

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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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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**OBJECTIVES**

determine through audit procedures whether: (a) bioequivalence data, (b) non-clinical laboratory study data, and (c) clinical data are substantiated by on-site documentation, are valid, scientifically accurate and the studies were conducted according to appropriate regulations.

GLP inspections in foreign laboratories may also provide an assessment of the effectiveness of an existing Memorandum of Understanding with that named nation.

**5. PROGRAM JUSTIFICATION**

An increasing number of bioequivalence studies are conducted by contract laboratories, private and university affiliated, located in Canada and Europe. In addition, large numbers of animal studies (GLP) and clinical studies are conducted in Europe and other foreign countries. Serious problems associated with lack of adherence to protocols, lack of and inadequate record keeping, inadequate and inaccurate analytical procedures, and fraud have been documented in such studies. These studies are required for drug approval in the United States.

**FIELD OBLIGATIONS**

Conduct the inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.

7a. ESTABLISHMENTS TO BE SELECTED:	<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 type="checkbox"/> DIRECTED
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c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60/61
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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

SPECIAL EQUIPMENT, METHODS, AND HANDLING

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)	<b>2. PPS PROJECT NAME/NUMBER</b> Bioresearch Monitoring: Human Drugs - 48
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 48001,A NDA &, ANDA *	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 6.9
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R E G I O N	0. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	4	5	6	7	8	9
		NDA INSP CTIONS PDUFA	ANDA INSP CTIONS	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>90</b>	<b>10</b>							
NE	HEADQUARTERS	3								
	REGIONAL STAFF									
	NEW ENGLAND	6								
	NEW YORK	4								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	6								
	CHICAGO	3	2							
	CINCINNATI	5								
	DETROIT	5								
	MINNEAPOLIS	2								
	NEW JERSEY	3	1							
	PHILADELPHIA	4	2							
FORENSIC CHEM. CTR										
SW	REGIONAL STAFF									
	ATLANTA	8								
	FLORIDA	10	2							
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	5								
	DENVER	2								
	KANSAS CITY	4	1							
SOUTHWEST IMPORT DISTRICT										
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	4								
	SAN FRANCISCO	6								
	SEATTLE	10	2							
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		60.0	91.0							
TOTAL HOURS		5400	910							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		5.93	1.00							

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

**9. REMARKS**  
 \* Planned inspections include: In Vivo Bioequivalence, Clinical Investigators, GLPs (PDUFA).  
 H PRIORITY inspections when the data have been submitted in a NDA.  
 .port hours used under appropriate PAC. Report foreign inspections under the operation code 11.  
 An estimate of percentage of time: PDUFA (NDA) 85% and Non-PDUFA, Pre-Approval (ANDA) 15%.

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Nonclinical Laboratory)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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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

assure compliance with current Good Laboratory Practice Regulations (21 CFR 58) by nonclinical laboratories and to assure validity of data through associated data audits.

5. PROGRAM JUSTIFICATION

Animal Studies are vital prerequisites to human clinical trials of drugs and other FDA regulated products. Past experience has shown serious deficiencies in the conduct of nonclinical laboratories in recordkeeping, adherence to study protocol, and in some cases fraudulent practices.

6. FIELD OBLIGATIONS

Conduct the inspections and forward EIRs directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.

7a. ESTABLISHMENTS TO BE SELECTED:  BY DISTRICT OFFICE  BY CENTER  BY BOTH

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60/61
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e. EXAM TYPE:  CHEMICAL  MICROBIOLOGICAL  PHYSICAL  ENGINEERING  
 MICROANALYTICAL  OTHERS (Specify)

f. CHECK THE FOLLOWING ATTRIBUTES

Presence and concentration of test article feed mixture used in the study audited. CDER will specify in the assignment when samples are to be collected and analyzed.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

methodology prescribed in protocol or actually used in nonclinical laboratory.

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48808			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.5					
REGION	6. DISTRICT/ SPECIALIZED LABORATORY		1	2	3	4	5	6	7	8	9
			INSP- CTIONS	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			81								
NE	HEADQUARTERS		7								
	REGIONAL STAFF										
	NEW ENGLAND		4								
	NEW YORK		5								
	REGIONAL LAB WEAC										
CE	REGIONAL STAFF										
	BALTIMORE		7								
	CHICAGO		3								
	CINCINNATI		4								
	DETROIT		5								
	MINNEAPOLIS		2								
	NEW JERSEY		12								
	PHILADELPHIA FORENSIC CHEM. CTR		6								
SE	REGIONAL STAFF										
	ATLANTA		4								
	FLORIDA										
	NEW ORLEANS		1								
	SAN JUAN REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS		4								
	DENVER		4								
	KANSAS CITY		3								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES		2								
	SAN FRANCISCO		6								
	SEATTLE		2								
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION			84.3								
TOTAL HOURS			6828								
CONVERSION FACTOR			910								
TOTAL OPERATIONAL FTEs			7.50								
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END	
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/01	09/30/02		
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN					
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY- TICAL				
PHYSICIST				MILK/FOOD SPEC							
ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER					
9. REMARKS Resources planned for inspections may also be used for DSCs. Assignments issued by the Center will contain designations for coverage under PDUFA when assignments identify data sites of studies submitted in NDAs.											

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure the quality and integrity of institutional review boards (21 CFR 56, 21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.	
5. PROGRAM JUSTIFICATION Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.	
FIELD OBLIGATIONS Conduct inspections of IRBs which may be evaluation of human drugs studies and forward the reports to the Division of Scientific Investigations, CDER.  Assist in presentation of IRB workshops.	
7a. ESTABLISHMENTS TO BE SELECTED <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	

1. PROGRAM/ASSIGNMENT TITLE <b>Institutional Review Board (PDUFA)</b> <b>Radioactive Drug Research Committee (PDUFA)</b>	2. PPS PROJECT NAME/NUMBER <b>Bioresearch Monitoring: Human Drugs - 48</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>48809</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>13.1</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1																	
		I R B INSPECTIONS	RDRC INSPECTIONS																	
	<b>TOTAL FIELD</b>	<b>234</b>																		
	HEADQUARTERS																			
NE	REGIONAL STAFF																			
	NEW ENGLAND	11																		
	NEW YORK	16																		
	REGIONAL LAB																			
	WEAC																			
CE	REGIONAL STAFF																			
	BALTIMORE	12																		
	CHICAGO	12																		
	CINCINNATI	14																		
	DETROIT	11																		
	MINNEAPOLIS	14																		
	NEW JERSEY	11																		
	PHILADELPHIA	12																		
	FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																			
	ATLANTA	14																		
	FLORIDA	18																		
	NEW ORLEANS	14																		
	SAN JUAN	2																		
SW	REGIONAL LAB																			
	REGIONAL STAFF																			
	DALLAS	18																		
	DENVER	6																		
	KANSAS CITY	13																		
PA	SOUTHWEST IMPORT DISTRICT																			
	REGIONAL LAB																			
	REGIONAL STAFF																			
	LOS ANGELES	17																		
	SAN FRANCISCO	12																		
SEATTLE	7																			
	PACIFIC REGIONAL LAB (SW)																			
	PACIFIC REGIONAL LAB (NW)																			
	HOURS PER OPERATION	51.0																		
	TOTAL HOURS	11934																		
	CONVERSION FACTOR	910																		
	TOTAL OPERATIONA FTES	13.11																		

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

9. REMARKS  
 Resources in the Radioactive Drug Research Committee (RDRC, PAC 4809A) have been collapsed into the Institutional Review Board (IRB, PAC 48809) program.

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
OBJECTIVES 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.	
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations and Monitors (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48					
3. PROGRAM/ASSIGNMENT CODE(S) 48810			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.8				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L	4 I M P O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>		<b>44</b>							
N E	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2								
	NEW YORK	5								
	REGIONAL LAB WEAC									
C E	REGIONAL STAFF									
	BALTIMORE	3								
	CHICAGO									
	CINCINNATI	2								
	DETROIT	2								
	MINNEAPOLIS	1								
	NEW JERSEY	7								
	PHILADELPHIA FORENSIC CHEM. CTR	5								
S W	REGIONAL STAFF									
	ATLANTA	2								
	FLORIDA	3								
	NEW ORLEANS SAN JUAN									
	REGIONAL LAB									
P A	REGIONAL STAFF									
	DALLAS	3								
	DENVER	1								
	KANSAS CITY	2								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
P A	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 EC T I O N A L	10/01/01	09/30/02	
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT				
PHYSICIST				MILK/FOOD SPEC			ANAL Y T I C A L			
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	
OBJECTIVES 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.	
ELD OBLIGATIONS Conduct the inspections and forward EIRs directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. ESTABLISHMENTS TO BE SELECTED	<input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:	<input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60/61
e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators (PDUFA)					2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 26.8				
R E G I O N	6. 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		348								
NE	HEADQUARTERS		4								
	REGIONAL STAFF										
	NEW ENGLAND		22								
	NEW YORK		13								
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE		22								
	CHICAGO		18								
	CINCINNATI		19								
	DETROIT		16								
	MINNEAPOLIS		9								
	NEW JERSEY		7								
SE	PHILADELPHIA		20								
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA		20								
	FLORIDA		19								
	NEW ORLEANS		19								
SW	SAN JUAN		3								
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS		45								
	DENVER		13								
PA	KANSAS CITY		18								
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES		29								
PA	SAN FRANCISCO		19								
	SEATTLE		13								
	PACIFIC REGIONAL LAB (SW)										
	PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		70.0									
TOTAL HOURS		24360									
CONVERSION FACTOR		910									
TOTAL OPERATIONAL FTEs		26.77									
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	10/01/01	09/30/02		
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN					
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY TICAL				
PHYSICIST				MILK/FOOD SPEC							
ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER					
9. REMARKS											



1. PROGRAM/ASSIGNMENT TITLE <b>New Drug (Prescription) Not Covered by Approved NDAs</b>	2. PPS PROJECT NAME/NUMBER <b>Generic Drug Evaluation - 52</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  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.	
FIELD OBLIGATIONS  -Assign District Coordinator, whose name shall be supplied to HFD-310. -Identify all drug products which require regulatory letters and prepare such letters to be signed by the District Director. -Maintain records of all activities under this program, including a list of drug products voluntarily removed from the market in compliance with the warning letters, products removed by recall, etc. -Initiate regulatory actions, where appropriate, to assure compliance with program. Submit monthly report to HFD-310.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH
b. INSPECTION TYPE:	<input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S)  <b>Human Prescription Drugs</b>	d. INDUSTRY/PRODUCT CODE(S)  <b>Industry Codes: 54, 56, and 60-66</b>
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	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> New Drugs (Prescription) Not Covered by Approved NDAs	<b>2. PPS PROJECT NAME/NUMBER</b> Generic Drug Evaluation - 52
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 52002	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 3.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL.	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
		<b>TOTAL FIELD</b>	<b>30</b>	<b>1500</b>	<b>40</b>					
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2	86	2						
	NEW YORK	3	172	4						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1	57	2						
	CHICAGO	1	67	2						
	CINCINNATI	1	38	1						
	DETROIT	1	67	2						
	MINNEAPOLIS		24	1						
	NEW JERSEY	4	220	5						
	PHILADELPHIA	2	86	2						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	110	3						
	FLORIDA	1	62	2						
	NEW ORLEANS	1	24	1						
	SAN JUAN	5	229	5						
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	1	33	1						
	DENVER	1	43	1						
	KANSAS CITY	1	67	2						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	1	72	2						
	SAN FRANCISCO	1	38	1						
	SEATTLE	1	5	1						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		50.0		5.0						
TOTAL HOURS		1500	1500	200						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		1.65	1.65	0.22						

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	10/01/01	09/30/02
	MICROBIOLOGIST	BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)	ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY T I C A L	10/15/01	09/30/02
	PHYSICIST			MILK/FOOD SPEC				
	ENTOMOLOGIST	OTHER		SHELLFISH SPEC	OTHER			

REMARKS

3: Documentary Import Sample Collections for this program are no longer planned.  
 4: 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 <b>In Vitro Research</b>	2. PPS PROJECT NAME/NUMBER <b>Generic Drug Evaluation - 52</b>
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.	
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) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>Industry Codes: 54, 56, and 60-66</b>
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 <b>In Vitro Research</b>	2. PPS PROJECT NAME/NUMBER <b>Generic Drug Evaluation - 52</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>52004</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>1.0</b>
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	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 METHODS DEVELOPMT. (Chem) (Hours)
	<b>TOTAL FIELD</b>			30						1062
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			2						
	NEW YORK			3						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			1						
	CHICAGO			1						
	CINCINNATI			1						
	DETROIT			1						
	MINNEAPOLIS			1						
	NEW JERSEY			4						
	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			1						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									531
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	INSPEC- TIONAL	10/01/01	09/30/02
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS

1. PROGRAM/ASSIGNMENT TITLE <b>ANDA - Pre-Approval Inspections/Investigations</b>	2. PPS PROJECT NAME/NUMBER <b>Generic Drug Evaluation - 52</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p style="margin-left: 20px;">verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their applications.  determine compliance of manufacturing establishments with GMPs prior to approval of pending ANDAs.  ANDA bulk products are collected for profile analysis.</p>	
5. PROGRAM JUSTIFICATION <p style="margin-left: 20px;">Compliance of manufacturing establishments must be assessed before ANDA approval.</p>	
6. FIELD OBLIGATIONS <p style="margin-left: 20px;">Conduct pre-approval inspections of establishments as requested by the Center for Drug Evaluation and Research.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:	<input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>All Human Drug Codes</b>
e. EXAM TYPE:	<input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ANDA - Methods Validation (DESI and Post 1962)	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p style="margin-left: 20px;">Validate the methodology of the drug products submitted as Abbreviated New Drug Applications (ANDAs) as described in the submissions.</p> <p style="margin-left: 20px;">To examine the drug samples for those ANDAs for any special testing (potency, purity, etc.) as required.</p>	
5. PROGRAM JUSTIFICATION <p>ANDAs are required per (21 CFR 314.55) for:</p> <p>1) 1938-1962 (DESI) drug products determined by the FDA to be safe, effective, and acceptable, and</p> <p>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.</p> <p>Approval for marketing is contingent upon, among other requirements, adequate analytical methodology and any special testing Requirements.</p>	
FIELD OBLIGATIONS <p>Perform tests of methodology (USP or other specifications) on samples submitted to the District Laboratories identified by ORA (HFC-140).</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
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 <p>Validate methods, potency, purity, and other requirements</p> <p>SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

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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
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PROGRAM/ASSIGNMENT CODE(S) 52832, B, C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 32.9
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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	145	1
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	5		14	5					
	NEW YORK	23		63	21					
	REGIONAL LAB		1000				20	20	30	1
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	9		25	8					
	CHICAGO	8		22	7					
	CINCINNATI	7		19	6					
	DETROIT	8	200	22	7				17	
	MINNEAPOLIS	2		5	2					
	NEW JERSEY	26		71	24					
	PHILADELPHIA	15	700	40	14				42	
FORENSIC CHEM. CTR		200				30	30			
SE	REGIONAL STAFF									
	ATLANTA	10		27	9					
	FLORIDA	6		16	5					
	NEW ORLEANS	6		16	5					
	SAN JUAN	15	150	41	14				13	
REGIONAL LAB		250						18		
SW	REGIONAL STAFF									
	DALLAS	2		5	2					
	DENVER	3	100	8	3				13	
	KANSAS CITY	9	100	25	8					
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	9		25	8					
	SAN FRANCISCO	2		6	2					
	SEATTLE									
PACIFIC REGIONAL LAB- SW								5		
PACIFIC REGIONAL LAB - NW		300						7		
HOURS PER OPERATION		65.0			8.0		50.0	35.0	106.0	106.0
TOTAL HOURS		10725	3000	450	1200		2500	1750	15370	106
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	13.03	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	10/01/01	09/30/02
X	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	X	NAT'L EXPERT	ANALY- TICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS  
 n estimated 75% of ANDAs will require methods validation @ 106 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 <b>ANDA Pre-Approval Inspections/Investigations - Foreign</b>	2. PPS PROJECT NAME/NUMBER <b>Generic Drug Evaluation - 52</b>
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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

verify that ANDA applicant has facilities, equipment, controls, etc., so specified in their applications. To determine apliance 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.

ELD 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
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b. INSPECTION TYPE:	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED
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c. PRODUCT(S) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>All Human Drug Codes</b>
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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





<b>1. PROGRAM/ASSIGNMENT TITLE</b> Enforcement of the Adverse Drug Experience Reporting Regulations	<b>2. PPS PROJECT NAME/NUMBER</b> Postmarketing Surveillance & Epidemiology: Human Drugs - 53
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> Conduct inspections and forward reports directly to the Division of Scientific Investigations/CDER, including recommendations for any indicated regulatory follow-up.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Human Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> Industry Codes: 54, 56, 60-66
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> <b>Enforcement of the Adverse Drug Experience Reporting Regulations</b>	<b>2. PPS PROJECT NAME/NUMBER</b> <b>Postmarketing Surveillance and Epidemiology: Human Drugs - 53</b>
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 53001A, 53001B	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 8.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1. INSPEC- TIONS		3. DOM. 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)
		DOMESTIC	FOREIGN							
	TOTAL FIELD	77	25							
NE	HEADQUARTERS		4							
	REGIONAL STAFF									
	NEW ENGLAND	8	1							
	NEW YORK	6	2							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	2	1							
	CHICAGO	5	1							
	CINCINNATI	3	1							
	DETROIT	3	1							
	MINNEAPOLIS	3								
	NEW JERSEY	18	2							
	PHILADELPHIA FORENSIC CHEM. CTR	7	1							
SE	REGIONAL STAFF									
	ATLANTA	3	1							
	FLORIDA	1	1							
	NEW ORLEANS	1								
	SAN JUAN REGIONAL LAB		2							
SW	REGIONAL STAFF									
	DALLAS	5	2							
	DENVER		1							
	KANSAS CITY	1	1							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	5	2							
	SAN FRANCISCO	5	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			
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR	RRHR	10/01/01	09/30/02
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	VETERINARIAN		
	PHYSICIST				MILK/FOOD SPEC	NAT'L EXPERT		
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER		
						ANALY- TICAL		

9. REMARKS

port 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 <b>Drug Process Inspections</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  <p style="margin-left: 20px;">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.</p> <p>To assess the adequacy of the CGMP regulations, guidelines and agency regulatory policies by gathering industry-wide data on changing practices and technology.</p>	
5. PROGRAM JUSTIFICATION  <p>The Drug Process Inspections program is FDA's primary means for evaluating the conditions under which drug products are manufactured, tested, packaged and held.</p>	
FIELD OBLIGATIONS  <p>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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>Industry Codes: 50, 54-56, 60-66</b>
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

Drug Process Inspections - Domestic

2. PPS PROJECT NAME/NUMBER

Drug Quality Assurance - 56

PROGRAM/ASSIGNMENT CODE(S)

56002, A, B, C, D, F 56832

4. WORK ALLOCATION PLANNED BY

ORA

CENTER

5. OPERATIONAL FTE POSITIONS

108.1(98.1)

REGION	6. DISTRICT/SPECIALIZED LABORATORY	1 INSPECTIONS *	1 CHEMIST INSPECTIONS (Hours)	1 MICRO INSPECTIONS (Hours)	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL **	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	9 CERTIFICATION HOURS ***	9 POST APPROVAL AUDIT HOURS ****
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	67			13	28			97	104
	NEW YORK	113			22	47			160	209
	REGIONAL LAB		1400	600			19	11		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	46			9	19			67	69
	CHICAGO	75			15	31			106	81
	CINCINNATI	48			10	20			70	46
	DETROIT	56	800		11	23	35		81	81
	MINNEAPOLIS	40			8	17			58	29
	NEW JERSEY	168			33	70			236	266
	PHILADELPHIA	76	2500		15	32	30		108	104
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	71			14	30			103	133
	FLORIDA	60			12	25			86	75
	NEW ORLEANS	37			7	15			54	29
SW	SAN JUAN	79	1100		16	33	9		122	278
	REGIONAL LAB		700	800			22	20		
	REGIONAL STAFF									
	DALLAS	62			12	25			90	40
	DENVER	45	700	100	9	19	20	5	65	52
PA	KANSAS CITY	57	600		11	24			83	81
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	105			19	40			140	87
PA	SAN FRANCISCO	34		500	8	15		4	54	46
	SEATTLE	26			6	12			40	10
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW		1000				15			
HOURS PER OPERATION		55.0				4.0	42.0	17.0		
TOTAL HOURS		69575	8800	2000	250	2100	6300	680	1820	1820
CONVERSION FACTOR		910	1180	1180	910	910	1180	1180	910	910
TOTAL OPERATIONAL FTEs		76.46	7.46	1.69	0.27	2.31	5.34	0.58	2.00	2.00

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

9. REMARKS  
 Inspections of RX & non-RX drug manufs., repackers/reblablers & control labs. The module is an average of all 4 estab.types.  
 firms are planned under a separate worksheet. \*\* Samples not analyzed are documentary samples.  
 \*\*\*Certification Audit hours report under 56002. \*\*\*\*Report post approval audit investigational hours under 46843.  
 Pending outcome of Pilot, stratification process may be modified mid-year to reflect an abbreviated/comprehensive approach.

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1. PROGRAM/ASSIGNMENT TITLE <b>DRUG Process Inspections- Domestic (Gas Manufacturer)</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <p style="text-align: center;">56002E</p>	4. WORK ALLOCATION PLANNED BY <p style="text-align: center;"><input checked="" type="checkbox"/> ORA    <input type="checkbox"/> CENTER</p>	5. OPERATIONAL FTE POSITIONS <p style="text-align: center;">(10.0)</p>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS MEDICAL GAS *	KNOWN INVENTORY FIRMS WITH MULTIPLE GAS PRODUCTS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLE ANALYSES	8 IMPORT SAMPLES ANALYSES	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		337	(194)						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	24	(16)							
	NEW YORK	20	(14)							
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE	14	(8)							
	CHICAGO	14	(9)							
	CINCINNATI	24	(16)							
	DETROIT	19	(10)							
	MINNEAPOLIS	14	(8)							
	NEW JERSEY	7	(5)							
	PHILADELPHIA	24	(15)							
FORENSIC CHEM. CTR										
SW	REGIONAL STAFF									
	ATLANTA	22	(13)							
	FLORIDA	21	(12)							
	NEW ORLEANS	25	(15)							
	SAN JUAN	2	(2)							
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	31	(16)							
	DENVER	12	(3)							
	KANSAS CITY	19	(11)							
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	18	(11)							
	SAN FRANCISCO	12	(4)							
	SEATTLE	15	(6)							
	PACIFIC REGIONAL-SW									
PACIFIC REGIONAL-NW										
HOURS PER OPERATION		27.0								
TOTAL HOURS		9099								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		10.00								

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

9. REMARKS  
**\* Total number of planned gas inspections in the Program for 2002.**  
**Resources are targeted for 100% of the inventory of known medical gas firms with multiple products.**  
**Remaining resources are spread based on the inventory of single product gas manufacturers.**  
**It is expected that some coverage of the medical gas inventory will be accomplished through outsourcing.**

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections/Equivalence Evaluations	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  <p style="margin-left: 20px;">-MRA inspectional work is to minimize the consumer's risk of exposure to defective drug products by preventing the marketing or removing from the market, violative drug products that are observed as a result of inspections performed under this Program.</p> <p>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.</p>	
5. PROGRAM JUSTIFICATION  <p>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.</p> <p>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.</p>	
.ELD OBLIGATIONS  <p>For Non-MRA work, the field will conduct drug process inspections and maintain profiles of foreign drug manufacturers. For the MRA, ORA will participate in the assessment of the EU and the EU's evaluation of the US system. Operational personnel will be used to review the other parties legal and regulatory system for pharmaceutical good manufacturing practice inspection and report preparation. This will involve a review of all documents relating to laws, regulations, procedures, etc.; on-site system evaluations of the regulatory authorities inspectional and analytical systems; and, verifications of the proper implementation of those requirements through audit inspections. Workplan allocations were modeled after the ranking of obligations for the domestic industry.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
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  <p>SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE <b>Foreign Drug Inspections/          Equivalence Evaluations</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 02, A, B, C, D, E, F 32, 56R841 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 18.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **	1 MRA INSPS. FOR Invest- igators ***	1 MRA INSP. HRS. FOR Chemists/ Microbiols. ** ***	9 MRA Invest- igator OTHER OPERATIONS HRs. ***	9 MRA Chemists/ Microbiols. OTHER OPERATIONS HRs. ***
	<b>TOTAL FIELD</b>	<b>111</b>	<b>4700</b>	<b>6</b>	<b>516</b>	<b>3830</b>	<b>2888</b>
NE	HEADQUARTERS	6				760	
	REGIONAL STAFF						
	NEW ENGLAND	5					
	NEW YORK	9		2		400	
	REGIONAL LAB		325		172		832
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE	4					
	CHICAGO	7				830	
	CINCINNATI	2					
	DETROIT	5					
	MINNEAPOLIS	3					
	NEW JERSEY	10		2		640	
SE	PHILADELPHIA	7	1700		172	640	544
	FORENSIC CHEM. CTR		150				
	REGIONAL STAFF						
	ATLANTA	6					
SW	FLORIDA	4					
	NEW ORLEANS	4					
	SAN JUAN	9	700				
	REGIONAL LAB		450		172		416
	DALLAS	5		2		280	
PA	DENVER	3	425				264
	KANSAS CITY	10	600			280	
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
PA	LOS ANGELES	7					
	SAN FRANCISCO	4					
	SEATTLE	1					
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW		350				832
HOURS PER OPERATION		55		86			
TOTAL HOURS		6105	4700	516	516	3830	2888
CONVERSION FACTOR		910	1180	910	1180	910	1180
TOTAL OPERATIONAL FTEs		6.71	3.98	0.57	0.44	4.21	2.45

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	10/01/01	09/30/02
<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	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

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

1. PROGRAM/ASSIGNMENT TITLE <b>Drug Product Surveillance</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>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.</p>	
5. PROGRAM JUSTIFICATION <p>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.</p>	
6. FIELD OBLIGATIONS <p>To collect samples and perform laboratory examinations. Upon assignment form CDER, conduct inspections to obtain specific information, such as analytical results, production data, formulation information, analytical methodology, stability data and expiration dating.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>Industry Codes: 50, 54-56 and 60-66</b>
e. EXAM TYPE: <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 <p>Potency, content uniformity, disintegration, dissolution, time release patterns, identification, microbial contamination, and other selected analyses are directed in Drug Surveillance Requests at CDER/District assignments.</p>	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - CDER 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 CTIONS	CHEM ON INSPS. (Hours)	DOMESTIC SAMPLES ANALYZED STERILITY *****	DOMESTIC SAMPLES COLLECTED *	Domestic SAMPLES ANALYZED (Chem) Hours **	DOMESTIC SAMPLES ANALYZED (Chem) (WEAC) ***	DOMESTIC SAMPLES ANALYZED (Micro) ( WEAC) ***	DOMESTIC SAMPLES ANALYZED (Chem) (FCC) ****	DOMESTIC SAMPLES ANALYZED (Chem) (NRL) *****
	TOTAL FIELD	10	411	81		443	25	10	5	38
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1								
	NEW YORK	1								
	REGIONAL LAB			31						38
	WEAC		411				25	10		
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY	1								
	PHILADELPHIA	1				66				
	FORENSIC CHEM. CTR								5	
SE	REGIONAL STAFF									
	ATLANTA	1								
	FLORIDA	1								
	NEW ORLEANS									
	SAN JUAN	2				67				
	REGIONAL LAB					67				
SW	REGIONAL STAFF									
	DALLAS									
	DENVER			20		84				
	KANSAS CITY	1								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	1								
	SAN FRANCISCO			30						
	SEATTLE									
	PACIFIC REGIONAL LAB - SW					75				
	PACIFIC REGIONAL LAB - NW					84				
	HOURS PER OPERATION	15.0		25		30.0	38.0	18.0	231.0	50.0
	TOTAL HOURS	150	411	2025		13290	950	180	1155	1900
	CONVERSION FACTOR	910	1180	1180		1180	1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.16	0.35	1.72		11.26	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 TIONAL	10/01/01	09/30/02
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	NAT'L EXPERT	ANALY TICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

9. REMARKS  
 \* DSCs are no longer planned- Chemists order drug products perHFD-333 Drug Surveys directly from drug wholesalers.  
 \*\* DSAs analytical module includes time for collection time by chem analyst.  
 \*\*\* DSAs analytical module may vary per drug product.\*\*\* Radioactive drugs-approx 10 of the 25 DSAs (Chem) tested also by 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**

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

4. WORK ALLOCATION PLANNED BY  
 ORA     CENTER

5. OPERATIONAL FTE POSITIONS  
**44.7 (18.1)**

REGION	6. DISTRICT/SPECIALIZED LABORATORY	2	2	2	9	2	6	4	8	
		IMPORT ENTRY REVIEW HOURS OPER 14	IMPORT FILER EVAL. HOURS OPER 95	REFUSAL Follow-Up HOURS	IMPORT LABEL EXAMS	IMPORT ALERT 66-66 INVEST. HOURS	IMPORT FIELD EXAMS	IMPORT SAMPLE COLLECTIONS *		IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	<b>TOTAL FIELD</b>	<b>14840</b>	<b>756</b>	<b>216</b>	<b>1000</b>	<b>1820</b>	<b>1500</b>	<b>50</b>		<b>50</b>
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	405	27		27	50	41	1		
	NEW YORK	4707	126	96	321	585	482	16		
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	400	27		27	49	40	1		
	CHICAGO	730	45	8	50	91	75	3		
	CINCINNATI	400	18		28	52	43	1		
	DETROIT	750	18		51	93	76	3		
	MINNEAPOLIS	150	18		5	9	8			
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR	470	18		32	59	48	2		
SE	REGIONAL STAFF									
	ATLANTA	500	54	8	35	63	52	2		
	FLORIDA	500	63	8	23	42	35	1		
	NEW ORLEANS	2900	27	8	209	381	314	10		
	SAN JUAN	539	9		30	54	44	1		
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT	929	135	24	63	114	94	3		
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	955	81	24	64	117	97	3		
	SAN FRANCISCO	235	45		17	29	24	2		
PA	SEATTLE	270	45	40	18	32	27	1		
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									50
HOURS PER OPERATION					1.0		0.3	2.0		22.0
TOTAL HOURS		14840	756	216	1000	1820	450	100		1100
CONVERSION FACTOR		1200	910	910	910	910	910	910		1180
TOTAL OPERATIONAL FTEs		12.37	0.83	0.24	1.10	2.00	0.49	0.11		0.93

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	10/01/01	09/30/02
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY-TICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

REMARKS  
 \*AC Reporting: Entry Reviews 56R833 (electronic and manual); Filer Evaluations 99R833;  
 Follow-Up to Refusals 56R824, 63R824;  
 Import Label Reviews, Import Field Exams and Import Alert Hours under PACs 52002, 56008H, 56014/A, 63001;  
 Report ISCs & ISAs of finished Dosage forms under 56008H.

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Drug Product Surveillance - Imported Drugs Center and District Initiated Surveys (Domestic Import)	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 56008J, 56008K *	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> (26.6)
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R E G I O N	6.	2	3	7	7	2			
	DISTRICT/ SPECIALIZED LABORATORY	INV. HOURS FOR IMPORTERS	DOMESTIC IMPORT SAMPLE COLLECTIONS QUALITY	DOMESTIC IMPORT ANALYSES CHEM HRS. QUALITY (CENTER)	DOMESTIC IMPORT ANALYSES CHEM FINGERPRT.	DOMESTIC IMPORT INVEST. HOURS FOR PILOT			
	<b>TOTAL FIELD</b>	<b>3730</b>	<b>90</b>	<b>80</b>	<b>51</b>	<b>5460</b>			
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND		3						
	NEW YORK	1400	21			1200			
	REGIONAL LAB			54	20				
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE		3						
	CHICAGO	500	6			400			
	CINCINNATI		9						
	DETROIT	300				250			
	MINNEAPOLIS								
	NEW JERSEY		9			1400			
	PHILADELPHIA	230	15			500			
FORENSIC CHEM. CTR					24				
SE	REGIONAL STAFF								
	ATLANTA		6						
	FLORIDA	100	3						
	NEW ORLEANS	500	3			700			
	SAN JUAN	500	9			700			
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY		3						
PA	SOUTHWEST IMPORT DISTRICT	200							
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL STAFF								
	LOS ANGELES					310			
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW			26					
	HOURS PER OPERATION		4.0	90.0	231.0				
	TOTAL HOURS	3730	360	7200	11781	5460			
	CONVERSION FACTOR	910	910	1180	1180	910			
	TOTAL OPERATIONAL FTEs	4.10	0.40	6.10	9.98	6.00			

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

9. REMARKS  
 \* Report BULK DISCs and DISAs from domestic manufacturers as follows: Quality 56008J; Fingerprinting 56008K.  
**ALL RESOURCES IN PROGRAM ARE FOR API SURVEY PILOT.**  
 Some sample collections to be analyzed by St. Louis Lab. Some samples will be analyzed for both quality and fingerprinting.

1. PROGRAM/ASSIGNMENT TITLE <b>Methods Validation Assessment</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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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

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) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>Industry Codes: 54, 56, 60-66</b>
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e. EXAM TYPE:  CHEMICAL  MICROBIOLOGICAL  PHYSICAL  ENGINEERING  
 MICROANALYTICAL  OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Methods Validation Assessment	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
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<b>PROGRAM/ASSIGNMENT CODE(S)</b> 56020/56020A	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 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
		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	METHODS VALIDATION (Hours) CHEM
	<b>TOTAL FIELD</b>			50						2120
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND			3						
	NEW YORK			6						
	REGIONAL LAB WEAC									238
CE	REGIONAL STAFF									
	BALTIMORE			2						
	CHICAGO			2						
	CINCINNATI			1						
	DETROIT			2						
	MINNEAPOLIS			1						
	NEW JERSEY			7						
	PHILADELPHIA			3						670
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA			4						
	FLORIDA			2						
	NEW ORLEANS			1						
	SAN JUAN			8						180
	REGIONAL LAB									200
SW	REGIONAL STAFF									
	DALLAS			1						
	DENVER			1						302
	KANSAS CITY			2						200
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			2						
	SAN FRANCISCO			1						
	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		
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSPEC- TIONAL	10/01/01	09/30/02
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

**9. REMARKS**

1. PROGRAM/ASSIGNMENT TITLE <b>Drug Quality Reporting System - DQRS NDA-Field Alert Reporting</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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3. PROGRAM TYPE:       COMPLIANCE PROGRAM       PROGRAM CIRCULAR       ASSIGNMENT

4. OBJECTIVES

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.

**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:       BY DISTRICT OFFICE       BY CENTER       BY BOTH

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) <b>All Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>All Human Drug Codes</b>
---	--

e. EXAM TYPE:       CHEMICAL       MICROBIOLOGICAL       PHYSICAL       ENGINEERING

MICROANALYTICAL       OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE <b>Drug Quality Reporting System (DQRS)/</b> <b>NDA-Field Alert Reporting</b>	2. PPS PROJECT NAME/NUMBER <b>Drug Quality Assurance - 56</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>56021A, 56021B</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>3.9</b>
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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 (Chem)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
		<b>TOTAL FIELD</b>	<b>100</b>	<b>200</b>	<b>40</b>				<b>30</b>	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	6	13	3						
	NEW YORK	8	17	3						
	REGIONAL LAB							5		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	4	7	1						
	CHICAGO	5	10	2						
	CINCINNATI	4	7	1						
	DETROIT	4	9	2				4		
	MINNEAPOLIS	4	8	2						
	NEW JERSEY	8	16	3						
PHILADELPHIA	5	10	2				5			
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	5	11	2						
	FLORIDA	6	11	2						
	NEW ORLEANS	4	7	1						
SW	SAN JUAN	5	9	2				3		
	REGIONAL LAB							2		
	REGIONAL STAFF									
	DALLAS	7	14	3						
	DENVER	4	9	2				6		
	KANSAS CITY	5	10	3						
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	9	17	3						
	SAN FRANCISCO	4	8	2						
	SEATTLE	3	7	1						
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW							5		
HOURS PER OPERATION		24.0		4.0				35.0		
TOTAL HOURS		2400	200	160				1050		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		2.64	0.22	0.18				0.89		

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

REMARKS

e: Not all samples collected will be analyzed. Samples not analyzed are documentary samples.

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  monitor, investigate and take regulatory action, (including working jointly with state regulatory officials), on complaints 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.	
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 ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM TYPE:       COMPLIANCE PROGRAM                       PROGRAM CIRCULAR                       ASSIGNMENT

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

5. PROGRAM JUSTIFICATION  
 Research

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

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING









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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Fraudulent Drugs	<b>2. PPS PROJECT NAME/NUMBER</b> Health Fraud: Human Drugs-63
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b>  63001	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b>  2.5
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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	INVE S T I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>	30	510	120				56		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	18	6						
	NEW YORK	3	46	10						
	REGIONAL LAB WEAC							6		
CE	REGIONAL STAFF									
	BALTIMORE	1	43	5						
	CHICAGO	1	13	1						
	CINCINNATI	1	8	4						
	DETROIT	1	2	5					2	
	MINNEAPOLIS	2	24	6						
	NEW JERSEY	1	8	4						
	PHILADELPHIA	1	11	1					11	
	FORENSIC CHEM. CTR									
SC	REGIONAL STAFF									
	ATLANTA	1	27	1						
	FLORIDA	6	44	26						
	NEW ORLEANS	1	8	4						
	SAN JUAN REGIONAL LAB							14		
SW	REGIONAL STAFF									
	DALLAS	1	26	5						
	DENVER	1	8	3					5	
	KANSAS CITY	1	21	4					2	
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	5	116	23						
	SAN FRANCISCO	1	50	6						
	SEATTLE	1	37	6						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW							16		
HOURS PER OPERATION		24.0		4.0				14.0		
TOTAL HOURS		720	510	480				784		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.79	0.56	0.53				0.66		

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	10/01/01	09/30/02
<input checked="" type="checkbox"/>	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	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 <b>Internet Drug Sales</b>	2. PPS PROJECT NAME/NUMBER <b>Health Fraud: Human Drugs -63</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES  itoring, investigating and taking regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal pharmacy operations off-shore associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases in an effort to Protect the public from fraudulent drug products.	
5. PROGRAM JUSTIFICATION  FDA has received several hundred complaints associated with the Internet, and has located over 200 web sites engaged in either illegal promotion sales and distribution activities. With increased interest in the use of the Internet by consumers, physicians, pharmacists, manufacturers, distribution/wholesalers, FDA must monitor and investigate allegations of wrong doing to determine those activities that violate the law and jeopardize the public health.	
6. FIELD OBLIGATIONS  Districts will conduct inspections and investigations, collect evidence, samples and develop case in accordance with assignments from HFD-310 and HFD-330.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>Industry Codes: 50, 54, and 60-66</b>
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Internet Drug Sales	<b>2. PPS PROJECT NAME/NUMBER</b> Health Fraud: Human Drugs - 63
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 63D012, 63D013, 63D014	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 11.0
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REG ION	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		573							
	NEW YORK		795							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		327							
	CHICAGO		513							
	CINCINNATI		446							
	DETROIT		363							
	MINNEAPOLIS		317							
	NEW JERSEY		794							
	PHILADELPHIA FORENSIC CHEM. CTR		618							
SE	REGIONAL STAFF									
	ATLANTA		642							
	FLORIDA		722							
	NEW ORLEANS		635							
	SAN JUAN REGIONAL LAB		530							
SW	REGIONAL STAFF									
	DALLAS		671							
	DENVER		300							
	KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB		421							
PA	REGIONAL STAFF									
	LOS ANGELES		805							
	SAN FRANCISCO		266							
	SEATTLE		272							
	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	10/01/01	09/30/02
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY- TICAL	10/15/01	09/30/02
	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 <b>Shelf Life Extension Projects</b>	2. PPS PROJECT NAME/NUMBER <b>Interagency Cooperative Activities - 88</b>
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3. PROGRAM TYPE:       COMPLIANCE PROGRAM                       PROGRAM CIRCULAR                       ASSIGNMENT

4 OBJECTIVES

evelop 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) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56, and 60-66
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e. EXAM TYPE:       CHEMICAL                       MICROBIOLOGICAL                       PHYSICAL                       ENGINEERING

MICROANALYTICAL                       OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING

Environmental chambers used to stress drug products.

1. PROGRAM/ASSIGNMENT TITLE <b>Shelf Life Extension Projects</b>	2. PPS PROJECT NAME/NUMBER <b>Interagency Cooperative Activities - 88</b>
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PROGRAM/ASSIGNMENT CODE(S) *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS * SEE REMARKS SECTION
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOME ST I C S A M P L E C O L L	4 IMP O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 IMP O R T F I E L D E X A M S	7 DOME ST I C S A M P L E S T O B E A N A L Y Z E D (Chem)	8 IMP 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								11550	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT							5900		
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA							4470		
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN							1180		
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS									
	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										
CONVERSION FACTOR										
TOTAL OPERATIONAL FTEs										

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

REMARKS  
**\* THIS SHEET IS FOR GUIDANCE ONLY.**  
 This program will be conducted "outside" the workplan using dollars reimbursed by DOD.  
 See Data Codes Manual for appropriate project reporting PACs.

**CENTER FOR VETERINARY MEDICINE  
RESOURCE SUMMARY  
FY 2002**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	103.8	19.8	2.4	126.0	202.3	39.6	4.3	246
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	12.4		2.0	14.4	25.3		3.6	28.9
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	91.4	19.8	0.4	111.6	177.0	39.6	0.7	217.3



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:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES

assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities  
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.

FIELD OBLIGATIONS

The Field will conduct NADA Pre-Approval Inspections at domestic and foreign plants in accordance with the assignment.  
Establishment inspection reports will be submitted to the New Animal Drug Evaluation (NADE) Program Manager (HFV-142)  
according to the procedures outlined for field reporting requirements in the compliance program.

Field laboratories on an assignment basis will validate methodology submitted with NADAs.

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

b. INSPECTION TYPE:  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)  
Animal Drugs, Type A Medicated Feed Articles

d. INDUSTRY/PRODUCT CODE(S)  
56, 67, 68

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

f. CHECK THE FOLLOWING ATTRIBUTES

Petition validation work.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

N/A

1. PROGRAM/ASSIGNMENT TITLE <b>NADA Pre-Approval Inspections</b>	2. PPS PROJECT NAME/NUMBER <b>Pre-Approval Evaluation of Animal Drugs and Food Additives - 68</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>68001</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>8.3</b>
---	--	--

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	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)								
	<b>TOTAL FIELD</b>	<b>67</b>	<b>50</b>	<b>599</b>	<b>40</b>						<b>40</b>	<b>1148</b>						
NE	HEADQUARTERS			1														
	REGIONAL STAFF																	
	NEW ENGLAND	3	2		2													
	NEW YORK	4	3		3													
	REGIONAL LAB WEAC			67								5	129					
CE	REGIONAL STAFF																	
	BALTIMORE	4	2		2													
	CHICAGO	3	2		2													
	CINCINNATI	2	1															
	DETROIT	3	1		3													
	MINNEAPOLIS	5	2		3													
	NEW JERSEY	5	3		3													
	PHILADELPHIA	3	2		2													
	FORENSIC CHEM. CTR																	
SE	REGIONAL STAFF																	
	ATLANTA	4	4		2													
	FLORIDA	2	2															
	NEW ORLEANS	2	1															
	SAN JUAN	3	5		3													
	REGIONAL LAB			101								5	194					
	REGIONAL STAFF																	
	DALLAS	5	3		5													
	DENVER	3	3										133					
	KANSAS CITY	9	10	328	4							21	495					
	SOUTHWEST IMPORT DISTRICT																	
	REGIONAL LAB			26								3	50					
	REGIONAL STAFF																	
	LOS ANGELES	4	2		2													
PA	SAN FRANCISCO	3	1		3													
	SEATTLE				1													
	PACIFIC REGIONAL LAB (SW)																	
	PACIFIC REGIONAL LAB (NW)			77								6	147					
	HOURS PER OPERATION	60.3	40.0		3.0							19.4						
TOTAL HOURS	4040	2000	599	123							776	1148						
CONVERSION FACTOR	1000	1000	1180	1000							1180	1180						
TOTAL OPERATIONAL FTEs	4.04	2.00	0.51	0.12							0.66	0.97						

7. PERSONNEL TYPES REQUIRED										8. WORK SCHEDULE		
ANALYTICAL					INVESTIGATIVE					PERSON TYPE	BEGIN	END
X	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC- TIONAL	10/1/01	9/30/02		
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN					
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY- TICAL	10/15/01	9/30/02		
	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
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3. PROGRAM TYPE:       COMPLIANCE PROGRAM       PROGRAM CIRCULAR       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:       BY DISTRICT OFFICE       BY CENTER       BY BOTH

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 68 or 69
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e. EXAM TYPE:    N/A     CHEMICAL     MICROBIOLOGICAL     PHYSICAL     ENGINEERING

MICROANALYTICAL     OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
--	---

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

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 68 or 69
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e. EXAM TYPE:    N/A     CHEMICAL     MICROBIOLOGICAL     PHYSICAL     ENGINEERING

MICROANALYTICAL     OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Clinical Investigators	<b>2. PPS PROJECT NAME/NUMBER</b> Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> o 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%.	
<b>5. PROGRAM JUSTIFICATION</b> As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. The program determines the validity of data submitted to FDA by inspecting clinical investigators' records.  Outcome: Assure data integrity and reduce drug development time.	
<b>6. FIELD OBLIGATIONS</b> Conduct inspections of clinical investigators identified by the Center in accordance with the guidance set forth in the basic compliance program 7348.811.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Animal Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 68 or 69
<b>e. EXAM TYPE:</b> N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	





<b>1. PROGRAM/ASSIGNMENT TITLE</b> Drug Process and New Animal Drug Inspections/Type A Medicated Articles	<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>OBJECTIVES</b> o 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>FIELD OBLIGATIONS</b> The field will conduct CGMP inspections of registered animal drug establishments. Top priority will be given to establishments which manufacture sterile products.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 54, 56, 67, 68
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Sterility, purity, identity, potency, decomposition	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> 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 12.6			
R E G I O N	6.	1	1	2	3	7	7	9		
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INSP EC T I O N S (Foreign)	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	DOMESTIC S A M P L E S T O B E A N A L Y Z E D (Chem)	DOMESTIC S A M P L E S T O B E A N A L Y Z E D (Micro)	O T H E R O P E R A T I O N S (Hours)		
TOTAL FIELD		200	10	435	165	113	37			
NE	HEADQUARTERS	4	1							
	REGIONAL STAFF									
	NEW ENGLAND	7		15	6					
	NEW YORK	7	1	15	7					
	REGIONAL LAB					9	3			
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	7		15	6					
	CHICAGO	15	1	33	12					
	CINCINNATI	10		22	8					
	DETROIT	6		13	5					
	MINNEAPOLIS	20	1	46	17					
	NEW JERSEY	16	2	35	14					
	PHILADELPHIA	10	1	22	9					
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	11		24	9					
	FLORIDA	7		15	6					
	NEW ORLEANS	5		11	4					
SW	SAN JUAN	3		7	2					
	REGIONAL LAB					40	12			
	REGIONAL STAFF									
	DALLAS	15	1	33	12					
	DENVER	5		11	4		17			
	KANSAS CITY	34	2	78	28	50				
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB					3	2			
	REGIONAL STAFF									
	LOS ANGELES	7		15	6					
	SAN FRANCISCO	6		14	6		3			
PA	SEATTLE	5		11	4					
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)					11				
HOURS PER OPERATION		43.4	40.0		4.0	18.4	21.1			
TOTAL HOURS		8680	400	435	660	2079	781			
CONVERSION FACTOR		1000	1000	1000	1000	1180	1180			
TOTAL OPERATIONAL FTEs		8.68	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	<input type="checkbox"/>	RRHR	INSPEC TIONAL	10/1/01	9/30/02
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR	<input type="checkbox"/>	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	<input checked="" type="checkbox"/>	NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC			ANALY TICAL	10/15/01	9/30/02
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			
9. REMARKS Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples. Investigational or official samples should be collected as appropriate. Type A Medicated Articles program (71005/A is now under 71001; continue to report work to PAC 71005/A. For district servicing laboratory see Servicing Laboratory Table.										

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
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3. PROGRAM TYPE:       COMPLIANCE PROGRAM       PROGRAM CIRCULAR       ASSIGNMENT

4. OBJECTIVES

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.

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:       BY DISTRICT OFFICE       BY CENTER       BY BOTH

b. INSPECTION TYPE:       COMPREHENSIVE       ABBREVIATED       DIRECTED

c. PRODUCT(S) Complete animal feeds and feed ingredients.	d. INDUSTRY/PRODUCT CODE(S) 69-72
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e. EXAM TYPE:       CHEMICAL       MICROBIOLOGICAL       PHYSICAL       ENGINEERING

MICROANALYTICAL       OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

\*Mycotoxins, Pesticides, Industrial Chemicals, Metals and Microbiologicals

SPECIAL EQUIPMENT, METHODS, AND HANDLING

A

PAF: prog problem ofed Aug 710056

1. PROGRAM/ASSIGNMENT TITLE  
Feed Contaminants - DOMESTIC

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

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

ORA       CENTER

5. OPERATIONAL FTE POSITIONS  
TOTAL 35.9  
DOMESTIC 16.1  
IMPORT 19.8

REG 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	792	1150	250	350	500	50	250	200	500	50
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	3	5	1	1	3					
	NEW YORK	97	141	32	42	61	7				
	REGIONAL LAB								33	92	
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE	18	26	6	8	11	1				
	CHICAGO	48	70	15	21	30	3				
	CINCINNATI	38	55	12	17	24	2				
	DETROIT	28	41	9	12	18	2				
	MINNEAPOLIS	74	107	23	33	47	5				
	NEW JERSEY	13	19	4	6	8	1				
	PHILADELPHIA	31	45	10	14	20	2				
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA	54	78	17	24	34	3				
	FLORIDA	13	19	4	6	8	1				
	NEW ORLEANS	21	30	6	9	13	1				
	SAN JUAN										
PA	REGIONAL LAB							27	21	90	
	REGIONAL STAFF										
	DALLAS	44	64	14	19	28	3				
	DENVER	36	52	11	16	23	2		91		
	KANSAS CITY	135	196	42	60	85	8	67		213	
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB							9	8	18	50
PA	REGIONAL STAFF										
	LOS ANGELES	67	97	21	30	42	4				
	SAN FRANCISCO	8	12	3	4	5	1		47	5	
	SEATTLE	64	93	20	28	40	4				
	PACIFIC REGIONAL LAB (SW)										42
	PACIFIC REGIONAL LAB (NW)										40
HOURS PER OPERATION		7.6	3.0					7.7	7.7	7.9	7.5
TOTAL HOURS		6019	3450					1925	1540	3950	375
CONVERSION FACTOR		1000	1000					1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		6.02	3.45					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	10/1/01	9/30/02
<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	10/15/01	9/30/02
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

9. REMARKS  
\*BSE inspections of renderers and protein blenders  
Numbers in columns "A", "B", "C", and "D" represent a guideline for district collection.  
NOTE: Domestic sample collections for "Micro" include an assignment to collect rendered feed ingredients to be sent to CVM lab - antimicrobial resistance analysis.

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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**

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

4. WORK ALLOCATION PLANNED BY  
 ORA       CENTER

5. OPERATIONAL FTE POSITIONS  
**19.8**

REG ION	DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW (Hours)	IMPORT FILER EVALUATION (Hours)	4			8	
				IMPORT SAMPLE COLL	IMPORT SAMPLE COLL** Chem "A"	IMPORT SAMPLE COLL** Myco "B"	IMPORT SAMPLE ANALYZED Chem	IMPORT SAMPLE ANALYZED Myco
	TOTAL FIELD	8628	3288	650	430	250	430	315
NE	HEADQUARTERS							
	REGIONAL STAFF							
	NEW ENGLAND	359	117	25	17	10		
	NEW YORK	2538	587	199	132	77		
	REGIONAL LAB						150	
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE	242	145	14	9	5		
	CHICAGO	168	167	12	8	5		
	CINCINNATI	571	76	21	14	8		
	DETROIT	675	76	50	33	18		
	MINNEAPOLIS	259	84	31	21	12		
	NEW JERSEY							
	PHILADELPHIA	80	68					
SW	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA	232	228	8	5	3		
	FLORIDA		268	4	3	2		
	NEW ORLEANS	81	104	5	3	2		
	SAN JUAN	79	26	2	1	1		
PA	REGIONAL LAB						35	
	REGIONAL STAFF							
	DALLAS			1	1			
	DENVER							
	KANSAS CITY							73
PA	SOUTHWEST IMPORT DISTRICT	288	625	66	44	25		
	REGIONAL LAB						33	32
	REGIONAL STAFF							
	LOS ANGELES	1255	354	49	32	19		
	SAN FRANCISCO	82	188					
PA	SEATTLE	1719	175	163	107	63		
	PACIFIC REGIONAL LAB (SW)						32	
	PACIFIC REGIONAL LAB (NW)						107	283
HOURS PER OPERATION				6.7			8.0	8.0
TOTAL HOURS		8628	3288	4355			3440	2520
CONVERSION FACTOR		1200	1000	1000			1180	1180
TOTAL OPERATIONAL FTEs		7.19	3.29	4.35			2.92	2.14

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	10/1/01	9/30/02
<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	10/15/01	9/30/02
	PHYSICIST				MILK/FOOD SPEC				
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC	OTHER			

9. REMARKS  
 Numbers in columns "A" and "B" represent a guideline for district collection.

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	
OBJECTIVES <p>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.</p> <p>Reduce by 5% the number of non-compliant (OAI-classified inspections) firms making animal feeds.</p>	
5. PROGRAM JUSTIFICATION <p>Under Sec. 510(h) of the Act, the Agency is obligated to inspect registered medicated feed establishments.</p> <p>Outcome: Ensure the marketing of safe and effective animal feeds.</p>	
FIELD OBLIGATIONS <p>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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
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	



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Illegal Drug Residues in Meat and Poultry	<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Meat and Poultry, Animal Feeds and Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 17, 67, 68, and 69
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Tissue Sample analysis by Denver laboratory when required, including confirmation on USDA CAST samples.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE <b>Illegal Residues in Meat &amp; Poultry</b>	2. PPS PROJECT NAME/NUMBER <b>Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</b>
--	--

3. PROGRAM/ASSIGNMENT CODE(S) <b>71006 71006F (BSE)</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>11.6</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1		1			7		7	
		INSPECTIONS	INSPECTIONS				DOMESTIC SAMPLES ANALYZED Chem (Hours)	DOMESTIC SAMPLES ANALYZED Micro (Hours)		
	<b>TOTAL FIELD</b>	<b>312</b>					<b>1801</b>	<b>520</b>		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	13								
	NEW YORK	34								
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	11								
	CHICAGO	7								
	CINCINNATI	13								
	DETROIT	14								
	MINNEAPOLIS	24								
	NEW JERSEY	2								
	PHILADELPHIA	41								
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	4								
	FLORIDA	2								
	NEW ORLEANS	5								
SW	SAN JUAN	13								
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	14								
	DENVER	13					1801	520		
PA	KANSAS CITY	9								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	20								
PA	SAN FRANCISCO	52								
	SEATTLE	21								
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		28.0					1.0	3.0		
TOTAL HOURS		8736					1801	1560		
CONVERSION FACTOR		1000					1180	1180		
TOTAL OPERATIONAL FTEs		8.74					1.53	1.32		

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	<input checked="" type="checkbox"/>	INSPEC- TIONAL	10/1/01	9/30/02	
<input checked="" type="checkbox"/>	MICROBIOLOGIST	<input checked="" type="checkbox"/>	BIO. SCIENCE TECH	<input checked="" type="checkbox"/>	INSPECTOR	<input checked="" type="checkbox"/>				VETERINARIAN
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)	<input checked="" type="checkbox"/>	ANALY- TICAL	10/15/01	9/30/02	
	PHYSICIST		OTHER		MILK/FOOD SPEC					NAT'L EXPERT
	ENTOMOLOGIST				SHELLFISH SPEC					OTHER

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> National Drug Residue Milk Monitoring Program	<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Grade "A" Milk/Non Grade "A" Milk	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 9
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Samples will be analyzed for eight sulfonamides, three tetracyclines, beta-lactams, novobiocin and chloramphenicol.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

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 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 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	
	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP EC T I O N A L	10/1/01	9/30/02	
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN				
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY TICAL	10/15/01	9/30/02	
	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.											







<b>1. PROGRAM/ASSIGNMENT TITLE</b> Forensic Evaluation and Sample Analysis				<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds and Devices - 71					
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 71R838			<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			<b>5. OPERATIONAL FTE POSITIONS</b> 0.7			
<b>R E G I O N</b>	<b>6. DISTRICT/SPECIALIZED LABORATORY</b>		<b>FORENSIC ANALYSIS CHEM (Hours)</b>						
	<b>TOTAL FIELD</b>		875						
<b>NE</b>	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
<b>CE</b>	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR		875						
<b>SE</b>	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
<b>PA</b>	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION									
TOTAL HOURS		875							
CONVERSION FACTOR		1180							
TOTAL OPERATIONAL FTEs		0.74							
<b>7. PERSONNEL TYPES REQUIRED</b>							<b>8. WORK SCHEDULE</b>		
<b>ANALYTICAL</b>				<b>INVESTIGATIVE</b>			<b>PERSON TYPE</b>	<b>BEGIN</b>	<b>END</b>
<input checked="" type="checkbox"/>	CHEMIST		PYS. SCIENCE TECH	<input type="checkbox"/>	INVESTIGATOR	<input type="checkbox"/>	INSPEC-TIONAL		
	MICROBIOLOGIST		BIO. SCIENCE TECH	<input type="checkbox"/>	INSPECTOR	<input type="checkbox"/>			
	ENGINEER(ANALYST)		ENGINEER TECH	<input type="checkbox"/>	ENGINEER (INV)	<input type="checkbox"/>			
	PHYSICIST			<input type="checkbox"/>	MILK/FOOD SPEC	<input type="checkbox"/>	ANALY-TICAL	10/15/01	09/30/02
	ENTOMOLOGIST	<input checked="" type="checkbox"/>	RESEARCH CHEMIST	<input type="checkbox"/>	SHELLFISH SPEC	<input type="checkbox"/>			
<b>9. REMARKS</b>									

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
RESOURCE SUMMARY  
FY 2002**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>178.7</b>	<b>32.3</b>	<b>19.8</b>	<b>230.8</b>	<b>360.5</b>	<b>72.5</b>	<b>42.0</b>	<b>475.0</b>
81	POSTMARKET ASSURANCE: DEVICES	1.5			1.5	3.4			3.4
82	COMPLIANCE: DEVICES	90.7	28.7	14.2	133.6	180.1	64.4	29.4	273.9
83	PRODUCT EVALUATION: DEVICES	28.2		3.5	31.7	63.3		7.9	71.2
84	SCIENCE: DEVICES	7.6			7.6	12.2			12.2
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	21.3		0.1	21.4	36.7		0.3	37.0
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	29.4	3.6	2.0	35.0	64.8	8.1	4.4	77.3



1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>Identify significant problems by analyzing recurring problems and performing trends analysis.</p> <p>Provide data on complaints, significant problems and potential hazards so that corrective action can be initiated for hazardous products in the marketplace.</p>	
5. PROGRAM JUSTIFICATION <p>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.</p>	
FIELD OBLIGATIONS <p>On assignment, follow up on MDR reports either at the medical facility or manufacturer.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All medical devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES Sterility Performance  SPECIAL EQUIPMENT, METHODS, AND HANDLING Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device Problem Reporting - MDR Follow-Up	<b>2. PPS PROJECT NAME/NUMBER</b> Postmarket Assurance: Devices - 81
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 81010	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 1.5
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E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	7	9
		INSP CTIONS  (1)	INVEST 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)
	<b>TOTAL FIELD</b>	51	61	5			1	1	1	
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	6	7							
	NEW YORK	3	4							
	REGIONAL LAB									
	WEAC						1	1	1	
CE	REGIONAL STAFF									
	BALTIMORE	1	1	1						
	CHICAGO	5	5							
	CINCINNATI	1	1	1						
	DETROIT	2	2							
	MINNEAPOLIS	1	1							
	NEW JERSEY	2	2							
	PHILADELPHIA	2	2							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	2							
	FLORIDA	3	4	1						
	NEW ORLEANS	5	6	1						
	SAN JUAN	1	1							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	1	1							
	DENVER	1	1							
	KANSAS CITY	2	2							
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	6	12	1						
	SAN FRANCISCO	5	5							
	SEATTLE	2	2							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	25.0		5.8			37.0	36.0	20.0	
	TOTAL HOURS	1275	61	29			37	36	20	
	CONVERSION FACTOR	950	950	950			1180	1180	1180	
	TOTAL OPERATIONAL FTEs	1.34	0.06	0.03			0.03	0.03	0.02	

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

9. REMARKS  
 See Continuation Sheet

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

2. PPS PROJECT NAME/NUMBER

Medical Device Problem Reporting - MDR Follow-Up

Postmarket Assurance: Devices - 81

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 <b>Monitoring Devices of Foreign Origin - Import</b>	2. PPS PROJECT NAME/NUMBER <b>Compliance: Devices - 82</b>
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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

**termine 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.**

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: <b>N/A</b>	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) <b>All Medical Devices</b>	d. INDUSTRY/PRODUCT CODE(S) <b>73-91</b>
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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

**SPECIAL EQUIPMENT, METHODS, AND HANDLING**

**refer to C.P. for procedures to handle initial distributors and/or foreign establishments which are not registered.**

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Monitoring Devices of Foreign Origin - Import	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
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<b>3: PROGRAM/ASSIGNMENT CODE(S)</b> 82008, 82R824, 82R833, 99R833	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 14.9
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R E G I O N	D. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	4	4	8	8	9
		INSP CTIONS	ENTRY REVIEW (Hours)	FILER EVAL (Hours)	INVESTI- GATIONS (Hours)	IMPORT FIELD EXAMS *	IMPORT SAMPLE COLL (Physical) **	IMPORT SAMPLES TO BE ANALYZED ENG	IMPORT SAMPLES TO BE ANALYZED MICRO ***	IMPORT LABEL EXAM
	<b>TOTAL FIELD</b>		6240	5978		1100	94	75	19	150
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		168	212		30				
	NEW YORK		781	1012		150	15			25
	REGIONAL LAB									
CE	WEAC							75	19	
	REGIONAL STAFF									
	BALTIMORE		71	243						
	CHICAGO		409	323		78	8			12
	CINCINNATI		118	149		20				
	DETROIT		119	151		30				
	MINNEAPOLIS		119	149		45	8			14
	NEW JERSEY									
SE	PHILADELPHIA		129	121		14				
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		126	452		30				
	FLORIDA		123	486		28				
SW	NEW ORLEANS		839	203		150	19			30
	SAN JUAN		32	44		20				
	REGIONAL LAB									
	REGIONAL STAFF									
PA	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		2392	1128		375	32			51
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES		442	647		53				9
	SAN FRANCISCO		265	341		50	12			9
	SEATTLE		107	317		27				
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
<b>HOURS PER OPERATION</b>						0.5	1.0	34.0	25.5	1.0
<b>TOTAL HOURS</b>			6240	5978		550	94	2550	485	150
<b>CONVERSION FACTOR</b>			1200	950		950	950	1180	1180	950
<b>TOTAL OPERATIONAL FTEs</b>			5.20	6.29		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		
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH	X	INSPECTOR		VETERINARIAN	INSPEC-TIONAL	10/01/01 09/30/02
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC			ANALY-TICAL	10/15/01 09/30/02
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		

9. REMARKS

See 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

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
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>evaluate the manufacturing processes used for general and radiation emitting medical devices and <i>in vitro</i> diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations.</p> <p>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.</p>	
5. PROGRAM JUSTIFICATION <p>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.</p> <p>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.</p>	
6. FIELD OBLIGATIONS <p>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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Class II and III Devices and all Class I Devices which have been finally classified for one year	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
<p>SPECIAL EQUIPMENT, METHODS, AND HANDLING</p> <p><i>Engineering Samples:</i> Subs/Sample will vary depending on cost, size, etc.</p> <p>Contact Center for guidance if the device presents such problems.</p>	

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) 82845A,B,C,G,S,R841, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 94.1 [77.39]
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REG I O N	6.	1	1	1	1	1	1	3	3	3
	DISTRICT/ SPECIALIZED LABORATORY	INSP E C T I O N S S I N G L E U S E R E P R O - C E S S O R S (1)	INSP E C T I O N S L E V E L I I (B A S E L I N E) 82845B I2)	INSP E C T I O N S L E V E L I I I (C O M P L I A N C E F O L L O W U P) 82845C	INSP E C T I O N S F O R E I G N	INSP E C T I O N S M R A	INSP E C T I O N S C O N T R A C T S T E R I L I Z E R S	D O M E S T I C S A M P L E S T O B E C O L L E C T E D	D O M E S T I C S A M P L E S T O B E C O L L E C T E D C O N T R A C T S T E R I L I Z E R S	D O M E S T I C S A M P L E S T O B E C O L L E C T E D B I O B U R D E N B I O I N D I C A T O R
	TOTAL FIELD	200	716	100	190	24	27	177	2	37
NE	HEADQUARTERS		16		27	3				
	REGIONAL STAFF									
	NEW ENGLAND	17	70	7	9		3	22	1	4
	NEW YORK	11	36	6	9	3	1	9		1
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	5	21	2	6		1	5		1
	CHICAGO	10	26	7	9		2	6		2
	CINCINNATI	9	21	7	6		1	4		2
	DETROIT	9	26	7	10		1	7		2
	MINNEAPOLIS	13	54	5	12	3		14		3
	NEW JERSEY	8	32	3	9	3	2	9		1
	PHILADELPHIA FORENSIC CHEM. CTR	9	35	4	6			9		2
SE	REGIONAL STAFF									
	ATLANTA	9	28	6	9		3	8		2
	FLORIDA	15	54	6	11	3	1	14		3
	NEW ORLEANS	7	17	6	6		1	4		
	SAN JUAN REGIONAL LAB	1	11		3		1	3		
PA	REGIONAL STAFF									
	DALLAS	12	42	5	12	3	2	9		2
	DENVER	7	29	3	13	3	2	8		1
	KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB	8	18	6	9		1	4		2
	REGIONAL STAFF									
PA	REGIONAL STAFF									
	LOS ANGELES	26	113	7	12	3	3	28	1	5
	SAN FRANCISCO	14	44	6	6		2	9		2
	SEATTLE	10	23	7	6			5		2
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		56.0	56.0	70.0	60.4	65.5	37.0	5.5	5.5	5.5
TOTAL HOURS		11200	40096	7000	11476	1572	999	974	11	204
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		11.79	42.21	7.37	12.08	1.65	1.05	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	INSPEC- TIONAL	10/01/01	09/30/02
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	10/15/01	09/30/02
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
(1) Single Use Reprocessors: Establishment Type MB. Refer also to Part 1, Section E (OEI Development/Maintenance) of the Workplan for additional information. Activation of the Establishment Type in FACTS is expected early in the 1st Quarter, FY 2002.  
(2) 16 Headquarters Inspections by HQ Investigators to assist in GMP inspections.  
stic Sample Collections for Contract Sterilizers and/or Bioburden, Bioindicator are to be collected "for cause".

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1. PROGRAM/ASSIGNMENT TITLE <b>Inspection of Medical Device Manufacturers</b>	2. PPS PROJECT NAME/NUMBER <b>Compliance: Devices - 82</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>82845A,B,C,G,S,R841, 81845R,T, 81011</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>94.1 [16.73]</b>
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REGION	6. DISTRICT/SPECIALIZED LABORATORY	3	7	7	7	7	7	7	9	9
		DOMESTIC SAMPLES TO BE COLLECTED MICRO STERILITY	DOMESTIC SAMPLES TO BE ANALYZED CHEM (3)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (4)	DOMESTIC SAMPLES TO BE ANALYZED	DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN BIOINDICATOR	DOMESTIC SAMPLES TO BE ANALYZED MICRO STERILITY	DOMESTIC SAMPLES TO BE ANALYZED ENG	OTHER OPERATIONS MRA	OTHER OPERATIONS TRAINING (LAPSE)
	<b>TOTAL FIELD</b>	<b>10</b>	<b>37</b>	<b>110</b>		<b>14</b>	<b>6</b>	<b>25</b>	<b>421</b>	<b>7200</b>
NE	HEADQUARTERS								127	
	REGIONAL STAFF									
	NEW ENGLAND	1								596
	NEW YORK								42	380
	REGIONAL LAB									
	WEAC		37	34		14	6	25		
CE	REGIONAL STAFF									
	BALTIMORE									176
	CHICAGO									358
	CINCINNATI									319
	DETROIT									329
	MINNEAPOLIS	2							42	473
	NEW JERSEY								42	292
	PHILADELPHIA									329
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	1								328
	FLORIDA	1							42	538
	NEW ORLEANS									267
	SAN JUAN									52
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1							42	427
	DENVER	1		76					42	250
	KANSAS CITY									283
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	2							42	966
	SAN FRANCISCO	1								494
	SEATTLE									343
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	5.5	31.2	61.2		25.0	25.0	72.0		
	TOTAL HOURS	55	1154	6732		350	150	1800	421	7200
	CONVERSION FACTOR	950	1180	1180		1180	1180	1180	950	950
	TOTAL OPERATIONAL FTEs	0.06	0.98	5.71		0.30	0.13	1.53	0.44	7.58

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	10/01/01	09/30/02
<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	ANALYTICAL	10/15/01	09/30/02
	PHYSICIST				MILK/FOOD SPEC					
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS  
 (3) Test Kit or Reagent Testing to support GMP observations (CHEM) at WEAC.  
 (4) Antisera and Products Media Testing to support GMP observations (MICRO) at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.

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

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Inspection of Medical Device Manufacturers

2. PPS PROJECT NAME/NUMBER

Compliance: Devices - 82

### 9. Remarks

#### QUALITY SYSTEMS (QSIT)/GMP INSPECTION STRATEGY

Fiscal Year 2002 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 compliance program.

Inspections of high risk device manufacturers and Class III device manufacturers are identified in Column 2 as "Baseline" inspections; followup inspections are identified in Column 3 as "Compliance Followup" inspections.

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).

#### **FOR INFO PURPOSES:**

##### LEVEL 1 "ABBREVIATED" INSPECTIONS

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 INSPECTIONS

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

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 <p style="margin-left: 20px;">1) To determine the extent to which manufacturers of condoms comply with the Device GMP requirements;</p> <p style="margin-left: 20px;">2) To assure that both domestic and imported condoms comply with the FDA standard.</p>	
5. PROGRAM JUSTIFICATION <p>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.</p>	
6. FIELD OBLIGATIONS <p>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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Condom Assignment	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 82Z002	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 4.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	4		4	350			4	350	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK				52					
	REGIONAL LAB									
CE	WEAC							3	253	
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA		1		1					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				193					
	FLORIDA									
	NEW ORLEANS		2		2	8				
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY		1		1					
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES					59				
	SAN FRANCISCO					38				
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW								1	97	
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.0		3.2	2.5			17.0	13.0	
TOTAL HOURS		32		13	875			68	4550	
CONVERSION FACTOR		950		950	950			1180	1180	
TOTAL OPERATIONAL FTEs		0.03		0.01	0.92			0.06	3.86	

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
X	CHEMIST	X	PYS. SCIENCE TECH	X	INVESTIGATOR	RRHR	INSPEC- TIONAL	10/01/01	09/30/02
	MICROBIOLOGIST		BIO. SCIENCE TECH	X	INSPECTOR	VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH	X	ENGINEER (INV)	NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC		ANALY- TICAL	10/15/01	09/30/02
	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 covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin. Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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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

(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.

FIELD OBLIGATIONS

Districts will, upon assignment, conduct GMP inspections of domestic manufacturers. Districts will also sample gloves for testing by the designated laboratories.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input checked="" type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	<input checked="" type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 79-80
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e. EXAM TYPE:	<input checked="" type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input checked="" type="checkbox"/> PHYSICAL	<input checked="" type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )		

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Manufacturers and Importers of Surgical/Examination Gloves	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 82Z003	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 9.2
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REGION	6. DISTRICT/SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8
		INSPCTIONS	INVESTIGATIONS (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)
	<b>TOTAL FIELD</b>	5		5	1000		2	3	153	847
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1		1	12					
	NEW YORK				73					
	REGIONAL LAB									
	WEAC						2	1	153	166
CE	REGIONAL STAFF									
	BALTIMORE				17					
	CHICAGO	1		1	68					
	CINCINNATI				4					
	DETROIT				4					
	MINNEAPOLIS				11					
	NEW JERSEY									
	PHILADELPHIA				21					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				74					
	FLORIDA				14					
	NEW ORLEANS	1		1	21					
	SAN JUAN									
v	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1		1						
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT				222					
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1		1	420					
	SAN FRANCISCO				27					
	SEATTLE				12					
	PACIFIC REGIONAL LABORATORY-SW							2		681
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		15.0		1.5	2.4		20.0	13.0	8.7	7.5
TOTAL HOURS		75		8	2400		40	39	1331	6353
CONVERSION FACTOR		950		950	950		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.08		0.01	2.53		0.03	0.03	1.13	5.38

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

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

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.	
5. PROGRAM JUSTIFICATION A number of potential or emerging problems which cannot be predicted must be handled rapidly. This workplan activity provides resources for Center assignments which can rapidly address potential or emerging problems.	
FIELD OBLIGATIONS Conduct inspections and investigations as directed by Center assignments.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH
b. INSPECTION TYPE:	<input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) All devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE:	<input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )
f. CHECK THE FOLLOWING ATTRIBUTES Sterility/Performance	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z800	4. WORK ALLOCATION PLANNED BY ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.1
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R G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS		2 INVESTI- GATIONS (Hours)		3 DOMESTIC SAMPLE COLL		5 FIELD EXAMS/ TESTS		7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (1)		7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)		7 DOMESTIC SAMPLES TO BE ANALYZED STER (3)		9 OTHER OPERATIONS (Hours) METH DEV ENG (4)	
		TOTAL FIELD		65		550	20		2	2	2	2	2	850			
	HEADQUARTERS																
NE	REGIONAL STAFF																
	NEW ENGLAND		5		46	2											
	NEW YORK		3		30	1											
	REGIONAL LAB																
	WEAC									2	2	2	850				
CE	REGIONAL STAFF																
	BALTIMORE		2		13												
	CHICAGO		3		27	1											
	CINCINNATI		3		24	1											
	DETROIT		3		25	1											
	MINNEAPOLIS		4		36	1											
	NEW JERSEY		3		22	1											
	PHILADELPHIA		3		25	1											
SE	REGIONAL STAFF																
	ATLANTA		3		25	1											
	FLORIDA		5		45	1											
	NEW ORLEANS		2		20	1											
	SAN JUAN		1														
PA	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS		4		33	1											
	DENVER		2		19	1											
	KANSAS CITY		3		22	1											
PA	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES		9		74	3											
	SAN FRANCISCO		4		38	1											
	SEATTLE		3		26	1											
PACIFIC REGIONAL LABORATORY-SW																	
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION			36.0			10.0		35.0		15.0		35.0					
TOTAL HOURS			2340		550	200		70		30		70					850
CONVERSION FACTOR			950		950	950		1180		1180		1180					1180
TOTAL OPERATIONAL FTEs			2.46		0.58	0.21		0.06		0.03		0.06					0.72

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

9. REMARKS  
NOTE: User Reporting Inspections are discontinued for this program; resources transferred to Inspections.  
(1) WEAC--Ad Hoc testing of media.  
(2) WEAC--Ad Hoc testing of test kits or reagents.  
(3) WEAC--Sterility samples.  
(4) WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

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

2. PPS PROJECT NAME/NUMBER  
Compliance: Devices - 82

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

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

SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.1
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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	4600	1200	800	700				
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC	4600	1200	800	700				
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								
PA	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
REGIONAL STAFF									
LOS ANGELES									
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS		4600	1200	800	700				
CONVERSION FACTOR		1205	1205	1205	1180				
TOTAL OPERATIONAL FTEs		3.82	1.00	0.66	0.59				

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

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE: N/A	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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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.

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
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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)	d. INDUSTRY/PRODUCT CODE(S) NA
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e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )		

f. CHECK THE FOLLOWING ATTRIBUTES

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 TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

4. OBJECTIVES  
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:  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 through 91

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

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device Premarket Approval and Postmarket Inspections	<b>2. PPS PROJECT NAME/NUMBER</b> Product Evaluation: Devices - 83
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 83001, A	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1. INSPEC- TIONS				5. FIELD EXAMS/ TESTS		6. IMPORT FIELD EXAMS	7. DOMESTIC SAMPLES TO BE ANALYZED	8. IMPORT SAMPLES TO BE ANALYZED	9. OTHER OPERATIONS (Hours)
		PRE- APPROVAL	POST- APPROVAL	FOREIGN INSP- CTIONS PRE- APPROVAL	FOREIGN INSP- CTIONS POST- APPROVAL						
	<b>TOTAL FIELD</b>	72	59	34	27						
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND	4	3	1	2						
	NEW YORK	2	3	1	2						
	REGIONAL LAB WEAC										
CE	REGIONAL STAFF										
	BALTIMORE	3	2		1						
	CHICAGO	2	2	1	2						
	CINCINNATI	2	2	1	2						
	DETROIT	1	3	1	2						
	MINNEAPOLIS	7	10	3	1						
	NEW JERSEY	3	3	2	2						
	PHILADELPHIA	3	1	3							
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA	3	2	2	2						
	FLORIDA	6	4	3	2						
	NEW ORLEANS	1	1	2	1						
	SAN JUAN	2	4								
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS	4	1	2	2						
	DENVER	4	4	2	2						
	KANSAS CITY	2	2	3	1						
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
PA	LOS ANGELES	15	7	3	1						
	SAN FRANCISCO	5	2	2	1						
	SEATTLE	3	3	2	1						
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	50.0	49.0	50.0	49.0						
	TOTAL HOURS	3600	2891	1700	1323						
	CONVERSION FACTOR	950	950	950	950						
	TOTAL OPERATIONAL FTEs	3.79	3.04	1.79	1.39						

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP- TIONAL	10/01/01	09/30/02
	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;  
 for domestic post-market requirements in PAC 83001A, OP CODE 12.  
 Report all time used for evaluating compliance with foreign pre-market requirements in PAC 83001, OP CODE 11;  
 for foreign post-market requirements in PAC 83001A, OP CODE 11.

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.	
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 truthful 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 (Specify)	
f. CHECK THE FOLLOWING ATTRIBUTES	
- SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE 510(k) Pre-Market Approval Inspections				2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83						
3. PROGRAM/ASSIGNMENT CODE(S) 83003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 2.0			
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)	FOR E I G N I N S P E C T I O N S	IM P O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IM 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	IM 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	18	29	7						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	3	1						
	NEW YORK		1	1						
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1	1							
	CHICAGO	1	1	1						
	CINCINNATI		1	1						
	DETROIT		1							
	MINNEAPOLIS	2	2							
	NEW JERSEY	1	1	1						
	PHILADELPHIA	1	1							
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	1	2	1						
	FLORIDA	1	2							
	NEW ORLEANS		1							
	SAN JUAN	1	1							
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1	2	1						
	DENVER	1	1							
PA	KANSAS CITY	1	1							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3	4							
	SAN FRANCISCO	1	2							
	SEATTLE	1	1							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	34.0	34.0	45.0						
	TOTAL HOURS	612	986	315						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	0.64	1.04	0.33						
7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/01	09/30/02
	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 domestic 510(k) pre-market requirements against PAC 83003, Op Code 12; for evaluating compliance with foreign 510(k) requirements in PAC 83003, Op Code 11.										
(1) Inspections of firms who declare conformity to standards/compliance with design controls.										

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>assure the quality, reliability and integrity of data and information supporting device applications (PMAs, 510(k)s or <i>is</i>) and their claims of safety and effectiveness.</p> <p>To ensure that human subjects taking part in clinical trials involving medical devices are protected from undue hazard or risk.</p> <p>To coordinate, implement and enforce the provisions of the Agency's Application Integrity Policy (AIP) for medical devices.</p> <p>To enforce the prohibition against promotion and/or commercialization of investigational devices.</p>	
5. PROGRAM JUSTIFICATION <p>Congress has mandated that the Agency maintain close surveillance of bioresearch activities done in support of application.</p> <p>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.</p>	
6. FIELD OBLIGATIONS <p>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.</p> <p>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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> <b>Bioresearch Monitoring</b> <b>(Pre-Market)</b>	<b>2. PPS PROJECT NAME/NUMBER</b> <b>Product Evaluation: Devices - 83</b>
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> <b>83808, 83809, 83810, 83811</b>	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> <b>19.7</b>
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	5	6	7	8	9
		INSP E C T I O N S (GLPs)	INSP E C T I O N S (IRBs)	INSP E C T I O N S (SPON/MON)	INSP E C T I O N S (CLINICAL INVEST)	F I E L D E X A M S / T E S T S	I M P O R T F I E L D E X A M S	D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	I M P O R T S A M P L E S T O B E A N A L Y Z E D	O T H E R O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>	8	93	68	127					
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		5	6	7					
	NEW YORK		2	2	4					
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		3	4	6					
	CHICAGO		6	1	3					
	CINCINNATI		6	1	7					
	DETROIT		8	4	4					
	MINNEAPOLIS	1	7	8	6					
	NEW JERSEY		3	4	3					
	PHILADELPHIA FORENSIC CHEM. CTR		3		8					
SE	REGIONAL STAFF									
	ATLANTA	1	5	1	5					
	FLORIDA	1	8	4	10					
	NEW ORLEANS		9	1	14					
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		11	3	12					
	DENVER	1	1	3	4					
	KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB		2	1	5					
PA	REGIONAL STAFF									
	LOS ANGELES	2	7	13	18					
	SAN FRANCISCO	2	4	12	5					
	SEATTLE PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW		3		6					
	HOURS PER OPERATION	76.0	38.4	68.0	78.0					
	TOTAL HOURS	608	3571	4624	9906					
	CONVERSION FACTOR	950	950	950	950					
	TOTAL OPERATIONAL FTEs	0.64	3.76	4.87	10.43					

<b>7. PERSONNEL TYPES REQUIRED</b>							<b>8. WORK SCHEDULE</b>		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSP E C T I O N A L	10/01/01	09/30/02
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
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3. PROGRAM TYPE: N/A	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

value the quality of devices through product analysis and data evaluation.

5. PROGRAM JUSTIFICATION

Product evaluation study projects provide comprehensive postmarket surveillance information about devices.

FIELD OBLIGATIONS

Conduct laboratory analysis using test methods from a variety of sources.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE	<input checked="" type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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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) To be assigned	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 (Specify)		

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation					2. PPS PROJECT NAME/NUMBER Science: Devices - 84						
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.2					
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY		1 INSP EC T I O N S	2 INVE STI G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	9 OTHER OPERATION (Hours) METH DEV CHEM	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	TOTAL FIELD								656	2084	4520
NE	HEADQUARTERS										
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC								656	2084	4520
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
PA	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
SEATTLE											
PACIFIC REGIONAL LABORATORY-SW											
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION											
TOTAL HOURS								656	2084	4520	
CONVERSION FACTOR								1180	1180	1180	
TOTAL OPERATIONAL FTEs								0.56	1.77	3.83	
7. PERSONNEL TYPES REQUIRED								8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE				PERSON TYPE	BEGIN	END	
X	CHEMIST		PYS. SCIENCE TECH		INVESTIGATOR		RRHR	INSP EC T I O N A L			
X	MICROBIOLOGIST	X	BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN				
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT				
	PHYSICIST				MILK/FOOD SPEC			ANALY TICAL	10/15/01	09/30/02	
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER				
9. REMARKS Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by the CDRH Laboratory Staff.											

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM TYPE: N/A	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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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
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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)	d. INDUSTRY/PRODUCT CODE(S)
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e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )		

f. CHECK THE FOLLOWING ATTRIBUTES

SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)				
	TOTAL FIELD				1660				
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC				1660				
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	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					1660				
CONVERSION FACTOR					1180				
TOTAL OPERATIONAL FTEs					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	INSP- TIONAL	
X	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT		
	PHYSICIST				MILK/FOOD SPEC			ANALY- TICAL	10/15/01    09/30/02
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER		

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Inspect certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA). 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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Mammography Facilities Inspection Program	<b>2. PPS PROJECT NAME/NUMBER</b> Mammography Quality Standards Act (MQSA) Authority - 85
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 85014 A,C,F	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 21.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	2	2	9	9
		INSP EC T I O N S	INSP EC T I O N S	INSP EC T I O N S	INSP EC T I O N S	INSP EC T I O N S F O R E I G N	INVEST I G A T I O N S (Hours)	INVEST I G A T I O N S (Hours)	OTHER O P E R A T I O N S (Hours)	OTHER O P E R A T I O N S (Hours)
	TOTAL FIELD	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	48		2	1		165	6	569	388
	NEW YORK		1	1	5		187	3	754	513
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			15	3	1	220	4	832	566
	CHICAGO			2	2		121		461	314
	CINCINNATI	20		4	1		165	3	675	460
	DETROIT			1			187	6	595	405
	MINNEAPOLIS			5			132		564	384
	NEW JERSEY									
	PHILADELPHIA	27		2	1		121	5	515	351
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		1	14	3		143		699	476
	FLORIDA			6	6	1	121		538	367
	NEW ORLEANS			8	3		165	6	674	459
	SAN JUAN	3		1		1	22	3	125	85
REGIONAL LAB										
W	REGIONAL STAFF	150	1	28	5	9	319	10	1684	1147
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	58	1	18	6		429	4	908	618
	SAN FRANCISCO			10	4	1			692	471
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
<b>HOURS PER OPERATION</b>		8.0	5.0	8.0	8.0	8.0				
<b>TOTAL HOURS</b>		2448	20	936	320	104	2497	50	10285	7004
<b>CONVERSION FACTOR</b>		1160	1160	1160	1160	1160	1160	1160	1160	1160
<b>TOTAL OPERATIONAL FTEs</b>		2.11	0.02	0.81	0.28	0.09	2.15	0.04	8.87	6.04

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

**9. REMARKS**      RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS.

1) Inspection of Certified Mammography Facilities not covered by the states. 2) Follow-up Inspections.  
 3) Federal Facility Inspections (does not include VHA Facility inspections).  
 4) VHA Facility Inspections. **NOTE--these inspections are paid through an Interagency Agreement and are not covered by MQSA resources.**  
 Inspection of Domestic Establishment Mammography Facilities in Foreign Countries. 6) Audit Investigations.  
 Investigations of Uncertified Mammography Facilities.  
 7) Compliance Activities.  
 9) Technical Assistance and Coordination Activities.

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1. PROGRAM/ASSIGNMENT TITLE  
Mammography Facilities Inspection Program

2. PPS PROJECT NAME/NUMBER  
Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM/ASSIGNMENT CODE(S)  
85014 A,C,F

4. WORK ALLOCATION PLANNED BY  
 ORA  CENTER

5. OPERATIONAL FTE POSITIONS  
21.4

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP CTIONS	INVEST IGATIONS (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)  (10)
	TOTAL FIELD									1200
NE	HEADQUARTERS									
	REGIONAL STAFF									200
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									400
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM: CTR										
SE	REGIONAL STAFF									200
	ATLANTA									
	FLORIDA									
	NEW ORLEANS SAN JUAN REGIONAL LAB									
/	REGIONAL STAFF									200
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									200
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS										1200
CONVERSION FACTOR										1200 1.00

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE		
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END
	CHEMIST		PYS. SCIENCE TECH	INVESTIGATOR	X	RRHR	INSP CTIONAL	10/01/01	09/30/02
	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  
10) Technical Assistance and Coordination Activities: RRHRs.



1. PROGRAM/ASSIGNMENT TITLE <b>Inspection of Manufacturers of Laser Products</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)          Authority - 86</b>
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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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**OBJECTIVES**

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
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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) Lasers and laser products	d. INDUSTRY/PRODUCT CODE(S) 95LS-99
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e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )		

f. CHECK THE FOLLOWING ATTRIBUTES

**SPECIAL EQUIPMENT, METHODS, AND HANDLING**

Caution: laser product may be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.



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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

ection 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.

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
<b>3. PROGRAM TYPE:</b> N/A <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> conduct a field enforcement program to determine the compliance of sunlamp and sunlamp products with both the performance standard and Agency issued recommendations.	
<b>5. PROGRAM JUSTIFICATION</b> FDA conducts program efforts to minimize radiation emissions from electronic products and devices that have proven to have harmful biological effects. Under the authority of Public Law 90-602 and the Medical Device Amendments to the Food, Drug and Cosmetic Act, FDA has published a performance standard and separate recommendations designed to control the emission of light radiation from sunlamp products. The performance standard for sunlamp products became effective May 7, 1980, and the amended standard on September 7, 1986. Recent studies suggest that exposure to excessive UVA radiation has resulted in malignant melanoma.	
<b>FIELD OBLIGATIONS</b> Districts will identify and schedule inspections of sunlamp product manufacturers for compliance with the FD&C Act. Districts will initiate and conduct field testing of suntanning facilities per the guidance set out in the compliance program. In addition, in that most states and local radiological health bureaus have no regulation on these products, the field should establish communications with them and offer assistance if they choose to develop such regulations. <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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Sunlamp, suntanning booths, and sunlamp products.	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 95 US-11
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> 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.	
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

3. PROGRAM/ASSIGNMENT CODE(S)  
 86002

4. WORK ALLOCATION PLANNED BY  
 ORA  CENTER

5. OPERATIONAL FTE POSITIONS  
 0.8

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S *	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S/ T E S T S **	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OTHER O P E R A T I O N S (Hours) ***
	TOTAL FIELD	10	175	2		101				218
NE	HEADQUARTERS									
	REGIONAL STAFF									31
	NEW ENGLAND	1	8			5				
	NEW YORK		11			7				
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									31
	BALTIMORE	1	9			5				
	CHICAGO		8			4				
	CINCINNATI	2	9	1		5				
	DETROIT	1	10			6				
	MINNEAPOLIS		8			4				
	NEW JERSEY	1	8			3				
PHILADELPHIA		8			5					
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									31
	ATLANTA	1	12	1		7				
	FLORIDA	1	11			6				
	NEW ORLEANS		10			7				
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									31
	DALLAS	1	18			11				
	DENVER					2				
	KANSAS CITY	1	12			5				
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									94
	LOS ANGELES		15			9				
	SAN FRANCISCO		10			6				
	SEATTLE		8			4				
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		16.8		3.3		1.7				
TOTAL HOURS		168	175	7		172				218
CONVERSION FACTOR		950	950	950		950				950
TOTAL OPERATIONAL FTEs		0.18	0.18	0.01		0.18				0.23

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

9. REMARKS  
 See Continuation Sheet

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

1 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

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

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

7. 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 <b>Field Compliance Testing of Diagnostic X-Ray Equipment</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)          Authority - 86</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <p style="text-align: center;">86003</p>	4. WORK ALLOCATION PLANNED BY <p style="text-align: center;"><input checked="" type="checkbox"/> ORA      <input checked="" type="checkbox"/> CENTER</p>	5. OPERATIONAL FTE POSITIONS <p style="text-align: center;">9.8</p>
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R E G I O N	6.	1	2	3	4	5	5B	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	I M P O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	A U D I T S	D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	I M P O R T S A M P L E S T O B E A N A L Y Z E D	O T H E R O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>	19	1076			1144	92			4110
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	44			61	4			178
	NEW YORK	1	60			57	2			239
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1	55			60	6			205
	CHICAGO	1	40			47	9			157
	CINCINNATI	1	61			43	4			235
	DETROIT	1	58			98	4			221
	MINNEAPOLIS	1	53			48	6			213
	NEW JERSEY	1	29			46				114
	PHILADELPHIA	1	42			30	6			174
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1	93			130	4			317
	FLORIDA	1	80			79	2			289
	NEW ORLEANS	1	97			77	8			372
	SAN JUAN	1	2			4	1			28
REGIONAL LAB										
W	REGIONAL STAFF									
	DALLAS	1	129			123	12			436
	DENVER	1	31			25	8			143
	KANSAS CITY	1	58			59	6			223
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	1	65			72	4			241
	SAN FRANCISCO	1	41			37	4			174
	SEATTLE	1	38			48	2			151
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		18.0				3.0	4.0			
TOTAL HOURS		342	1076			3432	368			4110
CONVERSION FACTOR		950	950			950	950			950
TOTAL OPERATIONAL FTEs		0.36	1.13			3.61	0.39			4.33

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	10/01/01	09/30/02
MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT	ANALY T I C A L		
PHYSICIST				MILK/FOOD SPEC					
ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER			

9. REMARKS

See Continuation Sheet

## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

2. PPS PROJECT NAME/NUMBER

Field Compliance Testing of Diagnostic X-Ray  
Equipment

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

3. 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**  
**2002 WORKPLAN FOR FIELD COMPLIANCE TESTING**  
**OF DIAGNOSTIC X-RAY SYSTEMS**  
**(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2002)**

**NEW ENGLAND DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
CT	109	-	15	1	
ME	52	8	-	1	2
MA	229	-	30	2	-
NH	43	-	6	1	-
RI	34	8	-	1	2
VT	19	-	3	1	-
<b>Total</b>	486	16	54	7	

**NEW YORK DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
NY	672	40	54	3	2

**BALTIMORE DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
DC	33	-	5	-	
MD	201	10	20	1	2
VA	310	10	30	2	2
WV	70	10	1	1	2
<b>Total</b>	614	30	56	4	6

## CHICAGO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IL	445	20	45	2	9

## CINCINNATI DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
KY	194	22	10	1	2
OH	486	40	30	2	2
<b>Total</b>	<b>680</b>	<b>62</b>	<b>40</b>	<b>3</b>	<b>4</b>

## DETROIT DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IN	271	-	40	2	4
MI	378	-	54	2	-
<b>Total</b>	<b>649</b>	<b>-</b>	<b>94</b>	<b>4</b>	<b>4</b>

## MINNEAPOLIS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
MN	239	20	16	1	2
ND	36	6	-	1	2
SD	42	-	6	1	-
WI	277	20	22	1	2
<b>Total</b>	<b>594</b>	<b>46</b>	<b>44</b>	<b>4</b>	<b>6</b>

### NEW JERSEY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NJ	321	-	44	2	-

### PHILADELPHIA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DE	28	-	4	1	-
PA	441	45	21	4	6
<b>Total</b>	469	45	25	5	6

### ATLANTA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
GA	340	-	51	2	-
NC	434	15	45	2	2
SC	257	-	30	-	2
<b>Total</b>	1031	15	126	4	4

### FLORIDA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
FL	893	52	75	4	2

### NEW ORLEANS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AL	313	20	24	2	2
LA	244	30	6	2	2
MS	154	10	11	1	2
TN	366	25	29	2	2
<b>Total</b>	<b>1077</b>	<b>85</b>	<b>70</b>	<b>7</b>	<b>8</b>

### SAN JUAN DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
PR	25	-	3	1	1

### DALLAS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AR	158	-	22	1	-
OK	163	-	24	1	-
TX	1113	80	70	5	12
<b>Total</b>	<b>1434</b>	<b>80</b>	<b>116</b>	<b>7</b>	<b>12</b>

### DENVER DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CO	166	10	14	1	4
NM	67	15	-	1	2
UT	86	10	4	1	2
WY	25	-	3	1	-
<b>Total</b>	<b>344</b>	<b>35</b>	<b>21</b>	<b>4</b>	<b>8</b>

## KANSAS CITY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IA	176	15	10	1	2
KS	127	15	4	1	2
NE	91	10	5	1	2
MO	255	-	36	1	-
<b>Total</b>	<b>649</b>	<b>40</b>	<b>55</b>	<b>4</b>	<b>6</b>

## LOS ANGELES DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AZ	240	-	33	1	-
CA	486	36	36	2	4
<b>Total</b>	<b>726</b>	<b>36</b>	<b>69</b>	<b>3</b>	<b>4</b>

## SAN FRANCISCO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CA	327	24	24	2	2
HI	40	14	-	1	2
NV	93	-	9	1	-
<b>Total</b>	<b>460</b>	<b>38</b>	<b>33</b>	<b>4</b>	<b>4</b>

## SEATTLE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AK	25	-	3	1	-
ID	49	-	8	1	-
MT	44	-	6	1	-
OR	113	-	15	1	-
WA	188	16	11	1	2
<b>Total</b>	<b>419</b>	<b>16</b>	<b>43</b>	<b>5</b>	<b>2</b>

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
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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 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.

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
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b. INSPECTION TYPE:	<input type="checkbox"/> COMPREHENSIVE	<input checked="" type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) Cabinet x-ray and baggage x-ray	d. INDUSTRY/PRODUCT CODE(S) 94 IS-11 94 IS-21
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e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS ( <i>Specify</i> )		

f. CHECK THE FOLLOWING ATTRIBUTES

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)  
86004

4. WORK ALLOCATION PLANNED BY  
 ORA  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
		INSP CTIONS *	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	33	42			68				
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3	7			4				
	NEW YORK	2				4				
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	5	7			4				
	CINCINNATI	1				4				
	DETROIT	3	7			4				
	MINNEAPOLIS	1				4				
	NEW JERSEY	1				4				
	PHILADELPHIA	1				4				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2				4				
	FLORIDA	3	8			4				
	NEW ORLEANS	1				4				
	SAN JUAN									
M	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1				4				
	DENVER	1				4				
	KANSAS CITY	1				4				
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3	7			4				
	SAN FRANCISCO	2	6			4				
SEATTLE	2				4					
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	8.2				2.7				
	TOTAL HOURS	271	42			184				
	CONVERSION FACTOR	950	950			950				
	TOTAL OPERATIONAL FTEs	0.28	0.04			0.19				

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

9. REMARKS  
\* 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
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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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\* OBJECTIVES

    issure, 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
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b. INSPECTION TYPE:	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED
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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
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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

SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE <b>Compliance Testing of Electronic Products at WEAC</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)</b> Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E,F	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.2
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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)
	<b>TOTAL FIELD</b>	27	52	27	3	1	12	3	1	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC	27	52	27	3	1	12	3	1	
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									
/	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		80.0	32.0	41.0	260.0	100.0	8.0	80.0	25.0	
TOTAL HOURS		2160	1664	1107	780	100	96	240	25	
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	
TOTAL OPERATIONAL FTEs		1.83	1.41	0.94	0.66	0.08	0.08	0.20	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	INSP-	
X	ENGINEER(ANALYST)	X	ENGINEER TECH	X	ENGINEER (INV)		NAT'L EXPERT	TIONAL	
	PHYSICIST				MILK/FOOD SPEC			ANALY-	10/15/01
	ENTOMOLOGIST		OTHER		SHELLFISH SPEC		OTHER	TICAL	09/30/02

9. REMARKS

See Continuation Sheet

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## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Compliance Testing of Electronic Products at WEAC

2. PPS PROJECT NAME/NUMBER

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

### 9. Remarks

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

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

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>assure that imported electronic products presented for entry into the U.S. are certified to be in compliance with appropriate standards where applicable.</p> <p>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.</p>	
5. PROGRAM JUSTIFICATION <p>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.</p>	
6. FIELD OBLIGATIONS <p>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.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE:      N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All electronic products or devices that emit radiation.	d. INDUSTRY/PRODUCT CODE(S) 94-97
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE <b>Imported Electronic Products</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)          Authority - 86</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	5	6	7	8	9
		INSP EC T I O N S	ENT RY R E V I E W (Hours)	F I L E R E V A L (Hours)	I N V E S T I G A T I O N S (Hours)	F I E L D E X A M S/ T E S T S	I M P O R T F I E L D E X A M S	D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	I M P O R T S A M P L E S T O B E A N A L Y Z E D	O T H E R O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>		447	3067						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		10	109						
	NEW YORK		63	519						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE			125						
	CHICAGO		14	165						
	CINCINNATI		11	77						
	DETROIT		24	77						
	MINNEAPOLIS			77						
	NEW JERSEY									
	PHILADELPHIA			62						
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		8	232						
	FLORIDA		16	249						
	NEW ORLEANS		19	104						
	SAN JUAN			23						
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		153	578						
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES		51	332						
	SAN FRANCISCO		37	175						
	SEATTLE		41	163						
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS			447	3067						
CONVERSION FACTOR			1200	950						
TOTAL OPERATIONAL FTEs			0.37	3.23						

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

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device and Radiological Health Use Control and Policy Implementation	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>OBJECTIVES</b> Provide technical assistance to State and Federal radiological health programs implementing FDA use control programs, including DENT (see the compliance program for a more complete statement of objectives and laboratory support); 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.	
<b>5. PROGRAM JUSTIFICATION</b> Rapidly changing technology requires that the FDA develop use control programs whose effective implementation will require training beyond that possessed by most State radiological health program personnel.	
<b>v. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b>
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>  SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device and Radiological Health Use Control and Policy Implementation	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 86008	<b>4. WORK ALLOCATION PLANNED BY</b> <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 4.6
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REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	9	9
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	MISC (Hours)  DENT *	MISC (Hours)  RRHR **
	<b>TOTAL FIELD</b>								750	4800
NE	HEADQUARTERS									
	REGIONAL STAFF									800
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC								750	
CE	REGIONAL STAFF									1600
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									800
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									800
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									800
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS								750	4800
	CONVERSION FACTOR								1180	1200
	TOTAL OPERATIONAL FTEs								0.64	4.00

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

### 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.

\*\* RRHR time for CDRH programs is planned under this program, the Emergency Response and Planning Activities program, and, beginning in FY 2002, the Mammography Facilities Inspection Program; 1200 hours will be shown in Mammography. A portion of this total block of time per RRHR position includes Federal/State liaison activities and use consultation to conduct this program.

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

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

As mentioned above, 1200 hours for technical assistance, etc. will be planned directly in the Mammography Facilities Inspection Program, beginning with the FY 2002 Workplan.

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Emergency Planning and Response Activities	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>OBJECTIVES</b> act as a focal point for emergency readiness response planning by States.	
<b>5. PROGRAM JUSTIFICATION</b> The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.	
<b>6. FIELD OBLIGATIONS</b> Provide consultation to states and attend regional emergency planning meetings.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 94YN-99
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE <b>Emergency Planning and Response Activities</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)</b> <b>Authority - 86</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 86009	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	9 TECHNICAL ASSISTANCE (Hours) RRHR	9 TECHNICAL ASSISTANCE (Hours) CSO
	TOTAL FIELD								1200	180
	HEADQUARTERS									
NE	REGIONAL STAFF								200	
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF								400	
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	REGIONAL STAFF								200	
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF								200	
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF								200	
	LOS ANGELES									100
SAN FRANCISCO										
SEATTLE									80	
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS								1200	180
	CONVERSION FACTOR								1.00	0.19
	TOTAL OPERATIONAL FTEs								1.00	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	10/01/01	09/30/02
	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; viewing and evaluating emergency plans related to nuclear power plants.

1. PROGRAM/ASSIGNMENT TITLE <b>Federal Facilities Survey Program</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)          Authority - 86</b>
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
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: <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) <b>X-Ray Equipment</b>	d. INDUSTRY/PRODUCT CODE(S) <b>73-91, 94</b>
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	

1. PROGRAM/ASSIGNMENT TITLE <b>Federal Facilities Survey Program</b>	2. PPS PROJECT NAME/NUMBER <b>Radiation Control and Health Safety Act (RCHSA)</b> <b>Authority - 86</b>
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3. PROGRAM/ASSIGNMENT CODE(S) 86010	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	INVEST I G A T I O N S (Hours)	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	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	IMP O R T S A M P L E S T O B E A N A L Y Z E D	O T H E R O P E R A T I O N S (Hours)
	<b>TOTAL FIELD</b>		1344							
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		27							
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		178							
	CHICAGO		14							
	CINCINNATI		69							
	DETROIT		27							
	MINNEAPOLIS		69							
	NEW JERSEY		27							
	PHILADELPHIA		96							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		82							
	FLORIDA		96							
	NEW ORLEANS		110							
	SAN JUAN		14							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		151							
	DENVER		27							
	KANSAS CITY		14							
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES		69							
	SAN FRANCISCO		96							
	SEATTLE		178							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS			1344							
CONVERSION FACTOR			950							
TOTAL OPERATIONAL FTEs			1.41							

7. PERSONNEL TYPES REQUIRED							8. WORK SCHEDULE			
ANALYTICAL				INVESTIGATIVE			PERSON TYPE	BEGIN	END	
	CHEMIST		PYS. SCIENCE TECH	X	INVESTIGATOR		RRHR	INSPEC TIONAL	10/01/01	09/30/02
	MICROBIOLOGIST		BIO. SCIENCE TECH		INSPECTOR		VETERINARIAN			
	ENGINEER(ANALYST)		ENGINEER TECH		ENGINEER (INV)		NAT'L EXPERT			
	PHYSICIST				MILK/FOOD SPEC					
	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 and hospitals require an average of 14 hours. Hours for radiological surveys of Federal Medical facilities includes time for field testing consultation and followup. Assistance by district X-Ray auditors.

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> ORA/Center Directed Research Projects	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 86R816	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 1.0
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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		1200						
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC		1200						
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS			1200						
CONVERSION FACTOR			1205						
TOTAL OPERATIONAL FTEs			1.00						

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

**9. REMARKS**

**PUBLIC AFFAIRS PROGRAMS  
RESOURCE SUMMARY  
FY 2002**

	OPERATIONAL FTEs	
<b>TOTAL ALL PROGRAMS</b>		<b>41.0</b>
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

NOTE: See following page for the FTEs allocation for Public Affairs Specialists or Technicians.

## Public Affairs Specialists and Technicians (PASs/TECHs)

Currently the Workplan assigns 41 FTEs to the Field and Headquarter's for Public Affairs activities. The FTEs are allocated as follows:

36 FTEs assigned to ORA Field Initiatives

5 FTEs assigned to Headquarters Initiatives:

3 assigned to the Office of the Associate Commissioner for Consumers Affairs Activities;

2 assigned to the Office of the Associate Commissioner for Regulatory affairs for the Agency-wide Health Fraud-Public Affairs activities.

The current allocation of 41 PASs/TECHs is based on population considerations calculated at one PAS/TECH per District Office, Large Resident Post, and special language requirement.

In FY 1989 DPEM discontinued the allocation of resources to the Districts for each Center. Hours were assigned based on the number of PASs/TECHs assigned to each District.

The ORA "CALL" contains the total number of FTEs contributed by each Center for Public Affairs activities.

ORA Senior Management (ACRA/Deputy ACRA), through ORA's functional committee for Public Affairs, approves or disapproves requests for increases in the current number of Public Affairs Specialists/Technicians. The recommended changes are sent to ORM/DPEM for inclusion in the Final ORA Field Workplan and Workplan Tables of Organization.

# PUBLIC AFFAIRS STRATEGY

## A. GENERAL

Public Affairs specialist (PAS) education programs identify appropriate target audiences and/or specific program topics. PASs help develop and communicate key Agency messages addressing public health issues, concerns, and emerging trends (e.g., food safety, drug interactions, etc.). The ORA Public Affairs Executive Council, (the representative body of the Field Public Affairs staff) selects one National FDA Education campaign each year with ACRA concurrence. All field Public Affairs staffs spend up to 10% to 20% of their time. (i.e. "Buying Medical Products Online" for FY'01) on this yearly campaign.

District demographics may identify additional audiences for whom programmatic activities are planned or specific program topics that need educational initiatives.

Work scheduling priorities are determined by the appropriateness of the program/activity to meet the needs and concerns of local constituents or to convey an important FDA message. Priority is given to working with multiplier groups who have follow-up outreach capabilities. This includes educational systems; health-related professional organizations/institutions/agencies; consumer organizations; community organizations; and, multicultural networks.

The media (electronic and print) will be utilized to reach large numbers of people. Workshops, meetings, seminars, and exhibits at national, regional or local conferences as well as responding to inquiries (telephone and written), should also be used to carry out programmatic activities.

## B. SPECIAL

As required, Public Affairs Specialists may also target specific program initiatives. Examples are: yibrio vulnificus in shellfish, MQSA, and current FDA priority areas. There are initiatives that also target specific audiences, e.g., the campaign to warn pregnant women about the potential risk of listeriosis associated with the consumption of "soft-style" cheeses.

Public Affairs Specialists also may provide special support to their districts and regions during emergencies and high priority field regulatory initiatives, i.e. public information relating to safety alerts and recalls, or other significant actions.

## C. REPORTING

### **Regional Internal Management Review**

Significant activities and emerging issues should be reported in this weekly review.

### **PAIRS**

Public Affairs Specialists shall report into PAIRS any significant activities plus summaries of other activities (by program area); cumulative audience data; feedback on public concerns; emerging/new concerns/issues; special initiatives; congressional visits; training given and received by Public Affairs staff; number of inquiries by program area and any other quantitative/qualitative pertinent information.

### **Other Reports**

Public Affairs Specialists may provide input into status reports and other special ad hoc reports relating to key field objectives and initiatives.

## **D. SPECIAL ASSIGNMENTS**

Special assignments are issued by different centers or agency components with ORA concurrence. The purpose of these assignments varies and usually involves special one-time issues. Assignments may be issued to survey the impact of a new public affairs strategy on a given audience, to identify evolving or ongoing problems for which a program has not yet issued, or to address a sudden critical situation which has come to the agency's attention. Assignments are a very useful tool for obtaining a given response or measurement in a short span of time. Some assignments may require monitoring and interim reporting.

Issues relevant to Public Affairs work in the field shall be communicated to the ORA PublicAffairs Executive Council through the ORA/ORO/DFSR Director.