

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>To ensure the safety and effectiveness of licensed vaccines by determining that they are manufactured in compliance with current Good Manufacturing Practice regulations and that they comply with standards and commitments made in license applications and/or supplements.</p> <p>To encourage voluntary compliance by identifying practices which establish and implement programs.</p> <p>To regulatory/administrative guidance to ensure that appropriate enforcement actions are initiated against those manufacturers found to be in significant noncompliance with applicable laws and regulations.</p> <p>To provide information and guidance to investigators assigned to perform biennial GMP or for cause inspections of manufacturers of licensed vaccines.</p>	
5. PROGRAM JUSTIFICATION <p>Vaccine and vaccine related products are biological products which are administered to man for the diagnosis and prevention of microbial disease and for the therapeutic treatment. Products are manufactured from viral and bacterial organisms and components and may include live attenuated, inactivated, and recombinant vaccines. These products are used in the prevention of childhood diseases and in the treatment, diagnosis, and prevention of diseases and thus are of immeasurable value to the Consumer.</p>	
FIELD OBLIGATIONS <p>JRA will perform single, comprehensive inspections that assess the adequacy of all significant processes and systems. These should be performed on at least a Biennial Basis. Inspections will be conducted as a team, whenever possible, consisting of a field investigator leading and a CBER Product Specialist participating.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS <i>(Specify)</i>	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45002, A Domestic/Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	5	6	7	8	9
		DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	INVESTI- GATIONS DOMESTIC (HOURS)	DOMESTIC INVESTI- GATIONS (HOURS)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	10	4	244						
NE	HEADQUARTERS	10	4							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK			61						
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT			61						
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES			61						
PA	SAN FRANCISCO			61						
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		247.0	233.0							
TOTAL HOURS		2470	932	244						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		2.71	1.02	0.27						

7. REMARKS

* 45002 GMP Inspection, 45002A Pre-License Inspections All inspections will be performed by Core Team Biologics. No separate resources are planned for 45002A, use above resources as needed.

Personnel Types Required: Core Team Biologics

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

1. PROGRAM/ASSIGNMENT TITLE
Clinical Investigators
(PDUFA)

2. PPS PROJECT NAME/NUMBER
Vaccines and Allergenic Products - 45

3. PROGRAM TYPE:

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

ASSIGNMENT

4. OBJECTIVES

To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of clinical investigators with the relevant regulations (21 CFR 312).

5. PROGRAM JUSTIFICATION

The Kefauver Harris amendment to the Act and the regulations promulgated thereunder, provided FDA with the responsibility and authority to review all clinical research involving FDA regulated products.

6. FIELD OBLIGATIONS

Conduct inspections as assigned by CBER and forward reports including recommendations for compliance follow-up as needed.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE

BY CENTER

BY BOTH

b. INSPECTION TYPE:

COMPREHENSIVE

ABBREVIATED

DIRECTED

c. PRODUCT(S)
Biologics

d. INDUSTRY/PRODUCT CODE(S)

57 / 99

99 is used for products n.e.c.

e. EXAM TYPE:

CHEMICAL

MICROBIOLOGICAL

PHYSICAL

ENGINEERING

MICROANALYTICAL

OTHERS
(Specify)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsors-Monitors, Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45809 IRBs, 45810 Spon/Mon, 45811 Clin. Invest.	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	SPECIALIZED									
	TOTAL FIELD	35								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3								
	NEW YORK	1								
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	3								
	CHICAGO									
	CINCINNATI	1								
	DETROIT	1								
	MINNEAPOLIS	1								
	NEW JERSEY	1								
	PHILADELPHIA	3								
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2								
	FLORIDA	2								
	NEW ORLEANS	4								
	SAN JUAN	1								
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	3								
	DENVER	2								
	KANSAS CITY	4								
	SOUTHWEST IMPORT OPERATION									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO	2								
	SEATTLE	1								
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		78.0								
TOTAL HOURS		2730								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		3.00								

7. REMARKS

* All resources are planned under 45811, Clinical Investigators. Report Accomplishment hours under Appropriate PAC.

Personnel Types Required: Investigator

**CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2004
FY 2004 ORA WORKPLAN
Bulletin FY2004-1**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	313.6	58.7	58.7	431.0	582.0	109.0	109.0	800.0
46	NEW DRUG EVALUATION	19.0		16.0	35.0	35.2		29.7	64.9
48	BIORESEARCH MONITORING HUMAN DRUGS	51.9		5.4	57.3	96.4		10.0	106.4
52	GENERIC DRUG EVALUATION	39.2		15.6	54.8	72.7		29.0	101.7
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	10.3		1.7	12.0	19.1		3.2	22.3
56	DRUG QUALITY ASSURANCE	166.7	58.7	20.0	245.4	309.4	109.0	37.1	455.5
61	OTC DRUG EVALUATION	2.0			2.0	3.7			3.7
63	HEALTH FRAUD: HUMAN DRUGS	12.5			12.5	23.2			23.2
88	INTERAGENCY COOPERATIVE ACTIVITIE	12.0			12.0	22.3			22.3

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

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/ Investigations	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input checked="" type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES
To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.

5. PROGRAM JUSTIFICATION
Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS
Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/> BY DISTRICT OFFICE	<input checked="" type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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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) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
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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

1. PROGRAM/ASSIGNMENT TITLE
NDA Methods Validations

2. PPS PROJECT NAME/NUMBER
New Drug Evaluation - 46

3. PROGRAM TYPE:

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

ASSIGNMENT

4. OBJECTIVES

Validate NDA methodology before approval.
This includes NDAs for radioactive drugs.

5. PROGRAM JUSTIFICATION

A validated analytical method is needed for compliance purposes after approval of an NDA.

6. FIELD OBLIGATIONS

Assigned district laboratory performs the validation study according to instructions in the assignment from the Division of Field Science (HFC-140).

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE

BY CENTER

BY BOTH

b. INSPECTION TYPE:

COMPREHENSIVE

ABBREVIATED

DIRECTED

c. PRODUCT(S)

All Human Drugs, Including Radioactive Drugs

d. INDUSTRY/PRODUCT CODE(S)

All Human Drug Codes

e. EXAM TYPE:

CHEMICAL

MICROBIOLOGICAL

PHYSICAL

ENGINEERING

MICROANALYTICAL

OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Inv. Methods Validation-Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46R845 46832M <input checked="" type="checkbox"/>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDAs TO INSPECT (Domestic) *	1 CHEMIST INSPECT (HOURS) (Domestic) **	2 INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	7 DSAs METH. VALID. (MICRO) ****	7	7 DSAs (METH.) (VALID) CHEM *****
	TOTAL FIELD	140	2311		30		30	6		66
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	5				1				
	NEW YORK	12				3				
	REGIONAL LAB			617			12	1		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	3				1				
	CHICAGO	9				2				
	CINCINNATI	5				1				
	DETROIT	8		77		2				
	MINNEAPOLIS	5				1				
	NEW JERSEY	16				3				
	PHILADELPHIA	14		462		2				30
FORENSIC CHEM. CTR			154				18			
	REGIONAL STAFF									
	ATLANTA	13				3				
	FLORIDA	3				1				
	NEW ORLEANS	2								
	SAN JUAN	17		289		4				16
SW	REGIONAL LAB			212						15
	REGIONAL STAFF									
	DALLAS	5				1				
	DENVER	6		77		1		5		
	KANSAS CITY	7		77		2				
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	6				1				
	SAN FRANCISCO	3				1				
	SEATTLE	1								
PACIFIC REGIONAL LAB - SW			173						5	
PACIFIC REGIONAL LAB - NW			173							
HOURS PER OPERATION		56.0				5.0	50.0	105.0		105.0
TOTAL HOURS		7840	2311			150	1500	630		6930
CONVERSION FACTOR		910	910			910	1180	1180		1180
TOTAL OPERATIONAL FTES		8.62	2.54			0.16	1.27	0.53		5.87

7. REMARKS

* An estimated 65% of NDAs require Methods Validation @ approx. 105 Hours. ** Includes Microbiologists on Inspections.
 *** NRL analyzes profile DSCs in NE & SE Regions. FCC analyzes profile DSCs in CE, SW AND PA Regions.
 **** Micro Meth. Val.105 hrs NRL; 525 HRS DEN LAB
 ***** Meth. Valid DSAs
 Use CT PAC 46R845 only when specific CT work is performed.

46832M Therapeutic Biologics Products PAC- Resources under 56002M.

1. PROGRAM/ASSIGNMENT TITLE
NDA Pre-Approval Inspections/ Investigations - Foreign

2. PPS PROJECT NAME/NUMBER
New Drug Evaluation - 46

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.

5. PROGRAM JUSTIFICATION
Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS
Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
All Human Drugs, Including Radioactive Drugs

d. INDUSTRY/PRODUCT CODE(S)
All Human Drug Codes

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations (Methods Validation) - Foreign (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	4	5	6	8	8	9
		INSPEC- TIONS FOREIGN	CHEMIST INSPS (Hours) FOREIGN **	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL ***	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	IMPORT SAMPLES ANALYSES PROFILE (CHEM) ****	IMPORT SAMPLES ANALYSES METH. VAL. (Chem) ****	OTHER OPERATIONS (Hours)
	TOTAL FIELD	174	3467		50			50	4	
NE	HEADQUARTERS	17								
	REGIONAL STAFF									
	NEW ENGLAND	9			3					
	NEW YORK	11			4					
	REGIONAL LAB		731					50	4	
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	9			3					
	CHICAGO	9			3					
	CINCINNATI	7			2					
	DETROIT	5			2					
	MINNEAPOLIS	2			1					
	NEW JERSEY	21			6					
	PHILADELPHIA	10	1155		3					
	FORENSIC CHEM. CTR		173							
SE	REGIONAL STAFF									
	ATLANTA	13			4					
	FLORIDA	2			1					
	NEW ORLEANS	2			1					
	SAN JUAN	23	308		5					
SW	REGIONAL LAB		289							
	REGIONAL STAFF									
	DALLAS	5			2					
	DENVER	2	231		1					
	KANSAS CITY	11	192		3					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	9			3					
	SAN FRANCISCO	5	220		2					
	SEATTLE	2			1					
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW		80 88							
HOURS PER OPERATION		55.0			3.0			30.0	75.0	
TOTAL HOURS		9570	3467		150			1500	300	
CONVERSION FACTOR		910	910		910			1180	1180	
TOTAL OPERATIONAL FTEs		10.52	3.81		0.16			1.27	0.25	

7. REMARKS
 * Report as follows: Insp./Chem on Insp. under new foreign operation code 11 Pac Code 46832;
 M. Valid.-46832; Profile ISCs & ISAs -46832B; Biotest ISCs & ISAs (not planned) if collected -46832C.
 ** Includes microbiologists on inspections. *** Profile samples are collected at foreign manufacturers.
 **** NRL analyzes all Profile ISCs and meth. valid. ISAs.
 Use CT PAC 46R845 only when specific CT work is performed.

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.

5. PROGRAM JUSTIFICATION
Bioequivalence studies are conducted mainly by private and university affiliated contract laboratories. Previous inspections noted deviations from protocols, poor recordkeeping, inadequate controls over test subjects, poor analytical procedures and fraud. Results of bioequivalence inspections have a direct relationship to approvability of NDA and ANDA applications.

7. FIELD OBLIGATIONS
Conduct the inspections and forward the reports directly to the Division of Scientific Investigations, CDER.

7a. ESTABLISHMENTS TO BE SELECTED BY DISTRICT OFFICE 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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (Pre-Approval)				2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.4			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDAs INSPEC- TIONS DOMESTIC	1 48001A NDA INSPEC- TIONS (PDUFA) DOMESTIC	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		50	23						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3	1							
	NEW YORK	3	1							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	6	4							
	CHICAGO	1	1							
	CINCINNATI	4	2							
	DETROIT	1	1							
	MINNEAPOLIS	4	2							
	NEW JERSEY									
	PHILADELPHIA	3	1							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2	1							
	FLORIDA	5	2							
	NEW ORLEANS	1								
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	5	2							
	DENVER	1								
	KANSAS CITY	3	1							
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	4	2							
	SAN FRANCISCO	3	1							
	SEATTLE	1	1							
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		70.6	60.2							
TOTAL HOURS		3530	1385							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		3.88	1.52							

7. REMARKS

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

An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 75%, PDUFA 48001A (NDA) 25%.

Personnel Types Required: Investigator

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

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

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

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

7a. ESTABLISHMENTS TO BE SELECTED:	<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 (<i>Specify</i>)		

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48001, A; 48808; 48811 NDA &, ANDA *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 NDA INSP EC TIONS (PDUFA)	1 ANDA INSP EC TIONS (PRE- APPROVAL)	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	57	19							
NE	HEADQUARTERS	4								
	REGIONAL STAFF									
	NEW ENGLAND	3								
	NEW YORK	3								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3								
	CHICAGO	3	3							
	CINCINNATI	3								
	DETROIT	3								
	MINNEAPOLIS	3								
	NEW JERSEY	3	2							
	PHILADELPHIA FORENSIC CHEM. CTR	3	4							
SW	REGIONAL STAFF									
	ATLANTA	3								
	FLORIDA	4	4							
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS	3								
	DENVER	3	2							
	KANSAS CITY	3								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3								
	SAN FRANCISCO	3								
	SEATTLE	4	4							
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		66.8	58.2							
TOTAL HOURS		3808	1106							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		4.18	1.22							

7. REMARKS

* Planned inspections include: PAC 48001,A In Vivo Bioequivalence, PAC 48811 Clinical Investigators, 48808 GLPs (PDUFA). Report Inspections under Appropriate PAC. Report Foreign Inspections under the Operation Code 11.

HIGH PRIORITY for NDA inspections.

Personnel Types Required: Investigator, National Expert

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: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

7a. ESTABLISHMENTS TO BE SELECTED: BY DISTRICT OFFICE 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
Use methodology prescribed in protocol or actually used in nonclinical laboratory.

1 PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3 PROGRAM/ASSIGNMENT CODE(S) 48808	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.5
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 NAT'L EXPERT 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	51	590							
	HEADQUARTERS		590							
NE	REGIONAL STAFF									
	NEW ENGLAND	6								
	NEW YORK	4								
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	4								
	CHICAGO	2								
	CINCINNATI	4								
	DETROIT	3								
	MINNEAPOLIS	1								
	NEW JERSEY	4								
	PHILADELPHIA	3								
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA	3								
	FLORIDA	1								
	NEW ORLEANS	2								
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1								
	DENVER	3								
	KANSAS CITY	2								
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3								
	SAN FRANCISCO	3								
	SEATTLE	2								
PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		86.6								
TOTAL HOURS		4417	590							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		4.85	0.65							

9. REMARKS

Resources Planned for Inspections may also be used for DSCs.

Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER from IND's and NDA's (i.e. Directed Inspections).

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To assure the quality and integrity of institutional review boards (21 CFR 56, 21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.

5. PROGRAM JUSTIFICATION
Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected.

6. FIELD OBLIGATIONS
Conduct inspections of IRBs which may be evaluation of human drugs studies and forward the reports to the Division of Scientific Investigations, CDER.

Assist in presentation of IRB workshops.

7a. ESTABLISHMENTS TO BE SELECTED By DISTRICT OFFICE 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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board (PDUFA) Radioactive Drug Research Committee (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48809, 48809A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I R B INSPECTIONS	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	168								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	14								
	NEW YORK	14								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	7								
	CHICAGO	5								
	CINCINNATI	13								
	DETROIT	8								
	MINNEAPOLIS	12								
	NEW JERSEY	4								
	PHILADELPHIA FORENSIC CHEM. CTR	8								
SE	REGIONAL STAFF									
	ATLANTA	10								
	FLORIDA	10								
	NEW ORLEANS	12								
	SAN JUAN REGIONAL LAB	2								
SW	REGIONAL STAFF									
	DALLAS	8								
	DENVER	7								
	KANSAS CITY	8								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	13								
	SAN FRANCISCO	7								
	SEATTLE	6								
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	60.1								
	TOTAL HOURS	10097								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTES	11.10								

7. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To assess adherence by sponsors, contract research organizations, and monitors to the regulations (21 CFR 312) and to assess their interaction with clinical investigators and the sponsors development of safety and efficacy data in NDAs.

5. PROGRAM JUSTIFICATION
Sections of the FD&C Act and the Public Health Service Act require the submission of data to FDA ensuring the safety of human drugs, as well as the filing of an Investigational New Drug Application and New Drug Applications. An inspectional program is required to assess compliance with current regulations.

6. FIELD OBLIGATIONS
Conduct inspections of sponsors, contract research organizations, and monitors for the IND/NDAs identified in the assignments. Forward reports directly to the Division of Scientific Investigations, CDER, for final classification, including District recommendations for compliance follow-up.

7a. ESTABLISHMENTS TO BE SELECTED: 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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators	2. PMS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To assess through audit procedures whether data submitted to FDA in a specific study are substantiated by records and whether clinical investigators have complied with regulations (21 CFR 312).

5. PROGRAM JUSTIFICATION
Clinical studies necessary for FDA evaluation of new drug applications are assessed for scientific accuracy, veracity, and regulatory compliance. Past experience has demonstrated deficiencies ranging from carelessness to fraudulent submissions.

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

7a. ESTABLISHMENTS TO BE SELECTED 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

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Not Covered by Approved NDAs	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.5
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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 - 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 M i s c. (Hours)
	TOTAL FIELD	125	2590	100						
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	7	149	6						
	NEW YORK	14	290	11						
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	5	99	4						
	CHICAGO	6	116	5						
	CINCINNATI	4	74	3						
	DETROIT	6	116	5						
	MINNEAPOLIS	2	33	1						
	NEW JERSEY	16	331	12						
	PHILADELPHIA	8	216	6						
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA	10	199	8						
	FLORIDA	5	99	4						
	NEW ORLEANS	2	41	2						
	SAN JUAN	18	389	14						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3	66	3						
	DENVER	3	66	3						
	KANSAS CITY	6	124	5						
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	6	116	5						
	SAN FRANCISCO	3	58	2						
	SEATTLE	1	8	1						
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION	30.0		5.0						
	TOTAL HOURS	3750	2590	500						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	4.12	2.85	0.55						

7. REMARKS

* Samples collected will not require analysis; These samples will be collected for documentary and label review.

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

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

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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3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C, 52R845		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 36.7	
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	3	7	7	7	9
		ANDAs TO INSPECT Domestic *	CHEMIST INSPECT. (Hours) **	DOMESTIC INV. Hrs.	DOMESTIC SAMPLE COLL ***	PROFILE/ PORTION OF DSCs FOR DDA ***	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ****	DOMESTIC SAMPLE ANALYSES BIOTEST (Chem) ****	DSAs (METH) (VALID) (Chem) (Hours) *	MISC. HOURS
	TOTAL FIELD	190	3750	2500	140	(50)	45	45	140	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	6		79	4					
	NEW YORK	23		303	17					
	REGIONAL LAB		906				17	17	28	
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	8		105	6					
	CHICAGO	16		211	12					
	CINCINNATI	7		92	5					
	DETROIT	6	285	79	5				18	
	MINNEAPOLIS	5		66	4					
	NEW JERSEY	25		329	18					
	PHILADELPHIA	14	800	184	10				38	
	FORENSIC CHEM. CTR		285				28	28		
SE	REGIONAL STAFF									
	ATLANTA	17		224	13					
	FLORIDA	7		92	5					
	NEW ORLEANS	3		39	2					
	SAN JUAN	15	378	197	11				13	
	REGIONAL LAB		324						18	
SW	REGIONAL STAFF									
	DALLAS	2		26	1					
	DENVER	7	204	92	5				13	
	KANSAS CITY	8	208	105	6					
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	17		224	13					
	SAN FRANCISCO	4	128	53	3					
	SEATTLE									
	PACIFIC REGIONAL LAB - SW		129						5	
	PACIFIC REGIONAL LAB - NW		103						7	
	HOURS PER OPERATION	65.0			5.0		50.0	30.0	105.0	
	TOTAL HOURS	12350	3750	2500	700		2250	1350	14700	
	CONVERSION FACTOR	910	910	910	910		1180	1180	1180	
	TOTAL OPERATIONAL FTEs	13.57	4.12	2.75	0.77		1.91	1.14	12.46	

7. REMARKS
 * An estimated 70% of ANDAs will require methods validation @ 105 hours each.
 Includes microbiologists on inspections. * DSCs for profile/biotest analyses.
 Includes 50 Profile DSCs to be analyzed by DDA (HFH-300). **** NRL-analyzes profile/biotest DSCs collected in NE & SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.
 Use CT PAC 52R845 only when specific CT work is performed.

1. PROGRAM/ASSIGNMENT TITLE
ANDA Pre-Approval Inspections/Investigations - Foreign

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

3. PROGRAM TYPE:

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

ASSIGNMENT

4. OBJECTIVES

To verify that ANDA applicant has facilities, equipment, controls, etc., so specified in their applications. To determine Compliance of foreign manufacturing establishments with GMPs prior to approval of pending ANDAs.

5. PROGRAM JUSTIFICATION

Compliance of foreign manufacturing establishments must be assessed before ANDA approval.

6. FIELD OBLIGATIONS

Conduct pre-approval inspections of foreign establishments as requested by the Center for Drug Evaluation and Research.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE:

COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

Human Drugs

d. INDUSTRY/PRODUCT CODE(S)

All Human Drug Codes

e. EXAM TYPE:

CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

ANDA Pre - Approval Inspections/Investigations
(Methods Validation) - Foreign

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

3. PROGRAM/ASSIGNMENT CODE(S)
52832, 52832B ,52832C
52R845 *

4. WORK ALLOCATION PLANNED BY
 ORA CENTER

5. OPERATIONAL FTE POSITIONS
15.6

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	3	5	6	8	8	8
		INSP. TIONS (Foreign)	CHEMIST INSP. (Hours) (Foreign) **	INVEST. HRS.	IMPORT SAMPLE COLL ***	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	IMPORT SAMPLE ANALYSES PROFILE (Chem) ****	IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****	IMPORT SAMPLE ANALYSES METH. VALID. ****
	TOTAL FIELD	96	2550	2900	140			70	70	15
NE	HEADQUARTERS	7								
	REGIONAL STAFF									
	NEW ENGLAND	4		130	6					
	NEW YORK	9		293	15					
	REGIONAL LAB		561					70	70	15
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	4		130	6					
	CHICAGO	4		130	7					
	CINCINNATI	4		130	6					
	DETROIT	6	169	196	9					
	MINNEAPOLIS	2		66	3					
	NEW JERSEY	12		391	20					
	PHILADELPHIA	4	700	130	6					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	5		163	7					
	FLORIDA	4		130	6					
	NEW ORLEANS	3		98	4					
	SAN JUAN	6	272	196	10					
	REGIONAL LAB		196							
SW	REGIONAL STAFF									
	DALLAS	3		98	4					
	DENVER	4	84	130	6					
	KANSAS CITY	6	257	196	9					
	Southwest Import District									
	REGIONAL LAB		89							
PA	REGIONAL STAFF									
	LOS ANGELES	5		163	10					
	SAN FRANCISCO	2		65	3					
	SEATTLE	2		65	3					
	PACIFIC REGIONAL LAB - SW		84							
	PACIFIC REGIONAL LAB - NW		138							
HOURS PER OPERATION		55.0			3.0			30.0	15.0	50.0
TOTAL HOURS		5280	2550	2900	420			2100	1050	750
CONVERSION FACTOR		910	910	910	910			1180	1180	1180
TOTAL OPERATIONAL FTEs		5.80	2.80	3.19	0.46			1.78	0.89	0.64

7. REMARKS
 * Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;
 Meth. Valid. under PAC 52832; Profile ISCs & ISAs -52832B; Biotest ISCs & ISAs under PAC 52832C.
 ** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers.
 **** NRL analyzes all Profile/Biotest ISCs and methods Validation ISAs.
 Use CT PAC 52R845 only when specific CT work is performed.

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation-52
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Research

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM/ASSIGNMENT CODE(S) 52R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS							
	TOTAL FIELD	1250							
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN	1250							
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	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	1250							
	CONVERSION FACTOR	1205							
	TOTAL OPERATIONAL FTEs	1.04							

7. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53
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3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B, 53R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	4	5	6	7	8	9
		INSP CTIONS DOMESTIC	INSP CTIONS FOREIGN	MEDICAL ERRORS INV HOURS	IMP ORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMP ORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMP ORT SAMPLES TO BE ANALYZED	MISC. HOURS
	TOTAL FIELD	100	26	3648						
NE	HEADQUARTERS		5							
	REGIONAL STAFF									
	NEW ENGLAND	7	1	192						
	NEW YORK	8	2	192						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	7	1	192						
	CHICAGO	8	1	192						
	CINCINNATI	1	1	192						
	DETROIT	1	1	192						
	MINNEAPOLIS	3	1	192						
	NEW JERSEY	15	1	192						
	PHILADELPHIA	9	1	192						
	FORENSIC CHEM. CTR									
S	REGIONAL STAFF									
	ATLANTA	11	1	192						
	FLORIDA	4	1	192						
	NEW ORLEANS	1	1	192						
	SAN JUAN	1	2	192						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	3	1	192						
	DENVER	1	1	192						
	KANSAS CITY	3	1	192						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	7	1	192						
	SAN FRANCISCO	8	1	192						
	SEATTLE	2	1	192						
	PACIFIC REGIONAL LAB - NW PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION		57.0	60.0							
TOTAL HOURS		5700	1560	3648						
CONVERSION FACTOR		910	910	910						
TOTAL OPERATIONAL FTEs		6.26	1.71	4.01						

7. REMARKS

*Report both Domestic and Foreign inspections and medical error investigations under 53001A for Center-Initiated, and 53001B for District -Initiated. Use CT PAC 53R845 only when specific CT work is performed.

Domestic Inspections are spread by CDER HFD-332 based upon where inspections are likely to occur. Numbers for domestic inspections may change slightly pending CDER assignment. Medical errors investigation time is spread evenly to all Districts. Foreign Inspections are spread by DFI/IOB. Foreign inspections must be reported under foreign operation code 11.

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
 To minimize the consumer's risk of exposure to defective drug products by preventing the marketing of, or removing from the market, violative drug products that are observed as a result of activities performed under this program.
 To assess the adequacy of the CGMP regulations, guidelines and agency regulatory policies by gathering industry-wide data on changing practices and technology.

5. PROGRAM JUSTIFICATION
 The Drug Process Inspections program is FDA's primary means for evaluating the conditions under which drug products are manufactured, tested, packaged and held.

6. FIELD OBLIGATIONS
 The field will conduct drug process inspections and maintain profiles or other monitoring systems which will insure that each drug firm receives the biennial inspection coverage provided for in the inspectional strategy.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 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

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832 56R845, 56R359, 56002M <input checked="" type="checkbox"/>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 126.6 (121.6)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 HIGH RISK Inspections	1 LOW RISK Inspections	1 CHEMISTS INSP CTIONS HOURS	1 MICRO INSP CTIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	9 CERTIFICATION HOURS for audits	9 MISC HOURS for team Biologics therapeutics INV hours
	TOTAL FIELD	376	1020	7574	1538	450	225	40	4800	2730
	HEADQUARTERS									2730
NE	REGIONAL STAFF									
	NEW ENGLAND	28	54			22			262	
	NEW YORK	30	81			39			416	
	REGIONAL LAB			1222	462		31	11		
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	8	29			15			133	
	CHICAGO	31	52			27			219	
	CINCINNATI	13	45			16			181	
	DETROIT	17	43	701		19	30		211	
	MINNEAPOLIS	11	48			16			220	
	NEW JERSEY	36	126			57			373	
	PHILADELPHIA	17	53	2100		26	56		192	
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	38	53			26			342	
	FLORIDA	19	51			21			308	
	NEW ORLEANS	11	37			15			203	
	SAN JUAN	30	53	960		32	16		319	
	REGIONAL LAB			600	616		32	18		
SW	REGIONAL STAFF									
	DALLAS	26	62			23			342	
	DENVER	11	33	528	75	17	31	6	156	
	KANSAS CITY	14	53	615		22			257	
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB			83						
PA	REGIONAL STAFF									
	LOS ANGELES	21	91			37			413	
	SAN FRANCISCO	6	30		385	11		5	143	
	SEATTLE	9	26			9			110	
	PACIFIC REGIONAL LAB - SW			382						
PACIFIC REGIONAL LAB - NW			383			29				
HOURS PER OPERATION		75.0	55.0			5.0	38.0	28.0		
TOTAL HOURS		28200	56100	7574	1538	2250	8550	1120	4800	2730
CONVERSION FACTOR		910	910	910	910	910	1180	1180	910	910
TOTAL OPERATIONAL FTEs		30.99	61.65	8.32	1.69	2.47	7.25	0.95	5.27	3.00

7. REMARKS

Performance Goal for 2004- To inspect 55 % of the high risk drug firms.
High risk inspections - represents best approximation of firms to be covered at the time the workplan was prepared.

The field may use resources from the low risk inspection column to compensate for any differences on lists of updated high risk firms. The number of inspections planned for drug firms in the high risk category represent 55% of RX drug manufacturers including API manufacturers and sterile drug firms. Any new registrants in the high risk categories should be inspected during the first 6 months.

Low Risk inspections- Include OTC manufacturers, repacker/relabelers and control labs.
The planned inspections for this PAC code is the total of high and low risk columns.

Investigational resources include 3 FTEs for transfer of therapeutics from Biologics planned as headquarters positions. Some firms are under a separate worksheet 56-4 . ** DSCs not analyzed are doc. samples. Certification Audit hrs report under 56R359.
Use CT PAC 56R845 only when specific CT work is performed. 56002M Therapeutic Biologic Products PAC

1. PROGRAM/ASSIGNMENT TITLE DRUG Process Inspections- Domestic (Gas Manufacturer)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002E	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (5.0)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS MEDICAL GAS *	2 Investigations Hours	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 MISC. HOURS
	TOTAL FIELD	152								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	13								
	NEW YORK	9								
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	5								
	CHICAGO	6								
	CINCINNATI	11								
	DETROIT	8								
	MINNEAPOLIS	4								
	NEW JERSEY	3								
SW	PHILADELPHIA	14								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	10								
	FLORIDA	11								
	NEW ORLEANS	13								
PA	SAN JUAN	2								
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	12								
	DENVER	5								
PA	KANSAS CITY	10								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	6								
PA	SAN FRANCISCO	5								
	SEATTLE	5								
	PACIFIC REGIONAL-SW									
	PACIFIC REGIONAL-NW									
HOURS PER OPERATION		30.0								
TOTAL HOURS		4560								
CONVERSION FACTOR		910								
TOTAL OPERATIONAL FTEs		5.01								

9. REMARKS
 * Total number of planned gas inspections in the Program for 2004
 Resources are targeted toward firms with multiple product medical gas with new registrants targeted during the 1st 6 monthes.
 Nationwide there are approximately 4000 gas manufacturers.
 There are approximately 288 parent companies with 2146 specific sites where medical gas is manufactured/repacked.
 It is expected that some coverage of the medical gas inventory will be accomplished through outsourcing.

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES inspectional work is to minimize the consumer's risk of exposure to defective drug products by preventing the marketing of or removing from the market, violative drug products that are observed as a result of inspections performed under this Program.	
5. PROGRAM JUSTIFICATION The international Drug Process Inspection program is FDA's primary means for evaluating the conditions under which foreign drug products are manufactured, tested, packaged and held.	
6. FIELD OBLIGATIONS The field will conduct drug process inspections and maintain profiles of foreign drug manufacturers.	
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	
SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections/ Equivalence Evaluations	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002,A,B,C,D,E,F 56832, 56R845 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 20.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **						
	TOTAL FIELD	210	5575						
	HEADQUARTERS	18							
NE	REGIONAL STAFF								
	NEW ENGLAND	9							
	NEW YORK	13							
	REGIONAL LAB		589						
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	8							
	CHICAGO	13							
	CINCINNATI	7							
	DETROIT	12	200						
	MINNEAPOLIS	8							
	NEW JERSEY	14							
	PHILADELPHIA	11	643						
FORENSIC CHEM. CTR			203						
SE	REGIONAL STAFF								
	ATLANTA	10							
	FLORIDA	8							
	NEW ORLEANS	8							
	SAN JUAN	13	823						
	REGIONAL LAB			531					
SW	REGIONAL STAFF								
	DALLAS	10							
	DENVER	8	611						
	KANSAS CITY	14	671						
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB			361					
PA	REGIONAL STAFF								
	LOS ANGELES	11							
	SAN FRANCISCO	8	101						
	SEATTLE	7							
	PACIFIC REGIONAL LAB - SW			421					
	PACIFIC REGIONAL LAB - NW			421					
HOURS PER OPERATION		60							
TOTAL HOURS		12600	5575						
CONVERSION FACTOR		910	910						
TOTAL OPERATIONAL FTEs		13.85	6.13						

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

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

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008A, C, D, G	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 21.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC SAMPLE COLLECTIONS	2	7 DOMESTIC SAMPLES ANALYZED STERILITY **	7 Domestic SAMPLES ANALYZED (CHEM) ***	7 DOMESTIC SAMPLES ANALYZED (CHEM) (WEAC) ****	7 DOMESTIC SAMPLES ANALYZED (MICRO) (WEAC) ****	7 DSAS METERED DOSAGE INHALERS (CHEM) ***	
	TOTAL FIELD	200		108	338	25	10	15	
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	10							
	NEW YORK	15							
	REGIONAL LAB			41					
	WEAC					25	10		
CE	REGIONAL STAFF								
	BALTIMORE	10							
	CHICAGO	10							
	CINCINNATI	10							
	DETROIT	10							
	MINNEAPOLIS	10							
	NEW JERSEY	10							
	PHILADELPHIA	10				7		15	
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	10							
	FLORIDA	10							
	NEW ORLEANS	10							
	SAN JUAN	10							
	REGIONAL LAB				23				
					36				
SW	REGIONAL STAFF								
	DALLAS	10							
	DENVER	10		27		80			
	KANSAS CITY	10				45			
		SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES	15							
	SAN FRANCISCO	10		40					
	SEATTLE	10							
		PACIFIC REGIONAL LAB - SW					62		
	PACIFIC REGIONAL LAB - NW					85			
	HOURS PER OPERATION	12.0		24.0		49.0	36.0	24.0	100.0
	TOTAL HOURS	2400		2592		16562	900	240	1500
	CONVERSION FACTOR	910		1180		1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	2.64		2.20		14.04	0.76	0.20	1.27

9. REMARKS

* DSCs in this column will be collected by the Field. CDER will be responsible for collecting other samples to be analyzed.

** Sterility - testing.

*** DSAs are assigned by DFS (HFC-140) per lab expertise for specific Drugs.

**** Radioactive drugs-approx 10 of the 25 DSAs (Chem) tested for micro.

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833 56R845 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 57.7 (31.1)
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6. REGION	DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT FILER EVAL. HOURS	2 REFUSAL Follow-Up HOURS	9 IMPORT LABEL EXAMS	MAIL entries REVIEWS INV HOURS **	6 IMPORT FIELD EXAMS	4 IMPORT SAMPLE COLLECT- IONS *	8 IMPORT SAMPLES ANALYZED APIs CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	17100	1138	376	2400	6640	1900	200	90	60
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	425	42	8	35		28	3		
	NEW YORK	4900	200	60	866	800	685	71		
	REGIONAL LAB								20	
	WEAC									
	REGIONAL STAFF									
	BALTIMORE	425	45	24	44		35	4		
	CHICAGO	1000	56	8	105	600	83	9		
	CINCINNATI	700	30	8	96	500	76	8		
CE	DETROIT	950	42	8	137	550	108	11	10	
	MINNEAPOLIS	200	25	8	13		10	1		
	NEW JERSEY									
	PHILADELPHIA	650	21	8	79	600	63	7	20	
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	550	75	24	79		63	7		
	FLORIDA	875	86	32	63	500	50	5		
SE	NEW ORLEANS	2825	32	8	439	300	347	37		
	SAN JUAN	550	11	24	56	400	44	5	15	
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER								5	
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT	1100	218	100	111	500	88	9		
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1100	137	24	162	700	129	14		
PA	SAN FRANCISCO	400	59	16	64	700	51	5		
	SEATTLE	450	59	16	51	490	40	4		
	PACIFIC REGIONAL LAB - SW								10	
	PACIFIC REGIONAL LAB - NW								10	60
	HOURS PER OPERATION				0.7		0.7	2.0	38.0	25.0
	TOTAL HOURS	17100	1138	376	1680	6640	1330	400	3420	1500
	CONVERSION FACTOR	1200	910	910	910	910	910	910	1180	1180
	TOTAL OPERATIONAL FTEs	14.25	1.25	0.41	1.85	7.30	1.46	0.44	2.90	1.27

7. REMARKS

* PAC Reporting: Entry Reviews 56R833; Filer Evaluations 99R833;
 Follow-Up to Refusals 56R824, 63R824;
 Import Label Reviews, Import Field Exams under PACs 52002, 56008H, 56014/A, 63001;
 Use CT PAC 56R845 only when specific CT work is performed.
 Report finished dosage form drugs and APIs collected at the site of entry under 56008H.

Samples collected and not analyzed are documentary samples.
 ISCs and ISAs of bulk Drugs/API collected at the docks/point of entry are now planned in the workplan.

**Mail entry review time is now planned in the workplan. (600 hours for Phila. includes 300 hours for Newark Airport.)
 Spread was based on location of Custom International Mail Branch Offices and related port Codes.

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Active Pharmaceutical Ingredients (Domestic Import)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008J, 56008K *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (27.6)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INV. HOURS FOR IMPORTERS	3 DOMESTIC IMPORT SAMPLE COLLECTIONS QUALITY	7 DOMESTIC IMPORT ANALYSES CHEM HRS. QUALITY	7 DOMESTIC IMPORT ANALYSES CHEM FINGERPRT. (HOURS)					
	TOTAL FIELD	8754	230	230	11781					
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	257	10							
	NEW YORK	2634	15							
	REGIONAL LAB			30	3465					
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	257	10							
	CHICAGO	734	10							
	CINCINNATI	257	10							
	DETROIT		10							
	MINNEAPOLIS		10							
	NEW JERSEY	1972	40							
	PHILADELPHIA	1129	10	70						
FORENSIC CHEM. CTR					5544					
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN	1343	40	20	2772					
	REGIONAL LAB			40						
SW	REGIONAL STAFF									
	DALLAS		10							
	DENVER		10	30						
	KANSAS CITY		10							
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	171	15							
	SAN FRANCISCO		10							
	SEATTLE		10							
	PACIFIC REGIONAL LAB - SW				20					
PACIFIC REGIONAL LAB - NW				20						
HOURS PER OPERATION			4.0	36.0						
TOTAL HOURS		8754	920	8280	11781					
CONVERSION FACTOR		910	910	1180	1180					
TOTAL OPERATIONAL FTEs		9.62	1.01	7.02	9.98					

9. REMARKS
* Report API DISCs and DISAs from domestic manufacturers as follows: Quality 56008J; Fingerprinting 56008K.

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

4. OBJECTIVES

To establish and operate a structured system for accumulating and evaluating data generated by Drug Quality Reporting System (DQRS) a voluntary reporting program, and NDA Field Alert Reports (FARs), a program mandated by 21CFR 314.81 for reporting by drug manufacturers.

To maintain a flexible capability for rapid investigations and product corrections of any drug product quality problems ascertained from these distinct reporting systems.

5. PROGRAM JUSTIFICATION

The DQRS and FAR programs respectively, provide a means for centralizing drug quality reports received by FDA from health professionals, consumers and drug product manufacturers.

6. FIELD OBLIGATIONS

Each FDA district Office will appoint a DQRS/FAR program coordinator(s) who will monitor the District's activity/follow-up activity and, serve as a contact person. Districts will perform inspections, sample collections, analyze samples and perform other assignments generated by CDER.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) All Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 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 (Chem)	8 IMPORT SAMPLES TO BE ANALYZED	9
	TOTAL FIELD	134	300	30				30		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	7	16	2						
	NEW YORK	12	26	3						
	REGIONAL LAB							5		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	4	9	1						
	CHICAGO	6	14	1						
	CINCINNATI	5	11	1						
	DETROIT	6	13	2				4		
	MINNEAPOLIS	6	14	1						
	NEW JERSEY	10	23	2						
PHILADELPHIA	5	12	1				5			
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	10	21	2						
	FLORIDA	9	19	2						
	NEW ORLEANS	6	13	1						
	SAN JUAN	6	13	1				2		
SW	REGIONAL LAB							4		
	REGIONAL STAFF									
	DALLAS	10	21	2						
	DENVER	4	10	1				5		
	KANSAS CITY	7	16	2						
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	14	32	3						
	SAN FRANCISCO	4	9	1						
	SEATTLE	3	8	1						
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW								5		
HOURS PER OPERATION		25.0		4.0				35.0		
TOTAL HOURS		3350	300	120				1050		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		3.68	0.33	0.13				0.89		

7. REMARKS

1. PROGRAM/ASSIGNMENT TITLE
Pharmacy Compounding Assignments

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

3. PROGRAM TYPE:

COMPLIANCE PROGRAM

PROGRAM CIRCULAR

ASSIGNMENT

OBJECTIVES

Monitor, investigate and take regulatory action, (including working jointly with state regulatory officials), on complaints involving pharmacy compounded drug products and pharmacy compounding operations that are in violation of applicable sections of the Federal Food, Drug, and Cosmetic Act (the Act).

5. PROGRAM JUSTIFICATION

While the pharmacy compounding law section 503A of the Act was recently struck down by the courts, the agency is still engaged in determining whether or not a pharmacy compounder and its compounded drug products comply with all other applicable sections of the Act. It continues to be FDA's policy to ensure the continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. The agency needs to investigate pharmacy-compounding reports of illnesses associated with compounded drug products. In those cases where it is determined that exercising the agency's enforcement discretion in regard to pharmacy compounding is not warranted, the agency will consider regulatory action, where necessary, to address applicable violations of the Act.

6. FIELD OBLIGATIONS

Districts will conduct inspections and investigations, collect evidence, samples and develop cases in accordance with Assignments from HFD-330.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:

BY DISTRICT OFFICE

BY CENTER

BY BOTH

b. INSPECTION TYPE:

COMPREHENSIVE

ABBREVIATED

DIRECTED

c. PRODUCT(S)

Human Drugs

d. INDUSTRY/PRODUCT CODE(S)

Industry Codes: 50, 54, 56 and 60-66

e. EXAM TYPE:

CHEMICAL

MICROBIOLOGICAL

PHYSICAL

ENGINEERING

MICROANALYTICAL

OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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PROGRAM/ASSIGNMENT CODE(S) 56D015 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	TOTAL FIELD		1820							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		61							
	NEW YORK		94							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		82							
	CHICAGO		72							
	CINCINNATI		92							
	DETROIT		82							
	MINNEAPOLIS		77							
	NEW JERSEY		103							
	PHILADELPHIA		71							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		118							
	FLORIDA		139							
	NEW ORLEANS		134							
	SAN JUAN		120							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		164							
	DENVER		69							
	KANSAS CITY		99							
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		97							
	SAN FRANCISCO		70							
	SEATTLE		76							
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION										
TOTAL HOURS			1820							
CONVERSION FACTOR			910							
TOTAL OPERATIONAL FTEs			2.00							

7. REMARKS
*A block of hours is planned for pharmacy compounding assignments.

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:	<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input checked="" type="checkbox"/> ASSIGNMENT
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1. OBJECTIVES
Develop new and/or improved methodology in support of regulatory analysis.

5. PROGRAM JUSTIFICATION
Research

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS								
	TOTAL FIELD	3700								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB	1300								
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT	600								
	MINNEAPOLIS									
	PHILADELPHIA	1800								
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	REGIONAL LAB									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL STAFF									
	DALLAS									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
TOTAL HOURS	3700									
CONVERSION FACTOR	1205									
TOTAL OPERATIONAL FTEs	3.07									

7. REMARKS

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

7. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE OTC Drug Monograph Implementation	2. PPS PROJECT NAME/NUMBER Over-the-Counter Drug Evaluation - 61
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3. PROGRAM/ASSIGNMENT CODE(S) 61003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.0
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6. REGION	DISTRICT/SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	34	600	30				15		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	122	1						
	NEW YORK	3		3						
	REGIONAL LAB							2		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1								
	CHICAGO	1								
	CINCINNATI	3		3						
	DETROIT	1		1				1		
	MINNEAPOLIS	2		2						
	NEW JERSEY	3		3						
PHILADELPHIA	1	166	1				4			
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	1								
	FLORIDA	5	34	5						
	NEW ORLEANS	1								
	SAN JUAN	2	7	2				1		
SW	REGIONAL LAB							2		
	REGIONAL STAFF									
	DALLAS	5	64	5						
	DENVER							2		
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	2	156	2						
	SAN FRANCISCO	2	51	2						
	SEATTLE									
HOURS PER OPERATION		26.0		4.0				20.0		
TOTAL HOURS		884	600	120				300		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.97	0.66	0.13				0.25		

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

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

1. PROGRAM/ASSIGNMENT TITLE Fraudulent Drugs	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs-63
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PROGRAM/ASSIGNMENT CODE(S) 63001, 63R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.5
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	6.	1	2	3	4	5	6	7	8	9
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	50	910	160				80		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	30	5						
	NEW YORK	4	90	12						
	REGIONAL LAB							6		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1	32	4						
	CHICAGO	1	65	4						
	CINCINNATI	1	11	3						
	DETROIT	4	30	14				7		
	MINNEAPOLIS	3	40	9						
	NEW JERSEY	1	21	3						
PHILADELPHIA	1	30	3				15			
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	1	25	4						
	FLORIDA	4	40	11						
	NEW ORLEANS	1	11	3						
	SAN JUAN	1	12	4				2		
SW	REGIONAL LAB							10		
	REGIONAL STAFF									
	DALLAS	3	25	9						
	DENVER	6	36	18				12		
	KANSAS CITY	1	6	3				3		
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	10	280	29						
	SAN FRANCISCO	2	76	8						
	SEATTLE	4	50	14						
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW								25		
HOURS PER OPERATION		28.0		4.0				18.0		
TOTAL HOURS		1400	910	640				1440		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		1.54	1.00	0.70				1.22		

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

 Use CT PAC 63R845 only when specific CT work is performed.

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

1. PROGRAM/ASSIGNMENT TITLE Internet Drug Sales	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63D012, 63D013, 63D014	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc Hours
	TOTAL FIELD		7280							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		305							
	NEW YORK		1295							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		155							
	CHICAGO		255							
	CINCINNATI		105							
	DETROIT		305							
	MINNEAPOLIS		205							
	NEW JERSEY		155							
	PHILADELPHIA		255							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		255							
	FLORIDA		405							
	NEW ORLEANS		205							
	SAN JUAN		255							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		405							
	DENVER		455							
	KANSAS CITY		105							
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES		1250							
	SAN FRANCISCO		505							
	SEATTLE		405							
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION										
TOTAL HOURS			7280							
CONVERSION FACTOR			910							
TOTAL OPERATIONAL FTEs			8.00							

7. 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.

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

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
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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 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem) Hours	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD							14160		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT							7080		
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA							3540		
	FORENSIC CHEM. CTR									
E	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN							3540		
	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							14160		
	CONVERSION FACTOR							1180		
	TOTAL OPERATIONAL FTEs							12.00		

7. REMARKS

Five FTEs are assigned to this Program using dollars reimbursed by DOD.
 Seven additional FTEs are assigned to this Program using dollars reimbursed by the Department of Homeland Security.
 See Data Codes Manual for appropriate project reporting PACs.

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
BULLETIN FY 2004-1**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	106.2	26.8	2.4	135.4	208.5	49.0	4.5	262.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	11.7		2.0	13.7	22.5		3.8	26.3
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	94.5	26.8	0.4	121.7	186.0	49.0	0.7	235.7

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

FY 2004

<p>1. PROGRAM/ASSIGNMENT TITLE</p> <p>NADA Pre-Approval Inspections</p>	<p>2. PPS PROJECT NAME/NUMBER</p> <p>Pre-Approval Evaluation of Animal Drugs and Food Additives - 68</p>
<p>3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES</p> <p>To assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities to fulfill their NADA commitments to manufacture, process, and pack new animal drugs that are safe and effective for their intended use.</p> <p>Increase the number of cooperative activities related to this program.</p>	
<p>5. PROGRAM JUSTIFICATION</p> <p>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.</p> <p>Outcome: Reduce new animal drug development and review time.</p>	
<p>6. FIELD OBLIGATIONS</p> <p>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.</p> <p>Field laboratories on an assignment basis will validate methodology submitted with NADAs.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S)</p> <p>Animal Drugs, Type A Medicated Feed Articles</p>	<p>d. INDUSTRY/PRODUCT CODE(S)</p> <p>56, 67, 68</p>
<p>e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING</p> <p> <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p> <p>Petition validation work.</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68				
3. PROGRAM/ASSIGNMENT CODE(S) 68001		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 7.6		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	1 INSPEC- TIONS (Foreign) ***	1 CHEMIST ON INSP ..	3 DOMESTIC SAMPLE COLL		7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	67	50	710	40		40	
NE	HEADQUARTERS		1					
	REGIONAL STAFF							
	NEW ENGLAND	3	2		2			
	NEW YORK	4	3		2			
	REGIONAL LAB WEAC			79			4	
CE	REGIONAL STAFF							
	BALTIMORE	3	2		1			
	CHICAGO	6	2		4			
	CINCINNATI	3	1					
	DETROIT	2	1		1			
	MINNEAPOLIS	6	2		4			
	NEW JERSEY	4	3		2			
	PHILADELPHIA	3	2		2			
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA	4	4		3			
	FLORIDA	3	2		2			
	NEW ORLEANS	3	1		2			
	SAN JUAN	1	5		1			
REGIONAL LAB			117			8		
SW	REGIONAL STAFF							
	DALLAS	3	3		3			
	DENVER	2	3					
	KANSAS CITY	11	10	412	5		21	
	SOUTHWEST IMPORT DISTRICT							
REGIONAL LAB			19			1		
PA	REGIONAL STAFF							
	LOS ANGELES	3	2		2			
	SAN FRANCISCO	3	1		3			
	SEATTLE				1			
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)			83			6	
HOURS PER OPERATION		60.3	40.0		3.0		19.4	
TOTAL HOURS		4040	2000	710	120		776	
CONVERSION FACTOR		1000	1000	1000	1000		1180	
TOTAL OPERATIONAL FTEs		4.05	2.00	0.71	0.12		0.67	
9. REMARKS								
<p>** Analyst will participate on inspections as necessary.</p> <p>*** Foreign inspections spread by DEIO/ITOB. Use new Operation Code 11 to report foreign inspections.</p>								
Workload Source: FACTS database (registered firms in IND 56, 67, and 68; Workload Obligation is "Yes" and Status is "Operational".)								

FY 2004

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-clinical Laboratory)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections of facilities and non-clinical laboratories engaged in the collection of data to determine whether the GLP regulations (21 CFR 58) are followed. To take appropriate action whenever a situation involving a serious violation of the GLPs is encountered or when fraud or other deliberate falsifications of test data has occurred. Improve compliance review process by reducing BIMO backlogs by 2%.	
5. PROGRAM JUSTIFICATION FDA requires that extensive animal and other types of testing be carried out before approving new animal drug applications or animal food petitions. The FDA's reliance on the basic accuracy of data submitted is essential to the review and approval of Agency-regulated products. The submission of faulty, erroneous, or distorted data increases the potential for wrong decisions and makes it difficult, if not impossible, to draw conclusions regarding the health hazards of the tested product. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS ORA will perform the inspections and submit EIRs in accordance with established procedures set forth in the basic compliance program 7348.808.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 68 or 69
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

FY 2004

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure the adherence of sponsors, contract research organizations and monitors to the clinical monitoring regulations specific (21 CFR 511.1 (b)) and to evaluate representative clinical investigators utilized by the sponsor with regard to their adherence to applicable regulations. Improve the compliance review by reducing the BIMO backlogs by 2%.	
5. PROGRAM JUSTIFICATION As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. Part of this comprehensive program was directed to sponsors, monitors, and clinical investigators under the above stated objective. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS Conduct inspections of sponsors, contract research organizations, and monitors, identified by the Center in accordance with the guidance set forth in the basic compliance program 7348.810.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 68 or 69
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

FY 2004

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assess through audit procedures (21 CFR 511.1 (b)) whether data submitted by clinical investigators to FDA in a specific clinical study are substantiated by records. Improve the compliance review by reducing the BIMO backlogs by 2%.	
5. PROGRAM JUSTIFICATION As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. The program determines the validity of data submitted to FDA by inspecting clinical investigators' records. Outcome: Assure data integrity and reduce drug development time.	
6. FIELD OBLIGATIONS Conduct inspections of clinical investigators identified by the Center in accordance with the guidance set forth in the basic compliance program 7348.811.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs	d. INDUSTRY/PRODUCT CODE(S) 68 or 69
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68						
3. PROGRAM/ASSIGNMENT CODE(S) 68808, 68810, 68811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.1			
R E G I O N	6.	1 68808 INSPEC- TIONS (GLPs) (SPON/MON) *	1 INSPEC- TIONS	1 68811 INSPEC- TIONS (CLINICAL INVEST)	3 DOMESTIC 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		50		71	15			15	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3		2	1					
	NEW YORK	2		5	1					
	REGIONAL LAB							2		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	2		3						
	CHICAGO			1						
	CINCINNATI	3		1	1					
	DETROIT	7		6	2					
	MINNEAPOLIS	2		2						
	NEW JERSEY	7		1	2					
	PHILADELPHIA	2		2						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2		7	1					
	FLORIDA			4						
	NEW ORLEANS	3		3						
	SAN JUAN									
SW	REGIONAL LAB							3		
	REGIONAL STAFF									
	DALLAS	1		11	1					
	DENVER	6		2	2			2		
	KANSAS CITY	9		9	3			5		
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB							2		
	REGIONAL STAFF									
	LOS ANGELES			2						
	SAN FRANCISCO			7	1					
	SEATTLE			3						
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)							1		
HOURS PER OPERATION		58.3		41.0	3.0			19.4		
TOTAL HOURS		2915		2911	45			291		
CONVERSION FACTOR		1000		1000	1000			1180		
TOTAL OPERATIONAL FTEs		2.92		2.91	0.05			0.25		

9. Remarks

* Resources for 68808 and 68810 are planned under 68808. Report inspections conducted under the appropriate PAC. inspections are to be conducted only when assignments are received from CVM.
Domestic Sample Collections are assigned by CVM and collected during the GLP inspections.

Workload Source: FACTS database (Bimo firms in IND 68 and 69 with Status of "Operational"; 3-year inspectional.) data from OPAS (PAC 68811).

FY 2004

<p>1. PROGRAM/ASSIGNMENT TITLE Drug Process and New Animal Drug Inspections/Type A Medicated Articles</p>	<p>2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</p>
<p>3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES To 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.</p>	
<p>5. PROGRAM JUSTIFICATION Section 510(h) of the Act obligates the Agency to inspect (pursuant to 704 of the Act) drug establishments required to register with FDA. In addition, it is one of the primary purposes of establishment inspections to assure that the drug product is being manufactured, processed, controlled, etc. under the same conditions as approved and that it maintains the same stability profile as originally demonstrated. Outcome: Ensure the marketing of safe and effective animal drugs.</p>	
<p>6. FIELD OBLIGATIONS The field will conduct CGMP inspections of registered animal drug establishments. Top priority will be given to establishments which manufacture sterile products.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 54, 56, 67, 68</p>
<p>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>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES Sterility, purity, identity, potency, decomposition</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A</p>	

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 checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 13.0			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS	Performance Goal Firms	1 INSP CTIONS (Hours)	1 CHEM ON INSP	1 INSP CTIONS (Foreign)	2 INVEST IGATIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	7 DOMESTIC SAMPLES TO BE ANALYZED (Micro)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	255	220	160	500	10	435	165	113	38	
	HEADQUARTERS			160		1					
	REGIONAL STAFF										
	NE NEW ENGLAND	13	11				22	8			
	NEW YORK	21	18			1	36	14			
	REGIONAL LAB				67				15	4	
	WEAC										
	CE REGIONAL STAFF										
	BALTIMORE	12	10				20	8			
	CHICAGO	20	17			1	33	13			
	CINCINNATI	13	11				22	8			
	DETROIT	5	4				8	3			
MINNEAPOLIS	23	20			1	40	15				
NEW JERSEY	9	8			2	15	6				
PHILADELPHIA	9	8			1	15	6				
FORENSIC CHEM. CTR											
SE REGIONAL STAFF											
ATLANTA	16	14				28	10				
FLORIDA	10	9				18	6				
NEW ORLEANS	8	7				13	5				
SAN JUAN	6	5				10	4				
SW REGIONAL LAB				160				37	12		
REGIONAL STAFF											
DALLAS	12	11			1	22	8				
DENVER	7	6				12	5			16	
KANSAS CITY	37	32			197	64	24	44			
SOUTHWEST IMPORT DISTRICT											
REGIONAL LAB				9				2	1		
PA REGIONAL STAFF											
LOS ANGELES	14	12				23	9				
SAN FRANCISCO	13	11				22	8			5	
SEATTLE	7	6				12	5				
PACIFIC REGIONAL LAB (SW)											
PACIFIC REGIONAL LAB (NW)					67				15		
HOURS PER OPERATION	33.0					40.0		4.0	18.4	21.1	
TOTAL HOURS	8415			160	500	400	435	660	2079	802	
CONVERSION FACTOR	1000			1000	1000	1000	1000	1000	1180	1180	
TOTAL OPERATIONAL FTEs	8.42			0.16	0.50	0.40	0.44	0.66	1.76	0.68	

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.

Workload Source: FACTS database (registered firms in IND 54,56 and 69 with Status of "Operational" and Workload Obligation of "Yes".) Foreign Inspections Spread by Division of Field Investigations, ORO.

FY 2004

<p>1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants</p>	<p>2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</p>
<p>3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES To 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.</p>	
<p>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.</p>	
<p>6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis. Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities. Anticipate inspection of renderers based on the BSE regulation.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) Complete animal feeds and feed ingredients.</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 69-72</p>
<p>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>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES *Mycotoxins, Pesticides, Industrial Chemicals, Metals and Microbiologicals</p>	
<p>j. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A</p>	

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-H, 71R845 *(99R833, 71R833, 71R824)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		2	4	6	8	8	8	8
			IMPORT ENTRY REVW HRS	IMPORT SAMPLE COLL	IMPORT FIELD EXAM	IMPORT SAMPLE ANALYZED CHEM	IMPORT SAMPLE ANALYZED MICRO	IMPORT SAMPLE COLL CHEM	IMPORT SAMPLE COLL MICRO
TOTAL FIELD			1200	175	500	125	50	125	50
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND		44	6	18			4	2
	NEW YORK		508	74	212			53	21
	REGIONAL LAB WEAC					58	23		
CE	REGIONAL STAFF								
	BALTIMORE		31	4	13			3	1
	CHICAGO		17	3	7			2	1
	CINCINNATI		8	1	3			1	
	DETROIT		129	18	54			14	5
	MINNEAPOLIS		61	9	25			6	2
	NEW JERSEY								
	PHILADELPHIA		12	2	5			1	1
	FORENSIC CHEM. CTR								
SW	REGIONAL STAFF								
	ATLANTA		17	2	7			1	1
	FLORIDA		12	2	5			1	1
	NEW ORLEANS		21	3	9			2	1
	SAN JUAN		4	1	2			1	
	REGIONAL LAB					9	5		
	REGIONAL STAFF								
	DALLAS DENVER KANSAS CITY						7		
SOUTHWEST IMPORT DISTRICT		100	15	42	19		11	4	
PA	REGIONAL LAB					14	5		
	REGIONAL STAFF								
	LOS ANGELES		74	11	31			8	3
	SAN FRANCISCO		25	4	10	3	10	3	1
	SEATTLE		137	20	57			14	6
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)						8 14		
HOURS PER OPERATION				2.5	1.0	5.8	10.7		
TOTAL HOURS			1200	438	500	725	535		
CONVERSION FACTOR			1200	1000	1000	1180	1180		
TOTAL OPERATIONAL FTEs			1.00	0.44	0.50	0.61	0.45		

9. REMARKS

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

Workload Source: FACTS database; hours in PAC 71R833 .

FY 2004

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturers	2. PMS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine compliance with GMP elements of registered establishments producing medicated feeds. To determine whether a firm has the appropriate approved applications to make medicated feeds. To initiate appropriate administrative and/or regulatory action. Reduce by 5% the number of non-compliant (OAI-classified inspections) firms making animal feeds.	
5. PROGRAM JUSTIFICATION Under Sec. 510(h) of the Act, the Agency is obligated to inspect registered medicated feed establishments. Outcome: Ensure the marketing of safe and effective animal feeds.	
6. FIELD OBLIGATIONS To conduct inspections of registered medicated feed establishments and State audit inspections as needed. Districts will collect and analyze samples when appropriate. Field will coordinate federal/state operations. Anticipate inspection of feed mills, medicated and non-medicated to support the BSE regulation.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Medicated Feeds	d. INDUSTRY/PRODUCT CODE(S) 69
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Drug analyses (potency) and drug contamination	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71				
3. PROGRAM/ASSIGNMENT CODE(S) 71004/A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.3		
R E G I O N	6	DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS LICENSED MEDICATED FEED ESTABS	Performance Goal Firms	3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES ANALYZED (Micro)	7 DOMESTIC SAMPLES ANALYZED (Chem)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		305	577	65	15	15	
NE	HEADQUARTERS		4					
	REGIONAL STAFF							
	NEW ENGLAND		7	6	1			
	NEW YORK		4	5	1			
	REGIONAL LAB WEAC							
CE	REGIONAL STAFF							
	BALTIMORE		4	15	2			
	CHICAGO		4	17	2			
	CINCINNATI		5	21	2			
	DETROIT		2	23	2			
	MINNEAPOLIS		24	68	2			
	NEW JERSEY		2	1	1			
	PHILADELPHIA		4	19	1			
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA		20	62	4			
	FLORIDA		8	7	2			
	NEW ORLEANS		35	32	7			
	SAN JUAN REGIONAL LAB		3	3	1			
SW	REGIONAL STAFF							
	DALLAS		68	81	14			
	DENVER		10	23	2	15	15	
	KANSAS CITY		38	144	8			
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES		11	8	2			
	SAN FRANCISCO		19	17	4			
	SEATTLE		33	31	7			
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)							
HOURS PER OPERATION		19.0			6.0	44.0	44.0	
TOTAL HOURS		5795			390	660	660	
CONVERSION FACTOR		1000			1000	1180	1180	
TOTAL OPERATIONAL FTEs		5.80			0.39	0.56	0.56	

9. REMARKS

Some inspection time may be used as investigation time where appropriate.
 Non-potency feed sample analysis should be charged to 71003 A/E. Some samples collected are documentary.

Workload Source: FACTS database (registered firms in IND 69; Workload Obligation is "YES", Firm Status is "Operational").
 *There are 577 Performance Goal firms and 355 State Contract inspections. The 305 FDA inspections include 25 contract audit inspections.

FY 2004

1. PROGRAM/ASSIGNMENT TITLE Illegal Drug Residues in Meat and Poultry	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To conduct follow-up investigations/inspections when illegal residues are reported to FDA by the USDA's Food Safety and Inspection Service. To initiate regulatory sanctions against those persistently causing residues.

Reduce future residues in edible animal tissues by increasing by 2% the number of follow-up investigations in violative tissue residues in targeted food producing animals. FDA will be partners with FSIS/HACCP on the environment, educational initiatives, and, as necessary, regulatory actions.

5. PROGRAM JUSTIFICATION

FDA is charged with the responsibility to ensure that food is free of adulterants which may render it injurious to health. FDA conducts investigations as a follow-up to USDA residue findings in meat and poultry to identify the source of adulteration and take corrective action to prevent it from re-occurring. This a cooperative program involving FDA, USDA, EPA, and a number of state governments.

Outcome: To provide a safe human food supply.

6. FIELD OBLIGATIONS

To conduct investigations or inspections in accordance with the compliance program requirements based on the Memoranda of Understanding between FDA, USDA and EPA. See CPG 7155a.19. Coordinate state activities with states having MOUs, informal and formal agreements or contracts with FDA to conduct inspections of first time violators.

Anticipate inspection of producers to support the BSE regulation.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Meat and Poultry, Animal Feeds and Drugs	d. INDUSTRY/PRODUCT CODE(S) 17, 67, 68, and 69
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

Tissue Sample analysis by Denver laboratory when required, including confirmation on USDA CAST samples.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71						
PROGRAM/ASSIGNMENT CODE(S) 71006		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.7				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 INVEST- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL			7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)	9 TECHNICAL SUPPORT (HOURS) **	METHODS VALID (HOURS) *
	TOTAL FIELD		240	1160	200			1801	1560	1000
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	12	58	10					37	
	NEW YORK	22	106	17					96	
	REGIONAL LAB									60
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	9	44	7					26	
	CHICAGO	4	19	3					13	
	CINCINNATI	7	34	6					35	
	DETROIT	14	68	12					62	
	MINNEAPOLIS	23	110	19					140	
	NEW JERSEY	3	15	3					2	
PHILADELPHIA	13	63	11					130		
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	4	19	3					13	
	FLORIDA	4	19	3					7	
	NEW ORLEANS	3	15	3					7	
SW	SAN JUAN	3	15	3					9	
	REGIONAL LAB									40
	REGIONAL STAFF									
	DALLAS	10	47	8					60	
	DENVER	7	34	6			1801	1560	29	180
PA	KANSAS CITY	9	44	8					47	
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									40
	REGIONAL STAFF									
PA	LOS ANGELES	28	135	23					59	
	SAN FRANCISCO	38	184	32					164	
	SEATTLE	27	131	23					64	
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									40
HOURS PER OPERATION		35.0		5.0						
TOTAL HOURS		8400	1160	1000			1801	1560	1000	360
CONVERSION FACTOR		1000	1000	1000			1180	1180	1000	1180
TOTAL OPERATIONAL FTEs		8.40	1.16	1.00			1.53	1.32	1.00	0.31

9. REMARKS

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

Sample collections represent FSIS repeat violator samples involving C/R's, no sample analysis.

* Additional time for method validation studies.

NEW ** Tech support for RVIS data management and support of state contract activities.

Workload Source: Inspections are planned by Center; State contracts.

1. PROGRAM/ASSIGNMENT TITLE National Drug Residue Milk Monitoring Program	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine if animal drug residues are present in milk and that farmers, distributors, and veterinarians comply with the Federal Food, Drug, and Cosmetic Act regulations and applicable policies. Improve milk residue surveillance by increasing the number of antibiotics in the test battery as new methods are developed.	
<div style="border: 2px solid black; border-radius: 20px; padding: 20px; display: inline-block;"> <h1 style="margin: 0;">PROGRAM CANCELLED</h1> </div>	
5. PROGRAM JUSTIFICATION The National Drug Residue Milk Monitoring Program will provide indications of drug residues in milk and the extent of compliance with federal regulations. The results will help in the design of future education and compliance efforts for use by federal, state and local authorities. This initiative will enhance the NCIM and industry residue testing program and provide information on which to focus regulatory priorities. Outcome: To provide a safe human food supply.	
6. FIELD OBLIGATIONS This is a joint FDA/State effort in collecting and analyzing samples for the presence of gentamicin, ivermectin, chlorouolon, novobiocin, and beta-lactams. Follow-up visits/collections/inspections are anticipated by states and FDA for samples found with detectable residues.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Grade "A" Milk/Non Grade "A" Milk	d. INDUSTRY/PRODUCT CODE(S) 9
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Samples will be analyzed for eight sulfonamides, three tetracyclines, beta-lactams, novobiocin and chloramphenicol.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE National Drug Residue Milk Monitoring Program		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71								
3. PROGRAM/ASSIGNMENT CODE(S) 71008		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED Micro	7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD									
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
SE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SW	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION										
TOTAL HOURS										
CONVERSION FACTOR										
TOTAL OPERATIONAL FTEs										
<p>9. Remarks</p> <p>FY 2004</p> <p>The resources in this program (1.4 FTEs) have been redirected to the Center Initiated program (71V800). CFSAN now has funding and responsibility for this program under its' National Drug Residue Milk Monitoring (03039) program. CVM will review and approve drug residue methods used for milk monitoring.</p>										

THIS PROGRAM HAS BEEN CANCELLED AT THE CENTER'S REQUEST. See Remarks Below.

FY 2004

1. PROGRAM/ASSIGNMENT TITLE BSE/Ruminant Feed Ban Inspections	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To enhance the FDA's uniformity in inspection and compliance of firms subject to the regulation prohibiting the utilization of specified animal proteins in ruminant feeds. 21 CFR 589.2000. To ensure that specified animal proteins do not enter the U.S. from BSE-at-risk countries.	
5. PROGRAM JUSTIFICATION Bovine Spongiform Encephalopathy (BSE) is the bovine form of a group of uniformly fatal neurological diseases known as Transmissible Spongiform Encephalopathies (TSEs). BSE appears to be spread through the feeding of infected material to cattle. BSE is a public health issue for the U.S. This disease has been linked to the human TSE known as variant Creutzfeldt-Jakob Disease (vCJD), presumably through people consuming ruminant tissues infected with the BSE agent. In addition, BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected. Outcome: To prevent the establishment and amplification of BSE through feed in the United States.	
6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. All firms that handle animal feed and feed ingredients containing ruminant-based material are the subject of this program. To provide guidance concerning the importation of animal feeds and feed ingredients from BSE at-risk countries, in accordance With Import Alert #99-25. Field activities will cover the assessment of all aspects of animal feed and feed ingredient manufacture and distribution, as described by the ruminant feed ban regulation, 21 CFR 589.2000.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DIST <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COM PREH <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal feeds and feed ingredients.	d. INDUSTRY/PRODUCT CODE(S) 67-72
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIO <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A	

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71								
3. PROGRAM/ASSIGNMENT CODE(S) 71009 71R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS Domestic 32.0 Import 23.7 55.7				
R E G I O N	6.	1		3	7	4	8	2	2	9	
	DISTRICT/ SPECIALIZED LABORATORY	BSE INSPECT- IONS	PERF. GOAL INSPECT- IONS	DOMESTIC SAMPLES COLL	DOMESTIC SAMPLES ANALYZED Chem	IMPORT SAMPLES COLL	IMPORT SAMPLES ANALYZED	IMPORT ENTRY REVIEW	FILER EVAL	TECHNICAL SUPPORT	
	TOTAL FIELD	2840	645	600	600	600	600	14280	5100	3000	
	HEADQUARTERS										
NE	REGIONAL STAFF										
	NEW ENGLAND	18	4	4		22		524	189		
	NEW YORK	138	16	29		254		6044	898	299	
	REGIONAL LAB				157		290				
	WEAC										
	REGIONAL STAFF										
CE	BALTIMORE	63	26	13		15		367	203	102	
	CHICAGO	111	16	23		9		206	249	48	
	CINCINNATI	239	56	50		4		86	133	189	
	DETROIT	135	28	29		64		1534	188	68	
	MINNEAPOLIS	474	60	99		30		726	111	478	
	NEW JERSEY	10	3	2						8	
	PHILADELPHIA	127	34	27		6		148	95		
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
SE	ATLANTA	112	75	24		9		203	337	376	
	FLORIDA	40	8	8		6		140	383	61	
	NEW ORLEANS	65	40	14		10		249	143		
	SAN JUAN	3		2		2		52	50		
	REGIONAL LAB				52		49				
	REGIONAL STAFF										
SW	DALLAS	290	62	61						523	
	DENVER	69	14	15	151		50			55	
	KANSAS CITY	644	129	136						285	
	SOUTHWEST IMPORT DISTRICT					50		1189	977		
	REGIONAL LAB				176		92				
	REGIONAL STAFF										
PA	LOS ANGELES	74	18	16		37		879	614	48	
	SAN FRANCISCO	131	25	28		13		299	264	262	
	SEATTLE	97	31	20		69		1634	266	198	
	PACIFIC REGIONAL LAB (SW)				44		50				
	PACIFIC REGIONAL LAB (NW)				20		69				
	HOURS PER OPERATION	7.5		6.0	8.0	5.0	7.4				
	TOTAL HOURS	21300		3600	4800	3000	4440	14280	5100	3000	
	CONVERSION FACTOR	1000		1000	1180	1000	1180	1200	1000	1000	
	TOTAL OPERATIONAL FTEs	21.30		3.60	4.07	3.00	3.76	11.90	5.10	3.00	

9. Remarks

Workload Source: All BSE and Performance Goal Firms (renderers, feedmills, protein blenders) in FACTS per checklist and that handle prohibited material for production; Workload Obligation is "YES", and Work Status is "Operational".

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program
71009

2. PPS PROJECT NAME/NUMBER

Monitoring of Marketed Animal Drugs, Feeds and
Devices - 71

Inspection Priorities.

21 CFR §589.2000 pertains to a variety of firms and animal production operations that involve the manufacture, distribution, transportation, and feeding of animal feeds. While the intent of the rule is to ensure that specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources from a to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with the regulations be encountered. In planning and prioritizing inspections, the following firm/industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- Firms that have a violative history
- Firms handling prohibited materials (Renderers, Protein Blenders, and Feed Mills)
- Rendering operations
- Protein blenders
- Commercial feed mills (licensed and unlicensed)
- Animal feed distributors/retailers (ruminant feeds involved)
- Pet food/animal feed salvage operations
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Haulers/transporters of animal feeds (ruminant feeds involved)
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feeds involved)
- Haulers/transporters of animal feeds (no ruminant feeds involved)
- On-farm feed mixers (only ruminant or no ruminant animals on farm premises)

Inspection planning should generally be based on the priority of firms as listed above. Information should be collected on whether a firm has been documented as receiving, processing or distributing prohibited material. This information can be obtained directly through the FACTS database, and through the BSE District Coordinator. A listing of these firms can also be found through the CVM Website (www.fda.gov/cvm).

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM/ASSIGNMENT CODE(S) 71R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER
5. OPERATIONAL FTE POSITIONS 5.6	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEM (Hours)					
	TOTAL FIELD	800		5877					
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER	800		4697					
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE			1180					
PACIFIC REGIONAL LAB (SW)									
PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION									
TOTAL HOURS		800		5900					
CONVERSION FACTOR		1205		1180					
TOTAL OPERATIONAL FTEs		0.66		5.00					

9. Remarks

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

FY 2004

1. PROGRAM/ASSIGNMENT TITLE Forensic Chemistry Center Sample Analyses	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To analyze domestic and imported animal feed and feed ingredients in support of criminal investigations. Prevent widespread abuses by nation's food suppliers.	
5. PROGRAM JUSTIFICATION	
6. FIELD OBLIGATIONS	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/A <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	875								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR	875								
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	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								

9. Remarks

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

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71V800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.0			
R E G I O N	6.	2								
	DISTRICT/ SPECIALIZED LABORATORY	INVESTIGATIONS (Hours)								
	TOTAL FIELD	3000								
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	92								
	NEW YORK	99								
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	105								
	CHICAGO	124								
	CINCINNATI	92								
	DETROIT	140								
	MINNEAPOLIS	302								
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR	118								
SE	REGIONAL STAFF									
	ATLANTA	287								
	FLORIDA	67								
	NEW ORLEANS	122								
	SAN JUAN REGIONAL LAB	76								
SW	REGIONAL STAFF									
	DALLAS	319								
	DENVER	124								
	KANSAS CITY	586								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	96								
	SAN FRANCISCO	99								
	SEATTLE	152								
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION										
TOTAL HOURS		3000								
CONVERSION FACTOR		1000								
TOTAL OPERATIONAL FTEs		3.00								

9. Remarks

These resources includes time for a Center-directed assignment to inspect pharmacies compounding animal drug products.

Workload Source: Based on pro-rated inventory in Feed Manufactg., Feed Contaminants and Pre-approval programs.

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
BULLETIN FY 2004-1**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	SUPPORTED FTEs			TOTAL SUPPORTED FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	175.4	44.9	19.2	239.5	343.1	92.0	36.9	472.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	1.0			1.0
82	COMPLIANCE: DEVICES	93.8	39.4	13.9	147.1	185.7	80.7	26.1	292.5
83	PRODUCT EVALUATION: DEVICES	29.1		4.2	33.3	59.6		8.6	68.2
84	SCIENCE: DEVICES	6.6			6.6	9.2			9.2
	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	16.5		0.1	16.6	28.4		0.2	28.6
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	28.9	5.5	1.0	35.4	59.2	11.3	2.0	72.5

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up					2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81					
3. PROGRAM/ASSIGNMENT CODE(S) 81010			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	7	9
		INSP CTIONS (1)	INVESTI GATIONS (Hours) (2)	DOMESTIC SAMPLE COLL (3)	IMPORT SAMPLE COLL (4)	FIELD EXAMS/ TESTS (5)	DOMESTIC SAMPLES TO BE ANALYZED ENG (4)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	DOMESTIC SAMPLES TO BE ANALYZED STER (6)	OTHER OPERATIONS (Hours) (9)
	TOTAL FIELD	27	62	4			1	1	1	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2		1						
	NEW YORK	2	10	1						
	REGIONAL LAB									
	WEAC						1	1	1	
CE	REGIONAL STAFF									
	BALTIMORE	1								
	CHICAGO	2	8							
	CINCINNATI	1								
	DETROIT	1								
	MINNEAPOLIS	1	8							
	NEW JERSEY	1								
	PHILADELPHIA	1								
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	1	8							
	FLORIDA	1								
	NEW ORLEANS	4	10	1						
	SAN JUAN	1								
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	1	8							
	DENVER	1								
	KANSAS CITY	1								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2	10	1						
	SAN FRANCISCO	2								
	SEATTLE	1								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		12.9		5.8			37.0	36.0	20.0	
TOTAL HOURS		348	62	23			37	36	20	
CONVERSION FACTOR		950	950	950			1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.37	0.07	0.02			0.03	0.03	0.02	

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine compliance of imported devices with the medical device registration and listing requirements, and other general controls.	
5. PROGRAM JUSTIFICATION There are indications that some foreign manufacturers are not registered or listed. Foreign manufacturers of Class II and III devices must be identified for scheduling GMP inspections. In addition, because foreign device manufacturers cannot be inspected as readily as domestic manufacturers, their products must be monitored at the port of entry.	
6. FIELD OBLIGATIONS The field will conduct examinations of Form 701 import records for medical devices and ascertain in conjunction with information provided by CDRH whether the manufacturer is listed and the initial distributor is registered with CDRH.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to Compliance Program for procedures to handle initial distributors and/or foreign establishments which are not registered.	

1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	2	4	4	8	8	9
		INSPEC- TIONS	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
	TOTAL FIELD		21875	1860		1600	120	80	70	1500
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		658	76		48	4			45
	NEW YORK		2679	316		196	15			184
	REGIONAL LAB									
CE	WEAC							80	70	
	REGIONAL STAFF									
	BALTIMORE		172	70		13				
	CHICAGO		1413	90		103	8			109
	CINCINNATI		654	51		48	4			45
	DETROIT		584	58		43	7			59
	MINNEAPOLIS		283	46		21				
	NEW JERSEY									
	PHILADELPHIA		439	36		32				30
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		472	119		35	5			32
	FLORIDA		388	138		28				27
	NEW ORLEANS		1491	53		111	8			105
	SAN JUAN		47	16						
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT		10221	379		748	56			701
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		1337	219		98	7			92
	SAN FRANCISCO		732	93		54	6			71
	SEATTLE		305	100		22				
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION						0.6	2.2	22.7	25.5	0.3
TOTAL HOURS			21875	1860		960	264	1816	1785	450
CONVERSION FACTOR			1200	950		950	950	1180	1180	950
TOTAL OPERATIONAL FTEs			18.23	1.96		1.01	0.28	1.54	1.51	0.47

9. REMARKS

Reporting Guidance:

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

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

Planning Guidance: Any unused resources for Filer Evaluations should be used, if necessary, towards Entry Reviews.

Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.

* 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. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the manufacturing processes used for general and radiation-emitting medical devices and <i>in vitro</i> diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations. To implement the United States-European Community (EC) Mutual Recognition Agreement, Medical Device Annex, as published in the Federal Register dated November 18, 1998. During the transition, or confidence-building period, of the MRA: to train, evaluate, and verify the ability of EC Conformance Assessment Bodies to conduct inspections and provide establishment inspection reports to FDA.	
5. PROGRAM JUSTIFICATION The Center's inspectional strategy requires that all manufacturers of Class II and III devices be inspected under the GMP Compliance Program on a biennial basis. FDA selects certain establishments for intensive GMP coverage. Establishments with a history of good GMP systems are subject to less-intensive inspections. All establishments are subject to complaint file reviews to assess compliance with the MDR regulation. MRA: The FDA Modernization Act of 1997 modified Section 803 of the Food, Drug, and Cosmetic Act to require the Secretary to encourage the mutual recognition of good manufacturing practice regulations under section 520(f) and to provide support to the Office of the United States Trade Representative to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biologics, and devices and the regulation of good manufacturing practices between the EU and the U.S.	
6. FIELD OBLIGATIONS Under the 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 district's resources allow, and scheduled according to the priority outline described in Part II of the compliance program. For more detailed instructions on QSIT/GMP inspections as they relate to device manufacturers, refer to the Workplanning Sheet's Remarks section. MRA: The field will participate in the evaluation of Conformance Assessment Bodies (CAB), conduct inspectional training and evaluative inspections/on-site evaluations of EU CABs. Workloads were modeled proportionally to foreign inspection assignments to enable using Performance Auditors wherever possible.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Class II and III Devices and all Class I Devices which have been finally classified for one year.	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING <i>Engineering Samples:</i> Subs/Sample will vary depending on cost, size, etc. Contact Center for guidance if the device presents such problems.	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,P,S,R841, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 102.4 [93.0]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	2	3
		INSP EC T I O N S L E V E L I 82845A	INSP EC T I O N S L E V E L II 82845B	INSP EC T I O N S L E V E L III C O M P L I A N C E F O L L O W U P 82845C	INSP EC T I O N S F O R E I G N	INSP EC T I O N S M R A	INSP EC T I O N S F O R C A U S E 82845G	INSP EC T I O N S A C C R E D I T E D P E R S O N S 82845P (1)	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L E C
	TOTAL FIELD	770	515	100	183	15	75	135	773	177
NE	HEADQUARTERS				30				773	
	REGIONAL STAFF									
	NEW ENGLAND	77	60	10	8		8	14		23
	NEW YORK	38	25	5	10		4	8		9
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	20	13	3	7		2	4		4
	CHICAGO	38	16	5	7		3	6		6
	CINCINNATI	31	12	4	7		3	6		4
	DETROIT	30	15	4	10		3	3		7
	MINNEAPOLIS	49	42	6	10	3	5	9		14
	NEW JERSEY	26	24	4	7	3	3	4		9
	PHILADELPHIA	36	22	5	7		4	5		9
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	36	21	4	7		2	5		7
	FLORIDA	58	38	8	10	3	6	10		13
	NEW ORLEANS	32	14	4	7		3	6		4
	SAN JUAN	3	13	1	5		1	1		3
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	52	24	6	10	3	4	7		9
	DENVER	31	19	4	11	3	3	5		8
	KANSAS CITY	26	13	3	8		2	5		3
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	102	90	14	10		11	21		28
	SAN FRANCISCO	50	37	6	7		5	11		11
	SEATTLE	35	17	4	5		3	5		6
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		34.0	51.0	90.0	65.0	65.0	72.0	50.8		5.5
TOTAL HOURS		26180	26265	9000	11895	975	5400	6858	773	974
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		27.56	27.65	9.47	12.52	1.03	5.68	7.22	0.81	1.03

9. REMARKS

QUALITY SYSTEMS INSPECTION PLANNING

The workplan reflects the number of operations to be performed for FY04 for each district. Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause" inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Any unused resources in those two areas should be reprogrammed into Level 1 and Level 2 inspections.

The hours per operation, or inspectional modules, reflect the most recent historical data. In previous years, the time for 82845S (sterilization) has been planned separately. That time is now built into the inspectional modules. Also in previous years, time spent on the QSIT satellites: MDR (81001), Corrections and Removals (81845R), Tracking (81845T) and Registration and Listing have not been planned time. Time spent on these satellites programs is averaged into the inspectional module for Level 2 inspections. For additional information regarding inspection strategies refer to the latest Compliance Program. Resources for Single Use Reprocessor inspections have been included in Level II Inspections.

() Credited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program. For informational purposes: 27 inspections under State Contract will be conducted in DAL-DO; 20 inspections under State Contract will be conducted in DEN-DO for FY 2004.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,P,S,R841, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 102.4 [9.4]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLLEC BIOBURDEN BIOINDICATOR	3 DOMESTIC SAMPLE COLLEC MICRO STERILITY	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (1)	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (2)	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN BIOINDICATOR	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO STERILITY	7 DOMESTIC SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) MRA
NE	HEADQUARTERS									127
	REGIONAL STAFF									
	NEW ENGLAND	3	1							
	NEW YORK	2								42
	REGIONAL LAB									
CE	WEAC			37	34	14	6	25		
	REGIONAL STAFF									
	BALTIMORE	1								
	CHICAGO	2								
	CINCINNATI	2								
	DETROIT	1								
	MINNEAPOLIS	3	2							42
	NEW JERSEY	1								42
	PHILADELPHIA	2								
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	1	1							
	FLORIDA	3	1							42
	NEW ORLEANS	2								
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2	1							42
	DENVER	1	1		76					42
PA	KANSAS CITY	1								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	5	2							42
PA	SAN FRANCISCO	3	1							
	SEATTLE	2								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		5.5	5.5	32.1	62.0	25.0	25.0	72.0		
TOTAL HOURS		204	55	1188	6820	350	150	1800		421
CONVERSION FACTOR		950	950	1180	1180	1180	1180	1180		950
TOTAL OPERATIONAL FTEs		0.21	0.06	1.01	5.78	0.30	0.13	1.53		0.44

9. REMARKS

- (1) Test Kit or Reagent Testing to support GMP observations (CHEM) at WEAC.
- (2) Antisera and Products Media Testing to support GMP observations (MICRO) at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.

Note: Domestic Sample Collections for Contract Sterilizers and/or Bioburden, Bioindicator are to be collected "for cause".

FY 2004 PERFORMANCE GOALS:

- Inspection of Class II and III domestic medical device manufacturers are planned to meet a critical performance goal of the FY 2004 FDA Performance Plan. In the GMP program 1,460 domestic inspections are planned. The FY 2004 Performance Plan's goal is to "utilize risk management to target inspection coverage for Class II and Class III domestic medical device manufacturers at 20 percent of estimated 5,550 firms." (Some inspections in PPS 83 will also contribute to meeting this performance goal.)
- Inspection of Class II and III foreign medical device manufacturers are also planned to meet a critical performance goal of the FY 2004 FDA Performance Plan. In the GMP program 183 foreign inspections are planned. The FY 2004 Performance Plan's goal is to "utilize risk management to target inspection coverage for Class II and Class III foreign medical device manufacturers at 9 percent of estimated 2,500 firms." (Some inspections in PPS 83 will also contribute to meeting this performance goal.)

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 Determine the extent to which manufacturers of condoms comply with the Device GMP requirements; Assure that both domestic and imported condoms comply with the FDA standards.	
5. PROGRAM JUSTIFICATION The Surgeon General has recommended the use of condoms to reduce the spread of AIDS. Consequently, FDA is committed to assuring that condoms are safe and effective.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic condom manufacturers and major repackers. Districts will also sample both domestic and imported condoms and conduct tests to assure conformance with the FDA standard.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 85
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82Z002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.0			
R E G I O N	6. 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 (PHYSICAL)	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D C H E M	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D C H E M (PHYSICAL)	9 O T H E R O P E R A T I O N S (Hours)
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK					27				
	REGIONAL LAB									
CE	WEAC							2	266	
	REGIONAL STAFF									
	BALTIMORE					8				
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS					5				
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1		1	223					
	FLORIDA									
	NEW ORLEANS	1		1	3					
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT					8				
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES					60				
	SAN FRANCISCO					32				
	SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									100	
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		8.0		3.0	2.5			12.2	13.0	
TOTAL HOURS		16		6	915			24	4758	
CONVERSION FACTOR		950		950	950			1180	1180	
TOTAL OPERATIONAL FTEs		0.02		0.01	0.96			0.02	4.03	

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine the extent to which manufacturers of both surgical and examination gloves comply with the Device GMP requirements; 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 transmission of the AIDS virus. Consequently, FDA is committed to assure that both surgical and examination gloves comply with published standards.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic manufacturers. Districts will also sample gloves for testing by the designated laboratories.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 85
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8
		INSP EC T I O N S	INVE ST 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 (PHYSICAL)	FIELD E X A M S/ T E S T S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D E N G	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M	IMP O R T S A M P L E S T O B E A N A L Y Z E D E N G (PHYSICAL)	IMP O R T S A M P L E S T O B E A N A L Y Z E D C H E M (PHYSICAL)
	TOTAL FIELD	2		2	1000		1	1	201	799
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1		1	19					
	NEW YORK				108					
	REGIONAL LAB									
	WEAC						1	1	201	226
CE	REGIONAL STAFF									
	BALTIMORE				27					
	CHICAGO				74					
	CINCINNATI				15					
	DETROIT				2					
	MINNEAPOLIS				16					
	NEW JERSEY									
	PHILADELPHIA				27					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA				93					
	FLORIDA				16					
	NEW ORLEANS	1		1	30					
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT				65					
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES				388					
	SAN FRANCISCO				94					
	SEATTLE				26					
		PACIFIC REGIONAL LABORATORY-SW								573
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	22.0		7.2	3.0		20.0	13.0	7.4	7.4
	TOTAL HOURS	44		14	3000		20	13	1487	5913
	CONVERSION FACTOR	950		950	950		1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.05		0.01	3.16		0.02	0.01	1.26	5.01
9. REMARKS Domestic Samples should only be collected on a for cause basis. Resources to cover Glove Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin. Reporting Guidance: Import Entry Reviews (Electronic & Manual--operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).										

1. PROGRAM/ASSIGNMENT TITLE BSE 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 To enhance FDA's uniformity in inspection and compliance of BSE firms subject to the regulation and to determine compliance with the BSE regulation.	
5. PROGRAM JUSTIFICATION FDA seeks to protect the public through the development of a comprehensive strategy of education, inspection and enforcement action on industry. These activities were initiated to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) regulations.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct inspections of BSE Device Firms to implement the objectives of this assignment.	
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)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE BSE Assignment					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z005			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 1.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INSPEC- TIONS FOREIGN	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		7	7						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1								
	NEW YORK		1							
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	1	1							
	CINCINNATI									
	DETROIT	2	1							
	MINNEAPOLIS	1	1							
	NEW JERSEY		1							
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA	1	1							
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1	1							
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		67.5	67.5							
TOTAL HOURS		473	473							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.50	0.50							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE
Center Initiated Assignments

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
A number of potential or emerging problems which cannot be predicted must be handled rapidly. This workplan activity provides resources for Center assignments which can rapidly address potential or emerging problems.

6. FIELD OBLIGATIONS
Conduct inspections and investigations as directed by Center assignments.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
All Devices

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

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

f. CHECK THE FOLLOWING ATTRIBUTES
Sterility/Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82Z800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1		2	3	5	7	7	7	9
		INSP EC T I O N S	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	FIELD E X A M S/ T E S T S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D M I C R O (1)	DOMESTIC S A M P L E S T O B E A N A L Y Z E D C H E M (2)	DOMESTIC S A M P L E S T O B E A N A L Y Z E D S T E R (3)	OTHER O P E R A T I O N S (Hours) METH DEV ENG (4)
	TOTAL FIELD	40		350	22		2	2	2	850
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	4		34	2					
	NEW YORK	2		19	1					
	REGIONAL LAB									
	WEAC						2	2	2	850
CE	REGIONAL STAFF									
	BALTIMORE	1		10	1					
	CHICAGO	2		17	1					
	CINCINNATI	2		15	1					
	DETROIT	1		13	1					
	MINNEAPOLIS	3		22	1					
	NEW JERSEY	1		12	1					
	PHILADELPHIA	2		16	1					
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2		15	1					
	FLORIDA	3		26	2					
	NEW ORLEANS	2		17	1					
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	2		21	1					
	DENVER	1		11	1					
	KANSAS CITY	1		13	1					
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	6		49	3					
	SAN FRANCISCO	3		23	1					
	SEATTLE	2		17	1					
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		34.5			10.0		50.0	15.0	50.0	
TOTAL HOURS		1380		350	220		100	30	100	850
CONVERSION FACTOR		950		950	950		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.45		0.37	0.23		0.08	0.03	0.08	0.72

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82				
3. PROGRAM/ASSIGNMENT CODE(S) 82R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 0.9			
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			400	700				
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC				700				
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW			400					
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS			400	700				
	CONVERSION FACTOR			1205	1180				
	TOTAL OPERATIONAL FTEs			0.33	0.59				

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related Acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize, and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spend 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 the Operation Code was new in FY 1999. Please consult the Division of Field Science and/or the Division of Planning, Evaluation, and Management for additional reporting guidance.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/A <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) N/A
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis			2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82R838			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.3		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)							
	TOTAL FIELD	360							
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR	360								
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	360							
	CONVERSION FACTOR	1205							
	TOTAL OPERATIONAL FTEs	0.30							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections/510(k) Premarket Approval Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>Medical Device Premarket Approval and Postmarket Inspections: To assure that both prior to and subsequent to approval of a PMA application, the manufacturer has the capability of manufacturing the PMA device in accordance with (1) the conditions specified in the PMA application and (2) the requirements of the device GMP regulation.</p> <p>510(k) Premarket Approval Inspections: 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.</p>	
5. PROGRAM JUSTIFICATION <p>Medical Device Premarket Approval and Postmarket Inspections: 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.</p> <p>510(k) Premarket Approval Inspections: 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.</p>	
6. FIELD OBLIGATIONS <p>Medical Device Premarket Approval and Postmarket Inspections: 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. 510(k) Inspections: On assignment from CDRH, conduct a comprehensive GMP inspection as instructed in the compliance program. Regarding Conformance Standards inspections, conduct inspections based on assignments by the Field Programs Branch: 100% of assignments issued should be completed as high priority. Class II or III devices in the applicable declaration will be covered.</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 checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES 	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING 	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83001, A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	6	7	8	9
		INSPEC- TIONS PRE- APPROVAL 83001	INSPEC- TIONS POST- APPROVAL 83001A	FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	FOREIGN INSPEC- TIONS POST- APPROVAL 83001A	INSPEC- TIONS MDUFMA USER FEE 83001	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	37	66	34	27	64				
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	3	6	2	2	6				
	NEW YORK	1	1	2	2	2				
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1	1		1	2				
	CHICAGO	1	1	2	2	2				
	CINCINNATI	1	1	2	2	2				
	DETROIT	1	1	2	2	1				
	MINNEAPOLIS	4	9	2	1	6				
	NEW JERSEY	2	4	2	2	3				
	PHILADELPHIA	1	1	2		2				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1	6	2	2	2				
	FLORIDA	3	8	2	2	5				
	NEW ORLEANS	1	1	2	1	2				
	SAN JUAN	1	5			2				
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2	5	2	2	4				
	DENVER	2	1	2	2	3				
	KANSAS CITY	1	1	2	1	1				
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	7	8	2	1	12				
	SAN FRANCISCO	3	5	2	1	5				
	SEATTLE	1	1	2	1	2				
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	44.0	30.0	50.7	49.4	44.0				
	TOTAL HOURS	1628	1980	1724	1334	2816				
	CONVERSION FACTOR	950	950	950	950	950				
	TOTAL OPERATIONAL FTEs	1.71	2.08	1.81	1.40	2.96				

9. REMARKS

Report all time used for evaluating compliance with domestic pre-market requirements in PAC 83001, OP CODE 12;
 report all time used 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;
 report all time used for foreign post-market requirements in PAC 83001A, OP CODE 11.

Domestic and Foreign 510(k) pre-market inspections have been canceled for FY 2004 due to Budget reductions. Also, Design Control Inspections have been canceled for FY 2004 due to Budget reductions.

1. PROGRAM/ASSIGNMENT TITLE
Bioresearch Monitoring

2. PPS PROJECT NAME/NUMBER
Product Evaluation: Devices - 83

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To assure the quality, reliability and integrity of data and information supporting device applications (PMAs, 510(k)s or IDEs) and their claims of safety and effectiveness;
To ensure that human subjects taking part in clinical trials involving medical devices are protected from undue hazard or risk;
To coordinate, implement and enforce the provisions of the Agency's Application Integrity Policy (AIP) for medical devices;
To enforce the prohibition against promotion and/or commercialization of investigational devices.

5. PROGRAM JUSTIFICATION

Congress has mandated that the Agency maintain close surveillance of bioresearch activities done in support of application.

CDRH issues assignments and provides inspectional/investigational support documents for transmission to the field through ORA's Office of Enforcement (HFC-230). The Center reviews and evaluates all Establishment Inspection Reports (EIRs) from the field and is responsible for the final classification of all bioresearch monitoring inspection reports and the issuance of all associated correspondence.

6. FIELD OBLIGATIONS

To conduct inspections, investigations and other activities related to the bioresearch monitoring programs or the Agency's Application Integrity Policy for medical devices and to submit EIRs to the Center for review, evaluation and final classification.

The field is encouraged to review and initially classify inspection reports generated under the bioresearch monitoring program. However, final classification authority rests with the Center and decisions will be communicated promptly to the field.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
All Medical Devices

d. INDUSTRY/PRODUCT CODE(S)
73Z, 74Z and 94Z, 95Z

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring (Pre-Market)					2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83					
3. GRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 23.3			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	7	8	9
		INSPEC- TIONS (GLPs)	INSPEC- TIONS (IRBs)	INSPEC- TIONS (SPON/MON)	INSPEC- TIONS (CLINICAL INVEST)	INSPEC- TIONS (SPON/MON) FOREIGN	INSPEC- TIONS (CLINICAL INVEST) FOREIGN	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	18	84	63	126	2	12			
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		6	4	6		1			
	NEW YORK		2	3	6	1	1			
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		4	4	7					
	CHICAGO		4		3					
	CINCINNATI	5	5	1	10		1			
	DETROIT	1	9	1	7					
	MINNEAPOLIS		6	8	5		2			
	NEW JERSEY	3	4	2	1					
	PHILADELPHIA		4	3	7					
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	2	3	2	10					
	FLORIDA		5	4	7		1			
	NEW ORLEANS		7	2	11		2			
	P.R. JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	3	6	2	13					
	DENVER		2	2	4		1			
	KANSAS CITY		2		7		2			
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1	7	19	14		1			
	SAN FRANCISCO	2	4	6	4	1				
	SEATTLE	1	4		4					
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	82.0	52.0	87.0	79.0	35.0	68.0			
	TOTAL HOURS	1476	4368	5481	9954	70	816			
	CONVERSION FACTOR	950	950	950	950	950	950			
	TOTAL OPERATIONAL FTEs	1.55	4.60	5.77	10.48	0.07	0.86			

9. REMARKS

FY 2004 PERFORMANCE GOAL:

GLP, IRB, Sponsor/Monitor, and Clinical Investigator Domestic Inspections are planned to meet a critical performance goal of the FY 2004 FDA Performance Plan. In FY 2004, 304 BIMO inspections overall are planned; the FY 2004 Performance Plan's goal is to "conduct 295 BIMO inspections with an emphasis on vulnerable populations."

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 COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To evaluate the quality of devices through product analysis and data evaluation.

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

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

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) To be assigned	d. INDUSTRY/PRODUCT CODE(S) 73-91
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e. EXAM TYPE: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE 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 5.2			
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	9 OTHER OPERATIONS (Hours) METH DEV CHEM	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	TOTAL FIELD								660	1495
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC							660	1495	3930
	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									
PA	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS								660	1495	3930
CONVERSION FACTOR								1180	1180	1180
TOTAL OPERATIONAL FTEs								0.56	1.27	3.33
9. REMARKS Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by the CDRH Laboratory Staff.										

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

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM/ASSIGNMENT CODE(S) 84R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 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								
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				1660				
	CONVERSION FACTOR				1180				
	TOTAL OPERATIONAL FTEs				1.41				

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To inspect certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA); To bring uncertified facilities into compliance with MQSA.	
5. PROGRAM JUSTIFICATION MQSA (Public Law 102-539) establishes uniform, national quality standards for mammography. It establishes a comprehensive statutory mechanism for certification and inspection of all mammography facilities under the regulatory jurisdiction of the United States. Under the MQSA, only certified facilities that are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation starting October 1, 1994. Operation after that date is contingent on receipt of a certificate from the FDA. The authority to implement the MQSA was delegated by the Secretary of Health and Human Services (HHS) to FDA in June 1993.	
6. FIELD OBLIGATIONS Inspect certified mammography facilities in accordance with procedures specified in the compliance program. Conduct followup inspections to determine whether the facility has complied with the terms of their corrective action plan, based on noncompliances found during a prior inspection. Perform on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections. Conduct investigations of suspected uncertified mammography facilities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Mammography equipment	d. INDUSTRY/PRODUCT CODE(S) 90
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.7 [8.0]
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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)	OT H E R O P E R A T I O N S (Hours)	OT H E R O P E R A T I O N S (Hours)
		85014 (1)	85014F (2)	85014 (3)	85014 (4)	85014 (5)	85014A (6)	85014 (7)	85014C (8)	85014 (9)
	TOTAL FIELD	196	36	122	35	15	2398	50	468	3048
	HEADQUARTERS									
NE	REGIONAL STAFF							10		
	NEW ENGLAND	47	2	3	1	5	154		26	173
	NEW YORK		2	1	3		198		26	246
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF							10		
	BALTIMORE		2	13	2		132		26	150
	CHICAGO			2	1		110			
	CINCINNATI		2	3	1		154		26	214
	DETROIT		2	1			154		26	192
	MINNEAPOLIS		2	7			143		26	189
	NEW JERSEY		2	2			55		26	75
	PHILADELPHIA		2	2	1		121		26	150
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF							10		
	ATLANTA		2	14	3	5	132		26	223
	FLORIDA		2	6	6		121		26	160
	NEW ORLEANS		2	7	3		143		26	220
	SAN JUAN	3	2	1		5	33		26	25
	REGIONAL LAB									
SW	REGIONAL STAFF	141	6	27	6		363	10	78	540
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF							10		
	LOS ANGELES		2	14	2		99		26	208
	SAN FRANCISCO	5	2	9	6		176		26	149
	SEATTLE		2	10			110		26	134
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	8.0	11.0	8.0	8.0	8.0				
	TOTAL HOURS	1568	396	976	280	120	2398	50	468	3048
	CONVERSION FACTOR	1160	1160	1160	1160	1160	1160	1160	1160	1160
	TOTAL OPERATIONAL FTEs	1.35	0.34	0.84	0.24	0.10	2.07	0.04	0.40	2.63

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.
- 5) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries.
- 6) Audit Investigations.
- 7) Investigations of Uncertified Mammography Facilities.
- 8) Compliance Activities.
- 9) Technical Assistance and Coordination Activities.

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 16.7 [8.6]
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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 85014F (10)	INVESTI- GATIONS (Hours) 85014F (11)	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) 85014 (12)
	TOTAL FIELD	72	8043							1200
NE	HEADQUARTERS									200
	REGIONAL STAFF									
	NEW ENGLAND	4	392							
	NEW YORK	4	945							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									400
	BALTIMORE	4	413							
	CHICAGO									
	CINCINNATI	4	574							
	DETROIT	4	511							
	MINNEAPOLIS	4	399							
	NEW JERSEY	4	343							
	PHILADELPHIA FORENSIC CHEM. CTR	4	329							
SE	REGIONAL STAFF									200
	ATLANTA	4	490							
	FLORIDA	4	245							
	NEW ORLEANS	4	434							
	SAN JUAN REGIONAL LAB	4	161							
SW	REGIONAL STAFF	12	1197							200
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									200
	LOS ANGELES	4	658							
	SAN FRANCISCO	4	546							
	SEATTLE	4	406							
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	11.0								
	TOTAL HOURS	792	8043							1200
	CONVERSION FACTOR	1160	1160							1200
		0.68	6.93							1.00

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

10) Follow-up Inspection after warning letter

11) Inspection Follow-Up Activities (Non-Warning Letter).

12) Technical Assistance and Coordination Activities: RRHRs.

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Inspection of Manufacturers of Laser Products: To determine if laser products are in compliance with the radiation safety emissions and other requirements of the "laser performance standard." Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: To conduct a field enforcement program to determine the compliance of sunlamp and sunlamp products with both the performance standard and Agency issued recommendations.	
5. PROGRAM JUSTIFICATION Inspection of Manufacturers of Laser Products: 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. Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: 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 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 and other skin cancers.	
6. FIELD OBLIGATIONS Inspection of Manufacturers of Laser Products: Field personnel will initiate and schedule their own inspections of laser manufacturers listed in the compliance program. In addition, they will participate on joint CDRH/ORR inspections when such inspections are scheduled by the Center. Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: 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 products in suntanning facilities per the guidance set out in the compliance program. In addition, in that most states and local radiological health bureaus have no regulation on these products, the field should establish communications with them and offer assistance if they choose to develop such regulations.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Lasers and laser products Sunlamp, suntanning booths, and sunlamp products.	d. INDUSTRY/PRODUCT CODE(S) 95LS-99 95 US-11
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Sunlamp Products: The investigator should use the inspectional Check-List (Review of Product Compliance) located in the compliance program when conducting field tests under this compliance program.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING <i>Caution:</i> laser product <i>may</i> be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.	

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.7 [6.2]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	2	3	3	5	5
		INSP CTIONS 86001 (1)	INSP CTIONS FOREIGN 86001 (2)	INSP CTIONS 86002 (3)	INVESTI GATIONS (Hours) 86001 (4)	INVESTI GATIONS (Hours) 86002	DOMESTIC SAMPLE COLL 86001	DOMESTIC SAMPLE COLL 86002	FIELD EXAMS/ TESTS 86001 (5)	FIELD EXAMS/ TESTS 86002 (6)
	TOTAL FIELD	133	15	7	2101	90	6	3	100	56
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	13		1	204	4	1	1	10	3
	NEW YORK	7			104				5	4
	REGIONAL LAB									
	WEAC		15							
CE	REGIONAL STAFF									
	BALTIMORE	4			71	5			3	3
	CHICAGO	5		1	73	4			3	2
	CINCINNATI	5		1	75	5		1	4	3
	DETROIT	6			99	5			5	3
	MINNEAPOLIS	6			95	4			4	2
	NEW JERSEY	4		1	64	3			3	2
	PHILADELPHIA	4			70	4			3	3
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	6		1	98	6		1	5	4
	FLORIDA	8		1	122	5	1		6	3
	NEW ORLEANS	3			44	7			2	4
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	7			104	9			5	6
	DENVER	6			96	2			5	1
	KANSAS CITY	4		1	57	4			3	3
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	36			575	8	3		27	5
	SAN FRANCISCO	2			34	5			2	3
SEATTLE	7			116	4	1		5	2	
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	18.4	14.6	13.8			3.0	2.0	6.2	6.2
	TOTAL HOURS	2447	219	97	2101	90	18	6	620	347
	CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	2.58	0.19	0.10	2.21	0.09	0.02	0.01	0.65	0.37

9. Remarks

Inspection of Manufacturers of Laser Products:

- 1) Comprehensive Inspections can only be claimed for manufacturers of radiation-emitting products on a recurring basis.
- 2) Number of inspections for Engineering Analyst.
- 4) Investigation Hours--refer to Compliance Program for reporting information.
- 5) Will include laser products located at a user facility and laser light shows.
- 7) To include all other activities such as technical assistance, coordination, and training.

Sunlamps and Sunlamp Products:

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

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

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products					2. PPS PROJECT NAME/NUMBER Optical Electronic Products					
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.7 [1.5]				
R E G I O N	6.	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVE ST I G A T I O N S (Hours)	DOMESTIC SAMPLE COLL	IMP O R T S A M P L E C O L L	FIELD EXA M S/ T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC SAMP 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) 86001 (7)	OTHER O P E R A T I O N S (Hours) 86002
	TOTAL FIELD								1216	216
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND							118	22	
	NEW YORK							60	5	
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE							41	11	
	CHICAGO							42	16	
	CINCINNATI							44	33	
	DETROIT							57	11	
	MINNEAPOLIS							55		
	NEW JERSEY							37	16	
	PHILADELPHIA							40	5	
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA							57	27	
	FLORIDA							71	16	
	NEW ORLEANS							25	5	
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS							60	11	
	DENVER							56		
	KANSAS CITY							33	22	
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES							333	11	
	SAN FRANCISCO							20	5	
SEATTLE							67			
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION										
TOTAL HOURS								1216	216	
CONVERSION FACTOR								950	950	
TOTAL OPERATIONAL FTEs								1.28	0.23	

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Field Compliance Testing of Diagnostic X-Ray Equipment: To determine if certified dental and medical x-ray diagnostic equipment meet the Federal performance requirement for diagnostic x-ray equipment (21 CFR 1020.30), in order to monitor the compliance of x-ray equipment component manufacturers and assemblers. Field Compliance Testing of Cabinet X-Ray Equipment: To determine compliance with the performance standard for cabinet x-ray equipment with respect to radiation emissions under conditions of use.	
5. PROGRAM JUSTIFICATION Field Compliance Testing of Diagnostic X-Ray Equipment: 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. Field Compliance Testing of Cabinet X-Ray Equipment: Under the authority of Public Law 90-602 FDA published a performance for cabinet x-ray equipment which became effective on April 10, 1975, (and on April 25, 1974, for carry-on baggage systems). This performance standard is designed to control the emission levels of radiation from cabinet x-ray systems and baggage x-ray equipment and to assure that radiation exposure will be reduced to, or maintained at, acceptable levels in accessible areas from those systems manufactured after the effective date of the standard. In addition, the standard will have the effect of minimizing incidences of system failure and associated excessive radiation exposure.	
6. FIELD OBLIGATIONS Diagnostic X-Rays: 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. Cabinet X-Rays: Districts will conduct record reviews of manufacturers in their inventory to determine locations of cabinet x-ray systems. Identified site locations will be sent to appropriate DDs so they can schedule field tests. Field personnel will conduct tests at locations identified by the district. Each site shall be investigated per the instructions of the compliance program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Diagnostic X-Ray Equipment Cabinet x-ray and baggage x-ray	d. INDUSTRY/PRODUCT CODE(S) 94DS--- 94 IS-11 94 IS-21
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROCANALYTICAL <input type="checkbox"/> OTHERS (Specify)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Diagnostic X-Rays: Field tests will be performed by consumer safety officers who have received specialized training which includes approximately two weeks of on-the-job training with a qualified auditor.	

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86003, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 11.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	2	5	5	5B	8	9
		INSP CTIONS 86003	INSP CTIONS 86004	INVEST GATIONS (Hours) 86003	INVEST GATIONS (Hours) 86004	FIELD EXAMS/ TESTS 86003	FIELD EXAMS/ TESTS 86004	AUDITS 86003	IMPOR T SAMPL ES TO BE AN ALYZED	OTHER OPERATIONS (Hours) 86003
TOTAL FIELD		18	28	980	227	946	285	85		4105
HEADQUARTERS										
REGIONAL STAFF										
NE	NEW ENGLAND	1	2	38	37	40	15	4		183
	NEW YORK	2	2	43	23	32	33	2		174
	REGIONAL LAB									
	WEAC									
REGIONAL STAFF										
CE	BALTIMORE	1		51		46	42	6		203
	CHICAGO	1	4	38	18	12	10	6		174
	CINCINNATI	1	1	55	5	27	17	4		238
	DETROIT		2	49	14	82	12	4		195
	MINNEAPOLIS		1	55	5	20	9	6		234
	NEW JERSEY		1	23	5	39	6			106
	PHILADELPHIA	2	1	42	5	33	10	6		187
	FORENSIC CHEM. CTR									
REGIONAL STAFF										
SE	ATLANTA		2	84	23	133	17	4		331
	FLORIDA	1	2	74	18	74		2		286
	NEW ORLEANS	2	1	81	18	75	5	8		376
	SAN JUAN			2		5	3	1		36
	REGIONAL LAB									
REGIONAL STAFF										
SW	DALLAS	2	1	122		119	22	8		436
	DENVER		1	35	5	31	8	8		162
	KANSAS CITY	1	1	56	5	57	5	6		226
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
REGIONAL STAFF										
PA	LOS ANGELES	2	3	62	23	62	46	4		228
	SAN FRANCISCO	1	2	33	18	26	15	4		158
	SEATTLE	1	1	37	5	33	10	2		172
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		16.4	10.0			3.0	4.9	4.0		
TOTAL HOURS		295	280	980	227	2838	1397	340		4105
CONVERSION FACTOR		950	950	950	950	950	950	950		950
TOTAL OPERATIONAL FTEs		0.31	0.29	1.03	0.24	2.99	1.47	0.36		4.32

9. REMARKS

* CSO trained for surveying X-Ray equipment. Inspections to be performed during first quarter of fiscal year.

Planning guidance:

1st quarter: Contact all X-Ray manufacturers in the District, and conduct an onsite inspection of 50% of the manufacturers (rather than phone contact only).

2nd quarter: Complete one-third of field tests.

3rd quarter: Complete two-thirds of field tests.

4th quarter: Complete remaining field tests.

Counter Terrorism PAC 86R845 is no longer used for planning purposes, but is still active for reporting purposes.

Diagnostic X-Rays (86003):

1) Inspections are spread based on the number of x-ray assemblers. Inspections are for compliance follow-up only.

2) Investigation hours are for review of assembler reports.

3) Field Tests and Audits are obtained from Attachment A, and are provided by CDRH's Compliance X-Ray Products Branch, Z 300 (Henry Knox). Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor to verify both Federal and State data.

4) Other Operations includes Coordination/Technical Assistance resources for Field Test Review.

Sources of Diag. X-Ray Workloads: Inspections are based on the OEI of Diag. X-Ray Assemblers; Investigation Hours are based on reviewing 2579 Reports (Assembler Reports of X-Ray Equip. Installations); Coordination Hours are based on the Total Field Test Records to review.

ATTACHMENT A
2004 WORKPLAN FOR FIELD COMPLIANCE TESTING
OF DIAGNOSTIC X-RAY SYSTEMS
(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2004)

NEW ENGLAND DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CT	77	-	14	1	-
ME	41	8	-	1	2
MA	178	20	10	1	-
NH	45	-	8	-	-
RI	36	8	-	1	2
VT	15	-	4	-	-
Total	392	36	36	4	4

NEW YORK DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NY	437	40	30	2	2

BALTIMORE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DC	35	-	5	-	-
MD	179	20	9	1	2
VA	254	10	29	1	2
WV	57	10	-	1	2
Total	525	40	43	3	6

CHICAGO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IL	392	60	10	2	6

CINCINNATI DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
KY	159	30	-	1	2
OH	404	46	24	2	2
Total	563	76	24	3	4

DETROIT DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IN	240	-	38	1	4
MI	264	-	42	1	-
Total	504	-	80	2	4

MINNEAPOLIS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
MN	226	35	4	2	2
ND	30	6	-	1	2
SD	39	-	6	-	-
WI	270	40	5	2	2
Total	565	81	15	5	6

NEW JERSEY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NJ	232	-	38	1	-

PHILADELPHIA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DE	24	-	5	1	-
PA	409	45	25	2	6
Total	433	45	30	3	6

ATLANTA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
GA	292	-	47	2	-
NC	367	15	45	2	2
SC	201	-	36	1	2
Total	860	15	128	5	4

FLORIDA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
FL	755	52	70	4	2

NEW ORLEANS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AL	226	20	36	2	2
LA	176	25	8	1	2
MS	133	25	-	1	2
TN	293	25	25	2	2
Total	828	95	69	6	8

SAN JUAN DISTRICT

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

DALLAS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AR	121	-	20	1	-
OK	146	-	24	1	-
TX	977	80	68	5	8
Total	1244	80	112	7	8

DENVER DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CO	180	10	20	1	4
NM	65	15	1	1	2
UT	86	10	2	1	2
WY	24	-	4	1	-
Total	355	35	27	4	8

KANSAS CITY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IA	142	15	7	1	2
KS	120	15	5	1	2
NE	90	10	4	1	2
MO	222	-	36	2	-
Total	574	40	52	5	6

LOS ANGELES DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AZ	210	-	33	1	-
CA	420	36	26	2	4
Total	630	36	59	3	4

SAN FRANCISCO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CA	214	24	8	1	2
HI	26	14	-	1	2
NV	92	-	15	1	-
Total	332	38	23	3	4

SEATTLE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AK	27	-	4	-	-
ID	50	10	-	1	-
MT	38	-	7	-	-
OR	86	12	3	1	-
WA	181	16	16	1	2
Total	382	38	30	3	2

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure, through laboratory testing, that electronic products meet the FDA performance standards.	
5. PROGRAM JUSTIFICATION Public Law 90-602 and subsequent regulations (21 Subchapter J) are intended to safeguard the public from radiation hazards associated with electronic products. The Act specifically authorizes the Secretary to promulgate performance standards imposing additional requirements on specific electronic products of special concern from a radiation safety standpoint. Such performance standards have been issued: Microwave ovens (21 CFR 1030.10); dental, portable and mobile x-ray equipment (21 CFR 1020.30); ultrasonic therapy devices (21 CFR 1050.10); and television receivers (21 CFR 1020.10); sunlamp and mercury vapor lamps (21 CFR 1040.20, 1040.30).	
6. FIELD OBLIGATIONS WEAC will test all products in accordance with the appropriate compliance program circular and submit each report to the Center. WEAC will return equipment to lenders when advised by the Center. In addition, WEAC will advise the Center with the status of all equipment on hand, being tested and returned to lenders. WEAC will conduct inspections to confirm conformance to the Radiological Health Standards Act.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Microwaves, TV Receivers, Diagnostic X-Ray Equipment, Mercury Vapor/Sunlamp, Ultrasonic Therapy Equipment	d. INDUSTRY/PRODUCT CODE(S) 96MS, 94VS, 94DS, 95US, 97US
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.2				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS (PL 90-602 STANDARD)	7 DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	7 DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY SOURCE	7 DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS	9 OTHER OPERATIONS (Hours)		
	TOTAL FIELD	12	52	27	4	1	18			
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC	12	52	27	4	1	18			
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		80.0	32.0	41.0	240.0	105.0	8.0			
TOTAL HOURS		960	1664	1107	960	105	144			
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs		0.81	1.41	0.94	0.81	0.09	0.12			
9. REMARKS All samples to be shipped by distributors/manufacturers to WEAC. -Diagnostic X-Ray Whole - For analysis of entire diagnostic X-Ray systems for compliance; Source - Leakage test of diagnostic source assembly only. Foreign Inspections--PL 90-602 Standard Inspections: Report accomplishments in PAC 86006; To ensure conformance to Rad Health Standards; to be conducted by Engineering Analyst.										

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that imported electronic products presented for entry into the U.S. are certified to be in compliance with appropriate standards where applicable. To provide a mechanism through which imported electronic products found to be in noncompliance with FDA regulations can be precluded from introduction into commerce in the United States.	
5. PROGRAM JUSTIFICATION FDA under the authority of Public Law 90-602 conducts program effort to minimize the effects of harmful radiation from electronic products and radiation emitting medical devices. The Act is very specific about restrictions and safeguards concerning such electronic products from foreign countries.	
6. FIELD OBLIGATIONS The district import program manager will monitor all custom entries of electronic products for which performance standards are in effect and determine whether imported models are contained on lists provided by CDRH and that these models are not among those which have been determined to be noncompliant. All information gathered as a result of these activities will be furnished to the Office of Compliance in accordance with the compliance program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All electronic products or devices that emit radiation.	d. INDUSTRY/PRODUCT CODE(S) 94-97
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
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 5.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI- GATIONS (Hours)	2 ENTRY REVIEW (Hours)	4 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		5850	500			200			
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		78	20						
	NEW YORK		617	85			24			
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE		23	19						
	CHICAGO		216	24			13			
	CINCINNATI		152	14						
	DETROIT		426	16			17			
	MINNEAPOLIS		37	12						
	NEW JERSEY									
	PHILADELPHIA		31	10						
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		132	32			10			
	FLORIDA		137	37						
	NEW ORLEANS		478	14			16			
	SAN JUAN		11	4						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		1916	102			66			
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES		646	59			30			
	SAN FRANCISCO		237	25						
	SEATTLE		713	27			24			
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION						0.60			
	TOTAL HOURS		5850	500			120			
	CONVERSION FACTOR		1200	950			950			
	TOTAL OPERATIONAL FTEs		4.88	0.53			0.13			

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).

Investigation Hours Based On:

- **Import Entry Review Hours (Electronic and Paper):**
 - APR 1, 2002 - MAR 31, 2003 Electronic Entry Review Hours Reported Under 86R833;
 - APR 1, 2002 - MAR 31, 2003 Entry Review Investigation Hours (Operation 14) Reported Under 86007.
- **Import Filer Evaluation Hours:**
 - APR 1, 2002 - MAR 31, 2003 Total Hours Reported in PODS; These hours are multiplied by 7% (ad Health's Percentage of the Total PODS Hours).

Not to Be Planned; Reporting PACS To Be Sent To Field.

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <u>Use Control:</u> Provide technical assistance to State and Federal radiological health programs implementing FDA use control programs, including DENT (see the compliance program for a more complete statement of objectives and laboratory support); Maintain liaison with State radiological health programs; Provide support for regional training activities and regional videotape library; Promote implementation of programs to optimize radiation exposure; Communicate FDA policies to State and local health agencies. <u>Emergency Planning & Response Activities:</u> To act as a focal point for emergency readiness response planning by States.	
5. PROGRAM JUSTIFICATION <u>Medical Device and Radiological Health Use Control and Policy Implementation:</u> 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. <u>Emergency Planning & Response Activities:</u> The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.	
6. FIELD OBLIGATIONS <u>Use Control:</u> RRHRs will maintain liaison and provide technical assistance to State/Federal radiological health program personnel; assist in the planning and presentation of quality assurance training with the region; help select State participants in new use control programs; serve as managers of the regional videotape library; and attend the following meetings: National Conference of State Program Directors; Regional meetings with state and local radiological health agencies; and Rockville, MD HQ annual meetings with CDRH, ORA and other FDA officials. WEAC will provide Laboratory Support for the DENT programs. <u>Emergency Planning & Response Activities:</u> Provide consultation to states and attend regional emergency planning meetings.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH <u>Emergency Planning & Response Activities</u>	
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) <u>Emergency Planning & Response Activities:</u> 94YN-99
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4		9	9	9	9
		INSP EC T I O N S	INVE ST 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		TECHNICAL A S S I S T A N C E (Hours) RRHR	TECHNICAL A S S I S T A N C E (Hours) CSO	MISC (Hours) DENT *	MISC (Hours) RRHR **
	TOTAL FIELD						86009 1200	86009 1305	86008 750	86008 4800
NE	HEADQUARTERS									
	REGIONAL STAFF						200	200		800
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC								750	
CE	REGIONAL STAFF						400	400		1600
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF						200	200		800
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF						200	200		800
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF						200	125		800
	LOS ANGELES							100		
	SAN FRANCISCO									
	SEATTLE							80		
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS							1200	1305	750	4800
CONVERSION FACTOR							1200	950	1180	1200
TOTAL OPERATIONAL FTEs							1.00	1.37	0.64	4.00

9. REMARKS

Counter Terrorism PAC 86R845 is no longer used for planning purposes, but is still active for reporting purposes.

86010, the Federal Facilities Survey Program, has been cancelled and its resources reassigned to other activities.

See Continuation Sheet for footnotes, guidance, etc.

CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

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

9. Remarks

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

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

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

** RRHR time for CDRH programs is planned under this program, the Emergency Response and Planning Activities program, and the Mammography Facilities Inspection Program; 1200 hours will be shown in Mammography.

A portion of this total block of time per RRHR position includes Federal/State liaison activities and use consultation to conduct this program.

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

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

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

FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):

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

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