death or serious injury, it may issue a priority assignment to the field for follow-up at the manufacturer reporting site (usually a medical facility). When the Center's evaluation of the problem report suggests that there is an actual or potential health hazard it issues an assignment to the field for immediate follow-up.	
6. FIELD OBLIGATIONS On assignment, follow up on MDR reports either at the medical facility or manufacturer.	
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 medical devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Sterility Performance	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM/ASSIGNMENT CODE(S) 81010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	7	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D E N G (4)	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M (5)	DOMESTIC S A M P L E S T O B E A N A L Y Z E D S T E R (6)	OTHER O P E R A T I O N S (Hours)
TOTAL FIELD		(1)	(2)	(3)			(4)	(5)	(6)	
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	4	5							
	NEW YORK	5	7							
	REGIONAL LAB									
	WEAC						1	1	1	
CE	REGIONAL STAFF									
	BALTIMORE			1						
	CHICAGO	5	6							
	CINCINNATI	1	1	1						
	DETROIT	1	1							
	MINNEAPOLIS	2	3							
	NEW JERSEY	1	2							
	PHILADELPHIA	1	2							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	3							
	FLORIDA	1	1	1						
	NEW ORLEANS	9	12	1						
	SAN JUAN	1	2							
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2	3							
	DENVER									
	KANSAS CITY	2	3							
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	5	6	1						
	SAN FRANCISCO	3	4							
	SEATTLE	1	2							
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		27.0		5.8			37.0	36.0	20.0	
TOTAL HOURS		1242	63	29			37	36	20	
CONVERSION FACTOR		950	950	950			1180	1180	1180	
TOTAL OPERATIONAL FTEs		1.31	0.07	0.03			0.03	0.03	0.02	

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
<input checked="" type="checkbox"/>	ENGINEER(ANALYST)		ENGINEER TECH	<input checked="" type="checkbox"/>	ENGINEER (INV)		NAT'L EXPERT	ANALY T I C A L	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
  
See Continuation Sheet

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Medical Device Problem Reporting - MDR Follow-Up

2. PPS PROJECT NAME/NUMBER

Postmarket Assurance: Devices - 81

## 9. Remarks

- (1) Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.
- (2) Investigational hours for MDR followup at medical facilities.
- (3) Includes Documentary samples.
- (4) MDR samples to confirm reported defects.
- (5) Performance testing of chemical and serological test kits.
- (6) Sterility testing to confirm reports of defective packaging and gross bacterial contamination of fill.



1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine compliance of imported devices with the medical device registration and listing requirements, and other general controls.	
5. PROGRAM JUSTIFICATION There are indications that some foreign manufacturers are not registered or listed. Foreign manufacturers of Class II and III devices must be identified for scheduling GMP inspections. In addition, because foreign device manufacturers cannot be inspected as readily as domestic manufacturers, their products must be monitored at the port of entry.	
6. FIELD OBLIGATIONS The field will conduct examinations of Form 701 import records for medical devices and ascertain in conjunction with information provided by CDRH whether the manufacturer is listed and the initial distributor is registered with CDRH.	
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 Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" 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 Refer to C.P. for procedures to handle initial distributors and/or foreign establishments which are not registered.	

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833, 82R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 20.0 [10.6]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 E N T R Y R E V I E W (Hours)	2 F I L E R E V A L (Hours)	2 I N V E S T I G A T I O N S (Hours)	4 I M P O R T F I E L D E X A M S *	4 I M P O R T S A M P L E C O L L (Physical) **	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 E N G	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 M I C R O ***	9 I M P O R T L A B E L E X A M
	TOTAL FIELD				7490		1100	83	65	19
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			310		32	2			4
	NEW YORK			1275		138	11			19
	REGIONAL LAB									
WEAC							65		19	
CE	REGIONAL STAFF									
	BALTIMORE			282		12				2
	CHICAGO			362		74	7			10
	CINCINNATI			206		29	2			4
	DETROIT			233		31	4			4
	MINNEAPOLIS			186		16				2
	NEW JERSEY									
	PHILADELPHIA			146		20				3
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA			479		23	3			3
	FLORIDA			555		19				3
	NEW ORLEANS			213		93	7			13
	SAN JUAN			63						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT			1522		486	37			66
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES			881		76	6			10
	SAN FRANCISCO			375		33	4			5
	SEATTLE			402		18				2
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION						0.6	2.4	22.3	25.5	1.0
TOTAL HOURS				7490		660	199	1450	485	150
CONVERSION FACTOR				950		950	950	1180	1180	950
TOTAL OPERATIONAL FTEs				7.88		0.69	0.21	1.23	0.41	0.16

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR		
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN	INSPEC-TIONAL	10/01/02 09/30/03
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL	10/15/02 09/30/03
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		

9. REMARKS

See Continuation Sheet for reporting guidance and footnotes.

Use CT PAC 82R845 ONLY when specific CT work is performed, otherwise use related program PACs.

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1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833, 82R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 20.0    [9.4]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC- TIONS	2 CT ENTR Y REVI EW (Hours)	4 CT IMP ORT FIELD EXAMS	4 CT IMP ORT SAMP LE COLL (Physical)	5 FIELD EXAMS/ TESTS	6 WHARF EXAMS	7 DOMESTIC SAMP LES TO BE ANALYZED	8 CT IMP ORT SAMP LES TO BE ANALYZED MICRO - Sterility	9 OTHER OPERATIO N (Hours)
	<b>TOTAL FIELD</b>		3290	551	41				41	
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		96	16						
	NEW YORK		413	69	6					
	REGIONAL LAB									
	WEAC								41	
CE	REGIONAL STAFF									
	BALTIMORE		35	6						
	CHICAGO		222	37	3					
	CINCINNATI		86	14	4					
	DETROIT		94	16						
	MINNEAPOLIS		49	8						
	NEW JERSEY									
	PHILADELPHIA		59	10						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		70	12						
	FLORIDA		57	10						
	NEW ORLEANS		267	47	5					
	SAN JUAN		13							
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT		1447	242	18					
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		228	38	5					
	SAN FRANCISCO		100	17						
PA	SEATTLE		54	9						
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION			0.6	1.0				25.5	
	TOTAL HOURS		3290	331	41				1046	
	CONVERSION FACTOR		500	500	500				500	
	TOTAL OPERATIONAL FTEs		6.58	0.66	0.08				2.09	

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC- TIONAL	10/01/02	09/30/03
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN			
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

9. REMARKS

Use CT PAC 82R845 ONLY when specific CT work is performed, otherwise use related program PACs.

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Monitoring Devices of Foreign Origin - Import

2. PPS PROJECT NAME/NUMBER

Compliance: Devices - 82

## 9. Remarks

## Reporting Guidance:

- Import Entry Reviews (Electronic and Manual--operation code 14, PAC 82R833);
- Filer Evaluations (operation code 95, PAC 99R833); and
- Follow-up to Refusals (PAC 82R824).

**Refer to Data Codes Manual when reporting these activities.**

NOTE: Determination of failure to register or list is included in the Entry Review operation.

Planning Guidance: Unused resources for Filer Evaluations should be used when necessary towards Entry Reviews, since more resources have been planned in Filer Evaluations.

Workplanning Page Footnotes:

- \* Import Field Exams to implement performance standard for lead wires and cables.
- \*\* Audit samples for problems other than failure to register or list (eg. special assignment, import alert).  
Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.
- \*\*\* Sterile devices to be tested by USP XX method.  
Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

Use CT PAC 82R845 ONLY when specific CT work is performed, otherwise use related program PACs.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers		2. PMS PROJECT NAME/NUMBER Compliance: Devices - 82	
3. PROGRAM TYPE:		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
4. OBJECTIVES To evaluate the manufacturing processes used for general and radiation emitting medical devices and <i>in vitro</i> diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations.  To implement the United States-European Community (EC) Mutual Recognition Agreement, Medical Device Annex, as published in the Federal Register dated November 18, 1998. During the transition, or confidence-building period, of the MRA: to train, evaluate, and verify the ability of EC Conformance Assessment Bodies to conduct inspections and provide establishment inspection reports to FDA.			
5. PROGRAM JUSTIFICATION The Center's inspectional strategy requires that all manufacturers of Class II and III devices be inspected under the GMP Compliance Program on a biennial basis. FDA selects certain establishments for intensive GMP coverage. Establishments with a history of good GMP systems are subject to less intensive inspections. All establishments are subject to complaint file reviews to assess compliance with the MDR regulation.  MRA: The FDA Modernization Act of 1997 modified Section 803 of the Food, Drug, and Cosmetic Act to require the Secretary to encourage the mutual recognition of good manufacturing practice regulations under section 520(f) and to provide support to the Office of the United States Trade Representative to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biologics, and devices and the regulation of good manufacturing practices between the EU and the US.			
6. FIELD OBLIGATIONS Under the new Quality Systems/GMP strategy, the field should conduct biennial inspections of: 100% of high risk device manufacturers; and 80% of Class III device manufacturers that are not considered to be high risk. The remaining manufacturers (Class III, II, and I devices) should be inspected as each districts resources allow, and scheduled according to the priority outline described in Part II of the compliance program. For more detailed instructions on QSIT/GMP inspections as they relate to device manufacturers, refer to the Continuation Sheet. MRA: the field will participate in the evaluation of Conformance Assessment Bodies (CABs), conduct inspectional training and evaluative inspections/on-site evaluations of EU CABs. Workloads were modeled proportionally to foreign inspection assignments to enable using Performance Auditors wherever possible.			
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 checked="" type="checkbox"/> ABBREVIATED
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Class II and III Devices and all Class I Devices which have been finally classified for one year		d. INDUSTRY/PRODUCT CODE(S) 73-91	
e. EXAM TYPE:		<input checked="" type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL
		<input type="checkbox"/> PHYSICAL	<input checked="" 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 <i>Engineering Samples:</i> Subs/Sample will vary depending on cost, size, etc. Contact Center for guidance if the device presents such problems.			

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,S,R841, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 112.1 [85.9]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	3	3
		INSP EC T I O N S L E V E L I  82845A	INSP EC T I O N S L E V E L II  82845B	INSP EC T I O N S L E V E L III (COMPLIANCE FOLLOWUP) 82845C	INSP EC T I O N S (FOREIGN)	INSP EC T I O N S (MRA)	INSP EC T I O N S (FOR CAUSE)  82845G	INVEST I G A T I O N S (Hours)  (1)	DOMESTIC S A M P L E S T O B E C O L L E C T E D	DOMESTIC S A M P L E S T O B E C O L L E C T E D B I O I N D I C A T O R
	<b>TOTAL FIELD</b>	<b>900</b>	<b>555</b>	<b>100</b>	<b>199</b>	<b>15</b>	<b>75</b>	<b>911</b>	<b>177</b>	<b>37</b>
	HEADQUARTERS				30			911		
NE	REGIONAL STAFF									
	NEW ENGLAND	85	61	10	9		8		23	3
	NEW YORK	50	28	6	9		4		9	2
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	20	14	3	6		2		4	1
	CHICAGO	47	18	5	9		3		6	2
	CINCINNATI	41	13	4	6		3		4	2
	DETROIT	39	18	4	12		3		7	1
	MINNEAPOLIS	59	45	6	12	3	5		14	3
	NEW JERSEY	33	27	4	9	3	3		9	1
	PHILADELPHIA	42	27	5	6		4		9	2
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	27	18	3	9		2		7	1
	FLORIDA	71	40	8	12	3	6		13	3
	NEW ORLEANS	39	14	4	6		3		4	2
	SAN JUAN	5	12		3		1		3	
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	53	31	6	12	3	4		9	2
	DENVER	33	26	3	13	3	3		8	1
	KANSAS CITY	33	13	4	9		2		3	1
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	119	97	13	12		11		28	5
	SAN FRANCISCO	58	36	7	9		5		11	3
	SEATTLE	46	17	5	6		3		6	2
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		26.0	54.2	78.0	60.4	65.5	71.0		5.5	5.5
TOTAL HOURS		23400	30081	7800	12020	983	5325	911	974	204
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		24.63	31.66	8.21	12.65	1.03	5.61	0.96	1.02	0.21
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)	X	ENGINEER TECH	X	ENGINEER (INV)	X	NAT'L EXPERT	ANALY T I C A L	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
(1) BULLETIN CHANGE, FY 2003-1: Headquarters Investigators now planned as Investigational hours.										
Domestic Sample Collections for Contract Sterilizers and/or Bioburden, Bioindicator are to be collected "for cause".										
See Continuation Sheet for additional explanations of specific operations and/or strategies.										

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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,S,R841, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 112.1 [26.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	7	7	7	7	7	7	9	9
		DOMESTIC SAMPLES TO BE COLLECTED MICRO STERILITY	DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (3)	DOMESTIC SAMPLES TO BE ANALYZED	DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN BIOINDICATOR	DOMESTIC SAMPLES TO BE ANALYZED MICRO STERILITY	DOMESTIC SAMPLES TO BE ANALYZED ENG	OTHER OPERATIONS MRA	OTHER OPERATIC PROGRA TRAININ 8% ATTRITC
TOTAL FIELD		10	37	110		14	6	25	421	16
NE	HEADQUARTERS								127	
	REGIONAL STAFF									
	NEW ENGLAND	1								1
	NEW YORK								42	
	REGIONAL LAB									
CE	WEAC		37	34		14	6	25		
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS	2							42	1
	NEW JERSEY								42	
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	1								
	FLORIDA	1							42	1
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	DALLAS	1							42	
	DENVER	1		76					42	
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	2							42	2
PA	SAN FRANCISCO	1								1
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		5.5	31.2	61.2		25.0	25.0	72.0		
TOTAL HOURS		55	1154	6732		350	150	1800	421	16
CONVERSION FACTOR		950	1180	1180		1180	1180	1180	950	
TOTAL OPERATIONAL FTEs		0.06	0.98	5.71		0.30	0.13	1.53	0.44	1
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/02
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)	X	ENGINEER TECH	X	ENGINEER (INV)	X	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS (2) Test Kit or Reagent Testing to support GMP observations (CHEM) at WEAC. (3) Antisera and Products Media Testing to support GMP observations (MICRO) at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.										

See Continuation Sheet for additional explanations of specific operations and/or strategies.

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**CONTINUATION SHEET**

<p>1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers</p>	<p>2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82</p>
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g. Remarks

QUALITY SYSTEMS INSPECTION PLANNING

The workplan reflects the number of operations to be performed for FY03 for each district. Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause " inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. **Any unused resources in those two areas should be reprogrammed into Level 1 and Level 2 inspections.**

The hours per operation, or inspectional modules, reflect the most recent historical data. In previous years, the time for 82845S (sterilization) has been planned separately. That time has been built into the inspectional modules for FY03. Also in previous years, time spent on the QSIT satellites: MDR (81001), Corrections and Removals (81845R), Tracking (81845T) and Registration and Listing have not been planned time. This year, time spent on these satellites programs is averaged into the inspectional module for Level 2 inspections.

For additional information regarding inspection strategies refer to the latest Compliance Program.

NOTE: Resources for Single Use Reprocessor inspections have been included in Level II Inspections.

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 1) To determine the extent to which manufacturers of condoms comply with the Device GMP requirements;  2) To assure that both domestic and imported condoms comply with the FDA standard.	
5. PROGRAM JUSTIFICATION The Surgeon General has recommended the use of condoms to reduce the spread of AIDS. Consequently, FDA is committed to assuring that condoms are safe and effective.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic condom manufacturers and major repackers. Districts will also sample both domestic and imported condoms and conduct tests to assure conformance with the FDA standard.	
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)	d. INDUSTRY/PRODUCT CODE(S) 85
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 type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.9
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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 (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>4</b>		<b>4</b>	<b>382</b>			<b>4</b>	<b>382</b>	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK				41					
	REGIONAL LAB									
CE	WEAC							3	276	
	REGIONAL STAFF									
	BALTIMORE				6					
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA	1		1						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				224					
	FLORIDA									
	NEW ORLEANS	2		2	5					
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY	1		1						
PA	SOUTHWEST IMPORT DISTRICT					6				
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES					72				
	SAN FRANCISCO					28				
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW							1	106	
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		8.0		2.7	2.4			12.0	11.9	
TOTAL HOURS		32		11	917			48	4546	
CONVERSION FACTOR		950		950	950			1180	1180	
TOTAL OPERATIONAL FTEs		0.03		0.01	0.97			0.04	3.85	

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
<input checked="" type="checkbox"/>	CHEMIST	<input checked="" type="checkbox"/>	PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR	<input type="checkbox"/>	RRHR	INSP- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR	<input type="checkbox"/>	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	<input checked="" type="checkbox"/>	ENGINEER (INV)	<input type="checkbox"/>	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC	<input type="checkbox"/>				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	<input type="checkbox"/>	OTHER			

9. REMARKS  
 Domestic Samples should only be collected on a for cause basis; Import Samples are estimated and should be collected to cover the districts' workload. Resources for Condom Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin. Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES (1) To determine the extent to which manufacturers of both surgical and examination gloves comply with the device GMP requirements, and (2) to assure that both domestic and imported gloves comply with the applicable FDA standard.	
5. PROGRAM JUSTIFICATION Healthcare providers rely heavily on gloves to prevent the transmittal of the AIDS virus. Consequently, FDA is committed to assure that both surgical and examination gloves comply with published standards.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic manufacturers. Districts will also sample gloves for testing by the designated laboratories.	
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)	d. INDUSTRY/PRODUCT CODE(S) 79-80
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" 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 Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.2
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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	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMPORT S A M P L E C O L L (PHYSICAL)	FIELD E X A M S/ T E S T S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D E N G	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M	IMPORT S A M P L E S T O B E A N A L Y Z E D E N G (PHYSICAL)	IMPORT S A M P L E S T O B E A N A L Y Z E D C H E M (PHYSICAL)
	<b>TOTAL FIELD</b>	5		5	955		2	3	182	773
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1		1	20					
	NEW YORK				95					
	REGIONAL LAB									
CE	WEAC						2	1	182	202
	REGIONAL STAFF									
	BALTIMORE				26					
	CHICAGO	1		1	67					
	CINCINNATI				13					
	DETROIT				3					
	MINNEAPOLIS				13					
	NEW JERSEY									
	PHILADELPHIA				32					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				80					
	FLORIDA				13					
	NEW ORLEANS	1		1	20					
	SAN JUAN				2					
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1		1						
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT				67					
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1		1	447					
	SAN FRANCISCO				33					
	SEATTLE				24					
	PACIFIC REGIONAL LABORATORY-SW							2		571
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		27.0		6.6	2.4		20.0	13.0	8.1	8.1
TOTAL HOURS		135		33	2292		40	39	1474	6261
CONVERSION FACTOR		950		950	950		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.14		0.03	2.41		0.03	0.03	1.25	5.31

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
<input checked="" type="checkbox"/>	CHEMIST	<input checked="" type="checkbox"/>	PYS. SCIENCE TECH	<input checked="" type="checkbox"/>	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
<input checked="" type="checkbox"/>	ENGINEER(ANALYST)	<input checked="" type="checkbox"/>	ENGINEER TECH	<input checked="" type="checkbox"/>	ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

Domestic Samples should only be collected on a for cause basis. Resources to cover Glove Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin.  
 Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.	
5. PROGRAM JUSTIFICATION A number of potential or emerging problems which cannot be predicted must be handled rapidly. This workplan activity provides resources for Center assignments which can rapidly address potential or emerging problems.	
6. FIELD OBLIGATIONS Conduct inspections and investigations as directed by Center assignments.	
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 checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Sterility/Performance	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.1				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOM EST I C S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D M I C R O (1)	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 C H E M (2)	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 S T E R (3)	9 O T H E R O P E R A T I O N S (Hours) M E T H D E V E N G (4)
	<b>TOTAL FIELD</b>	<b>65</b>		<b>547</b>	<b>22</b>		<b>2</b>	<b>2</b>	<b>2</b>	<b>850</b>
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	5		45	2					
	NEW YORK	3		29	1					
	REGIONAL LAB									
	WEAC						2	2	2	850
CE	REGIONAL STAFF									
	BALTIMORE	2		16	1					
	CHICAGO	3		27	1					
	CINCINNATI	3		25	1					
	DETROIT	3		24	1					
	MINNEAPOLIS	4		35	1					
	NEW JERSEY	3		21	1					
	PHILADELPHIA	3		24	1					
		FORENSIC CHEM. CTR								
SE	REGIONAL STAFF									
	ATLANTA	3		23	1					
	FLORIDA	5		41	2					
	NEW ORLEANS	3		23	1					
	SAN JUAN			4						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	4		33	1					
	DENVER	2		19	1					
	KANSAS CITY	3		22	1					
		SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	9		73	3					
	SAN FRANCISCO	4		37	1					
	SEATTLE	3		26	1					
		PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW									
		HOURS PER OPERATION	36.0			10.0	35.0	15.0	35.0	
		TOTAL HOURS	2340		547	220	70	30	70	850
		CONVERSION FACTOR	950		950	950	1180	1180	1180	1180
		TOTAL OPERATIONAL FTEs	2.46		0.58	0.23	0.06	0.03	0.06	0.72
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	ANAL Y T I C A L	10/15/02	09/30/03
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
NOTE: User Reporting Inspections are discontinued for this program; resources transferred to Inspections.										
(1) WEAC--Ad Hoc testing of media.										
(2) WEAC--Ad Hoc testing of test kits or reagents.										
(3) WEAC--Sterility samples.										
(4) WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.										

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Research	
6. FIELD OBLIGATIONS Accomplishment of goals of the individual research projects identified in Part IIA of the Workplan. All research will be distributed in-house and/or published in the referred scientific literature.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82				
3. PROGRAM/ASSIGNMENT CODE(S) 82R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	DISTRICT RESEARCH CHEM (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)			
	<b>TOTAL FIELD</b>		<b>1610</b>		<b>805</b>	<b>700</b>			
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC		1610		805	700			
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS		1610		805	700			
	CONVERSION FACTOR		1205		1205	1180			
	TOTAL OPERATIONAL FTEs		1.34		0.67	0.59			
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC- TIONAL	
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN		
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		
X	PHYSICIST				MILK/FOOD SPEC			ANALY- TICAL	10/15/02      09/30/03
X	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		
9. REMARKS									

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the office of Criminal Investigations.  This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law.  It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. The specific addition of Forensic Evaluation to this Operation Code was new in FY 1999. Please consult DFS and/or DPEM for additional reporting guidance.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/A <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) NA
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 Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	<b>TOTAL FIELD</b>	354								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR	354								
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	354								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.29								

7. PERSONNEL TYPES REQUIRED						8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	INVESTIGATOR	RRHR	INSP- TIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL	10/15/02	09/30/03
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER	SHELLFISH SPEC	OTHER			

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections/510(k) Premarket Approval Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b>Medical Device Premarket Approval and Postmarket Inspections:</b> To assure that both prior to and subsequent to approval of a PMA application, the manufacturer has the capability of manufacturing the PMA device in accordance with (1) the conditions specified in the PMA application and (2) the requirements of the device GMP regulation.  <b>510(k) Premarket Approval Inspections:</b> To assure, prior to approval of the 510(k) for selected devices, that the manufacturer is in compliance with the requirements of the device GMP regulation. To verify that the manufacturer has procedures in place and adequate documentation to support their premarket submission Declarations of Conformity to Standards, and/or their declaration of compliance with design controls.	
5. PROGRAM JUSTIFICATION <b>Medical Device Premarket Approval and Postmarket Inspections:</b> Section 515 of the Act requires that devices subject to Premarket Approval must be manufactured in conformance with the requirements of the device GMP regulation. Consequently, no PMA application can be approved until the Center has inspectional evidence that the manufacturer complies with the requirements set forth in the Premarket Approval application. <b>510(k) Premarket Approval Inspections:</b> The General Counsel has ruled that compliance with the GMP regulation is one of the elements of device safety which must be considered when reviewing a 510(k) application. This policy is being initially applied to all 510(k)s for preamendment Class III devices. In November 1997, the Federal Food, Drug, and Cosmetic Act (FFDCA) was modified by the FDA Modernization Act (FDAMA) to include Section 205, Device Standards. This section requires FDA to "recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization." After FDA recognizes a standard through publication in the Federal Register, "a person may submit a declaration of conformity in order to meet a premarket submission or other requirement under the FFDCA to which such standard is applicable." The use of standards is applicable to all types of pre-market submissions. These changes became effective on February 20, 1998.	
6. FIELD OBLIGATIONS <b>Medical Device Premarket Approval and Postmarket Inspections:</b> The field will conduct pre-approval inspections on assignment and submit an EIR to the Center along with the District's recommendation. The field will be responsible for scheduling post-approval inspections to occur approximately 8 months following approval of the PMA. Under certain conditions, a post-approval inspection will not be necessary. The Center will advise the district when a post-approval inspection is not necessary. <b>510(k) Inspections:</b> On assignment from CDRH, conduct a comprehensive GMP inspection as instructed in the compliance program. Regarding Conformance Standards inspections, conduct inspections based on assignments by the Field Programs Branch: 100% of assignments issued should be completed as high priority. Class II or III devices in the applicable declaration will be covered.	
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) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73 through 91
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 Medical Device Premarket Approval and Postmarket Inspections/510(k) Pre-Market Approval Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83001, A. 83003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	8	9
		INSPEC- TIONS PRE- APPROVAL 83001	INSPEC- TIONS POST- APPROVAL 83001A	FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	FOREIGN INSPEC- TIONS POST- APPROVAL 83001A	INSPEC- TIONS 510(K) 83003	INSPEC- TIONS DESIGN CONTROL (1) 83003	FOREIGN INSPEC- TIONS 510(K) 83003	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>100</b>	<b>65</b>	<b>34</b>	<b>27</b>	<b>7</b>	<b>13</b>	<b>7</b>		
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	7	5	1	2	1	1	1		
	NEW YORK	4	4	1	2		1	1		
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3	3		1					
	CHICAGO	3	1	1	2		1	1		
	CINCINNATI	3	1	1	2		1	1		
	DETROIT	2	1	1	2					
	MINNEAPOLIS	9	7	3	1	1	1			
	NEW JERSEY	5	3	2	2			1		
	PHILADELPHIA	4	1	3			1			
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	1	5	2	2			1		
	FLORIDA	8	6	3	2	1	1			
	NEW ORLEANS	3	3	2	1					
	SAN JUAN	3	4							
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	6	4	2	2	1	1	1		
	DENVER	5	1	2	2	1	1			
	KANSAS CITY	2	2	3	1		1			
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	20	6	3	1	1	1			
	SAN FRANCISCO	8	4	2	1	1	1			
SEATTLE	4	4	2	1		1				
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	46.5	33.5	47.3	39.1	34.0	34.0	35.0		
	TOTAL HOURS	4650	2178	1608	1056	238	442	245		
	CONVERSION FACTOR	950	950	950	950	950	950	950		
	TOTAL OPERATIONAL FTEs	4.89	2.29	1.69	1.11	0.25	0.47	0.26		

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		ANALY- TICAL		
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)				
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC				
					OTHER				

9. REMARKS  
 Report all time used for evaluating compliance with domestic pre-market requirements in PAC 83001, OP CODE 12;  
 for domestic post-market requirements in PAC 83001A, OP CODE 12.  
 Report all time used for evaluating compliance with foreign pre-market requirements in PAC 83001, OP CODE 11;  
 for foreign post-market requirements in PAC 83001A, OP CODE 11.  
 Report all time used for evaluating domestic 510(k) pre-market requirements against PAC 83003, Op Code 12;  
 for evaluating compliance with foreign 510(k) requirements in PAC 83003, Op Code 11.  
 (1) Inspections of firms who declare conformity to standards/compliance with design controls.

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure the quality, reliability and integrity of data and information supporting device applications (PMAs, 510(k)s or IDEs) and their claims of safety and effectiveness.  To ensure that human subjects taking part in clinical trials involving medical devices are protected from undue hazard or risk.  To coordinate, implement and enforce the provisions of the Agency's Application Integrity Policy (AIP) for medical devices.  To enforce the prohibition against promotion and/or commercialization of investigational devices.	
5. PROGRAM JUSTIFICATION Congress has mandated that the Agency maintain close surveillance of bioresearch activities done in support of application.  CDRH issues assignments and provides inspectional/investigational support documents for transmission to the field through ORA's Office of Enforcement (HFC-230). The Center reviews and evaluates all Establishment Inspection Reports (EIRs) from the field and is responsible for the final classification of all bioresearch monitoring inspection reports and the issuance of all associated correspondence.	
6. FIELD OBLIGATIONS To conduct inspections, investigations and other activities related to the bioresearch monitoring programs or the Agency's Application Integrity Policy for medical devices and to submit EIRs to the Center for review, evaluation and final classification.  The field is encouraged to review and initially classify inspection reports generated under the bioresearch monitoring program. However, final classification authority rests with the Center and decisions will be communicated promptly to the field.	
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 Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73Z, 74Z and 94Z, 95Z
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 Bioresearch Monitoring (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	7	8	9
		INSP EC T I O N S (GLPs)	INSP EC T I O N S (IRBs)	INSP EC T I O N S (SPON/MON)	INSP EC T I O N S (CLINICAL INVEST)	INSP EC T I O N S (SPON/MON) FOREIGN	INSP EC T I O N S (CLINICAL INVEST) FOREIGN	DOMESTIC SAMP LES TO BE ANALYZED	IMPOR T SAMP LES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>6</b>	<b>96</b>	<b>63</b>	<b>111</b>	<b>7</b>	<b>13</b>			
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	1	6	3	6					
	NEW YORK		3	5	6	2	2			
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		5	3	6	2				
	CHICAGO		4		2		2			
	CINCINNATI		6		8					
	DETROIT		10	2	6					
	MINNEAPOLIS	1	5	7	6					
	NEW JERSEY		5	3	1					
	PHILADELPHIA		3	2	6	1	3			
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA		7	3	8					
	FLORIDA	1	6	5	8	1	3			
	NEW ORLEANS		7	2	8					
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		11	2	11					
	DENVER		1	3	4					
	KANSAS CITY		2		4	1	3			
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	1	8	15	14					
	SAN FRANCISCO	2	4	7	3					
	SEATTLE		3	1	4					
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		94.0	42.0	73.0	75.0	26.0	78.0			
TOTAL HOURS		564	4032	4599	8325	182	1014			
CONVERSION FACTOR		950	950	950	950	950	950			
TOTAL OPERATIONAL FTEs		0.59	4.24	4.84	8.76	0.19	1.07			

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the quality of devices through product analysis and data evaluation.	
5. PROGRAM JUSTIFICATION Product evaluation study projects provide comprehensive postmarket surveillance information about devices.	
6. FIELD OBLIGATIONS Conduct laboratory analysis using test methods from a variety of sources.	
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 type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) To be assigned	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" 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 Test Method Development and Evaluation					2. PPS PROJECT NAME/NUMBER Science: Devices - 84						
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.2				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1 INSP EC T I O N S	2 INVEST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	9 OTHER OPERATIONS (Hours) METH DEV CHEM	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	TOTAL FIELD								660	2085	4520
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC								660	2085	4520
	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								660	2085	4520	
CONVERSION FACTOR								1180	1180	1180	
TOTAL OPERATIONAL FTEs								0.56	1.77	3.83	
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSP EC T I O N A L			
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03	
	PHYSICIST				MILK/FOOD SPEC						
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by the CDRH Laboratory Staff.											

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Research	
6. FIELD OBLIGATIONS Accomplishment of goals of the individual research projects identified in Part IIA of the Workplan. All research will be distributed in-house and/or published in the referred scientific literature.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)				
	<b>TOTAL FIELD</b>			1200	1660				
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC			1200	1660				
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS			1200	1660				
	CONVERSION FACTOR			1205	1180				
	TOTAL OPERATIONAL FTEs			1.00	1.41				

7. PERSONNEL TYPES REQUIRED					8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE		PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	INVESTIGATOR	RRHR		
X	MICROBIOLOGIST		BIO. SCIENCE TECH	INSPECTOR	VETERINARIAN		
X	ENGINEER(ANALYST)		ENGINEER TECH	ENGINEER (INV)	NAT'L EXPERT		
	PHYSICIST			MILK/FOOD SPEC		10/15/02	09/30/03
	ENTOMOLOGIST		OTHER	SHELLFISH SPEC	OTHER		

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To inspect certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA). To bring uncertified facilities into compliance with MQSA.	
5. PROGRAM JUSTIFICATION MQSA (Public Law 102-539) establishes uniform, national quality standards for mammography. It establishes a comprehensive statutory mechanism for certification and inspection of all mammography facilities under the regulatory jurisdiction of the United States. Under the MQSA, only certified facilities that are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation starting October 1, 1994. Operation after that date is contingent on receipt of a certificate from the FDA. The authority to implement the MQSA was delegated by the Secretary of Health and Human Services (HHS) to FDA in June 1993.	
6. FIELD OBLIGATIONS Inspect certified mammography facilities in accordance with procedures specified in the compliance program. Conduct followup inspections to determine whether the facility has complied with the terms of their corrective action plan, based on noncompliances found during a prior inspection. Perform on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections. Conduct investigations of suspected uncertified mammography facilities.	
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) Mammography equipment	d. INDUSTRY/PRODUCT CODE(S) 90
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 Mammography Facilities Inspection Program					2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85					
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 18.0 [9.0]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N  85014 (1)	1 INSP EC T I O N  85014F (2)	1 INSP EC T I O N  85014 (3)	1 INSP EC T I O N  85014 (4)	1 INSP EC T I O N F O R E I G N  85014 (5)	2 INVEST I G A T I O N S (Hours) 85014A (6)	2 INVEST I G A T I O N S (Hours) 85014 (7)	9 O T H E R O P E R A T I O N S (Hours) 85014C (8)	9 O T H E R O P E R A T I O N S (Hours) 85014 (9)
	<b>TOTAL FIELD</b>		<b>245</b>	<b>95</b>	<b>122</b>	<b>37</b>	<b>15</b>	<b>2409</b>	<b>50</b>	<b>325</b>
N E	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	48	5	3	1		176	6	18	207
	NEW YORK	11	7	1	4		176	3	24	281
	REGIONAL LAB WEAC									
C E	REGIONAL STAFF									
	BALTIMORE		5	14	2	1	154	3	16	185
	CHICAGO		4	2	1		110	2	15	172
	CINCINNATI	12	6	3	1		165	3	21	249
	DETROIT	18	6	1			154	3	19	227
	MINNEAPOLIS		6	5			154	2	19	223
	NEW JERSEY		3	2			55		9	109
	PHILADELPHIA FORENSIC CHEM. CTR		5	2	1		121	3	16	184
S E	REGIONAL STAFF									
	ATLANTA		6	14	3		132	2	22	258
	FLORIDA		5	6	6	1	110	3	16	194
	NEW ORLEANS		6	7	3		154	3	22	255
	SAN JUAN REGIONAL LAB	3	1	1		3	22	2	5	59
S W	REGIONAL STAFF	145	16	29	6	9	374	12	53	643
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
P A	REGIONAL STAFF									
	LOS ANGELES		6	13	6		110	3	20	243
	SAN FRANCISCO	8	5	9	3	1	154		16	183
	SEATTLE		3	10			88		14	168
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		8.0	5.0	8.0	8.0	8.0				
TOTAL HOURS		1960	475	976	296	120	2409	50	325	3840
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1160
TOTAL OPERATIONAL FTEs		1.69	0.41	0.84	0.26	0.10	2.08	0.04	0.28	3.31
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	X	RRHR	INSPEC TIONAL	10/01/02	09/30/03	
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL			
PHYSICIST				MILK/FOOD SPEC						
ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS										
<b>RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE &amp; COORDINATION HOURS</b>										
1) Inspection of Certified Mammography Facilities not covered by the states. 2) Follow-up Inspections.										
3) Federal Facility Inspections (does not include VHA Facility inspections).										
4) VHA Facility Inspections. <b>NOTE--these inspections are paid through an Interagency Agreement and are not covered by MQSA resources.</b>										
5) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries. 6) Audit Investigations.										
7) Investigations of Uncertified Mammography Facilities.										
8) Compliance Activities.										
9) Technical Assistance and Coordination Activities										

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1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program					2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85					
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 18.0 [9.0]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours) 85014F (10)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours) 85014 (11)
	TOTAL FIELD		9296							1200
	HEADQUARTERS									
NE	REGIONAL STAFF									200
	NEW ENGLAND		501							
	NEW YORK		681							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									400
	BALTIMORE		445							
	CHICAGO		416							
	CINCINNATI		602							
	DETROIT		550							
	MINNEAPOLIS		539							
	NEW JERSEY		264							
	PHILADELPHIA		446							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									200
	ATLANTA		625							
	FLORIDA		470							
	NEW ORLEANS		618							
	SAN JUAN		142							
	REGIONAL LAB									
SW	REGIONAL STAFF		1558							200
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									200
	LOS ANGELES		588							
	SAN FRANCISCO		444							
	SEATTLE		407							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS		9296							1200
	CONVERSION FACTOR		1160							1200
			8.01							1.00
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	X	RRHR	INSPEC T I O N A L	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY T I C A L		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS										
10) Inspection Follow-Up Activities (Non-Warning Letter)										
11) Technical Assistance and Coordination Activities: RRHRs.										

**CONTINUATION SHEET**

1. PROGRAM/ASSIGNMENT TITLE

Mammography Facilities Inspection Program

2. PPS PROJECT NAME/NUMBER

Mammography Quality Standards Act (MQSA) Authority - 85

9. Remarks

**RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS INTO PODS**

- 1) Inspection of Certified Mammography Facilities not covered by the states.
- 2) Follow-up inspections.
- 3) Federal Facility inspections.
- 4) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries.
- 5) Audit Investigations.
- 6) Investigations of Uncertified Mammography Facilities.
- 7) Domestic Sample Collections.
- 8) Includes Technical Assistance and Coordination activities.

## PROJECT SUMMARY SHEET

FY 2003

1. PROGRAM CATEGORY		2. PPS PROJECT NAME/NUMBER						
Medical Devices and Radiological Health		Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	<b>TOTAL</b>		<b>30.5</b>	<b>4.8</b>	<b>2.0</b>	<b>37.3</b>	<b>75.3</b>	
1	Optical Electronic Products:		7.5		0.2	7.7	16.7	2-7
	Inspection of Manufacturers of Laser Products	86001	(6.7)		(0.2)	(6.9)	(15.0)	
	Field Implementation of the Sunlamp & Sunlamp Products Performance Standard as Amended	86002	(0.8)			(0.8)	(1.7)	
2	X-Ray Surveillance Programs:		11.2			11.2	23.2	8-17
	Field Compliance Testing of Diagnostic X-Ray Equipment	86003	(9.8)			(9.8)	(21.2)	
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	(0.5)			(0.5)	(1.1)	
	Counter-Terrorism Activities	86R845	(0.9)			(0.9)	(0.9)	
3	Compliance Testing of Electronic Products at WEAC	86006, A, B, D, E, F	3.4		1.8	5.2	11.3	18-21
4	Imported Electronic Products:	86007 *		4.8		4.8	7.3	22-23
	* Import program (Includes reporting PACs 82R824, 82R833, and 99R833)			(2.1)		(2.1)	(4.6)	
	Counter-Terrorism Activities	86R845		(2.7)		(2.7)	(2.7)	
5	Radiological Health Control Activities:		8.4			8.4	16.8	24-27
	Medical Device and Radiological Health Use Control and Policy Implementation	86008	(4.6)			(4.6)	(10.0)	
	Emergency Planning and Response Activities	86009	(1.2)			(1.2)	(2.6)	
	Federal Facilities Survey Program	86010	(1.4)			(1.4)	(3.0)	
	Counter-Terrorism Activities	86R845	(1.2)			(1.2)	(1.2)	
CENTER PROJECT MANAGER/TELEPHONE			ORA PLANNER/TELEPHONE					
Lillian J. Gill 301-594-4692			John Aydinian 301-827-1634					

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b><u>Inspection of Manufacturers of Laser Products:</u></b> To determine if laser products are in compliance with the radiation emissions requirement of the "laser performance standard."  <b><u>Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:</u></b> To conduct a field enforcement program to determine the compliance of sunlamp and sunlamp products with both the performance standard and Agency issued recommendations.	
5. PROGRAM JUSTIFICATION <b><u>Inspection of Manufacturers of Laser Products:</u></b> FDA conducts a program effort to protect the public from the dangerous emission of radiation from laser products. Under the authority of Public Law 90-602 the FDA published a Laser Product Performance Standard designed to control dangerous emissions from these products and is applicable to laser products manufactured after August 2, 1976. In addition, those laser products that are used in medical applications are covered under this Agency's medical device authority. <b><u>Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:</u></b> FDA conducts program efforts to minimize radiation emissions from electronic products and devices that have proven to have harmful biological effects. Under the authority of Public Law 90-602 and the Medical Device Amendments to the Food, Drug and Cosmetic Act, FDA has published a performance standard and separate recommendations designed to control the emission of light radiation from sunlamp products. The performance standard for sunlamp products became effective May 7, 1980, and the amended standard on September 7, 1986. Recent studies suggest that exposure to excessive UVA radiation has resulted in malignant melanoma.	
6. FIELD OBLIGATIONS <b><u>Inspection of Manufacturers of Laser Products:</u></b> Electro-Optic specialists will initiate and schedule their own inspections of laser manufacturers listed in the compliance program. In addition, the Electro-Optic Specialist will participate on joint CDRH/ORA inspections when such inspections are scheduled by the Center. <b><u>Sunlamp and Sunlamp Products:</u></b> Districts will identify and schedule inspections of sunlamp product manufacturers for compliance with the FD&C Act. Districts will initiate and conduct field testing of suntanning facilities per the guidance set out in the compliance program. In addition, in that most states and local radiological health bureaus have no regulation on these products, the field should establish communications with them and offer assistance if they choose to develop such regulations.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Lasers and laser products Sunlamp, suntanning booths, and sunlamp products.	d. INDUSTRY/PRODUCT CODE(S) 95LS-99 95 US-11
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 <b><u>Sunlamp Products:</u></b> The investigator should use the inspectional Check-List (Review of Product Compliance) located in the compliance program when conducting field tests under this compliance program.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING <i>Caution:</i> laser product <i>may</i> be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.	

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.7      [6.2]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	2	3	3	5	5
		INSP CTIONS 86001 (1)	INSP CTIONS FOREIGN 86001 (2)	INSP CTIONS 86002 (3)	INVEST IGATIONS (Hours) 86001 (4)	INVEST IGATIONS (Hours) 86002	DOMESTIC SAMPLE COLL 86001 (5)	DOMESTIC SAMPLE COLL 86002	FIELD EXAMS/ TESTS 86001 (6)	FIELD EXAMS/ TESTS 86002 (7)
	<b>TOTAL FIELD</b>	<b>133</b>	<b>15</b>	<b>8</b>	<b>2100</b>	<b>90</b>	<b>7</b>	<b>3</b>	<b>98</b>	<b>56</b>
NE	HEADQUARTERS									
	REGIONAL STAFF	19			300		1		14	
	NEW ENGLAND									3
	NEW YORK						6			4
	REGIONAL LAB									
	WEAC		15							
CE	REGIONAL STAFF	19			300		1		14	
	BALTIMORE					5				3
	CHICAGO					4				2
	CINCINNATI			2		5		1		3
	DETROIT			1		5				3
	MINNEAPOLIS					4				2
	NEW JERSEY			1		3				2
	PHILADELPHIA					4				3
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	10		1	150	6		1	7	4
	FLORIDA			1		5		1		3
	NEW ORLEANS	9			150	7	1		7	4
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF	19			300		1		14	
	DALLAS			1		9				6
	DENVER					2				1
	KANSAS CITY			1		4				3
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	57			900		3		42	
	LOS ANGELES					8				5
	SAN FRANCISCO					5				3
	SEATTLE					4				2
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		18.4	14.6	13.8			3.0	2.0	6.2	6.2
TOTAL HOURS		2447	219	110	2100	90	21	6	608	347
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		2.58	0.19	0.12	2.21	0.09	0.02	0.01	0.64	0.37

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL		
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	X	OTHER			

9. REMARKS

See Continuation Sheet

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1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products					2. PPS PROJECT NAME/NUMBER Optical Electronic Products							
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 7.7 [1.5]					
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 DOM EST I C S A M P L E C O L L	4 IMP 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 IMP 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	9 O T H E R O P E R A T I O N S (Hours) 86001 (8)	9 O T H E R O P E R A T I O N S (Hours) 86002 (10)	
	TOTAL FIELD										1218	218
N E	HEADQUARTERS											
	REGIONAL STAFF											
	NEW ENGLAND										174	31
	NEW YORK											
	REGIONAL LAB WEAC											
C E	REGIONAL STAFF											
	BALTIMORE										174	31
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA FORENSIC CHEM. CTR											
S E	REGIONAL STAFF											
	ATLANTA										87	16
	FLORIDA											
	NEW ORLEANS										87	15
	SAN JUAN REGIONAL LAB											
S W	REGIONAL STAFF											
	DALLAS										174	31
	DENVER											
	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB											
P A	REGIONAL STAFF											
	LOS ANGELES										522	94
	SAN FRANCISCO											
	SEATTLE											
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION												
TOTAL HOURS										1218	218	
CONVERSION FACTOR										950	950	
TOTAL OPERATIONAL FTEs										1.28	0.23	
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE				
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END		
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/01/02	09/30/03		
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN					
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	ANAL Y T I C A L				
	PHYSICIST				MILK/FOOD SPEC							
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	X	OTHER					
9. REMARKS  See Continuation Sheet												

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Optical Electronic Products

2. PPS PROJECT NAME/NUMBER

Radiation Control and Health Safety Act (RCHSA)  
Authority - 86

9. Remarks

**NEW FOR FY 2003 WORKPLAN: INSPECTION OF MANUFACTURERS OF LASER PRODUCTS (86001) AND FIELD IMPLEMENTATION OF THE SUNLAMP AND SUNLAMP PRODUCTS PERFORMANCE STANDARD AS AMENDED (86002) HAVE BEEN CONSOLIDATED WITH THE TITLE OPTICAL ELECTRONIC PRODUCTS. THE PACs WILL REMAIN IN EFFECT FOR REPORTING PURPOSES.**

**FOOTNOTES:****Inspection of Manufacturers of Laser Products:**

- 1) Unless otherwise noted, to be performed by Electro-Optics Specialists (EOS), per their Multi-regional responsibilities. Comprehensive Inspections can only be claimed for manufacturers of radiation-emitting products on a recurring basis.
- 2) Number of inspections for Engineering Analyst.
- 4) Investigation Hours--refer to Compliance Program for reporting information.
- 5) To be performed by reserve EOS, or by CSOs trained by an EOS.
- 6) Will include laser products located at a user facility and laser light shows.
- 8) To include all other activities such as technical assistance, coordination, and training.

**Sunlamps and Sunlamp Products:**

- 3) Inspectional figures are only for biennial inspections of manufacturers of sunlamp products (to include sunlamps, booth beds, etc.). Inspections are to be conducted in conjunction with a GMP inspection. Examination of booth beds at tanning parlors, athletic clubs, etc. should be reported as field exams and not inspections.
- 7) The field test of each sunlamp product should be counted as a separate operation.
- 10) To be performed by Electro-Optic Specialist--Consultation.

NOTE: Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <b>Field Compliance Testing of Diagnostic X-Ray Equipment:</b> To determine if certified dental and medical x-ray diagnostic equipment meet the Federal performance requirement for diagnostic x-ray equipment (21 CFR 1020.30), in order to monitor the compliance of x-ray equipment component manufacturers and assemblers.  <b>Field Compliance Testing of Cabinet X-Ray Equipment:</b> To determine compliance with the performance standard for cabinet x-ray equipment with respect to radiation emissions under conditions of use.	
5. PROGRAM JUSTIFICATION <b>Field Compliance Testing of Diagnostic X-Ray Equipment:</b> Under the authority of Public Law 90-602, FDA has published a performance standard designed to control unnecessary radiation associated with diagnostic x-ray equipment. The promulgated standard became effective August 1, 1974, and this authority extends to all diagnostic x-ray equipment manufactured after that date.  <b>Field Compliance Testing of Cabinet X-Ray Equipment:</b> Under the authority of Public Law 90-602 FDA published a performance for cabinet x-ray equipment which became effective on April 10, 1975, (and on April 25, 1974, for carry-on baggage systems). This performance standard is designed to control the emission levels of radiation from cabinet x-ray systems and baggage x-ray equipment and to assure that radiation exposure will be reduced to, or maintained at, acceptable levels in accessible areas from those systems manufactured after the effective date of the standard. In addition, the standard will have the effect of minimizing incidences of system failure and associated excessive radiation exposure.	
6. FIELD OBLIGATIONS <b>Diagnostic X-Rays:</b> Assemblers will be inspected to ensure their capabilities to properly install diagnostic x-ray components. Field personnel will conduct tests using their discretion as far as site selection except where the CDRH identifies priorities. Equipment at each site will be tested per the instruction of the compliance program. ORA will monitor both State and Federal inspectors to assure quality and consistency in the collected test data. <b>Cabinet X-Rays:</b> Districts will conduct record reviews of manufacturers in their inventory to determine locations of cabinet x-ray systems. Identified site locations will be sent to appropriate DDs so they can schedule field tests. Field personnel will conduct tests at locations identified by the district. Each site shall be investigated per the instructions of the compliance program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      N/A <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Diagnostic X-Ray Equipment Cabinet x-ray and baggage x-ray	d. INDUSTRY/PRODUCT CODE(S) 94DS--- 94 IS-11 94 IS-21
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 <b>Diagnostic X-Rays:</b> Field tests will be performed by consumer safety officers who have received specialized training which includes approximately two weeks of on-the-job training with a qualified auditor.	

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. PROGRAM/ASSIGNMENT CODE(S) 86003, 86004, 86R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 11.2 [10.3]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS 86003	1 INSP CTIONS 86004	2 INVEST IGATIONS (Hours) 86003	2 INVEST IGATIONS (Hours) 86004	5 FIELD EXAMS/ TESTS 86003	5 FIELD EXAMS/ TESTS 86004	5B AUDITS 86003	8 IMPOR T SAM PLES TO BE ANAL YZED	9 OTHER OPER ATIONS (Hours) 86003
	<b>TOTAL FIELD</b>	<b>31</b>	<b>28</b>	<b>958</b>	<b>41</b>	<b>1058</b>	<b>32</b>	<b>92</b>		<b>4217</b>
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	2	39	4	39	3	4		175
	NEW YORK	2	2	45	3	45	2	2		215
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1		49		64		6		234
	CHICAGO	1	4	37	7	16	4	9		177
	CINCINNATI	1	1	56	2	42	1	4		263
	DETROIT	1	2	48	4	87	3	4		199
	MINNEAPOLIS	1	1	52	1	21	1	6		230
	NEW JERSEY	1	1	23	2	44	1			111
	PHILADELPHIA	2	1	39		34	1	6		183
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2	2	82	3	142	2	4		343
	FLORIDA	2	2	69	4	82	3	2		296
	NEW ORLEANS	3	1	84	2	65	1	8		370
	SAN JUAN REGIONAL LAB			2		5		1		30
SW	REGIONAL STAFF									
	DALLAS	3	1	121		139	1	12		471
	DENVER	2	1	32		31	1	8		156
	KANSAS CITY	2	1	56		56	1	6		218
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3	3	55	5	61	3	4		220
	SAN FRANCISCO	1	2	33	3	31	2	4		162
	SEATTLE	2	1	36	2	54	2	2		164
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		20.0	10.0			3.0	4.1	4.0		
TOTAL HOURS		620	280	958	41	3174	131	368		4217
CONVERSION FACTOR		950	950	950	950	950	950	950		950
TOTAL OPERATIONAL FTEs		0.65	0.29	1.01	0.04	3.34	0.14	0.39		4.44
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
CHEMIST		PYS. SCIENCE TECH		X	INVESTIGATOR	RRHR	INSPEC TIONAL	10/01/02	09/30/03	
MICROBIOLOGIST		BIO. SCIENCE TECH			INSPECTOR	VETERINARIAN				
ENGINEER(ANALYST)		ENGINEER TECH			ENGINEER (INV)	NAT'L EXPERT	ANALY TICAL			
PHYSICIST					MILK/FOOD SPEC					
ENTOMOLOGIST		OTHER			SHELLFISH SPEC	OTHER				
9. REMARKS										
* CSO trained for surveying X-Ray equipment. Inspections to be performed during first quarter of fiscal year.										
See Continuation Sheet for additional information and guidance.										
Use CT PAC 86R845 ONLY when specific CT work is performed, otherwise use related program PACs										

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1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA)					
3. PROGRAM/ASSIGNMENT CODE(S) 86003, 86004, 86R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 11.2    [0.93]				
R E G I O N	6	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP CTIONS	CT INVEST GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	CT FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
TOTAL FIELD			102			136				
HEADQUARTERS										
REGIONAL STAFF										
NE	NEW ENGLAND		9			8				
	NEW YORK		7			8				
	REGIONAL LAB									
	WEAC									
REGIONAL STAFF										
BALTIMORE										
CE	CHICAGO		16			8				
	CINCINNATI		4			8				
	DETROIT		9			8				
	MINNEAPOLIS		2			8				
	NEW JERSEY		4			8				
	PHILADELPHIA		2			8				
	FORENSIC CHEM. CTR									
REGIONAL STAFF										
SE	ATLANTA		7			8				
	FLORIDA		9			8				
	NEW ORLEANS		4			8				
	SAN JUAN									
	REGIONAL LAB									
REGIONAL STAFF										
SW	DALLAS		2			8				
	DENVER		2			8				
	KANSAS CITY		2			8				
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
REGIONAL STAFF										
PA	LOS ANGELES		11			8				
	SAN FRANCISCO		7			8				
	SEATTLE		5			8				
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION						2.7				
TOTAL HOURS			102			367				
CONVERSION FACTOR			500			500				
TOTAL OPERATIONAL FTEs			0.20			0.73				
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END		
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC- TIONAL	10/01/02	09/30/03	
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR	VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL			
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER				
9. REMARKS										
See Continuation Sheet for additional information and guidance.										
Use CT PAC 86R845 ONLY when specific CT work is performed, otherwise use related program PACs										
* CDRH requested that any approved CT increases be used in the Compliance Testing of Cabinet X-Ray Equipment program (86004) to support CT security issues.										

## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

X-Ray Surveillance Programs

2. PPS PROJECT NAME/NUMBER

Radiation Control and Health Safety Act (RCHSA)  
Authority - 86

9. Remarks

**NEW FOR FY 2003 WORKPLAN: FIELD COMPLIANCE TESTING OF DIAGNOSTIC X-RAY EQUIPMENT (86003) AND FIELD COMPLIANCE TESTING OF CABINET X-RAY EQUIPMENT (86004) HAVE BEEN CONSOLIDATED WITH THE TITLE X-RAY SURVEILLANCE PROGRAMS. THE PACs WILL REMAIN IN EFFECT FOR REPORTING PURPOSES.**

**Diagnostic X-Rays (86003):**

- 1) Inspections are spread based on the number of x-ray assemblers. Inspections are for compliance follow-up only.
- 2) Investigation hours are for review of assembler reports.
- 3) Field Tests and Audits are obtained from Attachment A, and are provided by CDRH's Compliance X-Ray Products Branch, HFZ 300 (Henry Knox). Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor to verify both Federal and State data.
- 4) Other Operations includes Coordination/Technical Assistance resources for Field Test Review.

Sources of Diagnostic X-Ray Workloads: Inspections are based on the OEI of Diagnostic X-Ray Assemblers; Investigation Hours are based on Reviewing 2579 Reports (Assembler Reports of X-Ray Equipment Installations); Coordination Hours are based on the Total Field Test Records to Review.

Use CT PAC 86R845 ONLY when specific CT work is performed, otherwise use related program PACs.  
CDRH requested that any approved CT increases be used in the Compliance Testing of Cabinet X-Ray program (86004) to support CT security issues.

**ATTACHMENT A**  
**2003 WORKPLAN FOR FIELD COMPLIANCE TESTING**  
**OF DIAGNOSTIC X-RAY SYSTEMS**  
**(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2003)**

**NEW ENGLAND DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CT	77	-	12	1	-
ME	38	8	-	1	2
MA	190	20	10	2	-
NH	45	-	7	1	-
RI	34	8	-	1	2
VT	13	-	3	1	-
<b>Total</b>	<b>397</b>	<b>36</b>	<b>32</b>	<b>7</b>	<b>4</b>

**NEW YORK DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NY	462	40	41	4	2

**BALTIMORE DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DC	33	-	5	-	-
MD	170	20	12	2	2
VA	245	10	40	4	2
WV	57	10	-	1	2
<b>Total</b>	<b>505</b>	<b>40</b>	<b>57</b>	<b>7</b>	<b>6</b>

**CHICAGO DISTRICT**

Number Partner-

**CHICAGO DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IL	382	60	10	6	9

**CINCINNATI DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
KY	158	30	2	3	2
OH	414	46	32	6	2
<b>Total</b>	<b>572</b>	<b>76</b>	<b>34</b>	<b>9</b>	<b>4</b>

**DETROIT DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IN	227	-	38	3	4
MI	259	-	42	4	-
<b>Total</b>	<b>486</b>	<b>-</b>	<b>80</b>	<b>7</b>	<b>4</b>

**MINNEAPOLIS DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
MN	210	35	5	2	2
ND	37	6	-	1	2
SD	41	-	6	1	-
WI	239	40	4	2	2
<b>Total</b>	<b>527</b>	<b>81</b>	<b>15</b>	<b>6</b>	<b>6</b>

**NEW JERSEY DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NJ	233	-	40	4	-

**PHILADELPHIA DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DE	26	-	5	1	-
PA	376	45	22	6	6
<b>Total</b>	<b>402</b>	<b>45</b>	<b>27</b>	<b>7</b>	<b>6</b>

**ATLANTA DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
GA	256	-	45	4	-
NC	367	15	50	5	2
SC	213	-	35	3	2
<b>Total</b>	<b>836</b>	<b>15</b>	<b>130</b>	<b>12</b>	<b>4</b>

**FLORIDA DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
FL	704	52	70	12	2

**NEW ORLEANS DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AL	245	20	20	4	2
LA	189	25	8	3	2
MS	128	25	-	2	2
TN	294	25	24	4	2
<b>Total</b>	<b>856</b>	<b>95</b>	<b>52</b>	<b>13</b>	<b>8</b>

**SAN JUAN DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
PR	20	-	4	1	1

**DALLAS DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AR	121	-	20	1	-
OK	138	-	24	1	-
TX	974	80	83	10	12
<b>Total</b>	<b>1233</b>	<b>80</b>	<b>127</b>	<b>12</b>	<b>12</b>

**DENVER DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CO	172	10	18	2	4
NM	58	15	-	1	2
UT	73	10	4	1	2
WY	24	-	4	1	-
<b>Total</b>	<b>327</b>	<b>35</b>	<b>26</b>	<b>5</b>	<b>8</b>

**KANSAS CITY DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IA	157	15	9	1	2
KS	114	15	4	1	2
NE	84	10	3	1	2
MO	216	-	35	2	-
<b>Total</b>	<b>571</b>	<b>40</b>	<b>51</b>	<b>5</b>	<b>6</b>

**LOS ANGELES DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AZ	195	-	30	2	-
CA	370	36	25	4	4
<b>Total</b>	<b>565</b>	<b>36</b>	<b>55</b>	<b>6</b>	<b>4</b>

**SAN FRANCISCO DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CA	223	24	12	2	2
HI	31	14	-	1	2
NV	84	-	15	1	-
<b>Total</b>	<b>338</b>	<b>38</b>	<b>27</b>	<b>4</b>	<b>4</b>

**SEATTLE DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AK	24	-	4	1	-
ID	43	-	7	1	-
MT	37	-	6	1	-
OR	96	-	17	1	-
WA	165	16	14	2	2
<b>Total</b>	<b>365</b>	<b>16</b>	<b>48</b>	<b>6</b>	<b>2</b>

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC	2. PMS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure, through laboratory testing, that electronic products meet the FDA performance standards.	
5. PROGRAM JUSTIFICATION Public Law 90-602 and subsequent regulations (21 Subchapter J) are intended to safeguard the public from radiation hazards associated with electronic products. The Act specifically authorizes the Secretary to promulgate performance standards imposing additional requirements on specific electronic products of special concern from a radiation safety standpoint. Such performance standards have been issued: Microwave ovens (21 CFR 1030.10); dental, portable and mobile x-ray equipment (21 CFR 1020.30); ultrasonic therapy devices (21 CFR 1050.10); and television receivers (21 CFR 1020.10); sunlamp and mercury vapor lamps (21 CFR 1040.20, 1040.30).	
6. FIELD OBLIGATIONS WEAC will test all products in accordance with the appropriate compliance program circular and submit each report to the Center. WEAC will return equipment to lenders when advised by the Center. In addition, WEAC will advise the Center with the status of all equipment on hand, being tested and returned to lenders. WEAC will conduct inspections to confirm conformance to the Radiological Health Standards Act.	
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) Microwaves, TV Receivers, Diagnostic X-Ray Equipment, Mercury Vapor/Sunlamp, Ultrasonic Therapy Equipment	d. INDUSTRY/PRODUCT CODE(S) 96MS, 94VS, 94DS, 95US, 97US
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" 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 Compliance Testing of Electronic Products at WEAC				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3 PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E,F			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 5.2			
R E G I O N	6	1	7	7	7	7	7	7	7	9
	DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPECTIONS (PL 90-602 STANDARD)	DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	DOMESTIC SAMPLES TO BE ANALYZED X-RAY SOURCE	DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS	DOMESTIC SAMPLES TO BE ANALYZED ULTRA- SONIC	DOMESTIC SAMPLES TO BE ANALYZED SONIC ENDUR	OTHER OPERATIONS (Hours)
	TOTAL FIELD	27	52	27	3	1	18	2	1	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC	27	52	27	3	1	18	2	1	
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		80.0	32.0	41.0	260.0	100.0	8.0	80.0	25.0	
TOTAL HOURS		2160	1664	1107	780	100	144	160	25	
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	
TOTAL OPERATIONAL FTEs		1.83	1.41	0.94	0.66	0.08	0.12	0.14	0.02	
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL			INVESTIGATIVE				PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSP- TIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)	X	ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/02  09/30/03	
	PHYSICIST		OTHER		MILK/FOOD SPEC		OTHER			
	ENTOMOLOGIST				SHELLFISH SPEC					
9. REMARKS										
See Continuation Sheet										

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Compliance Testing of Electronic Products at WEAC

2. PPS PROJECT NAME/NUMBER

Radiation Control and Health Safety Act (RCHSA)  
Authority - 86

9. Remarks

All samples to be shipped by distributors/manufacturers to WEAC.

- 1) Microwaves - Number includes 25 endurance testing samples.
- 2) Diagnostic X-Ray:
  - Whole - For analysis of entire diagnostic X-Ray systems for compliance;
  - Source - Leakage test of diagnostic source assembly only.
- 3) Foreign Inspections--PL 90-602 Standard Inspections:
  - Report accomplishments in PAC 86006;
  - To ensure conformance to Rad Health Standards; to be conducted by Engineering Analyst.

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that imported electronic products presented for entry into the U.S. are certified to be in compliance with appropriate standards where applicable.  To provide a mechanism through which imported electronic products found to be in noncompliance with FDA regulations can be precluded from introduction into commerce in the United States.	
5. PROGRAM JUSTIFICATION FDA under the authority of Public Law 90-602 conducts program effort to minimize the effects of harmful radiation from electronic products and radiation emitting medical devices. The Act is very specific about restrictions and safeguards concerning such electronic products from foreign countries.	
6. FIELD OBLIGATIONS The district import program manager will monitor all custom entries of electronic products for which performance standards are in effect and determine whether imported models are contained on lists provided by CDRH and that these models are not among those which have been determined to be noncompliant. All information gathered as a result of these activities will be furnished to the Office of Compliance in accordance with the compliance 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 electronic products or devices that emit radiation.	d. INDUSTRY/PRODUCT CODE(S) 94-97
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 Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833 86R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	2	4	7	8	9
		INSP EC T I O N S	ENT R Y R E V I E W (Hours)	F I L E R E V A L (Hours)	I N V E S T I G A T I O N S (Hours)	C T E N T R Y R E V I E W (Hours)	C T I M P O R T F I E L D E X A M S	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	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	O T H E R O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>		<b>2280</b>	<b>200</b>		<b>1025</b>	<b>550</b>			
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		40	8		28				
	NEW YORK		248	34		136	69			
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		9	8		29				
	CHICAGO		89	10		48	21			
	CINCINNATI		52	10		27	13			
	DETROIT		94	11		33	31			
	MINNEAPOLIS		15			16				
	PHILADELPHIA		10			13				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		32	13		53				
	FLORIDA		60	12		60	22			
	NEW ORLEANS		212	8		65	51			
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT		740	41		254	178			
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		244	24		119	60			
	SAN FRANCISCO		115	10		52	28			
SEATTLE		320	11		92	77				
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION							0.60			
TOTAL HOURS			2280	200		1025	330			
CONVERSION FACTOR			1200	950		500	500			
TOTAL OPERATIONAL FTEs			1.90	0.21		2.05	0.66			

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	ANALY TICAL		

9. REMARKS  
 Reporting Guidance:  
 - Import Entry Reviews (Electronic and Manual--operation code 14, PAC 86R833);  
 - Filer Evaluations (operation code 95, PAC 99R833); and  
 - Follow-up to Refusals (PAC 86R824).  
 Use CT PAC 86R845 ONLY when specific CT work is performed, otherwise use related program PACs.  
 Planning Guidance: Unused resources for Filer Evaluations should be used when necessary towards Entry Reviews, since more resources have been planned in Filer Evaluations.

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p><b>Use Control:</b> Provide technical assistance to State and Federal radiological health programs implementing FDA use control programs, including DENT (see the compliance program for a more complete statement of objectives and laboratory support); Maintain liaison with State radiological health programs; Provide support for regional training activities and regional videotape library; Promote implementation of programs to optimize radiation exposure; Communicate FDA policies to State and local health agencies.</p> <p><b>Emergency Planning &amp; Response Activities:</b> To act as a focal point for emergency readiness response planning by States.</p> <p><b>Federal Facilities Survey Program:</b> Assess Federal medical facilities' conformance with generally accepted standards on radiation safety and with: PL90-602 and PL97-35; Promote use control programs developed by CDRH in Federal medical facilities; Monitor for conformance with and to assist in collecting data related to the implementation of recommendations contained in the Presidential Directive "Radiation Protection Guidance to Federal Agencies for Diagnostic X-Rays"; Determine if Federal facilities are conforming to the Consumer-Patient Radiation Health and Safety Act of 1981 (PL 97-35).</p>	
5. PROGRAM JUSTIFICATION <p><b>Medical Device and Radiological Health Use Control and Policy Implementation:</b> Rapidly changing technology requires that the FDA develop use control programs whose effective implementation will require training beyond that possessed by most State radiological health program personnel.</p> <p><b>Emergency Planning &amp; Response Activities:</b> The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.</p> <p><b>Federal Facilities Survey Program:</b> A Presidential Executive Order, dated January 26, 1978, assigned to FDA the responsibility of assisting other federal agencies to be in conformance with safe radiological procedures and to ensure that their equipment meets the standards necessary to minimize exposure to radiation.</p>	
6. FIELD OBLIGATIONS <p><b>Use Control:</b> RRHRs will maintain liaison and provide technical assistance to State/Federal radiological health program personnel; assist in the planning and presentation of quality assurance training with the region; help select State participants in new use control programs; serve as managers of the regional videotape library; and attend the following meetings: National Conference of State Program Directors; Regional meetings with state and local radiological health agencies; and Rockville, MD HQ annual meetings with CDRH, ORA and other FDA officials. WEAC will provide Laboratory Support for the DENT programs.</p> <p><b>Emergency Planning &amp; Response Activities:</b> Provide consultation to states and attend regional emergency planning meetings.</p> <p><b>Federal Facilities Survey Program:</b> Districts will conduct field tests of equipment located in specified federal facilities.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <b>Emergency Planning &amp; Response</b> <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) <b>Federal Facilities Survey Program:</b> X-Ray Equipment	d. INDUSTRY/PRODUCT CODE(S) <b>Emergency Planning:</b> 94YN-99 <b>Federal Facilities Survey Program:</b> 73-91, 94
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 Radiological Health Control Activities				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009, 86010, 86R845			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 8.4		
R E G I O N	6	1	2	3	4	9	9	9	9	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	CT T E C H N I C A S S I S T A N C E (Hours) ***	T E C H N I C A S S I S T A N C E (Hours) RRHR	T E C H N I C A S S I S T A N C E (Hours) CSO	M I S C (Hours) DENT	M I S C (Hours) RRHR
			86010				86009	86009	*	**
	TOTAL FIELD		1343			600	1200	180	750	4800
NE	HEADQUARTERS									800
	REGIONAL STAFF									
	NEW ENGLAND		42							
	NEW YORK		42							
	REGIONAL LAB WEAC								750	
CE	REGIONAL STAFF					200	400			1600
	BALTIMORE		14							
	CHICAGO		71							
	CINCINNATI		71							
	DETROIT		57							
	MINNEAPOLIS		42							
	NEW JERSEY									
	PHILADELPHIA		127							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF					100	200			800
	ATLANTA		85							
	FLORIDA		127							
	NEW ORLEANS		71							
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF					100	200			800
	DALLAS		170							
	DENVER		57							
	KANSAS CITY		14							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF					100	200			800
	LOS ANGELES		141					100		
	SAN FRANCISCO		42							
	SEATTLE		170					80		
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS			1343			600	1200	180	750	4800
CONVERSION FACTOR			950			500	1200	950	1180	1200
TOTAL OPERATIONAL FTEs			1.41			1.20	1.00	0.19	0.64	4.00
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	X	RRHR	INSPEC TIONAL	10/01/02	09/30/03
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)	X	ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/02	09/30/03
	PHYSICIST		OTHER		MILK/FOOD SPEC		OTHER			
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS See Continuation Sheet for footnotes, guidance, etc.  NOTE: Use CT PAC 86R845 ONLY when specific CT work is performed, otherwise use related program PACs.										

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

Radiation Control and Health Safety Act (RCHSA)  
Authority - 86

9. Remarks

**NEW FOR FY 2003 WORKPLAN: MEDICAL DEVICE AND RADIOLOGICAL HEALTH USE CONTROL AND POLICY IMPLEMENTATION (86008); EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009); AND FEDERAL FACILITIES SURVEY PROGRAM (86010) HAVE BEEN CONSOLIDATED WITH THE TITLE RADIOLOGICAL HEALTH CONTROL ACTIVITIES. THE PACs WILL REMAIN IN EFFECT FOR REPORTING PURPOSES.**

FOOTNOTES FOR MEDICAL DEVICE AND RAD HEALTH USE CONTROL & POLICY IMPLEMENTATION ACTIVITIES (86008):

\* This block of time provides laboratory support for the DENT program; this include the following activities:

- a) reading exposed personnel radiation monitors (i.e. badges) from participating agencies;
- b) calibrating and checking the accuracy of DENT survey kits upon request.

\*\* RRHR time for CDRH programs is planned under this program, the Emergency Response and Planning Activities program, and the Mammography Facilities Inspection Program; 1200 hours will be shown in Mammography. A portion of this total block of time per RRHR position includes Federal/State liaison activities and use consultation to conduct this program.

This block of time also includes coordination, technical assistance, and other activities performed by RRHRs under the following programs:

- Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended (PAC 86002);
- Field Compliance Testing of Diagnostic X-Ray Equipment (PAC 86003);
- Field Compliance Testing of Cabinet X-Ray Equipment (PAC 86004);
- Medical Device and Radiological Health Use Control and Policy Implementation (PAC 86008);
- Emergency Planning and Response Activities (PAC 86009);
- Federal Facilities Survey Program (PAC 86010).

**Any time in excess of 0.5 hours used for these programs should be reported into FACTS against the applicable PAC**

FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):

Technical Assistance hours are performed by either RRHRs or CSOs trained in radiological and technological hazards.

Program activities include: providing technical assistance to state and local agencies regarding emergency response planning; reviewing and evaluating emergency plans related to nuclear power plants.

**600 HOURS HAVE BEEN PLANNED FOR THE FY 2003 WORKPLAN TO SUPPORT EXERCISES IN PREPARATION FOR COUNTER-TERRORISM THREATS. THESE HOURS HAVE BEEN PLANNED AS TECHNICAL ASSISTANCE HOURS.**

FOOTNOTES FOR FEDERAL FACILITIES SURVEY PROGRAM ACTIVITIES (86009):

Spreads are based on the number of X-Ray tests of Federal facilities required by interagency agreements. Testing at clinics and hospitals require an average of 14 hours. Hours for radiological surveys of Federal Medical facilities includes time for field testing consultation and followup. Assistance by district X-Ray auditors.

Use CT PAC 86R845 ONLY when specific CT work is performed, otherwise use related program PACs.

\*\*\* CDRH requested that any approved CT increases be used in the Emergency Planning & Response Activities program (86009) to support exercises in preparation for CT threats.

## **5 Year Strategic Plan The ORA Public Affairs Program**

The FDA's Public Affairs Specialists and Technicians (PAS/PAT) are the professional team of public health communicators located in the Agency's field offices. They are primary agents for delivery of FDA health messages directly to the American public. The PAS/PAT are educators, marketing agents, spokespersons, and public relations professionals.

The PAS/PAT respond to consumer inquiries, industry questions, and requests from health professionals, media and community service providers. They develop and implement FDA outreach initiatives and educational campaigns. They collect, compile and analyze information from their stakeholders to effectively identify future program needs.

The PAS/PAT use resources from all components within the agency. They are particularly qualified to leverage these resources by working with an extensive national network of multipliers in the field. PAS/PAT reach millions of consumers each year through this network of consumer, health professional and academic contacts and partnerships. This is the unique contribution of the PAS that adds value to the Food and Drug Administration.

Because of the PAS/PAT direct, hands-on involvement with their local communities, they are exceptionally qualified to analyze the public health messages needed by the American public. The PAS/PAT are the primary entity in ORA that communicates directly with the public regarding FDA emerging issues, risks, and recommendations about regulated product usage, potentially diminishing the risk of disease, injury or death. Capitalizing on the abilities and contributions of the PAS/PAT, this Strategic Plan for the ORA Public Affairs Program will improve the use of FDA's resources and programs resulting in a better informed, healthier public.

**Vision:** FDA Public Affairs Specialists and Technicians are a proactive and responsive team of professional communicators who assist consumers in making informed and responsible decisions about issues affecting their health.

**Mission:** The mission of the FDA Public Affairs staff is to protect public health by educating and informing diverse publics about FDA regulated products and health issues that will optimally decrease their risk of illness, injury, disease, or death.

## **Guiding Principles**

1. Work as a national team of public health communicators and educators.
2. Make effective and efficient use of resources through participation in partnerships and collaborations.
3. Strengthen FDA's ability to make sound public health decisions by keeping the agency informed of public concerns.
4. Establish program priorities based on actual or potential risk and public health benefit.
5. Be proactive and responsive to the diverse publics served.
6. Assess program effectiveness through program evaluation tools/surveys.

## **Measurement Tools**

In order to evaluate the contribution of the public affairs programs, the following are data and reporting systems utilized to capture the impact of Public Affairs programs.

- Public Affairs Information Reporting System (PAIRS)
- Focus Groups
- Campaign Effectiveness Studies
- MedWatch reporting changes
- Speaker evaluation forms data
- Materials distribution
- Web hit increases
- Healthy People 2010 Findings
- HHS/CDC Data

## **Goals and Objectives**

Emphasizing efficient use of agency resources, the PAS/PAT select specific work planning goals and target audiences based on:

- FDA priorities
- HHS public health directives
- White House Initiatives
- The public health needs of the American people

## **Strategic Goal:**

The strategic goal of the Public Affairs Specialist and Technicians is to provide information and guidance to the American public enabling them to make informed and responsible health decisions.

## **Outcomes:**

1. Increased understanding and confidence in the FDA as a consumer protection agency.
2. Decreased illness, injury, or disease associated with regulated products.
3. Better-informed and healthier consumers.

### **FDA Collaborators**

Virtually every component of the FDA collaborates with ORA PAS/PAT in the implementation of the agency's public affairs program. This encompasses the entire range of FDA jurisdiction including foods, drugs, cosmetics, dietary supplements, radiation emitting products, medical devices, biologics, and veterinary products. Effective development and delivery of programs and initiatives is contingent on resources (including training) contributed by the FDA components with programmatic responsibility.

#### Program Centers

- Funding and Training
- Materials
- Scientific basis for public health messages
- Technical support (i.e., Center/OC Public Affairs Liaisons)
- Intra and Inter-agency Communications

#### Office of Communications and Constituent Relations

- Fellowship programs
- Materials

#### Office of Regulatory Affairs

##### District Offices

- Funding and Training
- Materials
- Facility and Equipment
- Technical and Administrative Support

##### Division of Human Resources Development

- Training (ORAU for PAS)
- Certification

##### Division of Federal State Relations

- Champion/Marketing for the Public Affairs program at HQ
- Intelligence (emerging issues)
- Monitor milestones of strategic performance goals
- Funding and Training
- Management of PAIRS system

- Monitor publications process
- Intra and Inter-agency Communications
- Maintain Public Affairs Specialists' Intranet site
- Support the ORA Public Affairs Executive Council (PAEC)
- Utilize the PAEC as the Field PAS/PAT representatives
- Outreach Projects

### **Challenges and External Factors**

The PA Cadre will continually advise Agency management and DFSR of new and emerging consumer concerns and trends. The PAEC will revisit the action plan as necessary to refocus on priorities, and measure outcomes. This will enable Public Affairs programs to be more responsive to shifting public health needs.

Emergencies – Emergencies such as terrorist attacks, product tampering and other unforeseen circumstances may radically affect the implementation of this plan.

Stakeholders – Industry, academia, state and local governments and health care professionals have varying needs that may affect the priorities of the Public Affairs program.

Resources – Unsupported programs, in terms of time, funding, materials, etc., will be difficult if not impossible to implement.

Consumer Expectations – As consumer needs change, this strategic plan will be flexible enough to adjust performance goals accordingly.

Media – The media has a great impact on consumer perceptions and largely determines what issues are important to the public.

### **Summary**

This strategic plan provides a dynamic approach to renew FDA's commitment to public health education and supports the objectives of the Government Performance and Results Act (GPRA). The implementation of this plan will improve confidence in FDA as a consumer protection agency and improve public health by decreasing illness, injury, disease and death from regulated products.

**PUBLIC AFFAIRS PROGRAMS  
RESOURCE SUMMARY  
FY 2003**

	OPERATIONAL FTES	
<b>TOTAL ALL PROGRAMS</b>		41.0
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		16.0
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		9.0
CENTER FOR DRUG EVALUATION AND RESEARCH		2.0
CENTER FOR VETERINARY MEDICINE		1.0
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		5.0
<u>HEADQUARTERS INITIATED PUBLIC AFFAIRS ACTIVITIES</u>	5.0	5.0
OFFICE OF THE ASSOCIATE COMMISSIONER FOR CONSUMER AFFAIRS		
PUBLIC PARTICIPATION PROGAMS	3.0	
OFFICE OF THE ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS		
AGENCY-WIDE HEALTH FRAUD-PUBLIC AFFAIRS ACTIVITIES	2.0	
DISTRICT INITIATED ACTIVITIES		

**Note: See following page for the FTEs allocation for Public Affairs specialists or Technicians.**