

1. PROGRAM/ASSIGNMENT TITLE Radioactive Drug Research Committee	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input checked="" type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
OBJECTIVES To assure the quality and integrity of Radioactive Drug Research Committees and assure they are operating in compliance with (21 CFR 361.1).	
5. PROGRAM JUSTIFICATION The Nuclear Regulatory Commission and the FDA have decided that certain protocols involving radioactive drugs do not need an IND but must be reviewed by an institutional RDRC. These protocols are those intended for basic research purposes, not those protocols intended to determine the safety and efficacy of the drug in humans. The RDRC assures that the radiation doses and pharmacological doses are within specified limits. The Division of Scientific Investigations, Office of Compliance, CDER, issues assignments to the districts, reviews all completed EIRs and their classification, and issues letters as needed to RDRCs after such review.	
6. FIELD OBLIGATIONS Conduct inspections of RDRCs and forward the EIRs 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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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1. PROGRAM/ASSIGNMENT TITLE
 Institutional Review Board (PDUFA)
 Radioactive Drug Research Committee (PDUFA)

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

3. PROGRAM/ASSIGNMENT CODE(S)
 48809
 48809A

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
 10.1

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1						
		IRB INSPECTIONS	RDRC INSPECTIONS						
	TOTAL FIELD	174	5						
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	8	1						
	NEW YORK	12	1						
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	9							
	CHICAGO	9							
	CINCINNATI	11							
	DETROIT	8							
	MINNEAPOLIS	10							
	NEW JERSEY	8							
	PHILADELPHIA	8	1						
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	10							
	FLORIDA	15	1						
	NEW ORLEANS	10							
	SAN JUAN	2							
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS	15							
	DENVER	4							
	KANSAS CITY	9							
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	12	1						
	SAN FRANCISCO	9							
SEATTLE	5								
PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		51.0	54.8						
TOTAL HOURS		8874	274						
CONVERSION FACTOR		910	910						
TOTAL OPERATIONAL FTES		9.75	0.30						

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

9. REMARKS
 Report Institutional Review Board (IRB) work under PAC 48809. Report Radioactive Drug Research Committee (RDRC) to PAC 48809A.

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) 10			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.8			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2								
	NEW YORK	5								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3								
	CHICAGO									
	CINCINNATI	2								
	DETROIT	2								
	MINNEAPOLIS	1								
	NEW JERSEY	7								
	PHILADELPHIA	5								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	2								
	FLORIDA	3								
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3								
	DENVER	1								
	KANSAS CITY	2								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3								
	SAN FRANCISCO	3								
	SEATTLE									
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		77.5								
TOTAL HOURS		3410								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTES		3.75								
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL			INVESTIGATIVE				PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/00	09/30/01	
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) J11			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 23.4			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		304							
NE	HEADQUARTERS	6								
	REGIONAL STAFF									
	NEW ENGLAND	19								
	NEW YORK	13								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	19								
	CHICAGO	16								
	CINCINNATI	17								
	DETROIT	13								
	MINNEAPOLIS	7								
	NEW JERSEY	5								
	PHILADELPHIA	17								
FORENSIC CHEM. CTR										
SW	REGIONAL STAFF									
	ATLANTA	17								
	FLORIDA	17								
	NEW ORLEANS	17								
	SAN JUAN	2								
PA	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	39								
	DENVER	11								
	KANSAS CITY	16								
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	25								
	SAN FRANCISCO	17								
SEATTLE	11									
PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		70.0								
TOTAL HOURS		21280								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		23.37								
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC- TION AL	10/01/00	09/30/01	
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				
MARKS										

1. PROGRAM/ASSIGNMENT TITLE
New Drug (Prescription) Not Covered by Approved NDAs

2. PPS PROJECT NAME/NUMBER
Generic Drug Evaluation - 52

3. PROGRAM TYPE:

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

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:

BY DISTRICT OFFICE

BY CENTER

BY BOTH

b. INSPECTION TYPE:

COMPREHENSIVE

ABBREVIATED

DIRECTED

c. PRODUCT(S)

Human Prescription Drugs

d. INDUSTRY/PRODUCT CODE(S)

Industry Codes: 54, 56, and 60-66

e. EXAM TYPE:

CHEMICAL

MICROBIOLOGICAL

PHYSICAL

ENGINEERING

MICROANALYTICAL

OTHERS (Specify)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Not Covered by Approved NDAs	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52002	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	6	7	8	9
		INSP EC T I O N S	DOMESTIC INVEST- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	20	252	26						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	15	1						
	NEW YORK	2	30	3						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1	9	1						
	CHICAGO	1	11	1						
	CINCINNATI		6	1						
	DETROIT	1	11	1						
	MINNEAPOLIS		4							
	NEW JERSEY	3	36	4						
	PHILADELPHIA	1	13	1						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	17	2						
	FLORIDA	1	10	1						
	NEW ORLEANS		6							
	SAN JUAN	3	40	4						
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS		6	1						
	DENVER	1	7	1						
	KANSAS CITY	1	11	1						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	1	12	1						
	SAN FRANCISCO	1	6	1						
	SEATTLE			1						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		50.0		4.0						
TOTAL HOURS		1000	252	104						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		1.10	0.28	0.11						

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	10/01/00	09/30/01
	MICROBIOLOGIST	BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY T I C A L	10/15/00	09/30/01
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST	OTHER		SHELLFISH SPEC	OTHER			

REMARKS
 Note: Documentary Import Sample Collections for this program are no longer planned.
 The time has been transferred to PAC 56008H under label reviews.
 Label reviews conducted for this Program should be reported under 52002.

1. PROGRAM/ASSIGNMENT TITLE In Vitro Research	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 Develop new dissolution methodology when necessary. Survey the performance of dosage forms of innovator and generic drugs identified as having actual or potential bioequivalence problems. Emphasis will be given to drugs not yet covered by the USP including multi-ingredient products, controlled release dosage forms, transdermals, suspensions, suppositories, creams, and ointments.	
5. PROGRAM JUSTIFICATION There is a need to carry out general dissolution performance evaluations on drug products to identify those which should be introduced for in vivo studies because they pose bioequivalence issues. Dissolution methods development for product survey is also the first step towards a new or revised comendial method. The dissolution test is the most effective test to assure product performance.	
6. FIELD OBLIGATIONS 1. Collect sample brands and related production information of generic drug groups to be tested. 2. Adapt feasible chemical methods for use with standardized dissolution techniques for survey of drug products. 3. Perform dissolution studies on collected drug products. 4. Tabulate and report results to HFD-602.	
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: 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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE In Vitro Research	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52004	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP CTIONS	INVEST GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	METHODS DEVELOPMT. (Chem) (Hours)
	TOTAL FIELD			30						1062
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			2						
	NEW YORK			3						
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE			1						
	CHICAGO			1						
	CINCINNATI			1						
	DETROIT			1						
	MINNEAPOLIS			1						
	NEW JERSEY			5						
	PHILADELPHIA			1						531
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA			2						
	FLORIDA			1						
	NEW ORLEANS			1						
	SAN JUAN			5						
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS			1						
	DENVER			1						
	KANSAS CITY			1						
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES			1						
	SAN FRANCISCO			1						
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									531
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION				3.0						
TOTAL HOURS				90						1062
CONVERSION FACTOR				910						1180
TOTAL OPERATIONAL FTEs				0.10						0.90

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			
	MICROBIOLOGIST	BIO. SCIENCE TECH		INSPECTOR	VETERINARIAN	ANALY TICAL	10/15/00	09/30/01
	ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT			
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST	OTHER		SHELLFISH SPEC	OTHER			

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	
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	
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

PROGRAM/ASSIGNMENT CODE(S)
 52832, B, C

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
 34.5

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	3	7	7	7	7
		ANDAs TO INSPECT Domestic *	CHEMIST INSPECT. (Hours) **	INVESTI- GATIONS Hours	DOMESTIC SAMPLE COLL ***	PROFILE/ PORTION OF DSCs FOR DDA ***	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ****	DOMESTIC SAMPLE ANALYSES BIOTEST (Chem) ****	DSAs (METH) (VALID) (Chem) (Hours) *	DSAs METHODS VALIDATION (Micro) (Hours)
	TOTAL FIELD	165	3000	450	150	(50)	50	50	165	1
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	6		16	5					
	NEW YORK	22		60	21					
	REGIONAL LAB WEAC		1000				18	18	30	1
CE	REGIONAL STAFF									
	BALTIMORE	9		25	8					
	CHICAGO	11		30	10					
	CINCINNATI	8		22	7					
	DETROIT	8	200	22	7				17	
	MINNEAPOLIS	2		5	2					
	NEW JERSEY	28		76	26					
	PHILADELPHIA	9	700	25	8				53	
	FORENSIC CHEM. CTR		200				32	32		
	REGIONAL STAFF									
SE	ATLANTA	11		30	10					
	FLORIDA	7		19	6					
	NEW ORLEANS	3		8	3					
	SAN JUAN	10	150	27	9				13	
	REGIONAL LAB		250						18	
SW	REGIONAL STAFF									
	DALLAS	3		8	3					
	DENVER	6	100	16	5				17	
	KANSAS CITY	8	100	22	7					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	12		33	11					
	SAN FRANCISCO	2		6	2					
	SEATTLE									
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW		300						5 12	
HOURS PER OPERATION		65.0			8.0		50.0	35.0	105.0	105.0
TOTAL HOURS		10725	3000	450	1200		2500	1750	17325	105
CONVERSION FACTOR		910	1180	910	910		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		11.79	2.54	0.49	1.32		2.12	1.48	14.68	0.09

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

REMARKS

* Approx. 165 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	

1. PROGRAM/ASSIGNMENT TITLE
 ANDA Pre - Approval Inspections/Investigations
 (Methods Validation) - Foreign

2. PPS PROJECT NAME/NUMBER
 Generic Drug Evaluation - 52

PROGRAM/ASSIGNMENT CODE(S)
 52832, 52832B ,52832C

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
 10.6

REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	3	5	6	8	8	8
		INSPEC- TIONS (Foreign)	CHEMIST INSP. (Hours) [Foreign] **	DOMESTIC SAMPLE COLL	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	2300		155			70	70	15
NE	HEADQUARTERS	7								
	REGIONAL STAFF									
	NEW ENGLAND	3			6					
	NEW YORK	10			20					
	REGIONAL LAB		600					70	70	15
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	3			6					
	CHICAGO	3			8					
	CINCINNATI	3			6					
	DETROIT	5	220		10					
	MINNEAPOLIS	1			3					
	NEW JERSEY	13			30					
SE	PHILADELPHIA	3	700		6					
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	4			8					
	FLORIDA	3			6					
	NEW ORLEANS	2			4					
SW	SAN JUAN	4	240		8					
	REGIONAL LAB		170							
	REGIONAL STAFF									
	DALLAS	2			5					
	DENVER	3	200		6					
PA	KANSAS CITY	3			6					
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	6			12					
	SAN FRANCISCO	1			2					
PA	SEATTLE	1			3					
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW		170							
HOURS PER OPERATION		55.0			3.0			30.0	15.0	50.0
TOTAL HOURS		4400	2300		465			2100	1050	750
CONVERSION FACTOR		910	1180		910			1180	1180	1180
TOTAL OPERATIONAL FTEs		4.84	1.95		0.51			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	10/01/00	09/30/01
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

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.

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

2. PPS PROJECT NAME/NUMBER
Generic Drug Evaluation-52

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Research

6. FIELD OBLIGATIONS
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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation -52
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PROGRAM/ASSIGNMENT CODE(S) 52R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS							
	TOTAL FIELD	500							
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA	500							
	FORENSIC CHEM. CTR								
SW	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB-SW								
PACIFIC REGIONAL LAB-NW									
HOURS PER OPERATION									
TOTAL HOURS		500							
CONVERSION FACTOR		1205							
TOTAL OPERATIONAL FTEs		0.41							

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

REMARKS

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide guidance and instructions to field offices for inspecting drug manufacturers to determine compliance with the ADR reporting requirements of 21 CFR 310.305 and 314.80. Regulatory and/or administrative follow-up will be initiated in cases where significant violations of reporting regulations are detected. The program should also promote voluntary compliance by manufacturers.	
5. PROGRAM JUSTIFICATION Postmarketing surveillance for approved drugs has been strengthened through the publication of regulations effective August 22, 1985. Additional requirements became effective September 2, 1986, and revisions were published October 13, 1987 and July 10, 1989. Accurate and timely reporting of adverse drug reaction information is essential to the protection of the American public. It enables FDA to act when information affecting the use of marketed drug products suggests that new labeling, market withdrawal, or other effective action is required.	
6. FIELD OBLIGATIONS Conduct inspections and forward reports directly to the Division of Scientific Investigations/CDER, including recommendations for any indicated regulatory follow-up.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, 60-66
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE
Enforcement of the Adverse Drug Experience Reporting Regulations

2. PPS PROJECT NAME/NUMBER
Postmarketing Surveillance and Epidemiology:
Human Drugs - 53

PROGRAM/ASSIGNMENT CODE(S)
53001A, 53001B

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
8.0

REG I O N	6. DISTRICT/SPECIALIZED LABORATORY	1	1	3	4	5	6	7	8	9
		INSPEC-TIONS DOMESTIC	INSPEC-TIONS FOREIGN	DOM. 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	77	25							
NE	HEADQUARTERS		4							
	REGIONAL STAFF									
	NEW ENGLAND	5	1							
	NEW YORK	9	2							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3	1							
	CHICAGO	3	1							
	CINCINNATI	2	1							
	DETROIT	3	1							
	MINNEAPOLIS	1								
	NEW JERSEY	12	2							
	PHILADELPHIA	4	1							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	5	1							
	FLORIDA	3	1							
	NEW ORLEANS	1								
	SAN JUAN	12	2							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	2	2							
	DENVER	2	1							
	KANSAS CITY	3	1							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	4	2							
	SAN FRANCISCO	2	1							
	SEATTLE	1								
	PACIFIC REGIONAL LAB - NW PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION		75.0	60.0							
TOTAL HOURS		5775	1500							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		6.35	1.65							

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

REMARKS

*Report both Domestic and Foreign inspections under 53001A for Center-Initiated and 53001B for District -Initiated. Foreign inspections must now be reported under new foreign operation code 11.

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	

PROGRAM/ASSIGNMENT CODE(S) 4. WORK ALLOCATION PLANNED BY 5. OPERATIONAL FTE POSITIONS
 56002, A, B, C, D, F 56832 ORA CENTER 93.7 (82.0)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	1	1	2	3	5	7	7	9
			CHEMIST INSP- CTIONS (Hours)	MICRO INSP- CTIONS (Hours)	INVEST- IGATIONS (Hours)	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED (Chem)	DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	OTHER OPERATIONS (Hours)
	TOTAL FIELD	1193	6700	2000	800	525		145	45	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	54			36	24				
	NEW YORK	101			68	44				
	REGIONAL LAB		1400	600				20	12	
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	43			29	20				
	CHICAGO	76			51	33				
	CINCINNATI	45			30	20				
	DETROIT	54	500		36	24		12		
	MINNEAPOLIS	42			28	19				
	NEW JERSEY	166			111	73				
	PHILADELPHIA	68	2000		46	30		41		
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	67			45	29				
	FLORIDA	53			36	23				
	NEW ORLEANS	41			27	18				
	SAN JUAN	73	600		49	32		10		
SW	REGIONAL LAB		700	800				24	22	
	REGIONAL STAFF									
	DALLAS	64			43	28				
	DENVER	44	500	100	30	19		22	6	
	KANSAS CITY	57			38	25				
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	97			65	43				
	SAN FRANCISCO	29		500	19	13			5	
PA	SEATTLE	19			13	8				
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW		1000					16		
HOURS PER OPERATION		50.0				4.0		42.0	20.0	
TOTAL HOURS		59650	6700	2000	800	2100		6090	900	
CONVERSION FACTOR		910	1180	1180	910	910		1180	1180	
TOTAL OPERATIONAL FTEs		65.55	5.68	1.69	0.88	2.31		5.16	0.76	

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	INSP- TIONAL	10/01/00	09/30/01
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	<input checked="" type="checkbox"/>	NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS
 * Gas manufacturers are now planned under a separate worksheet under PAC 56002E.
 Inspections are for rx and non-rx drug manufacturers, repackers/relabelers and control labs.
 Inspections exclusively devoted to GMP Audits. Pre-Approval (NDA/ANDA) Inspections
 are planned under PACs 46832 and 52832 .Samples not analyzed are documentary samples.

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Drug Process Inspections - Domestic
(Gas Manufacturers)

2. PPS PROJECT NAME/NUMBER
Drug Quality Assurance - 56

PROGRAM/ASSIGNMENT CODE(S)

56002E

4. WORK ALLOCATION PLANNED BY

ORA CENTER

5. OPERATIONAL FTE POSITIONS

(11.7)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	WHARF EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	462								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	28								
	NEW YORK	19								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	21								
	CHICAGO	18								
	CINCINNATI	30								
	DETROIT	35								
	MINNEAPOLIS	21								
	NEW JERSEY	8								
	PHILADELPHIA	34								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	33								
	FLORIDA	31								
	NEW ORLEANS	32								
	SAN JUAN	1								
	REGIONAL LAB									
	SW	REGIONAL STAFF								
DALLAS		36								
DENVER		22								
KANSAS CITY		32								
SOUTHWEST IMPORT DISTRICT REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	15								
	SAN FRANCISCO	16								
	SEATTLE	30								
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	23.0								
	TOTAL HOURS	10626								
	CONVERSION FACTOR	910								
		11.67								

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

REMARKS

Note: FDA Inspection of Gas manufacturers have been reduced for the final 2001 workplan due to resource constraints.
Center priorities are to target resources toward Rx & non Rx manufacturers, repackers/relabelers and control labs.
It is anticipated that coverage of a portion 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 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	

1. PROGRAM/ASSIGNMENT TITLE
Foreign Drug Inspections/
Equivalence Evaluations

2. PPS PROJECT NAME/NUMBER
Drug Quality Assurance - 56

PROGRAM/ASSIGNMENT CODE(S)
56002, A, B, C, D, E, F
56832, 56R841 *

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
14.8

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	9	9
		INSP CTIONS FOREIGN	CHEMIST INSP CTIONS (Hours) FOREIGN **	MRA INSP. FOR Invest- igators ***	MRA INSP. HRS. FOR Chemists/ Microbiols. ** ***	MRA Invest- igator OTHER OPERATIONS HRs. ***	MRA Chemists/ Microbiols. OTHER OPERATIONS HRs. ***
	TOTAL FIELD	111	2900	6	516	3300	1218
NE	HEADQUARTERS	6				760	
	REGIONAL STAFF						
	NEW ENGLAND	5					
	NEW YORK	9		2		540	
	REGIONAL LAB WEAC		325		172		200
CE	REGIONAL STAFF						
	BALTIMORE	4					
	CHICAGO	7				400	
	CINCINNATI	3					
	DETROIT	4					
	MINNEAPOLIS	3					
	NEW JERSEY	13		2		600	
	PHILADELPHIA FORENSIC CHEM. CTR	7	1200 150		172		500
SE	REGIONAL STAFF						
	ATLANTA	6				400	
	FLORIDA	4					
	NEW ORLEANS	4					
	SAN JUAN REGIONAL LAB	7	200 450		172		518
SW	REGIONAL STAFF						
	DALLAS	6		2		600	
	DENVER	3	225				
	KANSAS CITY	7					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB						
PA	REGIONAL STAFF						
	LOS ANGELES	8					
	SAN FRANCISCO	4					
	SEATTLE	1					
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW		350				
HOURS PER OPERATION		55.0		86.0			
TOTAL HOURS		6105	2900	516	516	3300	1218
CONVERSION FACTOR		910	1180	910	1180	910	1180
TOTAL OPERATIONAL FTEs		6.71	2.46	0.57	0.44	3.63	1.03

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 TIONAL	10/01/00	09/30/01
<input checked="" type="checkbox"/>	MICROBIOLOGIST	BIO. SCIENCE TECH		INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)	<input checked="" type="checkbox"/> NAT'L EXPERT	ANALY TICAL	10/15/00	09/30/01
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST	OTHER		SHELLFISH SPEC	OTHER			

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 personel; 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 on the quality of the nation's drug supply by computerizing data for specific drug companies and specific products from surveillance information obtained by FDA investigation and product analysis. The computerized results will provide a basis for industry wide comparisons.	
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 bulk drug substances through sampling and analysis.	
6. FIELD OBLIGATIONS To collect samples and perform laboratory examinations. Upon assignment from CDER, conduct inspections to obtain specific information, such as analytical results, production data, formulation information, analytical methodology, stability data and expiration dating.	
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 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 - ORDER Initiated	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	3	7	7	7	7	7
		INSP ECTIONS	CHEM ON INSPS. (Hours)	DOMESTIC SAMPLES ANALYZED STERILITY *****	DOMESTIC SAMPLES COLLECTED	Domestic SAMPLES ANALYZED (Chem) **	DOMESTIC SAMPLES ANALYZED (Chem) (WEAC) ***	DOMESTIC SAMPLES ANALYZED (Micro) (WEAC) ***	DOMESTIC SAMPLES ANALYZED (Chem) (FCC) *****	DOMESTIC SAMPLES ANALYZED (Chem) (NRL) *****
	TOTAL FIELD	9	411	60	205	510	25	10	5	38
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1			12					
	NEW YORK	1			25					
	REGIONAL LAB			45						38
	WEAC		411				25	10		
CE	REGIONAL STAFF									
	BALTIMORE				8					
	CHICAGO	1			9					
	CINCINNATI				5					
	DETROIT	1			9					
	MINNEAPOLIS				3					
	NEW JERSEY	1			30					
	PHILADELPHIA	1			10	76				
	FORENSIC CHEM. CTR									5
SE	REGIONAL STAFF									
	ATLANTA	1			14					
	FLORIDA				8					
	NEW ORLEANS				3					
	SAN JUAN	1			33	76				
	REGIONAL LAB					76				
SW	REGIONAL STAFF									
	DALLAS				5					
	DENVER			15	6	100				
	KANSAS CITY				9					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	1			10					
	SAN FRANCISCO				5					
	SEATTLE				1					
	PACIFIC REGIONAL LAB - SW					82				
	PACIFIC REGIONAL LAB - NW					100				
HOURS PER OPERATION		13.0		25	4.0	25.0	38.0	18.0	231.0	50.0
TOTAL HOURS		117		1500	820	12750	950	180	1155	1900
CONVERSION FACTOR		910	1180	1180	910	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.13	0.35	1.27	0.90	10.81	0.81	0.15	0.98	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 ECTION AL	10/01/00	09/30/01
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS
 * DSCs by HFD-333 Drug Surveys; KAN_DO DSCs include approx. 20 radiopharm samples to be analyzed by WEAC.
 DSCs reduced from 595 to 205 since FY 2000; Most drug purchases to be made directly via orders to Drug Wholesalers.
 DSAs assigned by DFS per lab expertise for specific drugs .*** Radioactive drugs-approx 10 of the 25 DSAs (Chem) tested also by
 for MICRO. **** Counterfeit bulk drug analysis. ***** Quality test bulk drug analysis. ***** Sterility - testing.

1. PROGRAM/ASSIGNMENT TITLE
Drug Product Surveillance - Imported Drugs
Center and District Initiated Surveys

2. PPS PROJECT NAME/NUMBER
Drug Quality Assurance-56

3. PROGRAM/ASSIGNMENT CODE(S)
56008H, 56R833, 56R824, 99R833

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
31.0 (16.1)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2	2	2	9		6	4	8
		IMPORT ENTRY REVIEW HOURS OPER 14	IMPORT FILER EVAL. HOURS OPER 95	REFUSAL Follow-Up HOURS	IMPORT LABEL EXAMS		IMPORT FIELD EXAMS	IMPORT SAMPLE COLLECT- IONS	IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	13602	586	152	1525		3700	50	50
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	400	12		45		110	2	
	NEW YORK	4227	108	112	530		1291	16	
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	550	28		46		111	2	
	CHICAGO	900	36		83		201	3	
	CINCINNATI	360	18	8	41		99	2	
	DETROIT	1050	18		132		322	4	
	MINNEAPOLIS	250	18		10		24	1	
	NEW JERSEY								
	PHILADELPHIA	375	12		50		119	2	
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA	425	48	8	57		139	2	
	FLORIDA	400	54		23		55	1	
	NEW ORLEANS	1815	24		243		591	6	
SW	SAN JUAN	600	6		48		117	2	
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT	825	60	8	94		228	3	
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	900	72	8	70		166	2	
PA	SAN FRANCISCO	300	36		26		60	1	
	SEATTLE	225	36	8	27		67	1	
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								50
HOURS PER OPERATION					1.0		0.3	2.0	22.0
TOTAL HOURS		13602	586	152	1525		1110	100	1100
CONVERSION FACTOR		1200	910	910	910		910	910	1180
TOTAL OPERATIONAL FTEs		11.34	0.64	0.17	1.68		1.22	0.11	0.93

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	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 PACs 52002, 56008H, 56014/A, 63001;
Report ISCs & ISAs of finished Dosage forms under 56008H.

1. PROGRAM/ASSIGNMENT TITLE
Drug Product Surveillance - Imported Drugs
Center and District Initiated Surveys (Domestic Import)

2. PPS PROJECT NAME/NUMBER
Drug Quality Assurance - 56

PROGRAM/ASSIGNMENT CODE(S)
56008J, 56008K

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
(14.9)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC BULK IMPORT SAMPLE COLL	7 DOMESTIC IMPORT ANALYSES CHEM QUALITY (DISTRICT)*	7 DOMESTIC IMPORT ANALYSES CHEM FINGERPRNT. **	7 DOMESTIC IMPORT ANALYSES CHEM QUALITY (CENTER) *	9 ACTIVE PHARM. INGREDIENT IMPURITIES CHEM HRS ***				
							TOTAL FIELD	274	150	24
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	16								
	NEW YORK	33								
	REGIONAL LAB			27		100		1180		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	10								
	CHICAGO	12								
	CINCINNATI	7								
	DETROIT	12								
	MINNEAPOLIS	4								
	NEW JERSEY	40								
	PHILADELPHIA	14		55						
	FORENSIC CHEM. CTR					24				
SE	REGIONAL STAFF									
	ATLANTA	19								
	FLORIDA	11								
	NEW ORLEANS	4								
	SAN JUAN	44		31						
SW	REGIONAL LAB			12						
	REGIONAL STAFF									
	DALLAS	6								
	DENVER	8		14						
	KANSAS CITY	12								
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	13								
	SAN FRANCISCO	7								
	SEATTLE	2								
	PACIFIC REGIONAL LAB - SW			7						
	PACIFIC REGIONAL LAB - NW			4						
HOURS PER OPERATION		4.0		30.0		231.0		50.0		
TOTAL HOURS		1096		4500		5544		5000		1180
CONVERSION FACTOR		910		1180		1180		1180		1180
TOTAL OPERATIONAL FTEs		1.20		3.81		4.70		4.24		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	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

Report DISCs and DISAs of BULKS for QUALITY from domestic manufacturers under 56008J.

Report DISCs and DISAs of BULKS for FINGERPRINTING from domestic manufacturers under 56008K.

***Report time spent on Active Pharmaceutical ingredient impurities Testing Research under 56R816.

Note: IF ISCs & ISAs of BULKS are collected at point of entry report under 56008J,K.

1. PROGRAM/ASSIGNMENT TITLE
Methods Validation Assessment

2. PPS PROJECT NAME/NUMBER
Drug Quality Assurance - 56

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)
Industry Codes: 54, 56, 60-66

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

f. CHECK THE FOLLOWING ATTRIBUTES

1. PROGRAM/ASSIGNMENT TITLE Methods Validation Assessment	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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PROGRAM/ASSIGNMENT CODE(S) 56020/56020A	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. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVE ST I G A T I O N S (Hours)	DOMESTIC SAMPLE COLL	IMP ORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMP ORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMP ORT SAMPLES TO BE ANALYZED	METHODS VALIDATION (Hours) CHEM
	TOTAL FIELD			50						2120
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			3						
	NEW YORK			6						
	REGIONAL LAB									238
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE			2						
	CHICAGO			2						
	CINCINNATI			1						
	DETROIT			2						
	MINNEAPOLIS			1						
	NEW JERSEY			7						
PHILADELPHIA			3						670	
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA			4						
	FLORIDA			2						
	NEW ORLEANS			1						
	SAN JUAN			8						180
SW	REGIONAL LAB									200
	REGIONAL STAFF									
	DALLAS			1						
	DENVER			1						302
	KANSAS CITY			2						200
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			2						
	SAN FRANCISCO			1						
TOTAL	SEATTLE			1						
	PACIFIC REGIONAL LAB - SW									100
	PACIFIC REGIONAL LAB - NW									230
	HOURS PER OPERATION			4.0						
	TOTAL HOURS			200						2120
	CONVERSION FACTOR			910						1180
	TOTAL OPERATIONAL FTEs			0.22						1.80

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

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) Reports and NDA Field Alert Reports. To maintain a flexible capability for rapid investigations and correction of any drug product quality problems ascertained from these reports.	
5. PROGRAM JUSTIFICATION The program provides a system for centralizing and evaluating reports received by FDA which pertain to drug product problems reported by pharmacists and other health care professionals, and by manufacturers under the NDA-Field reporting requirements.	
6. FIELD OBLIGATIONS Each district will appoint appropriate coordinators who will monitor the respective District's activities resulting from implementation of this program. Districts will perform inspections, investigations, sample collections, analyze samples and perform other necessary work to complete assignments 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 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 concerning violations of section 503A of the act.	
5. PROGRAM JUSTIFICATION Section 127 of the FDA Modernization Act amended the FD&C Act with section 503A Application of Federal Law to the Practice of Pharmacy Compounding. This provision became effective on November 21, 1997 and set forth the requirements that Compounded products must meet to qualify for exemption from sections 505, 502(f)(1) and 501(a)(2)(B) of the Act. It was the intent of Congress with the enactment of section 503A to ensure the continued availability of compounded products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the Guise of compounding. The agency is receiving complaints concerning possible violations of section 503A which must be investigated. As more provisions of the law are implemented through the issuance of final regulations the number of complaints is increasing.	
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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PROGRAM/ASSIGNMENT CODE(S) 56D015 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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REGION	6. DISTRICT/SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSPECTIONS	INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD		910							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		32							
	NEW YORK		51							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		55							
	CHICAGO		32							
	CINCINNATI		48							
	DETROIT		42							
	MINNEAPOLIS		35							
	NEW JERSEY		24							
	PHILADELPHIA		36							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		66							
	FLORIDA		67							
	NEW ORLEANS		80							
	SAN JUAN		60							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		85							
	DENVER		24							
	KANSAS CITY		44							
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		54							
	SAN FRANCISCO		38							
	SEATTLE		37							
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS		910							
	CONVERSION FACTOR		910							
	TOTAL OPERATIONAL FTÉs		1.00							

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	INSPECTORIAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALYTICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

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 Det 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: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Research

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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PROGRAM/ASSIGNMENT CODE(S) 56R816	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	DISTRICT RESEARCH CHEMIST HOURS	DISTRICT RESEARCH MICRO HOURS						
	TOTAL FIELD	4600	1300						
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB	2500	300						
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA	1700	1000						
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN	400							
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
PA	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION									
TOTAL HOURS		4600	1300						
CONVERSION FACTOR		1205	1205						
TOTAL OPERATIONAL FTEs		3.82	1.08						

7. PERSONNEL TYPES REQUIRED						8. WORK SCHEDULE		
ANALYTICAL			INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR			
X	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			
					OTHER	ANALY- TICAL	10/15/00	09/30/01

REMARKS

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		
X	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR	VETERINARIAN		
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC		10/15/00	09/30/01
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER		

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.

1. PROGRAM/ASSIGNMENT TITLE
Fraudulent Drugs

2. PPS PROJECT NAME/NUMBER
Health Fraud: Human Drugs -63

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)
Industry Codes: 50, 54, and 60-66

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE
 Fraudulent Drugs

2. PPS PROJECT NAME/NUMBER
 Health Fraud: Human Drugs-63

PROGRAM/ASSIGNMENT CODE(S)
 63001

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
 2.5

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	36	500	120				56		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2	9	6						
	NEW YORK	3	41	8						
	REGIONAL LAB							6		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1	83	3						
	CHICAGO		12	1						
	CINCINNATI	2	5	5						
	DETROIT	1	10	4				2		
	MINNEAPOLIS	2	77	5						
	NEW JERSEY	1		4						
	PHILADELPHIA	1	8	4				10		
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		23	1						
	FLORIDA	6	18	23						
	NEW ORLEANS	1	11	4						
SW	SAN JUAN									
	REGIONAL LAB							12		
	REGIONAL STAFF									
	DALLAS	3	56	9						
	DENVER	3	5	9				10		
	KANSAS CITY	1	9	3				2		
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	6	64	23						
	SAN FRANCISCO	2	60	5						
	SEATTLE	1	9	3						
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW								14		
HOURS PER OPERATION		20.0		4.0				14.0		
TOTAL HOURS		720	500	480				784		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.79	0.55	0.53				0.66		

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

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
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, and 60-66
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (Specify)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Internet Drug Sales	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs - 63
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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 11.0
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		10010							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		526							
	NEW YORK		771							
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE		297							
	CHICAGO		519							
	CINCINNATI		440							
	DETROIT		376							
	MINNEAPOLIS		342							
	NEW JERSEY		784							
	PHILADELPHIA		624							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		675							
	FLORIDA		700							
	NEW ORLEANS		677							
	SAN JUAN		545							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		730							
	DENVER		332							
	KANSAS CITY		440							
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES		769							
	SAN FRANCISCO		238							
	SEATTLE		225							
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION										
TOTAL HOURS			10010							
CONVERSION FACTOR			910							
TOTAL OPERATIONAL FTEs			11.00							

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

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.

1. PROGRAM/ASSIGNMENT TITLE
Shelf Life Extension Projects

2. PPS PROJECT NAME/NUMBER
Interagency Cooperative Activities - 88

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Human Drugs

d. INDUSTRY/PRODUCT CODE(S)
Industry Codes: 50, 54, 56, and 60-66

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
Environmental chambers used to stress drug products.

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2001**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	65.0	2.8	2.0	69.8	137.4	5.6	4.0	147.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	11.8		1.6	13.4	26.0		3.0	29.0
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	53.2	2.8	0.4	56.4	111.4	5.6	1.0	118.0

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-102) 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 N/A	

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)

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
8.3

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	3	5	6	7	7	9
		INSPEC- TIONS	INSPEC- TIONS (Foreign ***	INSPEC- TIONS (Chemist Hours **	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	METHODS VALID Chem Hours *	OTHER OPERATIONS (Hours)
	TOTAL FIELD	74	40	599	40			40	1148	
NE	HEADQUARTERS		1							
	REGIONAL STAFF									
	NEW ENGLAND	4	2		2					
	NEW YORK	5	3		3					
	REGIONAL LAB			67			5	129		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	4	2		2					
	CHICAGO	4	2		2					
	CINCINNATI	2	1							
	DETROIT	3	1		3					
	MINNEAPOLIS	5	2		3					
	NEW JERSEY	5	3		3					
SE	PHILADELPHIA	4	2		2					
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	4	4		2					
	FLORIDA	3								
SW	NEW ORLEANS	2	1							
	SAN JUAN	3	1		3					
	REGIONAL LAB			101			5	194		
	REGIONAL STAFF									
	DALLAS	6	3		5					
PA	DENVER	3	1						133	
	KANSAS CITY	10	6	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		2		1					
	PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)			77			6	147			
HOURS PER OPERATION		60.0	40.0		3.0		19.4			
TOTAL HOURS		4440	1600	599	123		776	1148		
CONVERSION FACTOR		1000	1000	1180	1000		1180	1180		
TOTAL OPERATIONAL FTEs		4.44	1.60	0.51	0.12		0.66	0.97		

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	INSPEC- TIONAL	10/1/00	9/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/00	9/30/01
	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) 68Z or 69Z
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	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 the adherence of sponsors, contract research organizations and monitors to the clinical monitoring regulations specific §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%.	
5. PROGRAM JUSTIFICATION 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.	
6. FIELD OBLIGATIONS 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.	
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) 68Z or 69Z
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators	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 assess through audit procedures (21 CFR 511.1 (b)) whether data submitted by clinical investigators to FDA in a specific clinical study are substantiated by records. Improve the compliance review by reducing the BIMO backlogs by 2%.	
5. PROGRAM JUSTIFICATION 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. The program determines the validity of data submitted to FDA by inspecting clinical investigators' records. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS Conduct inspections of clinical investigators identified by the Center in accordance with the guidance set forth in the basic compliance program 7348.811.	
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) 68Z or 69Z
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE GLPs, Sponsor-Monitors, Clinical Investigators (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 5.1			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	3	5	6	7	8	9
		INSP CTIONS (GLPs) (SPON/MON)	INSP CTIONS	INSP CTIONS (CLINICAL INVEST)	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	40		61	15			15		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			1						
	NEW YORK	2		1	1					
	REGIONAL LAB WEAC							1		
CE	REGIONAL STAFF									
	BALTIMORE	2		2						
	CHICAGO	1		1						
	CINCINNATI	2		3	1					
	DETROIT	5		5	2					
	MINNEAPOLIS	2		3						
	NEW JERSEY	8		1	4					
	PHILADELPHIA	2		1						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SW	ATLANTA	3		11	2					
	FLORIDA			4						
	NEW ORLEANS	1		3						
	SAN JUAN									
	REGIONAL LAB							6		
	REGIONAL STAFF									
SW	DALLAS	1		8	1					
	DENVER	1		6						
	KANSAS CITY	8		6	3					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB							2		
PA	REGIONAL STAFF									
	LOS ANGELES			1						
	SAN FRANCISCO	2		1	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		2332		2501	45			291		
CONVERSION FACTOR		1000		1000	1000			1180		
TOTAL OPERATIONAL FTEs		2.33		2.50	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	INSP EC TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR	X	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/00	09/30/01
	PHYSICIST		OTHER		MILK/FOOD SPEC					
	ENTOMOLOGIST				SHELLFISH SPEC		OTHER			
9. REMARKS Sources 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.										

PROJECT SUMMARY SHEET

PROGRAM CATEGORY Animal Drugs and Feeds		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71						
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL SUPPORTED FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		53.2	2.8	0.4	56.4	118.0	
1	Drug Process and New Animal Drug Inspections	71001/71R841	14.8		0.4	15.2	33.3	2-3
2	Feed Contaminants*	71003A-E	10.4	2.8		13.2	29.0	4-7
	BSE Feed Contaminants	71003F	(0.9)					
3	Feed Manufacturers	71004/A	8.3			8.3	18.0	8-9
	BSE Medicated Feeds (Licensed)	71004F	(0.3)					
	BSE Medicated Feeds (Unlicensed)	71004G	(2.7)					
4	Illegal Drug Residues in Meat and Poultry	71006	11.6			11.6	28.0	10-11
	BSE Illegal Drug Residue	71006F	(0.4)					
5	National Drug Residue Milk Monitoring Program	71008	1.4			1.4	3.0	12-13
6	ORA/Center Directed Research Projects**	71R816	6.0			6.0	6.0	14-15
7	Forensic Evaluation and Analysis	71R831/71R838	0.7			0.7	0.7	16-17
	*Includes: 71R833, 99R833, and 71R824							
	**Research FTEs are not supported.							
CENTER PROJECT MANAGER/TELEPHONE					ORA PLANNER/TELEPHONE			
Dr. Linda Tollefson, D.V.M. (301) 827-6644					Anita T. McCurdy 301-827-1632			

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	

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 15.2				
REG I O N	6. DISTRICT/SPECIALIZED LABORATORY	1		2		3		7		9
		INSP E C T I O N S	INSP E C T I O N S (Foreign)	INVEST I G A T I O N S (Hours)		DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES TO BE ANALYZED (Chem)	DOMESTIC SAMPLES TO BE ANALYZED (Micro)	OTHER OPERATIONS (Hours)	
TOTAL FIELD		260	10	435		165	113	37		
NE	HEADQUARTERS	4	1							
	REGIONAL STAFF									
	NEW ENGLAND	9		20		6				
	NEW YORK	9	1	17		7				
	REGIONAL LAB						9	3		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	9		11		6				
	CHICAGO	19	1	33		12				
	CINCINNATI	12		22		8				
	DETROIT	8		9		5				
	MINNEAPOLIS	26	1	50		17				
	NEW JERSEY	20	2	41		14				
	PHILADELPHIA	12	1	24		9				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	16		24		11				
	FLORIDA	10		20		6				
	NEW ORLEANS	7		7		4				
	SAN JUAN	5		9		3				
REGIONAL LAB						42	13			
SW	REGIONAL STAFF									
	DALLAS	20	1	26		13				
	DENVER	7		11		4		16		
	KANSAS CITY	43	2	72		24	48			
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB						3	1			
PA	REGIONAL STAFF									
	LOS ANGELES	8		15		5				
	SAN FRANCISCO	9		11		7		4		
	SEATTLE	7		13		4				
	PACIFIC REGIONAL LAB (SW)						11			
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		43.5	40.0			4.0	18.4	21.1		
TOTAL HOURS		11310	400	435		660	2079	781		
CONVERSION FACTOR		1000	1000	1000		1000	1180	1180		
TOTAL OPERATIONAL FTEs		11.31	0.40	0.44		0.66	1.76	0.66		
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		INSPEC-TIONAL	10/1/00	9/30/01	
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR	RRHR VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	<input checked="" type="checkbox"/> NAT'L EXPERT	ANALY-TICAL	10/15/00	9/30/01	
	PHYSICIST		OTHER		MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER				
9. REMARKS Domestic Inspections include resources for: follow-up to product defects and adverse drug reaction; Type "A" Medicated Articles. Report inspection of Type "A" Medicated Articles under PAC 71005/A. Investigational or official samples should be collected as appropriate. Samples not analyzed are documentary samples. Consult the Servicing Laboratory Table, Part I of the ORA Workplan (Appendix III) for each district's servicing laboratory.										

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	

1. PROGRAM/ASSIGNMENT TITLE
Feed Contaminants - DOMESTIC

2. PPS PROJECT NAME/NUMBER
Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

PROGRAM/ASSIGNMENT CODE(S)
003 A-E, 71003F (BSE)
*(99R833, 71R833, 71R824)

ORA CENTER

5. OPERATIONAL FTE POSITIONS
13.2 (10.4)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	3	3	4	7	7	7	7
		INSPEC- TIONS BSE *	DOMESTIC SAMPLES COLL	DOMESTIC SAMPLE COLL** Myco "A"	DOMESTIC SAMPLE COLL** Micro "B"	DOMESTIC SAMPLE COLL** Chem "C"	DOMESTIC SAMPLE COLL** DIOXIN "D"	DOMESTIC SAMPLES TO BE ANALYZED Myco	DOMESTIC SAMPLES TO BE ANALYZED Micro	DOMESTIC SAMPLES TO BE ANALYZED Chem	DOMESTIC SAMPLES TO BE ANALYZED DIOXIN
	TOTAL FIELD	120	1000	250	200	500	50	250	200	500	50
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	2	17	4	3	8	1				
	NEW YORK	7	58	15	12	29	3				
	REGIONAL LAB								15	66	
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE	3	25	6	5	13	1				
	CHICAGO	9	75	19	15	38	4				
	CINCINNATI	11	92	23	18	46	5				
	DETROIT	4	33	8	7	17	2				
	MINNEAPOLIS	13	109	27	21	53	5				
	NEW JERSEY	1	8	2	2	4					
SE	PHILADELPHIA	6	50	13	10	25	3				
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	8	67	17	13	33	3				
	FLORIDA	2	17	4	3	8	1				
SW	NEW ORLEANS	12	100	25	20	50	5				
	SAN JUAN	1	8	2	2	4					
	REGIONAL LAB							48	73	154	
	REGIONAL STAFF										
	DALLAS	3	25	6	5	13	1				
PA	DENVER	4	33	8	7	17	2		78		
	KANSAS CITY	18	150	38	30	75	7	52		196	
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB							8	7	17	50
PA	REGIONAL STAFF										
	LOS ANGELES	4	33	8	7	17	2				
	SAN FRANCISCO	10	83	21	17	42	4		27	42	
	SEATTLE	2	17	4	3	8	1				
	PACIFIC REGIONAL LAB (SW)										17
PACIFIC REGIONAL LAB (NW)								142		8	
HOURS PER OPERATION		7.6	3.0					7.7	7.7	7.9	7.5
TOTAL HOURS		912	3000					1925	1540	3950	375
CONVERSION FACTOR		1000	1000					1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.91	3.00					1.63	1.31	3.35	0.32

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	INSPECTIONAL	10/1/00	9/30/01
<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	ANALYTICAL	10/15/00	9/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS
 * Regular inspections replaced in support of BSE inspections of 120 renderers and protein blenders .
 *Numbers in shaded areas (columns "A", "B", "C", and "D) represent a guideline for district collection.
 Please note the new DIOXIN assignment.

Note: Continued on Page 71-7

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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

PROGRAM/ASSIGNMENT CODE(S)
003 A-E, 71003F (BSE)
*(99R833, 71R833, 71R824)

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
(2.8)

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW (Hours)	IMPORT FILER EVALUATION (Hours)	4			8		8	
				IMPORT SAMPLE COLL	IMPORT SAMPLE COLL** Chem "A"	IMPORT SAMPLE COLL** Myco "B"	IMPORT SAMPLE ANALYZED Chem	IMPORT SAMPLE ANALYZED Myco		
	TOTAL FIELD	1422	291	174	100	74	100	74		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	71	9	8	5	3				
	NEW YORK	370	75	42	24	18				
	REGIONAL LAB							29		
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	26	21	3	2	1				
	CHICAGO	24	3	3	2	1				
	CINCINNATI	67	2	8	5	3				
	DETROIT	243	13	28	16	12				
	MINNEAPOLIS	43	8	6	3	3				
	NEW JERSEY									
	PHILADELPHIA	8	8							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SW	ATLANTA	18	19	2	1	1				
	FLORIDA		20							
	NEW ORLEANS	9	2	2	1	1				
	SAN JUAN	7	2							
	REGIONAL LAB							9		
	REGIONAL STAFF									
PA	DALLAS									
	DENVER									
	KANSAS CITY							5		
	SOUTHWEST IMPORT DISTRICT		53	12	7	5				
	REGIONAL LAB							20	15	
	REGIONAL STAFF									
PA	LOS ANGELES	103	26	13	7	6				
	SAN FRANCISCO	10	15							
	SEATTLE	423	15	47	27	20				
	PACIFIC REGIONAL LAB (SW)							7		
	PACIFIC REGIONAL LAB (NW)							30	59	
HOURS PER OPERATION				2.0			6.8	6.8		
TOTAL HOURS		1422	291	348			680	503		
CONVERSION FACTOR		1200	1000	1000			1180	1180		
TOTAL OPERATIONAL FTEs		1.19	0.29	0.35			0.58	0.43		

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	10/1/00	9/30/01
<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	10/15/00	9/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS
Numbers in shaded areas (columns "A" and "B") represent a guideline for district collections.

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 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)
 71000
 71006F (BSE)

4. WORK ALLOCATION PLANNED BY
 X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
 11.6

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1		3	3	7	7		
		INSPECTIONS BSE INCLUDE (Add-Ons) *	INSPECTIONS BSE (For Cause) **		INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLES ANALYZED Chem	DOMESTIC SAMPLES ANALYZED Micro		
	TOTAL FIELD	100	17		8291		2185	394		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2			511					
	NEW YORK	1			1009					
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	4	1		222					
	CHICAGO	5	1		94					
	CINCINNATI	5	1		242					
	DETROIT	5	1		455					
	MINNEAPOLIS	12	1		507					
	NEW JERSEY	2			29					
	PHILADELPHIA	3	1		803					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	4	1		123					
	FLORIDA	1			27					
	NEW ORLEANS	3	1		89					
	SAN JUAN				96					
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	6	1		560					
	DENVER	3	1		426		2185	394		
	KANSAS CITY	24	3		218					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	5	1		784					
	SAN FRANCISCO	10	2		1561					
	SEATTLE	5	1		535					
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		3.0	8.0				1.0	3.0		
TOTAL HOURS		300	136		8291		2185	1180		
CONVERSION FACTOR		1000	1000		1000		1180	1180		
TOTAL OPERATIONAL FTEs		0.30	0.14		8.29		1.85	1.00		

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
<input checked="" type="checkbox"/> X	CHEMIST		PYS. SCIENCE TECH	<input checked="" type="checkbox"/> X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/1/00	9/30/01
<input checked="" type="checkbox"/> X	MICROBIOLOGIST	<input checked="" type="checkbox"/> X	BIO. SCIENCE TECH	<input checked="" type="checkbox"/> X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/00	9/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

MARKS

Unfilled analytical time may be converted to methods development per CVM's concurrence. Methods development work will be assigned by CVM. *Add-on BSE inspections at producers and **for cause inspections. States are to accomplish a significant number of inspections as pertaining to first time violators. NOTE: If a tissue residue investigation leads to a GMP inspection involving on-farm/feeder or a feed mill, charge inspection time to 71004; for non-drug chemicals charge to 71003.

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 DOMESTIC SAMPLE COLL	4 IMPOR T SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPOR T FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED Micro	7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD				200				400		
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND				6						
	NEW YORK				6						
	REGIONAL LAB WEAC										
CE	REGIONAL STAFF										
	BALTIMORE				20						
	CHICAGO				6						
	CINCINNATI				11						
	DETROIT				9						
	MINNEAPOLIS				20						
	NEW JERSEY				4						
	PHILADELPHIA				8						
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA				5						
	FLORIDA				6						
	NEW ORLEANS				10						
	SAN JUAN REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS				12						
	DENVER				21				400		
	KANSAS CITY				18						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB										
PA	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	
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPE CTION AL	10/1/00	9/30/01	
	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/00	9/30/01	
	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
 ORA/Center Directed Research Projects

2. PPS PROJECT NAME/NUMBER
 Monitoring of Marketed Animal Drugs,
 Feeds and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)
 16

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
 6.0

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours) *	RESEARCH CENTER RESEARCH CHEM (Hours)								
NE	HEADQUARTERS											
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
CE	WEAC											
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
SE	FORENSIC CHEM. CTR											
	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
SW	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER	1200		4720								
PA	KANSAS CITY											
	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE			1180								
	PACIFIC REGIONAL LAB (SW)											
	PACIFIC REGIONAL LAB (NW)											
HOURS PER OPERATION												
TOTAL HOURS		1200		5900								
CONVERSION FACTOR		1205		1180								
TOTAL OPERATIONAL FTEs		1.00		5.00								

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		
<input checked="" type="checkbox"/>	MICROBIOLOGIST		BIO. SCIENCE TECH	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	ENGINEER (INV)	NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER	SHELLFISH SPEC	OTHER			

9. REMARKS
 Food Safety Initiative.

1. PROGRAM/ASSIGNMENT TITLE Forensic Chemistry Center Sample Analyses	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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 <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: 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 (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) 8			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)									
	TOTAL FIELD		875									
NE	HEADQUARTERS											
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
CE	WEAC											
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
SE	FORENSIC CHEM. CTR		875									
	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
	NEW ORLEANS											
	SAN JUAN											
SW	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
	DENVER											
	KANSAS CITY											
PA	SOUTHWEST IMPORT DISTRICT											
	REGIONAL LAB											
	REGIONAL STAFF											
	LOS ANGELES											
	SAN FRANCISCO											
	SEATTLE											
PACIFIC REGIONAL LAB (SW)												
PACIFIC REGIONAL LAB (NW)												
HOURS PER OPERATION												
TOTAL HOURS			875									
CONVERSION FACTOR			1180									
TOTAL OPERATIONAL FTEs			0.74									
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	10/15/00	09/30/01		
	PHYSICIST				MILK/FOOD SPEC							
	ENTOMOLOGIST	X	RESEARCH CHEMIST		SHELLFISH SPEC		OTHER					
9. REMARKS												

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2001**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	163.8	30.6	17.5	211.9	344.2	74.1	39.7	458.0
81	POSTMARKET ASSURANCE: DEVICES	2.0			2.0	4.8			4.8
82	COMPLIANCE: DEVICES	78.3	27.0	14.0	119.3	159.8	65.4	31.1	256.3
83	PRODUCT EVALUATION: DEVICES	28.5		1.4	29.9	69.1		3.4	72.5
84	SCIENCE: DEVICES	7.8			7.8	12.0			12.0
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	21.7		0.1	21.8	36.7		0.3	37.0
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	25.5	3.6	2.0	31.1	61.8	8.7	4.9	75.4

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 TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) All medical devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

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)	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 CTIONS (1)	INVESTI GATIONS (Hours) (2)	DOMESTIC SAMPLE COLL (3)	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED ENG (4)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	DOMESTIC SAMPLES TO BE ANALYZED STER (6)	OTHER OPERATIONS (Hours)
	TOTAL FIELD	59	98	9			5	5	4	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	6	10							
	NEW YORK	1	2							
	REGIONAL LAB									
CE	WEAC						5	5	4	
	REGIONAL STAFF									
	BALTIMORE			1						
	CHICAGO	4	8							
	CINCINNATI	1		3						
	DETROIT	3	6							
	MINNEAPOLIS									
	NEW JERSEY	2	4							
SE	PHILADELPHIA	1	2							
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	3	4							
	FLORIDA	4	7	1						
SW	NEW ORLEANS	1	3	1						
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	DALLAS									
	DENVER	3	4							
	KANSAS CITY	3	4	2						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	22	37	1						
	SAN FRANCISCO	4	7							
	SEATTLE	1								
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		15.6		5.5			37.0	36.0	20.0	
TOTAL HOURS		920	98	50			185	180	80	
CONVERSION FACTOR		950	950	950			1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.97	0.10	0.05			0.16	0.15	0.07	

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

9. REMARKS

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 filth.

1. PROGRAM/ASSIGNMENT TITLE MDR User Reporting F/U Inspections	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 To monitor device user facilities' compliance with requirements of the Medical Device Reporting Regulation (MDR).	
5. PROGRAM JUSTIFICATION Approximately 60,000 - 70,000 user facilities are subject to the reporting requirements of MDR. These facilities are the initial source of many device-related death, serious injury, and malfunction reports that CDRH receives. In addition, most MDRs submitted by manufacturers originate in a user facility. Consequently, monitoring user facility compliance with MDR is crucial to the identification, reporting, and accuracy of CDRH's Postmarket Surveillance program.	
6. FIELD OBLIGATIONS Conduct assignment-directed inspections and initiate appropriate regulatory follow up.	
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 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 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 MDR User Reporting F/U Inspections	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM/ASSIGNMENT CODE(S) 5	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST I G A T I O N S (Hours)	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	25								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1								
	NEW YORK	1								
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1								
	CHICAGO	1								
	CINCINNATI	2								
	DETROIT	2								
	MINNEAPOLIS	2								
	NEW JERSEY									
SE	PHILADELPHIA	1								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	2								
	FLORIDA	1								
SW	NEW ORLEANS	2								
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2								
PA	DENVER	1								
	KANSAS CITY	2								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	2								
	SAN FRANCISCO	1								
	SEATTLE	1								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		20.5								
TOTAL HOURS		513								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.54								

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	INSPEC- TIONAL	
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	10/01/00	
	PHYSICIST				MILK/FOOD SPEC			09/30/01	
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		
								ANALY- TICAL	

9. REMARKS
INSPECTIONS WILL BE CONDUCTED ON ASSIGNMENT BY CDRH ONLY.
 User Facilities subject to reporting requirements of the Safe Medical Device Act will be inspected to confirm violations of these reporting requirements--eg. failures to report device-related deaths and serious injuries/illnesses.
 User Facility List has been generated as a planning basis for each district for this program. A percentage of the overall user facility list will be violative and will require an in-depth inspection by FDA.

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

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
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b. INSPECTION TYPE:	N/A	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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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					
3. PROGRAM/ASSIGNMENT CODE(S) 3, 82R824, 82R833, 833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI- GATIONS (Hours)	4 IMPORT FIELD EXAMS *	4 IMPORT SAMPLE COLL (Physical) **	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 IMPORT LABEL EXAM
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		298	70		26				
	NEW YORK		1701	591		155	15			25
	REGIONAL LAB									
CE	WEAC							75	19	
	REGIONAL STAFF									
	BALTIMORE		96	166						
	CHICAGO		600	23		82	8			12
	CINCINNATI		182	18		22				
	DETROIT		279	101		28				
	MINNEAPOLIS		248	67		41	8			14
	NEW JERSEY									
SE	PHILADELPHIA		255	66		17				
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		201	154		31				
	FLORIDA		236	157		25				
	NEW ORLEANS		1031	11		153	19			30
SW	SAN JUAN		53	11		17				
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		4150	418		371	32			51
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		770	207		52				9
PA	SAN FRANCISCO		563	122		53	12			9
	SEATTLE		167	121		27				
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION						0.5	1.0	34.0	25.5	1.0
TOTAL HOURS			10830	2303		550	94	2550	485	150
CONVERSION FACTOR			1200	950		950	950	1180	1180	950
TOTAL OPERATIONAL FTEs			9.03	2.42		0.58	0.10	2.16	0.41	0.16
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/00	09/30/01
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS Continuation Sheet										

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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.

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.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PMS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

To evaluate the manufacturing processes used for general and radiation emitting medical devices and *in vitro* 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 draft compliance program. For more detailed instructions on QSIT/GMP inspections as they relate to device manufacturers, refer to the "Continuation Sheet" on page 82-11. 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
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b. INSPECTION TYPE:	<input checked="" type="checkbox"/> COMPREHENSIVE	<input checked="" type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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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
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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

Engineering Samples: 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) A,B,C,G,S,R841,82012			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 80.0 [70.96]			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	3	3	3
		INSP CTIONS	INSP CTIONS LEVEL II (BASELINE) 82845B 1/	INSP CTIONS LEVEL III (COMPLIANCE FOLLOWUP) 82845C	INSP CTIONS FOREIGN	INSP CTIONS MRA	INSP CTIONS CONTRACT STERILIZERS	DOMESTIC SAMPLES TO BE COLLECTED	DOMESTIC SAMPLES TO BE COLLECTED CONTRACT STERILIZERS	DOMESTIC SAMPLES TO BE COLLECTED BIOBURDEN BIOINDICATOR
TOTAL FIELD			738	157	178	24	30	177	2	37
NE	HEADQUARTERS		31		26	3				
	REGIONAL STAFF									
	NEW ENGLAND		73	16	9		1	22		4
	NEW YORK		30	4	9	3		9		1
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		23	2	6			5		1
	CHICAGO		26	11	9		4	6		2
	CINCINNATI		21	8	6		2	4		2
	DETROIT		25	8	9		1	7		2
	MINNEAPOLIS		56	11	12	3	1	14		3
	NEW JERSEY		32	6	6	3	3	9		1
	PHILADELPHIA		35	8	6		1	9		2
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		36	11	6		4	8	1	2
	FLORIDA		56	13	12	3	1	14		3
	NEW ORLEANS		14		4		1	4		
	SAN JUAN		13		3		1	3		
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS		39	9	12	3	3	9		2
	DENVER		33	3	10	3	2	8		1
	KANSAS CITY		19	7	9		1	4		2
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		113	19	12	3	3	28	1	5
	SAN FRANCISCO		40	10	6		1	9		2
SEATTLE		23	11	6			5		2	
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION			56.0	70.0	64.2	65.0	31.0	5.5	5.5	5.5
TOTAL HOURS			41328	10990	11428	1560	930	974	11	204
CONVERSION FACTOR			950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs			43.50	11.57	12.03	1.64	0.98	1.02	0.01	0.21
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP CTIONAL	10/01/00	09/30/01
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)	X	ENGINEER TECH	X	ENGINEER (INV)	X	NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY- TICAL	10/15/00	09/30/01
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS See Continuation Sheet (Page 82-11) for column footnotes, explanations of specific operations and strategies, as well as more information on the new QSIT/GMP inspection strategy. Domestic Sample Collections for Contract Sterilizers and/or Bioburden, Bioindicator are to be collected "for cause".										

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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 5A,B,C,G,S,R841,82012	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 80.0 [9.09]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	7	7	7	7	7	7	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
	TOTAL FIELD	10	37	110		14	6	25	336
NE	HEADQUARTERS								42
	REGIONAL STAFF								
	NEW ENGLAND	1							
	NEW YORK								42
	REGIONAL LAB								
CE	WEAC		37	34		14	6	25	
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS	2							42
	NEW JERSEY								42
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	1							
	FLORIDA	1							42
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS	1							42
	DENVER	1		76					42
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	2							42
	SAN FRANCISCO	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	336
CONVERSION FACTOR		950	1180	1180		1180	1180	1180	950
TOTAL OPERATIONAL FTEs		0.06	0.98	5.71		0.30	0.13	1.53	0.35

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	INSPEC- TIONAL	10/01/00	09/30/01
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
<input checked="" type="checkbox"/>	ENGINEER(ANALYST)	<input checked="" type="checkbox"/>	ENGINEER TECH	<input checked="" type="checkbox"/>	ENGINEER (INV)	<input checked="" type="checkbox"/>	NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST		OTHER		MILK/FOOD SPEC		OTHER			
	ENTOMOLOGIST				SHELLFISH SPEC					

9. REMARKS
Continuation Sheet for column footnotes and explanations of specific operations and strategies.

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

ction of Medical Device Manufacturers

2. PPS PROJECT NAME/NUMBER

Compliance: Devices - 82

9. Remarks

QUALITY SYSTEMS (QSIT)/GMP INSPECTION STRATEGY

Fiscal Year 2001 Quality Systems/GMP inspections are based on CDRH's risk-based strategy. Under this strategy, the Field should conduct biennial inspections of 100% of high risk device manufacturers. The Field should also conduct biennial inspections of 80% of manufacturers of Class III device manufacturers that are not considered to be high risk. The remaining manufacturers--Class III, Class II, and Class I devices, should be inspected as each district's resources allow; they should be scheduled according to the priority outline in Part II of the draft compliance program.

Inspections of high risk device manufacturers and Class III device manufacturers are identified in Column 2 as "Baseline" inspections on Page 82-7;

followup inspections are identified in Column 3 as "Compliance Followup" inspections. Lastly, inspections of foreign manufacturers are identified in Column 4 as "Foreign" inspections.

When districts begin using QSIT inspections of high risk and Class III manufacturers, the investigator should cover four subsystems (Level 2 in the QSIT chart of the compliance program) for their initial biennial quality system/GMP inspections. After the initial Level 2 QSIT inspections, firms that were found satisfactory (VAI or NAI), can be reinspected biennially under Level 1 (CAPA plus one subsystem).

NOTE: FOR FY 2001, NO LEVEL I "ABBREVIATED" INSPECTIONS WILL BE CONDUCTED. FOR INFO PURPOSES:

A Level 1 QSIT inspection (CAPA plus one--with emphasis on management and/or design controls for the "one") can be conducted for Class I and II manufacturers that have received a previous non-violative inspection covering design controls.

Level 2 inspection should be conducted for any other manufacturer receiving its first QSIT inspection.

WORKPLANNING SHEET COLUMN HEADING FOOTNOTES:

- 1/ 31 Headquarters Inspections represent the number of inspections for HQ Investigators to assist in GMP inspections.
- 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-DO.

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) 02	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL (PHYSICAL)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	OTHER OPERATIONS (Hours)
	TOTAL FIELD	7		7	265			7	265	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND					5				
	NEW YORK					30				
	REGIONAL LAB									
	WEAC							2	55	
CE	REGIONAL STAFF									
	BALTIMORE	1		1						
	CHICAGO					5				
	CINCINNATI	1		1						
	DETROIT					10				
	MINNEAPOLIS					5				
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2		2	130					
	FLORIDA									
	NEW ORLEANS	2		2	5					
	SAN JUAN									
	REGIONAL LAB							4	135	
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY	1		1						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB					5				
PA	REGIONAL STAFF									
	LOS ANGELES					30				
	SAN FRANCISCO					40				
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW							1	75	
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		40.0		2.5	2.4			17.0	13.0	
TOTAL HOURS		280		18	636			119	3445	
CONVERSION FACTOR		950		950	950			1180	1180	
TOTAL OPERATIONAL FTEs		0.29		0.02	0.67			0.10	2.92	

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	INSP CTIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	<input checked="" type="checkbox"/>	ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/00	09/30/01
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		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 reported 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
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 79-80
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 03	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
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL (PHYSICAL)	FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED ENG	DOMESTIC SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
	TOTAL FIELD	6		8	1025		3	5	216	809
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2		2	15					
	NEW YORK				88					
	REGIONAL LAB									
CE	WEAC						3	3	216	297
	REGIONAL STAFF									
	BALTIMORE				22					
	CHICAGO	1		1	113					
	CINCINNATI				8					
	DETROIT				6					
	MINNEAPOLIS				15					
	NEW JERSEY									
	PHILADELPHIA				28					
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1		1	88					
	FLORIDA	1		1	16					
	NEW ORLEANS				22					
	SAN JUAN				2					
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1		1						
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT				90					
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			1	460					
	SAN FRANCISCO			1	37					
PA	SEATTLE				15					
	PACIFIC REGIONAL LABORATORY-SW							2		512
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		15.0		1.5	2.4		20.0	13.0	8.0	7.2
TOTAL HOURS		90		12	2460		60	65	1728	5825
CONVERSION FACTOR		950		950	950		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.09		0.01	2.59		0.05	0.06	1.46	4.94

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		INSPEC- TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR				
<input checked="" type="checkbox"/>	ENGINEER(ANALYST)	<input checked="" type="checkbox"/>	ENGINEER TECH	<input checked="" type="checkbox"/>	ENGINEER (INV)		ANALY- TICAL	10/15/00	09/30/01
	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, 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
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3. PROGRAM TYPE:	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input checked="" type="checkbox"/> ASSIGNMENT
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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
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b. INSPECTION TYPE:	<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED
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c. PRODUCT(S) All devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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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 ORA/Center Directed Research Program	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) 316			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.8		
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)			
	TOTAL FIELD		4500	2200	800	700			
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC		4500	2200	800	700			
	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			4500	2200	800	700			
CONVERSION FACTOR			1205	1205	1205	1180			
TOTAL OPERATIONAL FTEs			3.73	1.83	0.66	0.59			
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH	<input type="checkbox"/>	INVESTIGATOR	<input type="checkbox"/>	RRHR	INSPEC-TIONAL	
<input checked="" type="checkbox"/>	MICROBIOLOGIST		BIO. SCIENCE TECH	<input type="checkbox"/>	INSPECTOR	<input type="checkbox"/>	VETERINARIAN		
<input checked="" type="checkbox"/>	ENGINEER(ANALYST)		ENGINEER TECH	<input type="checkbox"/>	ENGINEER (INV)	<input type="checkbox"/>	NAT'L EXPERT		
<input checked="" type="checkbox"/>	PHYSICIST			<input type="checkbox"/>	MILK/FOOD SPEC	<input type="checkbox"/>		ANALY-TICAL	10/15/00
<input checked="" type="checkbox"/>	ENTOMOLOGIST		OTHER	<input type="checkbox"/>	SHELLFISH SPEC	<input type="checkbox"/>	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) 338	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)								
	TOTAL FIELD	354								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR	354								
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	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 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	INSPEC- TIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	ENGINEER (INV)	NAT'L EXPERT			
	PHYSICIST			MILK/FOOD SPEC		ANALY- TICAL	10/15/00	09/30/01
	ENTOMOLOGIST		OTHER	SHELLFISH SPEC	OTHER			

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket 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 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.	
5. PROGRAM JUSTIFICATION 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.	
6. FIELD OBLIGATIONS 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.	
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					2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83					
3. PROGRAM/ASSIGNMENT CODE(S) 1, A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	5	6	7	8	9
		INSP EC T I O N S P R E - A P P R O V A L	INSP EC T I O N S P O S T - A P P R O V A L	F O R E I G N I N S P E C T I O N S P R E - A P P R O V A L	F O R E I G N I N S P E C T I O N S P O S T - A P P R O V A 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)
TOTAL FIELD		101	50	25	5					
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	6	3	1	1					
	NEW YORK	3	1	1	1					
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	4	2							
	CHICAGO	3	2	1	1					
	CINCINNATI	2	1	1	1					
	DETROIT	2	1							
	MINNEAPOLIS	10	5	3						
	NEW JERSEY	4	2	1	1					
SE	PHILADELPHIA	4	2	3						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	4	2	2						
	FLORIDA	8	4	3						
SW	NEW ORLEANS	1		2						
	SAN JUAN	3	2							
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	6	3	2						
PA	DENVER	5	3	2						
	KANSAS CITY	3	1	3						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	22	10							
	SAN FRANCISCO	7	4							
	SEATTLE	4	2							
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		50.0	49.0	32.0	50.0					
TOTAL HOURS		5050	2450	800	250					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		5.32	2.58	0.84	0.26					
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL		
	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; 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.										

1. PROGRAM/ASSIGNMENT TITLE 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 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. The following performance goals were included in the FY 2001 Budget: To improve quality conformance of high-risk products, like cardiovascular devices, by redirecting compliance priorities toward higher-risk devices; To assure that the domestic medical device manufacturing establishments inspected by FDA achieve a 95% rate of conformance with FDA requirements.	
5. PROGRAM JUSTIFICATION 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. In addition, applicants are permitted to declare compliance with design controls as a means of streamlining review of 510(k) pre-market notifications. Focused inspections of manufacturers that make such declarations are necessary to assure that they are truth and accurate.	
6. FIELD OBLIGATIONS On assignment from CDRH, conduct a comprehensive GMP inspection as instructed in the compliance program. Regarding Conformance Standards inspections, the field should conduct inspections based on assignments by the Field Programs Branch: 100% of assignments issued should be completed as high priority. Specific devices (which are Class II or III) referenced in the applicable declaration of conformity will be covered. For more detailed instructions on Declarations of Conformity to Standards inspections as they relate to device manufacturers, refer to Part III of the compliance program.	
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 510(k) Pre-Market Approval Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 3	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	4	5	6	7	8	9
		INSP EC T I O N S	INSP EC T I O N S (1)	FORE IGN INSP EC T I O N S	IMP ORT S A M P L E C O L L	FI E L D E X A M S / T E S T S	IMP ORT F I E L D E X A M S	DO 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	IMP ORT S A M P L E S T O B E A N A L Y Z E D	OT H E R O P E R A T I O N S (Hours)
	TOTAL FIELD	40	55	7						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2	5	1						
	NEW YORK	1	2	1						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	2	1							
	CHICAGO	1	3	1						
	CINCINNATI	1	2	1						
	DETROIT	1	2							
	MINNEAPOLIS	4	4							
	NEW JERSEY	2	2	1						
	PHILADELPHIA	2	3							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	4	1						
	FLORIDA	3	4							
	NEW ORLEANS		1							
	SAN JUAN	1	1							
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	3	3	1						
	DENVER	2	2							
	KANSAS CITY	1	2							
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	7	8							
	SAN FRANCISCO	3	4							
SEATTLE		2	2							
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		37.0	37.0	45.0						
TOTAL HOURS		1480	2035	315						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.56	2.14	0.33						

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	INSPEC TIONAL	10/01/00 09/30/01
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC			ANALY TICAL	
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		

9. REMARKS
 Report all time used for evaluating domestic 510(k) pre-market requirements against PAC 83003, Op Code 12;
 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 GLPs, IRBs, Sponsor-Monitors, Clinical Investigators (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.9
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REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	5	6	7	8	9
		INSP- CTIONS (GLPs)	INSP- CTIONS (IRBs)	INSP- CTIONS (SPON/MON)	INSP- CTIONS (CLINICAL INVEST)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	8	59	51	132					
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	3	6	6					
	NEW YORK		1		4					
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		1	2	8					
	CHICAGO			5	2	4				
	CINCINNATI			2		7				
	DETROIT			5	3	9				
	MINNEAPOLIS	1		5	7	4				
	NEW JERSEY			3	3	3				
	PHILADELPHIA	1		2	1	7				
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	1		3	1	8				
	FLORIDA			4	2	11				
	NEW ORLEANS	1		5		12				
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS			4	1	8				
	DENVER	1		1	2	5				
	KANSAS CITY			3		10				
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1		6	12	17				
	SAN FRANCISCO	1		3	9	5				
	SEATTLE			3		4				
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	74.0	38.0	65.0	75.0					
	TOTAL HOURS	592	2242	3315	9900					
	CONVERSION FACTOR	950	950	950	950					
	TOTAL OPERATIONAL FTEs	0.62	2.36	3.49	10.42					

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL		
	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 COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
To be assigned

d. INDUSTRY/PRODUCT CODE(S)
73-91

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 02	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	9	9	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	OTHER O P E R A T I O N (Hours) METH DEV CHEM	OTHER O P E R A T I O N (Hours) METH DEV MICRO	OTHER O P E R A T I O N (Hours) METH DEV ENG
	TOTAL FIELD							656	2084	4337
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC							656	2084	4337
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS								656	2084	4337
CONVERSION FACTOR								1180	1180	1180
TOTAL OPERATIONAL FTEs								0.56	1.77	3.68

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

9. REMARKS
Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by DRH Laboratory Staff.

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

2. PPS PROJECT NAME/NUMBER
Science: Devices - 84

3. PROGRAM TYPE: N/A

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

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:

CHEMICAL

MICROBIOLOGICAL

PHYSICAL

ENGINEERING

MICROANALYTICAL

OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) J16	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.8
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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)				
	TOTAL FIELD			500	1660				
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC			500	1660				
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
		REGIONAL STAFF							
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS			500	1660				
	CONVERSION FACTOR			1205	1180				
	TOTAL OPERATIONAL FTEs			0.41	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	INSPEC- TIONAL	
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC			ANALY- TICAL	10/15/00
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		09/30/01

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) A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 21.8			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	2	2	9	9
		INSP CTIONS (1)	INSP CTIONS (2)	INSP CTIONS (3)	INSP CTIONS (4)	INSP CTIONS FOREIGN (5)	INVEST IGATIONS (Hours) (6)	INVEST IGATIONS (Hours) (7)	OTHER OPERATIONS (Hours) (8)	OTHER OPERATIONS (Hours) (9)
TOTAL FIELD		453	4	126	44	18	2343	350	10448	7003
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	97		2	2		165	44	578	387
	NEW YORK		1	1	6		176	11	766	513
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			16	2		143	22	534	358
	CHICAGO			2	3		110	11	485	331
	CINCINNATI	20		3	1		154	11	668	443
	DETROIT	115			1		165	33	604	405
	MINNEAPOLIS			5	1		132	11	573	384
	NEW JERSEY			2	1		66	11	310	208
	PHILADELPHIA	27		2	1		121	22	523	351
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		1	14	4		132	11	711	476
	FLORIDA			8	6	1	110	11	547	367
	NEW ORLEANS			8	3		154	44	685	459
	SAN JUAN			1		1	22	11	127	85
REGIONAL LAB										
SW	REGIONAL STAFF	145	1			16	297	64	1711	1147
	DALLAS			31	5					
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	49	1	9	8		396	22	923	618
	SAN FRANCISCO			10				11	703	471
	SEATTLE			12						
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		8.0	5.0	8.0	8.0	8.0				
TOTAL HOURS		3624	20	1008	352	144	2343	350	10448	7003
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1160
TOTAL OPERATIONAL FTEs		3.12	0.02	0.87	0.30	0.12	2.02	0.30	9.01	6.04
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP CTIONAL	10/01/00	09/30/01	
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 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. Federal Facility Inspections (does not include VHA Facility inspections). IA Facility Inspections. NOTE--these inspections are paid through an Interagency Agreement and are not covered by MQSA resources.										
3) 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.										

1. PROGRAM/ASSIGNMENT TITLE Inspection of Manufacturers of Laser 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 determine if laser products are in compliance with the radiation emissions requirement of the "laser performance standard."	
5. PROGRAM JUSTIFICATION 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.	
6. FIELD OBLIGATIONS 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/ORR inspections when such inspections are scheduled by the Center.	
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	d. INDUSTRY/PRODUCT CODE(S) 95LS-99
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 <i>Caution: laser product may be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.</i>	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Manufacturers of Laser Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	5	6	7	8	9
		INSP CTIONS (1)	INSP CTIONS FOREIGN (2)	INVEST GATIONS (Hours) (3)	DOMESTIC SAMPLE COLL (4)	FIELD EXAMS/ TESTS (5)	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours) (6)
	TOTAL FIELD	105	15	1120	7	175				630
NE	HEADQUARTERS									
	REGIONAL STAFF	15		160	1	25				90
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC		15							
	REGIONAL STAFF	15		160	1	25				90
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF	15		160	1	25				90
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF	15		160	1	25				90
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF	45		480	3	75				270
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	17.0	14.6		6.0	2.5				
	TOTAL HOURS	1785	219	1120	42	438				630
	CONVERSION FACTOR	950	1180	950	950	950				950
	TOTAL OPERATIONAL FTEs	1.88	0.19	1.18	0.04	0.46				0.66

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

9. REMARKS

Continuation Sheet

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Inspection of Manufacturers of Laser Products

2. PPS PROJECT NAME/NUMBER

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

9. Remarks

- 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.
- 3) Investigation Hours--refer to Compliance Program for reporting information.
- 4) To be performed by reserve EOS, or by CSOs trained by an EOS.
- 5) Will include laser products located at a user facility and laser light shows.
- 6) To include all other activities such as technical assistance, coordination, and training.

1. PROGRAM/ASSIGNMENT TITLE Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: N/A <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 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 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 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. <u>SOURCE OF WORKLOADS:</u> Inspections and Domestic Sample Collections are based on the CDRH OEI of Sunlamp Product Manufacturers; Investigations and Field Tests are based on the resident population of the states, obtained from the Bureau of the Census.	
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 checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Sunlamp, suntanning booths, and sunlamp products.	d. INDUSTRY/PRODUCT CODE(S) 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 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	

1. PROGRAM/ASSIGNMENT TITLE Field Implementation of the Sunlamp and Sunlamp Products Performance Standard As Amended	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 2	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	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 T O B E A N A L Y Z E D	IMP O R T S A M P L E 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	9	200	3		31				216
NE	HEADQUARTERS									
	REGIONAL STAFF									36
	NEW ENGLAND	1	10			2				
	NEW YORK		14			2				
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									36
	BALTIMORE		11			2				
	CHICAGO		9			1				
	CINCINNATI	2	12	1		2				
	DETROIT	1	12			2				
	MINNEAPOLIS		8			1				
	NEW JERSEY	1	6			1				
PHILADELPHIA		10			1					
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									36
	ATLANTA	1	13	1		2				
	FLORIDA	1	10	1		2				
	NEW ORLEANS		12			2				
	SAN JUAN		3							
REGIONAL LAB										
SW	REGIONAL STAFF									36
	DALLAS	1	18			3				
	DENVER		6			1				
	KANSAS CITY	1	9			1				
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									72
	LOS ANGELES		17			3				
	SAN FRANCISCO		12			2				
	SEATTLE		8			1				
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		16.8		3.3		1.5				
TOTAL HOURS		151	200	10		47				216
CONVERSION FACTOR		950	950	950		950				950
TOTAL OPERATIONAL FTEs		0.16	0.21	0.01		0.05				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	10/01/00	09/30/01
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
 Continuation Sheet

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE Implementation of the Sunlamp and Sunlamp Products Performance Standard As Amended	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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9. Remarks

- * 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.
- ** The field test of each sunlamp product should be counted as a separate operation.
- *** To be performed by Electro-Optic Specialist--Consultation.

NOTE: Technical Assistance and Coordination under this program is planned under PAC 86008: Medical Device and Radiological Health Use Control and Policy Implementation.

1. PROGRAM/ASSIGNMENT TITLE Field Compliance Testing of Diagnostic X-Ray Equipment	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

To determine 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.

5. PROGRAM JUSTIFICATION

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.

6. FIELD OBLIGATIONS

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.

Sources of 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.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input checked="" type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	N/A	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) Diagnostic X-Ray Equipment	d. INDUSTRY/PRODUCT CODE(S) 94DS---
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e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)		

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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 Field Compliance Testing of Diagnostic X-Ray Equipment					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.8			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	5B AUDITS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		31	1108			1086	98		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	47			46	8			183
	NEW YORK	2	62			53	2			231
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1	57			62	6			209
	CHICAGO	1	41			47	9			154
	CINCINNATI	1	64			41	4			234
	DETROIT	1	60			94	4			214
	MINNEAPOLIS	1	54			45	6			207
	NEW JERSEY	1	33			47				110
	PHILADELPHIA FORENSIC CHEM. CTR	2	45			37	6			187
SE	REGIONAL STAFF									
	ATLANTA	2	95			124	4			313
	FLORIDA	2	81			73	2			282
	NEW ORLEANS	3	105			73	8			375
	SAN JUAN					4	1			16
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3	129			117	12			440
	DENVER	2	29			23	8			124
	KANSAS CITY	2	60			59	6			214
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3	64			63	4			225
	SAN FRANCISCO	1	43			32	6			198
	SEATTLE	2	39			46	2			143
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		14.4				3.0	4.0			
TOTAL HOURS		446	1108			3258	392			4059
CONVERSION FACTOR		950	950			950	950			950
TOTAL OPERATIONAL FTEs		0.47	1.17			3.43	0.41			4.27
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL			INVESTIGATIVE				PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/00	09/30/01	
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										
Continuation Sheet										

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Field Compliance Testing of Diagnostic X-Ray Equipment

2. PPS PROJECT NAME/NUMBER

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

9. Remarks

- 1) Column 1 - Inspections are spread based on the number of x-ray assemblers. Inspections are for compliance follow-up only.
- 2) Column 2 - Investigation hours are for review of assembler reports.
- 3) Columns 5 and 5B - 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) Column 9 - Other Operations includes Coordination/Technical Assistance resources for Field Test Review.

ATTACHMENT A
2001 WORKPLAN FOR FIELD COMPLIANCE TESTING
OF DIAGNOSTIC X-RAY SYSTEMS
(BASED ON PARTNERSHIP AGREEMENTS IN FY 2001)

NEW ENGLAND DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CT	117	18	-	1	2
ME	58	8	-	1	2
MA	234	-	30	2	-
NH	49	-	6	1	2
RI	36	8	-	1	2
VT	24	-	3	1	-
Total	518	34	39	7	8

NEW YORK DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NY	692	40	50	3	2

BALTIMORE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DC	42	-	6	-	-
MD	208	10	20	1	2
VA	300	10	30	2	2
WV	78	10	2	1	2
Total	628	30	58	4	6

CHICAGO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IL	459	20	45	2	9

CINCINNATI DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
KY	221	22	10	1	2
OH	489	40	28	2	2
Total	710	62	38	3	4

DETROIT DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IN	276	-	38	2	4
MI	391	-	52	2	-
Total	667	-	90	4	4

MINNEAPOLIS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
MN	229	20	14	1	2
ND	35	6	-	1	-
SD	43	-	6	1	2
WI	288	20	21	1	2
Total	595	46	41	4	6

NEW JERSEY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NJ	364	-	45	2	-

PHILADELPHIA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DE	32	-	4	1	-
PA	466	45	28	4	6
Total	498	45	32	5	6

ATLANTA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
GA	367	-	54	-	-
NC	426	15	40	2	2
SC	260	-	28	-	2
Total	1053	15	122	2	4

FLORIDA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
FL	897	52	70	3	2

NEW ORLEANS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AL	329	20	22	2	2
LA	245	30	6	2	2
MS	162	10	10	1	2
TN	389	25	28	2	2
Total	1125	85	66	7	8

SAN JUAN DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
PR	31	-	3	1	1

DALLAS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AR	156	-	20	1	-
OK	164	-	20	1	-
TX	1113	80	70	5	12
Total	1433	80	110	7	12

DENVER DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CO	149	10	12	1	4
NM	60	10	-	1	2
UT	85	10	4	1	2
WY	24	-	3	1	-
Total	318	30	19	4	8

KANSAS CITY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IA	170	15	7	1	2
KS	132	10	7	1	2
NE	100	10	5	1	2
MO	261	-	36	1	-
Total	663	35	55	4	6

LOS ANGELES DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AZ	236	-	30	1	-
CA	472	36	30	2	4
Total	708	36	60	3	4

SAN FRANCISCO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CA	353	24	28	2	2
HI	38	14	-	1	2
NV	89	17	-	1	2
Total	480	55	28	4	6

SEATTLE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AK	29	-	3	1	-
ID	54	-	8	1	-
MT	44	-	6	1	-
OR	115	-	14	1	-
WA	188	16	10	1	2
Total	430	16	41	5	2

1. PROGRAM/ASSIGNMENT TITLE Field Compliance Testing of Cabinet X-Ray Equipment	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 determine compliance with the performance standard for cabinet x-ray equipment with respect to radiation emissions under conditions of use.	
5. PROGRAM JUSTIFICATION 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 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 checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Cabinet x-ray and baggage x-ray	d. INDUSTRY/PRODUCT CODE(S) 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	

1. PROGRAM/ASSIGNMENT TITLE Field Compliance Testing of Cabinet X-Ray Equipment					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSPEC- TIONS *	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	28	102			51				
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		6			3				
	NEW YORK	2	12			6				
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	5	6			3				
	CINCINNATI	1	6			3				
	DETROIT	2	6			3				
	MINNEAPOLIS	1	6			3				
	NEW JERSEY		6			3				
	PHILADELPHIA	1								
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2	6			3				
	FLORIDA	3	6			3				
	NEW ORLEANS	1	6			3				
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1	6			3				
	DENVER	1	6			3				
	KANSAS CITY	1	6			3				
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	4	6			3				
	SAN FRANCISCO	2	6			3				
	SEATTLE	1	6			3				
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.2				2.7				
TOTAL HOURS		230	102			138				
CONVERSION FACTOR		950	950			950				
TOTAL OPERATIONAL FTEs		0.24	0.11			0.14				
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	10/01/00		
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	09/30/01		
	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.										

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)
5 A,B,D,E,F

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
5.2

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	7	7	7	7	7	7	7	9
		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	30	5	1	19	4	1	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC	27	52	30	5	1	19	4	1	
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		80.0	20.0	31.0	260.0	100.0	15.0	80.0	25.0	
TOTAL HOURS		2160	1040	930	1300	100	285	320	25	
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	
TOTAL OPERATIONAL FTEs		1.83	0.88	0.79	1.10	0.08	0.24	0.27	0.02	

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

9. REMARKS
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
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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
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) All electronic products or devices that emit radiation.	d. INDUSTRY/PRODUCT CODE(S) 94-97
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE
Imported Electronic Products

2. PPS PROJECT NAME/NUMBER
Radiation Control and Health Safety Act (RCHSA)
Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)
86R824, 86R833, 86R833

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
3.6

REGION	DISTRICT/SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI-GATIONS (Hours)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		3051	970						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		118	30						
	NEW YORK		544	249						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		19	70						
	CHICAGO		110	10						
	CINCINNATI		105	8						
	DETROIT		133	42						
	MINNEAPOLIS		26	28						
	NEW JERSEY									
	PHILADELPHIA		12	28						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		80	65						
	FLORIDA		108	66						
	NEW ORLEANS		101	9						
	SAN JUAN		6							
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		500	176						
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		572	87						
PA	SAN FRANCISCO		354	51						
	SEATTLE		263	51						
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS			3051	970						
CONVERSION FACTOR			1200	950						
TOTAL OPERATIONAL FTEs			2.54	1.02						

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

9. REMARKS
Reporting Guidance:
 Report Entry Reviews (Electronic and Manual--operation code 14, PAC 86R833);
 Evaluations (operation code 95, PAC 99R833); and
 Follow-up to Refusals (PAC 86R824).

1. PROGRAM/ASSIGNMENT TITLE Medical Device and Radiological Health Use Control and Policy Implementation	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 1. 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); 2. Maintain liaison with State radiological health programs; 3. Provide support for regional training activities and regional videotape library; 4. Promote implementation of programs to optimize radiation exposure; 5. Communicate FDA policies to State and local health agencies.	
5. PROGRAM JUSTIFICATION 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.	
6. FIELD OBLIGATIONS 1. The Regional Radiological Health Representatives will maintain liaison and provide technical assistance to State and Federal radiological health program personnel; assist in the planning and presentation of quality assurance training with the region; assist the Division of training and Medical Applications in the selection of States to participate in new use control programs and serve as managers of the regional videotape library; attend the following meetings: (A) National Conference of State Program Directors; (B) regional meetings with state and local radiological health agencies; (C) at least one meeting in Rockville, MD in conjunction with CDRH, ORA and other FDA officials. 2. WEAC will provide Laboratory Support for the DENT programs.	
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 Medical Device and Radiological Health Use Control and Policy Implementation					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) <i>80005</i>			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.8			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 MISC (Hours) DENT *	9 MISC (Hours) RRHR **
NE	HEADQUARTERS									
	REGIONAL STAFF									1000
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC								750	
	REGIONAL STAFF									1000
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									1000
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									1000
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									1000
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS									750	5000
CONVERSION FACTOR									1180	1200
TOTAL OPERATIONAL FTEs									0.64	4.17
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR	X	RRHR	INSP EC T I O N A L	10/01/00	09/30/01
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
X	ENGINEER(ANALYST)	X	ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY T I C A L	10/15/00	09/30/01
	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 and Radiological Health Use Control Policy Implementation	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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9. Remarks

- * 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.
 - ** All RRHR time for CDRH programs is planned under this program and the Emergency Response and Planning Activities program. 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.

1. PROGRAM/ASSIGNMENT TITLE
Emergency Planning and Response Activities

2. PPS PROJECT NAME/NUMBER
Radiation Control and Health Safety Act (RCHSA)
Authority - 86

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To act as a focal point for emergency readiness response planning by States.

5. PROGRAM JUSTIFICATION
The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.

6. FIELD OBLIGATIONS
Provide consultation to states and attend regional emergency planning meetings.

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) d. INDUSTRY/PRODUCT CODE(S)
94YN-99

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Emergency Planning and Response Activities					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 1.0				
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 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 T E C H N I C A S S I S T A N C E (Hours) R R H R	9 T E C H N I C A S S I S T A N C E (Hours) C S O
	TOTAL FIELD										1000
N E	HEADQUARTERS										
	REGIONAL STAFF										200
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
C E	WEAC										
	REGIONAL STAFF										200
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
S E	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										200
	ATLANTA										
	FLORIDA										
S W	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										200
	DALLAS										
P A	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										200
P A	LOS ANGELES										100
	SAN FRANCISCO										80
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION											
TOTAL HOURS										1000	180
CONVERSION FACTOR										1200	950
TOTAL OPERATIONAL FTEs										0.83	0.19
7. PERSONNEL TYPES REQUIRED									8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR	X	RRHR	INSP EC T I O N A L	10/01/00	09/30/01	
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANAL Y T I C A L			
	PHYSICIST				MILK/FOOD SPEC						
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS											
* 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.											

1. PROGRAM/ASSIGNMENT TITLE
Federal Facilities Survey Program

2. PPS PROJECT NAME/NUMBER
Radiation Control and Health Safety Act (RCHSA)
Authority - 86

3. PROGRAM TYPE:

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

ASSIGNMENT

4. OBJECTIVES

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).

5. PROGRAM JUSTIFICATION

A Presidential Executive Order, dated January 26, 1978, assigned to FDA the responsibility of assisting other federal agencies to be in conformance with safe radiologic procedures and to ensure that their equipment meets the standards necessary to minimize exposure to radiation.

6. FIELD OBLIGATIONS

Districts will conduct field tests of equipment located in specified federal facilities.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE

BY CENTER

BY BOTH

b. INSPECTION TYPE:

N/A

COMPREHENSIVE

ABBREVIATED

DIRECTED

c. PRODUCT(S)

X-Ray Equipment

d. INDUSTRY/PRODUCT CODE(S)

73-91, 94

e. EXAM TYPE:

CHEMICAL

MICROBIOLOGICAL

PHYSICAL

ENGINEERING

MICROANALYTICAL

OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Federal Facilities Survey Program	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 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)	2 I N V E S T I G A T I O N S (Hours)	4 I M P O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours)
	TOTAL FIELD		1086							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		41							
	NEW YORK		41							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO		54							
	CINCINNATI		41							
	DETROIT									
	MINNEAPOLIS		14							
	NEW JERSEY		27							
	PHILADELPHIA		95							
SE	REGIONAL STAFF									
	ATLANTA		122							
	FLORIDA		244							
	NEW ORLEANS		122							
	SAN JUAN		14							
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS		136							
	DENVER		54							
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		27							
	SAN FRANCISCO		27							
	SEATTLE		27							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS		1086							
	CONVERSION FACTOR		950							
	TOTAL OPERATIONAL FTEs		1.14							

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	INSPEC-TIONAL	
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	10/01/00	
	PHYSICIST				MILK/FOOD SPEC			09/30/01	
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		
								ANALY-TICAL	

9. REMARKS
 Spreads are based on the number of X-Ray tests of Federal facilities required by interagency agreements. Testing at clinics requires an average of 20 hours; testing of hospitals requires an average of 30 hours. Hours for radiological surveys of Federal facilities includes time for field testing consultation and followup. Assistance by district X-Ray auditors.

**PUBLIC AFFAIRS PROGRAMS
RESOURCE SUMMARY
FY 2001**

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