

**CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2007 ORA WORKPLAN
October 1, 2006**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES	PROGRAM FTES			TOTAL PROGRAM FTES
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	276.5	34.5	43.0	354.0	478.9	59.6	74.5	613.0
46	NEW DRUG EVALUATION	12.3		15.0	27.3	21.3		26.0	47.3
48	BIORESEARCH MONITORING HUMAN DRUGS	49.0		3.0	52.0	84.8		5.2	90.0
52	GENERIC DRUG EVALUATION	15.0		9.0	24.0	26.0		15.6	41.6
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	8.0		1.0	9.0	13.9		1.7	15.6
56	DRUG QUALITY ASSURANCE	171.2	34.5	15.0	220.7	296.5	59.6	26.0	382.1
63	UNAPPROVED AND MISBRANDED DRUGS	9.0			9.0	15.6			15.6
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0	20.8			20.8

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

FY 2007

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

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations -Domestic (PDUFA)	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
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3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46832M <input checked="" type="checkbox"/>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3		7	7	7
		NDAs TO INSPECT (Domestic)	CHEMIST INSPECT (HOURS) (Domestic) *	INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) **	DSAs METH. VALID. (MICRO)	DSAs METH. VALID CHEM	
	TOTAL FIELD	112	2275		30		30	6	15
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	5			1				
	NEW YORK	10			3				
	REGIONAL LAB		418				9	1	
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	7			2				
	CHICAGO	6			2				
	CINCINNATI	6			2				
	DETROIT	4	80		1				
	MINNEAPOLIS	6			2				
	NEW JERSEY	20			4				
	PHILADELPHIA	6	872		2				10
	FORENSIC CHEM. CTR						21		
SE	REGIONAL STAFF								
	ATLANTA	5			2				
	FLORIDA	1							
	NEW ORLEANS	2							
	SAN JUAN	10	261		3				3
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS	4			1				
	DENVER	5	135		1			5	
	KANSAS CITY	3	205		1				
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	8			2				
	SAN FRANCISCO	4			1				
	SEATTLE								
	PACIFIC REGIONAL LAB - SW		170						2
PACIFIC REGIONAL LAB - NW		134							
HOURS PER OPERATION		56.0			5.0		50.0	105.0	105.0
TOTAL HOURS		6272	2275		150		1500	630	1575
CONVERSION FACTOR		950	950		950		1180	1180	1180
TOTAL OPERATIONAL FTES		6.60	2.39		0.16		1.27	0.53	1.33

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

FY 2007

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

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46						
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C, 46832D			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 15.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS ++ FOREIGN	1 CHEMIST INSPS (Hours) FOREIGN **						9 OTHER OPERATIONS (Hours)
TOTAL FIELD		190	3325						
NE	HEADQUARTERS	11							
	REGIONAL STAFF								
	NEW ENGLAND	9							
	NEW YORK	15							
	REGIONAL LAB		749						
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE	3							
	CHICAGO	9							
	CINCINNATI	9							
	DETROIT	6							
	MINNEAPOLIS	9							
	NEW JERSEY	21							
PHILADELPHIA	9	573							
SE	FORENSIC CHEM. CTR		143						
	REGIONAL STAFF								
	ATLANTA	13							
	FLORIDA	6							
	NEW ORLEANS	6							
SW	SAN JUAN	18	429						
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS	6							
	DENVER	6	286						
PA	KANSAS CITY	13	573						
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	9							
PA	SAN FRANCISCO	6							
	SEATTLE	6							
	PACIFIC REGIONAL LAB - SW		286						
	PACIFIC REGIONAL LAB - NW		286						
HOURS PER OPERATION		57.5							
TOTAL HOURS		10925	3325						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		11.50	3.50						
7. REMARKS * Report as follows: Insp./Chem on Insp. under foreign operation code 11, Pac Code 46832; M. Valid.-46832; Profile ISCs & ISAs - 46832B; Biotest ISCs & ISAs (not planned) if collected -46832C. ** Includes microbiologists on inspections. + + Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).									

PROJECT SUMMARY SHEET FY 2007 ORA WORKPLAN

1. PROGRAM CATEGORY Human Drugs	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		49.0		3.0	52.0	90.0	
1	In Vivo Bioequivalence - ANDAs & NDAs	48001,A	5.0			5.0	8.7	2-3
	PDUFA (NDAs)		(3.0)					
	Foreign Inspections (In Vivo Bioequivalence, GLPs, Clinical Investigators)	48001,A; 48808; 48811			3.0	3.0	5.2	4-5
	National Experts PDUFA				(0.4)			
	Field PDUFA				(1.3)			
	* Foreign Inspections PEPFAR (AIDS Relief) (planned under 48001A and 48001)	48001D,E;						
	National Experts (NDAs & ANDAs 0.1)	48811D						
2	Bioresearch Monitoring							6-11
	Good Laboratory Practices (Non-Clinical Lab)	48808	5.0			5.0	8.7	
	National Experts		(0.4)					
	** Institutional Review Board	48809, 48809A	8.0			8.0	13.7	
	Sponsors, Contract Research Organizations, and Monitors	48810	2.7			2.7	4.7	
	Clinical Investigators	48811	28.3			28.3	49.0	
	National Experts		(0.4)					

* PEPFAR work is not planned separately, NDA PEPFAR resources are planned under 48001A and ANDA PEPFAR resources are planned under 48001.

** Resources in the Radioactive Drug Research Committee (48809A) have been collapsed into Institutional Review Board (48809).

CENTER PROJECT MANAGER/TELEPHONE
Joanne L. Rhoads, (301) 594-0020

ORA PLANNER/TELEPHONE
Carrie M. Mampilly, (301) 827-1635

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.	
5. PROGRAM JUSTIFICATION Bioequivalence studies are conducted mainly by private and university affiliated contract laboratories. Previous inspections noted deviations from protocols, poor recordkeeping, inadequate controls over test subjects, poor analytical procedures and fraud. Results of bioequivalence inspections have a direct relationship to approvability of NDA and ANDA applications.	
6. FIELD OBLIGATIONS Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60 , 61
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (Pre-Approval)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48							
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)			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 48001 ANDA INSP EC T I O N S D O M E S T I C	1 48001A NDA INSP EC T I O N S (P D U F A) D O M E S T I C	2 I M P O R T I N V E S T I G A T I O N H O U R S	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	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
	TOTAL FIELD	30	36							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		1							
	NEW YORK	1	1							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1	2							
	CHICAGO	1	1							
	CINCINNATI	1	1							
	DETROIT	1	1							
	MINNEAPOLIS	2	3							
	NEW JERSEY	2	2							
	PHILADELPHIA	2	2							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	3							
	FLORIDA	2	3							
	NEW ORLEANS		1							
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	6	6							
	DENVER		1							
	KANSAS CITY	4	3							
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3	4							
	SAN FRANCISCO	1	1							
	SEATTLE	1								
PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		65.0	78.5							
TOTAL HOURS		1950	2826							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.05	2.97							

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) 41%, PDUFA 48001A (NDA) 59%.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE
Foreign Inspections

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

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

The President's Emergency Plan for AIDS Relief (PEPFAR) requires inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs. Data audit under PEPFAR will be verified by on site inspections.

6. FIELD OBLIGATIONS

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

The audit of data from bioequivalence manufacturers and clinical studies will be verified.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:
 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

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 Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3. PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48811; 48001D,E; 48811D NDA &, ANDA *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSP EC- TIONS (PDUFA)	1 FOREIGN 48001 ANDA INSP EC- TIONS (PRE-APPR)	2 IMPORT INVESTIGATION HOURS	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9
	TOTAL FIELD	25	19						
	HEADQUARTERS	6							
NE	REGIONAL STAFF								
	NEW ENGLAND	3							
	NEW YORK		2						
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	2							
	CHICAGO								
	CINCINNATI		2						
	DETROIT								
	MINNEAPOLIS	2							
	NEW JERSEY		2						
	PHILADELPHIA	2							
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA	2	2						
	NEW ORLEANS	2	1						
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS		2						
	DENVER								
	KANSAS CITY	2	2						
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES	2	2						
	SAN FRANCISCO		2						
	SEATTLE	2	2						
	PACIFIC REGIONAL LAB (SW)								
	PACIFIC REGIONAL LAB (NW)								
	HOURS PER OPERATION	62.7	67.7						
	TOTAL HOURS	1568	1286						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	1.65	1.35						
7. REMARKS * Planned inspections include: 48001,A In Vivo Bioequivalence, 48811 Clinical Investigators, 48808 GLPs (PDUFA), PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence, and 48811D PEPFAR Clinical Investigator. Report Inspections under Appropriate PAC, Foreign Inspections under Operation Code 11. HIGH PRIORITY for NDA inspections. ** President's Emergency Plan for AIDS Relief (PEPFAR): 48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator. NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001. We are not planning separate PEPFAR work. Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs. Data audit under PEPFAR will be verified by on site inspections. Personnel Types Required: Investigator, National Expert									

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Nonclinical Laboratory)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure compliance with current Good Laboratory Practice Regulations (21 CFR 58) by nonclinical laboratories and to assure validity of data through associated data audits.	
5. PROGRAM JUSTIFICATION Animal Studies are vital prerequisites to human clinical trials of drugs and other FDA regulated products. Past experience has shown serious deficiencies in the conduct of nonclinical laboratories in recordkeeping, adherence to study protocol, and in some cases fraudulent practices.	
6. FIELD OBLIGATIONS Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER. District may make classification and recommend compliance actions.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60 , 61
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, & Monitors	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure adherence by sponsors, contract research organizations, and monitors to the regulations (21 CFR 312) and to assess their interaction with clinical investigators and the sponsors development of safety and efficacy data in NDAs.	
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. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) 60 , 61
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

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1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors; Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48808, 48809, 48809A, 48810, 48811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 44.0
--	---	---

	6.	1	2	1	1	2	1			
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	GLP INSP CTIONS 48808	NAT'L EXPERT INVESTI- GATIONS (Hours) 48808 - GLP	SPONSOR, CRO, MONITORS INSPECTIONS 48810 *	CLINICAL INVESTIGA- TORS INSPECTIONS 48811	NAT'L EXPERT INVESTI- GATIONS (Hours) 48811 - CI **	IRB INSPECTIONS 48809, 48809A §			
	TOTAL FIELD	50	380	35	282	333	123			
	HEADQUARTERS		380			333				
NE	REGIONAL STAFF									
	NEW ENGLAND	4		3	11		12			
	NEW YORK	3		4	12		10			
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	4		1	13		6			
	CHICAGO	2		1	9		3			
	CINCINNATI	3		1	11		10			
	DETROIT	4		1	10		5			
	MINNEAPOLIS	2		1	8		8			
	NEW JERSEY	6		4	7		3			
	PHILADELPHIA	4		4	12		5			
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	3		3	19		7			
	FLORIDA	1		2	28		8			
	NEW ORLEANS	1		1	16		9			
	SAN JUAN				1		2			
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2		2	31		6			
	DENVER	2		2	15		3			
	KANSAS CITY	2		1	9		5			
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3		2	44		11			
	SAN FRANCISCO	3		1	14		6			
SEATTLE		1		1	12		4			
PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		87.8		73.4	94.1		62.0			
TOTAL HOURS		4390	380	2569	26536	333	7626			
CONVERSION FACTOR		950	950	950	950	950	950			
TOTAL OPERATIONAL FTEs		4.62	0.40	2.70	27.93	0.35	8.03			

9. REMARKS
 48808:
 Resources planned for Inspections may also be used for DSCs.

Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER. CDER assignments, i.e. Directed Inspections, cover studies associated with IND's and NDA's.

Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-5).

* Sponsors, Contract Research Organizations, and Monitors
 ** Clinical Investigators
 *** Institutional Review Board

48809A: Resources for the Radioactive Drug Research Committee (RDRC, PAC 48809A) are not planned, please use above resources as needed.

Personnel Types Required: Investigator, National Expert

FY 2007

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 Pre - Approval Inspections/Inv. - Domestic				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52						
3. PROGRAM/ASSIGNMENT CODE(S) 52832, B, C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 15.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	3	7	7	9	
		ANDAs TO INSPECT Domestic	CHEMIST INSPECT. (Hours) *	DOMESTIC INVEST (Hours)	DOMESTIC SAMPLE COLL **	PROFILE/ PORTION OF DSCs FOR **	DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	BIOTEST (Chem) ***	DSAs (METH) (VALID) (Chem)	MISC. HOURS
TOTAL FIELD		110	1931	1593	140	(50)	45	45	10	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	7		101	9					
	NEW YORK	14		203	17					
	REGIONAL LAB		421				14	14	2	
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	2		29	3					
	CHICAGO	6		87	8					
	CINCINNATI	3		43	4					
	DETROIT	2	200	29	3					
	MINNEAPOLIS	2		29	3					
	NEW JERSEY	19		275	23					
	PHILADELPHIA	4	363	58	5				6	
FORENSIC CHEM. CTR						31	31			
SE	REGIONAL STAFF									
	ATLANTA	6		87	8					
	FLORIDA	2		29	3					
	NEW ORLEANS	2		29	3					
	SAN JUAN	4	230	58	5				2	
	REGIONAL LAB		193							
SW	REGIONAL STAFF									
	DALLAS	2		29	3					
	DENVER	3	112	43	4					
	KANSAS CITY	12	114	174	14					
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	16		232	19					
	SAN FRANCISCO	2		29	3					
	SEATTLE	2		29	3					
	PACIFIC REGIONAL LAB - SW		154							
PACIFIC REGIONAL LAB - NW		144								
HOURS PER OPERATION		57.5			5.0		50.0	30.0	105.0	
TOTAL HOURS		6325	1931	1593	700		2250	1350	1050	
CONVERSION FACTOR		950	950	950	950		1180	1180	1180	
TOTAL OPERATIONAL FTEs		6.65	2.03	1.68	0.74		1.91	1.14	0.89	

7. REMARKS

*Includes microbiologists on inspections. ** DSCs for profile/biotest analyses. Includes 50 Profile DSCs to be analyzed by Division of Drug Analysis (HFD-920). *** NRL-analyzes profile/biotest DSCs collected in NE & SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.

FY 2007

<p>1. PROGRAM/ASSIGNMENT TITLE ANDA Pre-Approval Inspections/Investigations - Foreign</p>	<p>2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52</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 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.</p>	
<p>5. PROGRAM JUSTIFICATION Compliance of foreign manufacturing establishments must be assessed before ANDA approval.</p>	
<p>6. FIELD OBLIGATIONS Conduct pre-approval inspections of foreign establishments as requested by the Center for Drug Evaluation and Research.</p>	
<p>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH</p>	
<p>b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED</p>	
<p>c. PRODUCT(S) Human Drugs</p>	<p>d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes</p>
<p>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>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B, 52832C, 52832E				2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52				3. OPERATIONAL FTE POSITIONS 9.0		
4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS + (Foreign) ++	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS	5 IMPORT SAMPLE COLL ***	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****	8 IMPORT SAMPLE ANALYSES METH. VALID ****		
	TOTAL FIELD	42	1900	950	140	70	70	15		
NE	HEADQUARTERS	4								
	REGIONAL STAFF									
	NEW ENGLAND	2		50	7					
	NEW YORK	3		75	12					
	REGIONAL LAB		544			70	70	15		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	2		50	7					
	CHICAGO									
	CINCINNATI									
	DETROIT	2		50	7					
	MINNEAPOLIS	2		50	7					
	NEW JERSEY	6		150	22					
PHILADELPHIA	2	593	50	7						
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	2		50	7					
	FLORIDA	2		50	7					
	NEW ORLEANS	2		50	7					
	SAN JUAN	3	218	75	12					
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2		50	7					
	DENVER		145							
	KANSAS CITY	3	218	75	12					
PA	Southwest Import District									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3		75	12					
	SAN FRANCISCO	2		50	7					
	SEATTLE									
PACIFIC REGIONAL LAB - SW			73							
PACIFIC REGIONAL LAB - NW			109							
HOURS PER OPERATION		50.0			3.0	30.0	15.0	50.0		
TOTAL HOURS		2100	1900	950	420	2100	1050	750		
CONVERSION FACTOR		950	950	950	950	1180	1180	1180		
TOTAL OPERATIONAL FTEs		2.21	2.00	1.00	0.44	1.78	0.89	0.64		

7. REMARKS
 * Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;
 ++ PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's
 Emergency Plan for AIDS Relief (PEPFAR).

 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 development ISAs.

FY 2007

<p>1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations</p>	<p>2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53</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 provide assignments, guidance and instructions to field offices for inspecting drug firms to determine compliance with the ADE reporting requirements of 21 CFR 310.305,314.80 and 318.98. Regulatory and/or administrative follow-up will be coordinated between the field and headquarters in cases where significant violations of reporting regulations or deficiencies in following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by responsible parties, including applicants, manufacturers, packers and distributors.</p>	
<p>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 ADE information is essential to the safety evaluation of marketed drug products. It enables FDA to act when information concerning the use and safety of marketed drug products suggests that new labeling, market withdrawal or other action is required.</p>	
<p>6. FIELD OBLIGATIONS Conduct inspections and forward reports directly to the Division of Compliance Risk Management and Surveillance (DCRMS)/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up. Issue regulatory letters as approved by DCRMS. Notify DCRMS of findings from other inspectional program activities which are relevant to ADE reporting.</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) Human Drugs</p>	<p>d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, 60-66</p>
<p>e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations				2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53						
3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1		2	4	5	6	7	8	9
		INSPEC- TIONS DOMESTIC	INSPEC- TIONS FOREIGN	INVESTI- GATION	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	MISC. HOURS
	TOTAL FIELD	133	16							
NE	HEADQUARTERS		4							
	REGIONAL STAFF									
	NEW ENGLAND	11								
	NEW YORK	12	2							
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	6								
	CHICAGO	11								
	CINCINNATI	4								
	DETROIT	4								
	MINNEAPOLIS	4								
	NEW JERSEY	19	3							
	PHILADELPHIA FORENSIC CHEM. CTR	8								
SE	REGIONAL STAFF									
	ATLANTA	13	2							
	FLORIDA	8								
	NEW ORLEANS	2								
	SAN JUAN REGIONAL LAB	1								
SW	REGIONAL STAFF									
	DALLAS	4								
	DENVER	2								
	KANSAS CITY	4								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	8	3							
	SAN FRANCISCO	10	2							
	SEATTLE	2								
	PACIFIC REGIONAL LAB - NW PACIFIC REGIONAL LAB - SW									
	HOURS PER OPERATION	57.0	60.0							
TOTAL HOURS	7581	960								
CONVERSION FACTOR	950	950								
TOTAL OPERATIONAL FTEs	7.98	1.01								

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

FY 2007

<p>1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections</p>	<p>2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56</p>
<p>3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES To 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.</p>	
<p>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.</p>	
<p>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 inspection coverage provided for in the inspectional strategy.</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) Human Drugs</p>	<p>d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66</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</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

FY 2007 ORA Workplan

October 1, 2006

Drug Process Inspections - Domestic						2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832, 56R359, 56002M*			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 120.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I N S P E C T I O N S	1 I N V E S T I G A T I O N S (Hours)	1 C H E M I S T O N I N S P E C T I O N S (Hours)	1 M I C R O O N I N S P E C 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 **	D O M E S T I C S A M P L E C O L L (CHEM)	D O M E S T I C S A M P L E C O L L (MICRO)	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 (CHEM)	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 (MICRO)	9 C E R T I F I C A T I O N H O U R S F O R A U D I T S
NE	HEADQUARTERS		755								
	REGIONAL STAFF										
	NEW ENGLAND	90	133			29	15	3			184
	NEW YORK	112	167			37	19	3			232
	REGIONAL LAB			1222	462				34	12	
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE	42	63			14	7	1			87
	CHICAGO	86	128			28	14	2			178
	CINCINNATI	50	75			16	8	1			103
	DETROIT	63	94	701		21	11	2	11		130
	MINNEAPOLIS	62	93			20	10	2			128
	NEW JERSEY	150	222			49	24	4			308
	PHILADELPHIA	69	103	2100		23	12	2	75		143
SE	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA	83	119			26	13	2			166
	FLORIDA	67	98			22	11	2			137
	NEW ORLEANS	47	70			15	8	1			97
	SAN JUAN	69	103	1260		23	12	2	12		143
SW	REGIONAL LAB			300	616				32	15	
	REGIONAL STAFF										
	DALLAS	90	134			29	15	3			186
	DENVER	29	44	428	75	9	5	1	32	6	60
	KANSAS CITY	75	110	798		24	12	2			153
	SOUTHWEST IMPORT DISTRICT										
PA	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES	131	196			43	22	4			272
	SAN FRANCISCO	39	57		385	12	6	2		7	79
	SEATTLE	23	46			10	5	1			64
	PACIFIC REGIONAL LAB - SW			382							
PACIFIC REGIONAL LAB - NW			383					33			
HOURS PER OPERATION		65.0				5.0			38.0	28.0	
TOTAL HOURS		89505	2810	7574	1538	2250			8702	1120	2850
CONVERSION FACTOR		950	950	950	950	950			1180	1180	950
TOTAL OPERATIONAL FTEs		94.22	2.96	7.97	1.62	2.37			7.37	0.95	3.00
7. REMARKS * Investigations hours are for additional drug inspections or investigations as needed. Any new registrants in the high risk categories should be inspected during the first 6 months after registration. Gas firms are under a separate worksheet 56-5. ** DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.											
The shaded area breaks out the sample collections and is only a guideline for Districts.											

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FY 2007

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	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002,A,B,C,D,E,F 56832	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 15.0
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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	174	3800						
	HEADQUARTERS	15							
NE	REGIONAL STAFF								
	NEW ENGLAND	15							
	NEW YORK	12							
	REGIONAL LAB		468						
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	6							
	CHICAGO	6							
	CINCINNATI	6							
	DETROIT	6	195						
	MINNEAPOLIS	6							
	NEW JERSEY	15							
	PHILADELPHIA	9	391						
	FORENSIC CHEM. CTR			130					
SE	REGIONAL STAFF								
	ATLANTA	9							
	FLORIDA	3							
	NEW ORLEANS	6							
	SAN JUAN	15	977						
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS	9							
	DENVER	3	488						
	KANSAS CITY	6	488						
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	15							
	SAN FRANCISCO	6	143						
	SEATTLE	6							
	PACIFIC REGIONAL LAB - SW			260					
PACIFIC REGIONAL LAB - NW			260						
	HOURS PER OPERATION	60.0							
	TOTAL HOURS	10440	3800						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	10.99	4.00						

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

FY 2007

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							
3. PROGRAM/ASSIGNMENT CODE(S) 56008A, C			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTIGATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTIONS	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	3 DOMESTIC SAMPLE COLLECTIONS (API)	7 DOMESTIC SAMPLES ANALYZED (CHEM)	7 DOMESTIC SAMPLES ANALYZED (MICRO)	6 DOMESTIC SAMPLES ANALYZED (API) (Chem)	7 METHODS DEVELOPMENT HOURS (Chem)
	TOTAL FIELD		950	870	750	120	180	750	120	180
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	38	35	30	5	7				
	NEW YORK	71	65	56	9	13				
	REGIONAL LAB WEAC						86	35		850
CE	REGIONAL STAFF									
	BALTIMORE	43	39	34	5	8				
	CHICAGO	85	78	67	11	16				
	CINCINNATI	52	48	41	7	10				
	DETROIT	40	37	32	5	8	32			600
	MINNEAPOLIS	37	34	29	5	7				
	NEW JERSEY	94	85	74	11	18				
	PHILADELPHIA	57	52	45	7	11	290			650
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	47	43	37	6	9				
	FLORIDA	68	62	53	9	13				
	NEW ORLEANS	54	49	42	7	10				
	SAN JUAN	26	24	21	3	5	21		180	600
REGIONAL LAB						132	55		240	
SW	REGIONAL STAFF									
	DALLAS	71	65	56	9	13				
	DENVER	22	20	17	3	4	73	17		120
	KANSAS CITY	43	40	35	5	8	35			120
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	71	64	56	8	13				
	SAN FRANCISCO	22	20	17	3	4		13		
	SEATTLE	9	10	8	2	3				
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW						56 25			120 240
HOURS PER OPERATION			4.0			4.0	19.0	22.0	19.5	
TOTAL HOURS		950	3480			720	14250	2640	3510	3540
CONVERSION FACTOR		950	950			950	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.00	3.66			0.76	12.08	2.24	2.97	3.00
9. REMARKS										
*DSAs are assigned by Division of Field Science, ORO per lab expertise for specific Drugs.										
<input type="checkbox"/> The shaded area breaks out the sample collections and is only a guideline for Districts.										

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1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56				
3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 34.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGATIONS HOURS **		MAIL/ COURIERS REVIEWS INV HOURS	4 IMPORT SAMPLE COLLECT- IONS *	8 IMPORT SAMPLES ANALYZED APIs CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	14700	7510		10260	120	60	60
	HEADQUARTERS							
NE	REGIONAL STAFF							
	NEW ENGLAND	312	103			2		
	NEW YORK	4775	2620		2410	42		
	REGIONAL LAB						22	
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE	227	122			2		
	CHICAGO	597	237		1000	4		
	CINCINNATI	417	230		900	4		
	DETROIT	1006	415			6	6	
	MINNEAPOLIS	98	42			2		
	NEW JERSEY							
	PHILADELPHIA	726	284		700	5	5	
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA	415	195			3		
	FLORIDA	676	255		700	4		
	NEW ORLEANS	2509	1455		900	25		
	SAN JUAN	214	152		450	3	15	
	REGIONAL LAB						2	
SW	REGIONAL STAFF							
	DALLAS							
	DENVER						3	
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT	687	507		400	6		
REGIONAL LAB								
PA	REGIONAL STAFF							
	LOS ANGELES	742	448		1200	7		
	SAN FRANCISCO	505	229		900	3		
	SEATTLE	794	216		700	2		
	PACIFIC REGIONAL LAB - SW						4	
PACIFIC REGIONAL LAB - NW						3	60	
HOURS PER OPERATION						2.7	38.0	25.0
TOTAL HOURS		14700	7510		10260	324	2280	1500
CONVERSION FACTOR		1200	950		950	950	1180	1180
TOTAL OPERATIONAL FTEs		12.25	7.91		10.80	0.34	1.93	1.27

7. REMARKS

* Reporting Guidance:

- Import Entry Reviews (electronic and manual-- operation code 14) PAC 56R833;
- Filer Evaluations (operation code 95) PAC 99R833;
- Follow-Up to Refusals 56R824, 63R824

- Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001, 63002;
- Report finished dosage form drugs and APIs collected at the site of entry under 56008H.

** Import investigation hours are for field exams, filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

Use CT PAC 56R845 only when specific CT work is performed.

FY 2007

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

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56						
3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL				7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)		
	TOTAL FIELD	100	300	30				30		
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	5	16	2						
	NEW YORK	9	27	3						
	REGIONAL LAB							5		
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	3	9	1						
	CHICAGO	5	13	1						
	CINCINNATI	4	11	1						
	DETROIT	4	13	2				5		
	MINNEAPOLIS	5	16	2						
	NEW JERSEY	8	20	2						
	PHILADELPHIA	4	13	1				5		
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	7	22	2						
	FLORIDA	7	20	2						
	NEW ORLEANS	5	16	1						
	SAN JUAN	4	16	1				2		
REGIONAL LAB							4			
SW	REGIONAL STAFF									
	DALLAS	7	20	2						
	DENVER	3	9	1				5		
	KANSAS CITY	6	16	2						
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	10	27	2						
	SAN FRANCISCO	2	9	1						
	SEATTLE	2	7	1						
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW								4		
HOURS PER OPERATION		25.0		4.0				35.0		
TOTAL HOURS		2500	300	120				1050		
CONVERSION FACTOR		950	950	950				1180		
TOTAL OPERATIONAL FTEs		2.63	0.32	0.13				0.89		
7. REMARKS										

FY 2007

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

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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PROGRAM/ASSIGNMENT CODE(S) 56022, 56022A	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 (Chem)	8 IMPORT SAMPLES TO BE ANALYZED
	TOTAL FIELD	41	950	34				34	
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	2	46	2					
	NEW YORK	5	117	4					
	REGIONAL LAB							6	
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	2	46	1					
	CHICAGO	2	46	2					
	CINCINNATI	1	23	1					
	DETROIT	2	46	2					
	MINNEAPOLIS	1	23						
	NEW JERSEY	5	117	4					
	PHILADELPHIA	2	46	2				12	
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA	4	93	3					
	FLORIDA	1	23	1					
	NEW ORLEANS	1	23	1					
	SAN JUAN	6	140	4				9	
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS	1	23	1					
	DENVER	1	23	1				4	
	KANSAS CITY	2	46	2					
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES	2	46	2					
	SAN FRANCISCO	1	23	1					
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW							3		
	HOURS PER OPERATION	15.0		2.0				11.0	
	TOTAL HOURS	615	950	68				374	
	CONVERSION FACTOR	950	950	950				1180	
	TOTAL OPERATIONAL FTEs	0.65	1.00	0.07				0.32	

7. REMARKS

FY 2007

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

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments					2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
PROGRAM/ASSIGNMENT CODE(S) 56D015 *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	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			3800						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		152							
	NEW YORK		186							
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		120							
	CHICAGO		159							
	CINCINNATI		172							
	DETROIT		226							
	MINNEAPOLIS		137							
	NEW JERSEY		104							
	PHILADELPHIA		142							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA		503							
	FLORIDA		298							
	NEW ORLEANS		301							
	SAN JUAN		84							
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS		372							
	DENVER		96							
	KANSAS CITY		229							
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		252							
	SAN FRANCISCO		119							
	SEATTLE		148							
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION										
TOTAL HOURS			3800							
CONVERSION FACTOR			950							
TOTAL OPERATIONAL FTEs			4.00							

7. REMARKS

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

Resources for collection and analysis of any samples under this program should be taken from Drug Product Surveillance - Domestic Drugs (56008A,C).

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R838, 56R831	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION								
	TOTAL FIELD	12050								
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR	12050									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB - SW										
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION										
TOTAL HOURS		12050								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		10.00								

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; PODs operation 41 or 43 domestic or import sample analysis, PAC 56R838 or OCI PAC 56R831.

FY 2007

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, and OTC Monographs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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 with specific OTC drug monographs or other regulations; 2) to detect, investigate and take action against fraudulent drug products that present the public with a direct and indirect health hazard and economic fraud; and, 3) to monitor, investigate and take regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal off-shore pharmacy operations associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases.	
5. PROGRAM JUSTIFICATION 1) In the Federal Register of 1/5/72, the Commissioner announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory panels. As a result, final monographs are published (21 CFR Part 330 through Part 358) which establish conditions under which OTC drugs can be generally recognized as safe and effective and not misbranded; 2) to combat the deceptive and misleading sale of fraudulent drug products; and, 3) FDA must monitor the promotion and sale of drug products on the Internet to identify activities which violate the law and pose a risk to the public health.	
6. FIELD OBLIGATIONS The Field conducts inspections and investigations, develops evidence, collects and analyzes samples, evaluates product labeling, performs surveillance activities, and recommends compliance actions concerning OTC drugs, fraudulent drugs and drugs sold on the Internet as set forth in applicable compliance programs and CDER guidance and requests for follow-up.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input 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, Health Fraud, & OTC Monographs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 6.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL. *	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED Chem	8 IMPORT SAMPLES TO BE ANALYZED	9 MISC. (Hours)
	TOTAL FIELD	32	3325	118				59		
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	2	161	6						
	NEW YORK	2	258	9						
	REGIONAL LAB							4		
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	2	161	6						
	CINCINNATI	2	129	5						
	DETROIT	2	97	3				2		
	MINNEAPOLIS		65	2						
	NEW JERSEY									
	PHILADELPHIA							10		
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA	5	517	17						
	NEW ORLEANS									
	SAN JUAN		32	2				1		
	REGIONAL LAB							8		
SW	REGIONAL STAFF									
	DALLAS		129	5						
	DENVER	2	161	6				6		
	KANSAS CITY	2	65	2				1		
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	8	1065	38						
	SAN FRANCISCO	2	194	7						
	SEATTLE	3	291	10						
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW							27		
HOURS PER OPERATION		30.0		4.0				20.0		
TOTAL HOURS		960	3325	472				1180		
CONVERSION FACTOR		950	950	950				1180		
TOTAL OPERATIONAL FTEs		1.01	3.50	0.50				1.00		

7. REMARKS

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

Report Health Fraud and OTC Monograph work to PAC 63001A.
Report Internet Drugs work to PAC 63D012.

FY 2007

1. PROGRAM/ASSIGNMENT TITLE New Drug (Prescription) Without Approved NDAs	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63
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) Without Approved NDAs				2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63					
3. PROGRAM/ASSIGNMENT CODE(S) 63002			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 INSPEC- TIONS	2 INVEST- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL. *			7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	TOTAL FIELD	47	950	95					
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	2	56	4					
	NEW YORK	5	117	10					
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	2	37	4					
	CHICAGO	2	43	4					
	CINCINNATI	2	31	4					
	DETROIT	2	46	4					
	MINNEAPOLIS	2	12	4					
	NEW JERSEY	4	108	9					
	PHILADELPHIA	2	46	4					
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA	4	83	8					
	FLORIDA	2	34	4					
	NEW ORLEANS	2	22	4					
	SAN JUAN	6	142	12					
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS	2	25	4					
	DENVER	2	25	4					
	KANSAS CITY	2	49	4					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES	2	46	4					
	SAN FRANCISCO	2	25	4					
	SEATTLE		3						
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		30.0		5.0					
TOTAL HOURS		1410	950	475					
CONVERSION FACTOR		950	950	950					
TOTAL OPERATIONAL FTEs		1.48	1.00	0.50					
7. REMARKS * Samples collected will not require analysis; These samples will be collected for documentary and label review. Report work under New Drugs (Rx) without Approved NDAs (formerly PAC 52002) to PAC 63002.									

FY 2007

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.	

FY 2007

1. PROGRAM/ASSIGNMENT TITLE United States Pharmacopeia (USP) Reference Standards	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 formalize a partnership between the USP and the FDA to further ensure the quality and standard of marketed pharmaceutical products. Also, to ensure that high quality reference standards are available in the USA.	
5. PROGRAM JUSTIFICATION The USP Reference Standards Program is essential to the FDA laboratory-based regulatory programs and to the pharmaceutical industry. The Reference Standards serve as a tool to FDA in enforcing the quality requirements for marketed drugs. The Standards are recognized by governments of more than 35 other countries.	
6. FIELD OBLIGATIONS Selected ORA laboratories will receive, analyze, evaluate, review, and report findings on candidate samples.	
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 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 USP Reference Standards	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
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3. PROGRAM/ASSIGNMENT CODE(S) 88R451	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.0
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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 CHEM HOURS	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD							8260		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB							3540		
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
PHILADELPHIA								2360		
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB							2360		
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS									
	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								8260		
CONVERSION FACTOR								1180		
TOTAL OPERATIONAL FTEs								7.00		

7. REMARKS
Seven FTEs are assigned to this Program using dollars reimbursed by United States Pharmacopeia.

**CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2007**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	97.3	21.8	4.0	123.1	168.4	37.7	6.9	213.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	7.1		3.6	10.7	12.3		6.2	18.5
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	90.2	21.8	0.4	112.4	156.1	37.7	0.7	194.5

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities to fulfill their NADA commitments to manufacture, process, and pack new animal drugs that are safe and effective for their intended use. Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION Domestic and foreign plant inspections are necessary to determine whether the establishment can produce the new animal drug in accordance with current good manufacturing practice regulations and comply with the commitments in the NADA. Inspections will be issued by assignment. Priority will be specified by CVM. Outcome: Reduce new animal drug development and review time.	
6. FIELD OBLIGATIONS The Field will conduct NADA Pre-Approval Inspections at domestic and foreign plants in accordance with the assignment. Establishment inspection reports will be submitted to the New Animal Drug Evaluation (NADE) Program Manager (HFV-142) according to the procedures outlined for field reporting requirements in the compliance program. Field laboratories on an assignment basis will validate methodology submitted with NADAs.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs, Type A Medicated Feed Articles	d. INDUSTRY/PRODUCT CODE(S) 56, 67, 68
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Petition validation work.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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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 5.7
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	6.	1	1	1	3	7	9			
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	CHEMIST O N I N S P **	INSP EC T I O N S (Foreign) ***	DOMESTIC S A M P L E C O L L	DOMESTIC S A M P L E S T O B E A N A L Y Z E D				
	TOTAL FIELD	38	285	47						
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND	2		3						
	NEW YORK	2		3						
	REGIONAL LAB		36							
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	1		2						
	CHICAGO	3		2						
	CINCINNATI	1								
	DETROIT	1								
	MINNEAPOLIS	5		3						
	NEW JERSEY	2		3						
	PHILADELPHIA	1		3						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	3		3						
	FLORIDA	2		3						
	NEW ORLEANS	1								
	SAN JUAN	1		3						
	REGIONAL LAB		48							
SW	REGIONAL STAFF									
	DALLAS	2		3						
	DENVER	1		3						
	KANSAS CITY	6	169	9						
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	2		2						
	SAN FRANCISCO	1		2						
	SEATTLE	1								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW		32							
	HOURS PER OPERATION	45.4		72.5						
	TOTAL HOURS	1725	285	3408						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	1.82	0.30	3.59						

7. REMARKS

** Analyst will participate on inspections as necessary.

Districts and Laboratories should collect and analyze samples as needed by the program, time for these operations is planned under inspections and chemist on inspections.

*** Foreign inspections spread by DFI. Use Operation Code 11 to report foreign inspections.

Workload Source: FACTS database (registered firms in IND 56, 67, and 68; Workload Obligation is "Yes" and Status is "Operational".)

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.	
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 7368.808.	
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) 67, 68, or 69
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, and Monitors	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 (21 CFR 511.1 (b)) and to evaluate representative clinical investigators utilized by the sponsor with regard to their adherence to applicable regulations.	
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 7368.810.	
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) 67, 68, or 69
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

2. PPS PROJECT NAME/NUMBER
Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To 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.

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 7368.811.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
Animal Drugs

d. INDUSTRY/PRODUCT CODE(S)
67, 68, or 69

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 GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
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3. PROGRAM/ASSIGNMENT CODE(S) 68808, 68810, 68811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 68808 INSPEC- TIONS (GLPs) (SPON/MON) *	1 68811 INSPEC- TIONS (CLINICAL INVEST)						
	TOTAL FIELD	43	44						
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	2							
	NEW YORK	2	1						
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	2	2						
	CHICAGO		2						
	CINCINNATI	2	1						
	DETROIT	4	4						
	MINNEAPOLIS	2	5						
	NEW JERSEY	4	1						
	PHILADELPHIA	2	1						
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	2	1						
	FLORIDA		4						
	NEW ORLEANS	1	3						
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS	1	5						
	DENVER	5	4						
	KANSAS CITY	8	5						
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES	1	2						
	SAN FRANCISCO	4	1						
	SEATTLE	1	2						
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	63.3	46.0						
	TOTAL HOURS	2722	2024						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	2.87	2.13						

7. REMARKS

* Resources for 68808 and 68810 are planned under 68808. Report inspections under the appropriate PAC. Inspections are to be conducted only when assignments are received from CVM.

Workload Source: FACTS database (BIMO firms in IND 67, 68, and 69 with Status of "Operational"; 3-year inspectional data from OPAS (PAC 68811)).

1. PROGRAM/ASSIGNMENT TITLE Drug Process and New Animal Drug Inspections / Type A Medicated Articles	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21 CFR 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).	
5. PROGRAM JUSTIFICATION Section 510(h) of the Act obligates the Agency to inspect (pursuant to 704 of the Act) drug establishments required to register with FDA. In addition, it is one of the primary purposes of establishment inspections to assure that the drug product is being manufactured, processed, controlled, etc. under the same conditions as approved and that it maintains the same stability profile as originally demonstrated. Outcome: Ensure the marketing of safe and effective animal drugs.	
6. FIELD OBLIGATIONS The field will conduct CGMP inspections of registered animal drug establishments. Top priority will be given to establishments which manufacture sterile products.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.	d. INDUSTRY/PRODUCT CODE(S) 56, 60-66, 67-69
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Sterility, purity, identify, potency, decomposition	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A	

1. PROGRAM/ASSIGNMENT TITLE Drug Process and New Animal Drug Inspections / Type A Medicated Articles	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71001 /A /B, 71005 /A, 71R841	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2	3			7	7
		INSP CTIONS		CHEM ON INSP (Hours)	INSP CTIONS (Foreign)	INVEST IGATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	DOMESTIC SAMPLE COLL (Micro)	DOMESTIC SAMPLES TO BE ANALYZED (Chem)	DOMESTIC SAMPLES TO BE ANALYZED (Micro)
	TOTAL FIELD	194		475	10	250	76	30	15	30	15
	HEADQUARTERS										
NE	REGIONAL STAFF										
	NEW ENGLAND	9			1	12	4	2	1		
	NEW YORK	10				13	4	2	1		
	REGIONAL LAB			62						4	2
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE	6				8	2	1	1		
	CHICAGO	16			1	21	6	2	1		
	CINCINNATI	6			1	8	2	1	1		
	DETROIT	5				6	2	1			
	MINNEAPOLIS	24			1	31	10	3	1		
	NEW JERSEY	6			1	8	2	1			
	PHILADELPHIA	8			1	10	3	1	1		
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA	14				18	5	2	1		
	FLORIDA	12			1	15	5	2	1		
	NEW ORLEANS	6				8	2	1			
	SAN JUAN	4				5	2	1			
	REGIONAL LAB			144						10	5
SW	REGIONAL STAFF										
	DALLAS	9			1	12	4	2	1		
	DENVER	6				8	2	1	1		5
	KANSAS CITY	28		206	1	35	11	3	1	12	
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES	10			1	13	4	2	1		
	SAN FRANCISCO	7				9	3	1	1		3
	SEATTLE	8				10	3	1	1		
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW			63						4	
	HOURS PER OPERATION	35.9			35.0		5.5			18.4	21.1
	TOTAL HOURS	6965		475	350	250	418			552	317
	CONVERSION FACTOR	950		950	950	950	950			1180	1180
	TOTAL OPERATIONAL FTEs	7.33		0.50	0.37	0.26	0.44			0.47	0.27

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.

The shaded area serves as a **guideline** for Districts on the specific types of samples that should be collected in order to match samples sent to the laboratories for analysis.

Workload Source: FACTS database (registered firms in IND 56, 67, 68 with Status of "Operational" and Workload Obligation of "Yes".)

Foreign Inspections spread by Division of Field Investigations, ORO.

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To monitor domestic and imported animal feed and feed ingredients to prevent widespread contamination of the nation's food supply. Increase the number of cooperative activities related to this program.	
5. PROGRAM JUSTIFICATION The use of contaminated feed ingredients has resulted in adulterated animal feeds and in economic losses to producers and processors when food-producing animals consume adulterated feeds. A hazard to human health may result from subsequent deposition of residues in meat, poultry, eggs, fish and dairy products. These foods constitute a significant portion of the human diet and fraud. Outcome: Prevention or containment of potential human or animal health hazard.	
6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis. Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Complete animal feeds and feed ingredients.	d. INDUSTRY/PRODUCT CODE(S) 69-72
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES *Mycotoxins, Pesticides, Industrial Chemicals, Metals, and Microbiologicals	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING N/A	

1. PROGRAM/ASSIGNMENT TITLE			2. PPS PROJECT NAME/NUMBER										
Feed Contaminants - DOMESTIC			Monitoring of Marketed Animal Drugs, Feeds and Devices - 71										
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY					5. OPERATIONAL FTE POSITIONS					
71003 A-J			<input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					TOTAL 14.2 DOMESTIC 12.0 IMPORT 2.2					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	3	3	3	3	3	3	7	7	7	7	7
		INSPEC- TIONS (Dioxin) *	DOMESTIC SAMPLE COLL ** ***	DOMESTIC SAMPLE COLL Metals 71003B	DOMESTIC SAMPLE COLL Myc 71003C	DOMESTIC SAMPLE COLL Micro 71003E	DOMESTIC SAMPLE COLL Chem 71003A	DOMESTIC SAMPLE COLL Dioxin 71003G	DOMESTIC SAMPLE ANALYSIS Metals 71003B	DOMESTIC SAMPLE ANALYSIS Myc 71003C	DOMESTIC SAMPLE ANALYSIS Micro *** 71003E	DOMESTIC SAMPLE ANALYSIS Chem 71003A	DOMESTIC SAMPLE ANALYSIS Dioxin 71003G
TOTAL FIELD		10	1005	20	250	200	200	135	20	250	200	200	135
HEADQUARTERS													
REGIONAL STAFF													
NE	NEW ENGLAND	1	29		3	10	3	3					
	NEW YORK		26		2	10	2	2					
	REGIONAL LAB								1		20	11	
	WEAC												
REGIONAL STAFF													
	BALTIMORE		38	1	8	10	5	4					
	CHICAGO		37	1	7	10	6	3					
CE	CINCINNATI	1	59	1	15	11	12	9					
	DETROIT		40		9	10	6	5					
	MINNEAPOLIS	1	104	3	33	12	26	18					
	NEW JERSEY		21			10		1					
	PHILADELPHIA		38	1	7	10	6	4					
	FORENSIC CHEM CTR												
REGIONAL STAFF													
SE	ATLANTA	1	79	2	24	12	18	11					
	FLORIDA		28		3	10	3	2					
	NEW ORLEANS	1	55	1	14	11	11	7					
	SAN JUAN		25		2	10	1	2					
	REGIONAL LAB								5	43	84	50	
REGIONAL STAFF													
SW	DALLAS	1	97	3	30	12	24	16					
	DENVER		51	2	12	10	10	7			56		
	KANSAS CITY	2	160	4	58	12	47	27	13	100		113	
	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB										10	6	135
REGIONAL STAFF													
PA	LOS ANGELES		28		3	10	2	3					
	SAN FRANCISCO	1	42		9	10	8	5			30		
	SEATTLE	1	48	1	11	10	10	6					
	PACIFIC REGIONAL LABORATORY-SW											10	
	PACIFIC REGIONAL LABORATORY-NW								1	107		10	
HOURS PER OPERATION		17.0	4.2						12.0	7.7	16.0	5.5	16.7
TOTAL HOURS		170	4221						240	1925	3200	1100	2255
CONVERSION FACTOR		950	950						1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.18	4.44						0.20	1.63	2.71	0.93	1.91

9. REMARKS

* Inspections performed as F/U to violative dioxin samples

The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.

**Domestic Sample Collections: 200 micro samples are to be collected and shipped to CVM's Office of Research for additional analysis. They will not be analyzed by ORA laboratories.

***Domestic Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods.

Workload Source: FACTS database; firms in IND 69-72 with Workload Obligation of "YES" and Firm Status of "OPERATIONAL".

NOTE: Continued on Page 71-7

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1. PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER							
Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-5		Monitoring of Marketed Animal Drugs, Feeds and Devices -71							
3. PROGRAM/ASSIGNMENT CODE(S)			4. WORK ALLOCATION PLANNED BY				5. OPERATIONAL FTE POSITIONS		
71003 A-H (99R833, 71R833, 71R824)			<input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				2.2		
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLL	IMPORT SAMPLE COLL Chem	IMPORT SAMPLE COLL Micro	IMPORT SAMPLE ANALYSIS Chem	IMPORT SAMPLE ANALYSIS Micro			
	TOTAL FIELD	220	155	65	155	65			
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	43	30	13					
	NEW YORK	65	45	19					
	REGIONAL LAB				77	32			
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	4	3	1					
	CHICAGO	1	1						
	CINCINNATI	1	1						
	DETROIT	25	18	7					
	MINNEAPOLIS	17	12	5					
	NEW JERSEY								
	PHILADELPHIA	2	1	1					
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA	1	1						
	FLORIDA								
	NEW ORLEANS	2	1	1					
	SAN JUAN								
SW	REGIONAL LAB				6	3			
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY				13				
PA	SOUTHWEST IMPORT DISTRICT	9	6	3					
	REGIONAL LAB				24	10			
	REGIONAL STAFF								
	LOS ANGELES	8	6	2					
	SAN FRANCISCO	3	2	1					
PA	SEATTLE	39	27	12					
	PACIFIC REGIONAL LABORATORY-SW				8				
	PACIFIC REGIONAL LABORATORY-NW				27				
	HOURS PER OPERATION	2.5			7.5	12.0			
TOTAL HOURS	550			1163	780				
CONVERSION FACTOR	950			1180	1180				
TOTAL OPERATIONAL FTEs	0.58			0.99	0.66				

9 REMARKS

Dioxin Samples, 71003G, will be analyzed by ARL and chem samples, 71003 A/B, will follow the distribution of this workplan and Servicing Laboratory Table.
Mycotoxin samples, 71003C, will be analyzed by PRN. Mycotoxin and dioxin samples should be collected as necessary.

The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.

*Import Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods

Workload Source: FACTS and OASIS databases.

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing	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 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.	
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.	
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 analysis (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
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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 6.1
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	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FEED ESTABS	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED (Chem)	7 DOMESTIC SAMPLES ANALYZED (Micro)	1 VSIP INSPECTIONS (Hours) *			
	TOTAL FIELD	220	52	15	5	238			
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND	6	1						
	NEW YORK	2	1						
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE	5	1						
	CHICAGO	1							
	CINCINNATI	4	1						
	DETROIT	3	1						
	MINNEAPOLIS	21	5			48			
	NEW JERSEY								
	PHILADELPHIA	2	1						
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA	8	2						
	FLORIDA	5	1						
	NEW ORLEANS	30	7			47			
	SAN JUAN	2							
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS	52	13			48			
	DENVER	5	1	15	5				
	KANSAS CITY	30	7			48			
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES	4	1						
	SAN FRANCISCO	14	3						
SEATTLE	26	6			47				
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	19.7	7.8	49.0	44.0				
	TOTAL HOURS	4334	406	735	220	238			
	CONVERSION FACTOR	950	950	1180	1180	950			
	TOTAL OPERATIONAL FTEs	4.56	0.43	0.62	0.19	0.25			

9. REMARKS

Resources are allocated for 20 physical samples, remaining resources may be used for the collection of documentary samples.

Non-potency feed sample analysis should be charged to 71003 A/E.

There are 347 State Contract inspections.

* Resources are for the Voluntary Self Inspection Program (VSIP)

Workload Source: FACTS database (registered firms in IND 69); Workload Obligation is "YES", Firm Status is "Operational".

1. PROGRAM/ASSIGNMENT TITLE Illegal Drug Residues in Meat and Poultry	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct follow-up investigations/inspections when illegal residues are reported to FDA by the USDA's Food Safety and Inspection Service. To initiate regulatory sanctions against those persistently causing residues. Reduce future residues in edible animal tissues. FDA will partner with FSIS and will develop educational initiatives, and, as necessary, regulatory actions. Starting in FY 07 CVM will issue assignments for Repeat Violators, 50X Tolerance Residues, and AMDUCA Prohibited residues.	
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 is 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 (MOU) between FDA, USDA, and EPA. Coordinate state activities with states having MOUs, informal and formal agreements or contracts with FDA to conduct inspections of first time violators.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Meat and Poultry, Animal Feeds and Drugs	d. INDUSTRY/PRODUCT CODE(S) 16, 17, 67, 68, 69
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES Tissue Sample analysis by Denver laboratory when required.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry				2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71						
3. PROGRAM/ASSIGNMENT CODE(S) 71006			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)	9 METHODS VALID (Hours) *			
	TOTAL FIELD		233	950	175	600	500	360		
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	17	69	13						
	NEW YORK	24	98	18						
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	5	20	4						
	CHICAGO	2	8	2						
	CINCINNATI	11	45	8						
	DETROIT	5	20	4						
	MINNEAPOLIS	23	94	17						
	NEW JERSEY	2	8	2						
	PHILADELPHIA	25	102	19						
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	4	16	3						
	FLORIDA	2	8	2						
	NEW ORLEANS	7	28	5						
	SAN JUAN	3	12	2						
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	7	28	5						
	DENVER	9	37	7	600	500	360			
	KANSAS CITY	19	77	14						
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	8	33	6						
	SAN FRANCISCO	43	175	31						
	SEATTLE	17	72	13						
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		35.0		6.6						
TOTAL HOURS		8155	950	1155	600	500	360			
CONVERSION FACTOR		950	950	950	1180	1180	1180			
TOTAL OPERATIONAL FTEs		8.58	1.00	1.22	0.51	0.42	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 CR's of FSIS violative samples and should not be analyzed further unless approved by CVM.

Feed and Animal Drug samples are analyzed by Denver Laboratory.

Investigation hours: Hours not utilized for investigations may be used for inspections.

The Center will issue FACTS assignments to request Federal inspections of repeat violators, residues involving AMDUCA prohibited drugs, residues of drugs not approved for food animal use, and very high level residues. Districts should contact CVM to discuss a regulatory strategy before expending resources on other cases.

Workload Source: Inspections and investigation hours are assigned by Center.

1. PROGRAM/ASSIGNMENT TITLE		2. PPS PROJECT NAME/NUMBER									
Ruminant Feed Ban Rule/BSE Program		Monitoring of Marketed Animal Drugs, Feeds and Devices - 71									
3. PROGRAM/ASSIGNMENT CODE(S)		4. WORK ALLOCATION PLANNED BY						5. OPERATIONAL FTE POSITIONS			
71009, 71R844, 71R843 (99R833, 71R833, 71R824)		<input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER						Domestic 39.9		59.5	
		Import 19.6									
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSPECTIONS *	BSE PARTNERSHIP INSEPTIONS	DOMESTIC INVESTIGATION HOURS	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INVESTIGATION HOURS **	3 DOMESTIC SAMPLE COLLECTIONS	4 IMPORT SAMPLES COLLECTIONS	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES ANALYZED	9 TECHNICAL SUPPORT (HOURS) ***
	TOTAL FIELD	2594	895	2850	11700	3800	855	855	855	855	4921
HEADQUARTERS											
REGIONAL STAFF											
NE	NEW ENGLAND	20		80	2318	69	7	119			
	NEW YORK	100		85	3393	968	33	251			255
	REGIONAL LAB								58	254	
	WEAC										
REGIONAL STAFF											
	BALTIMORE	68		80	208	161	22	33			184
	CHICAGO	80		80	63	46	26	19			117
CE	CINCINNATI	240		190	49	92	79	4			247
	DETROIT	143	70	130	1554	92	47	114			351
	MINNEAPOLIS	600		400	936	92	198	68			901
	NEW JERSEY	6		80			2				30
	PHILADELPHIA	50	250	115	86	138	16	3			22
	FORENSIC CHEM. CTR										
REGIONAL STAFF											
SE	ATLANTA	60		135	65	207	20	5			674
	FLORIDA	82		80	23	299	27	2			301
	NEW ORLEANS	87		110	72	115	29	5			226
	SAN JUAN	12		80	10		4	1			
	REGIONAL LAB								181	50	
REGIONAL STAFF											
SW	DALLAS	186	175	250			61				220
	DENVER	78		80			26		156		80
	KANSAS CITY	210	400	500			69				927
	SOUTHWEST IMPORT DISTRICT				393	369		45			
	REGIONAL LAB								271	246	
REGIONAL STAFF											
PA	LOS ANGELES	152		115	454	415	50	46			60
	SAN FRANCISCO	230		160	143	253	76	10			75
	SEATTLE	190		100	1933	484	63	130			251
	PACIFIC REGIONAL LABORATORY-SW								126	56	
	PACIFIC REGIONAL LABORATORY-NW								63	249	
HOURS PER OPERATION		7.5	2.5				5.0	2.5	6.0	5.0	
TOTAL HOURS		19455	2238	2850	11700	3800	4275	2138	5130	4275	4921
CONVERSION FACTOR		950	950	950	1200	950	950	950	1180	1180	950
TOTAL OPERATIONAL FTEs		20.48	2.36	3.00	9.75	4.00	4.50	2.25	4.35	3.62	5.18

9. REMARKS

* Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills should be covered once per year, and other establishment types handling or not handling prohibited material as specified in the inspectional priorities listed on the next page.

BSE inspections are based on CVM's risk based analysis.

*** Technical support hours includes supporting state activities under the Ruminant Feed Ban Regulation, and for supporting state activities under the Feed Manufacturing Program, 71004. These hours also include resources for audits of state contract inspections.

Domestic Investigation Hours are to be utilized for OEI Improvement with a focus on searching for new firms that fall under the high risk category.

Report CVM State Contract Inspection Audit time under 71R843 operation 13 (Investigation operations)

** Import Investigation Hours are for field exams, filer evaluations, follow-up to refusals, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

Reporting Guidance: Import Entry Review (Electronic and Manual—operation code 14, PAC 71R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refused Import Entries (PAC 71R824).

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program

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 should 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. Certain higher risk firm types, such as renderers, protein blenders, and feed mills, generally require regular re-inspections, even if the firm did not manufacture with prohibited material at their last inspection. Efforts should also be placed on regulatory agencies in identifying additional firms to be inspected under this program. In the identification, planning, and prioritization of inspections conducted under this program, the following firm / industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- 'For Cause' inspections
- Firms that have a violative history
- Renderers, Protein Blenders, and Feed Mills manufacturing with prohibited materials (Performance Goal Firms)
- Rendering operations (involving any product)
- Protein Blenders (involving any product)
- Commercial feed mills (ruminant feeds involved)
- Commercial feed mills (non-ruminant feeds involved)
- Animal feed distributors/retailers (ruminant feed or feed ingredients involved)
- Pet food/animal feed salvage operations
- Commercial feed mills (pet food manufacturing ONLY)
- Haulers/transporters of animal feeds (ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (non-ruminant feed or feed ingredients involved)
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Mobile feed mixers
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feed or feed ingredients involved)
- Haulers/transporters of animal feeds (no ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (pet foods ONLY 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 FACTS database, and through the BSE District Coordinator. A listing of these firms can also be found through the CVM website (<http://www.fda.gov/cvm/RuminantFeedInspections.htm>).

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input 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 Methods Validation/Development Program			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 5.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)						
	TOTAL FIELD	1205	4720						
NE	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB	150							
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
PHILADELPHIA									
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB	150							
	REGIONAL STAFF								
	DALLAS								
	DENVER	150	4130						
PA	KANSAS CITY	150							
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB	305							
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW	150							
	PACIFIC REGIONAL LABORATORY-NW	150	590						
HOURS PER OPERATION									
TOTAL HOURS		1205	4720						
CONVERSION FACTOR		1205	1180						
TOTAL OPERATIONAL FTEs		1.00	4.00						

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE
Forensic Evaluation and Sample Analyses

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

3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To analyze domestic and imported animal feed and feed ingredients in support of criminal investigations.

To prevent widespread abuses by the nation's food suppliers.

5. PROGRAM JUSTIFICATION

6. FIELD OBLIGATIONS

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE 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 1.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		FORENSIC ANALYSIS CHEM (Hours)							
	TOTAL FIELD		1205							
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		1205							
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			1205							
CONVERSION FACTOR			1205							
TOTAL OPERATIONAL FTEs			1.00							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments, Pandemic Preparedness	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.	
5. PROGRAM JUSTIFICATION A number of potential or emerging problems which cannot be predicted must be handled. The resources for these Center initiated assignments are planned under this umbrella program.	
6. FIELD OBLIGATIONS Conduct inspections, investigations, sample collections and analyses as directed by Center assignments.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All veterinary products	d. INDUSTRY/PRODUCT CODE(S) 54, 56, 67-72
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 N/A	

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments / Pandemic Preparedness	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71V800, 71R852	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	2 INVESTIGATIONS 71V800 (Hours)	PANDEMIC PREPAREDNESS 71R852 (Hours)						
	TOTAL FIELD	950	3800						
	HEADQUARTERS								
NE	REGIONAL STAFF								
	NEW ENGLAND	20	105						
	NEW YORK	19	105						
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE	27	142						
	CHICAGO	39	105						
	CINCINNATI	39	105						
	DETROIT	33	105						
	MINNEAPOLIS	120	117						
	NEW JERSEY	11	105						
	PHILADELPHIA	34	127						
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA	86	669						
	FLORIDA	18	105						
	NEW ORLEANS	48	792						
	SAN JUAN	8	105						
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS	109	556						
	DENVER	38	105						
	KANSAS CITY	208	137						
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES	18	105						
	SAN FRANCISCO	30	105						
	SEATTLE	45	105						
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS		950	3800						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		1.00	4.00						

9. REMARKS

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

PANDEMIC PREPAREDNESS: Resources for investigating avian flu incidents at domestic sites by examining poultry products used in animal feed/feed ingredients including poultry litter (this may require inspections at renderers to determine distribution of poultry products from diseased poultry). Gather Import information on receipt and distribution of adamantane class antiviral drugs; investigate the use of these drugs in domestic status. Investigational details will be provided via directed assignments from CVM.

71R852: Workload Source: Based on poultry production data obtained from USDA/AMS but also ensuring minimal coverage for all Districts. Hours are assigned by CVM.

71V800: Workload Source: Based on a pro-rated inventory in Feed Manufacturing, Feed Contaminants and Pre-Approval programs.

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2007**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	170.3	48.0	18.7	237.0	295.6	83.1	32.3	411.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	94.7	39.8	13.7	148.2	163.9	68.9	23.7	256.5
83	PRODUCT EVALUATION: DEVICES	32.6		3.9	36.5	56.4		6.7	63.1
84	SCIENCE: DEVICES	4.7			4.7	8.1			8.1
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.8		0.1	14.9	26.5		0.2	26.7
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	23.0	8.2	1.0	32.2	39.8	14.2	1.7	55.7

"Operational FTEs" are those FTEs specifically planned in the Workplan. This includes the categories of Mission Direct: Annual Planned and Mission Direct: Pre-Planned from the Workplan Call.

"Program FTEs" covers all FTEs and includes: 1) all categories of Mission Direct and Program Direction & Assistance (PDA) from the Workplan Call, and 2) all user fee and reimbursable FTEs. This replaces the previous category of "Supported FTEs".

These changes are in terminology only. There have been no changes in types of positions planned in the Workplan.

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting – MDR Follow-up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES
 Rapidly identify immediate hazards to health;
 Identify significant problems by analyzing recurring problems and performing trends analysis;
 Provide data on complaints, significant problems and potential hazards so that corrective action can be initiated for hazardous products in the marketplace.

5. PROGRAM JUSTIFICATION
 Early detection of device problems is necessary to protect the public from health hazards. Reports of device defects are often the first warning of manufacturing or other problems. When the Center receives notices from manufacturers that a device has been associated with a death or serious injury, it may issue a priority assignment to the field for follow-up at the manufacturer reporting site (usually a medical facility). When the Center's evaluation of the problem report suggests that there is an actual or potential health hazard it issues an assignment to the field for immediate follow-up.

6. FIELD OBLIGATIONS
 On assignment, follow up on MDR reports either at the medical facility or manufacturer.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input type="checkbox"/>	BY DISTRICT OFFICE	<input checked="" type="checkbox"/>	BY CENTER	<input type="checkbox"/>	BY BOTH
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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 Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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e. EXAM TYPE:	<input checked="" type="checkbox"/>	CHEMICAL	<input checked="" type="checkbox"/>	MICROBIOLOGICAL	<input type="checkbox"/>	PHYSICAL	<input checked="" type="checkbox"/>	ENGINEERING
	<input type="checkbox"/>	MICROANALYTICAL	<input type="checkbox"/>	OTHERS (Specify)				

f. CHECK THE FOLLOWING ATTRIBUTES
 Sterility Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
 Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up	2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81
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3. PROGRAM/ASSIGNMENT CODE(S) 81010	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S (1)	2 INVE ST I G A T I O N S (Hours) (2)	3 D O M E S T I C S A M P L E C O L L E N G	3 D O M E S T I C S A M P L E C O L L C H E M	3 D O M E S T I C S A M P L E C O L L S T E R	7 D O M E S T I C S A M P L E T O B E A N A L Y Z E D E N G (3)	7 D O M E S T I C S A M P L E T O B E A N A L Y Z E D C H E M (4)	7 D O M E S T I C S A M P L E T O B E A N A L Y Z E D S T E R (5)	9 O T H E R O P E R A T I O N S (Hours)
	TOTAL FIELD		21	74	1	1	1	1	1	1
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		18				1			
	NEW YORK	3		1	1					
	REGIONAL LAB									
	WEAC							1	1	1
CE	REGIONAL STAFF									
	BALTIMORE	2								
	CHICAGO	2	22							
	CINCINNATI									
	DETROIT	1								
	MINNEAPOLIS			10						
	NEW JERSEY									
SE	PHILADELPHIA	2								
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA	2								
	FLORIDA	1								
SW	NEW ORLEANS	2								
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	2	24							
PA	DENVER	1								
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES	2								
	SAN FRANCISCO									
	SEATTLE	1								
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		14.8		10.5	10.5	10.5	37.0	36.0	20.0	
TOTAL HOURS		311	74	11	11	11	37	36	20	
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.33	0.08	0.01	0.01	0.01	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) MDR samples to confirm reported defects.

(4) Performance testing of chemical and serological test kits.

(5) 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
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3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES
Determine compliance of imported devices with the medical device registration and listing requirements, and other general controls.

5. PROGRAM JUSTIFICATION
There are indications that some foreign manufacturers are not registered or listed. Foreign manufacturers of Class II and III devices must be identified for scheduling GMP inspections. In addition, because foreign device manufacturers cannot be inspected as readily as domestic manufacturers, their products must be monitored at the port of entry.

6. FIELD OBLIGATIONS
The field will conduct electronic examinations and/or examine entry documentation for medical devices and ascertain, in conjunction with information provided by CDRH, whether the manufacturer is listed and the initial distributor is registered with CDRH.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:	<input checked="" type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
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b. INSPECTION TYPE:	N/A	<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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e. EXAM TYPE:	<input type="checkbox"/> CHEMICAL	<input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input checked="" type="checkbox"/> ENGINEERING
	<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (Specify)		

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 28.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 ENTRY REVIEW (Hours)	2 IMPORT INV HOURS *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (Physical) ENG	4 IMPORT SAMPLE COLL (Physical) MICRO **	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		23111	5663		60	60	60	60	
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND		685	149		2				
	NEW YORK		2472	882		6				
	REGIONAL LAB									
	WEAC							60	60	
CE	REGIONAL STAFF									
	BALTIMORE		106	95						
	CHICAGO		497	299		2				
	CINCINNATI		599	145		2				
	DETROIT		408	119		1				
	MINNEAPOLIS		211	75		1				
	NEW JERSEY									
	PHILADELPHIA		398	138		1				
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA		378	167		1				
	FLORIDA		205	188		1				
	NEW ORLEANS		1195	253		3				
	SAN JUAN		35	8						
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		13211	2332		34	60			
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES		1214	404		3				
	SAN FRANCISCO		797	251		2				
	SEATTLE		700	158		1				
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION					2.2	2.2	25.5	25.5	
	TOTAL HOURS		23111	5663		132	132	1530	1530	
	CONVERSION FACTOR		1200	950		950	950	1180	1180	
	TOTAL OPERATIONAL FTEs		19.26	5.96		0.14	0.14	1.30	1.30	

9. REMARKS

* Import investigation hours are for field exams, filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

** 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.

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).

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

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
To evaluate the manufacturing processes used for general and radiation-emitting medical devices and *in vitro* diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations.

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.

6. FIELD OBLIGATIONS
Under the Quality Systems/GMP strategy, the field should conduct biennial inspections of high-risk device manufacturers and 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.

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED 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
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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
Engineering Samples: Subs/Sample will vary depending on cost, size, etc. Contact Center for guidance if the device presents such problems.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 104.4 [101.6]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	2	2
		INSP CTIONS LEVEL I DOMESTIC 82845A	INSP CTIONS LEVEL II DOMESTIC 82845B	INSP CTIONS LEVEL III COMPLIANCE DOMESTIC 82845C	INSP CTIONS FOREIGN 82845B	INSP CTIONS FOR CAUSE DOMESTIC 82845G	INSP CTIONS FOR CAUSE HIGH RISK DOMESTIC 82845G	INSP CTIONS ACCRED PERSONS DOMESTIC 82845P	INVEST GATIONS (Hours) 82845B	INVEST GATIONS (Hours) A.P. AUDITS MDUFMA 82845J
	TOTAL FIELD	707	470	107	200	75	75	24	3103	255
NE	HEADQUARTERS				15				2629	
	REGIONAL STAFF									
	NEW ENGLAND	65	43	2	15	7	7	2		51
	NEW YORK	40	27	2	12	4	4	1		
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	20	13	6	6	2	2	1		
	CHICAGO	33	22	6	9	3	3	1		
	CINCINNATI	27	18	10	6	3	3	1		
	DETROIT	22	14	6	6	2	2	1		
	MINNEAPOLIS	56	37	2	15	6	6	2		51
	NEW JERSEY	29	19	5	6	3	3	1		
	PHILADELPHIA	29	19	3	6	3	3	1		
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	37	25	5	12	4	4	1		
	FLORIDA	46	31	11	14	5	5	1		
	NEW ORLEANS	28	19	5	6	3	3	1		
	SAN JUAN	6	4	2	6	1	1			51
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS	22	15	8	12	4	4	1	474	
	DENVER	27	18	4	6	3	3	1		
	KANSAS CITY	27	18	1	6	3	3	1		51
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES	113	75	19	21	11	11	4		
	SAN FRANCISCO	52	34	6	15	5	5	2		
	SEATTLE	28	19	4	6	3	3	1		51
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		36.0	65.0	89.0	65.0	71.0	100.0	78.0		
TOTAL HOURS		25452	30550	9523	13000	5325	7500	1872	3103	255
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		26.79	32.16	10.02	13.68	5.61	7.89	1.97	3.27	0.27

9. REMARKS
For FY 2007, the hours/operation module for Level I inspections has been planned at 36 hours/operation to include additional time for MDR review. Level II inspection hours/operation modules have also been adjusted to reflect increased levels of work.
 Quality Systems Inspection Technique (QSIT) 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. Reprogram any unused resources into Level 1 and 2 inspections.
 Inspectional modules include time for 82845S (sterilization), MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections. Investigational Hours resources have also been planned for National Experts (HQ line) and State Contract Monitoring (DAL-DO line).
 Foreign inspections include resources for Level I, II, III, and For Cause-related inspections. For planning purposes Foreign inspections will be planned under the Level II inspection PAC (82845B); use the appropriate reporting PAC to record accomplishments associated with these Foreign inspections.
 Accredited 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. Accredited Person Audits are conducted by UWE-DO, MIN-DO, S.JN-DO, KAN-DO, SEA-DO.

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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 104.4 [2.3]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL 82845C	3 DOMESTIC SAMPLE COLL ENG 82845C	3 DOMESTIC SAMPLE COLL MICRO 82845C	3 DOMESTIC SAMPLE COLL CHEM 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C		
	TOTAL FIELD	41	10	24	7	10	24	7		
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	4	1	2	1					
	NEW YORK	3	1	1	1					
	REGIONAL LAB									
	WEAC					10	14	7		
CE	REGIONAL STAFF									
	BALTIMORE	2	1	1						
	CHICAGO	1		1						
	CINCINNATI	1		1						
	DETROIT	1		1						
	MINNEAPOLIS	4	1	2	1					
	NEW JERSEY	1		1						
	PHILADELPHIA	1		1						
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	2	1	1						
	FLORIDA	3	1	1	1					
	NEW ORLEANS	1		1						
	SAN JUAN									
W	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	3	1	1	1					
	DENVER	1		1			10			
	KANSAS-CITY	1		1						
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	7	2	4	1					
	SAN FRANCISCO	4	1	2	1					
SEATTLE	1		1							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	6.0				72.0	62.0	32.5		
	TOTAL HOURS	246				720	1488	228		
	CONVERSION FACTOR	950				1180	1180	1180		
	TOTAL OPERATIONAL FTEs	0.26				0.61	1.26	0.19		

9. REMARKS

NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

MICRO Sample Analyses: Antisera and Products Media Testing to support GMP observations at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.

CHEM Sample Analyses: Test Kit or Reagent Testing to support GMP observations at WEAC.

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1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 104.4 [0.5]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL 82845S	3 DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR 82845S	3 DOMESTIC SAMPLE COLL STERILITY 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82845S	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		17	11	6	11	6			
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2	1	1						
	NEW YORK	2	1	1						
	REGIONAL LAB									
CE	WEAC				11	6				
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO	1	1							
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS	2	1	1						
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1	1							
	FLORIDA	2	1	1						
	NEW ORLEANS	1	1							
	SAN JUAN									
W	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1	1							
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	3	2	1						
	SAN FRANCISCO	2	1	1						
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		6.0			25.0	25.0				
TOTAL HOURS		102			275	150				
CONVERSION FACTOR		950			1180	1180				
TOTAL OPERATIONAL FTEs		0.11			0.23	0.13				

9. REMARKS

NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

Note: Domestic Sample Collections for Bioburden, Bioindicator are to be collected "for cause".

Domestic Sample Collections for Contract Sterilizers are to be collected "for cause".

1. PROGRAM/ASSIGNMENT TITLE
Condom Assignment

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
d. INDUSTRY/PRODUCT CODE(S)
85

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE
Manufacturers and Importers of Surgical/Examination Gloves

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

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

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)
85

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.6				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL ENG (PHYSICAL)	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
	TOTAL FIELD					225	680			225
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND				31					
	NEW YORK				112					
	REGIONAL LAB WEAC								225	223
CE	REGIONAL STAFF									
	BALTIMORE					30				
	CHICAGO				82					
	CINCINNATI					17				
	DETROIT									
	MINNEAPOLIS					16				
	NEW JERSEY									
	PHILADELPHIA					29				
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA					88				
	FLORIDA					16				
	NEW ORLEANS					27				
	SAN JUAN									
W	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT					78				
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES					295				
	SAN FRANCISCO					58				
PA	SEATTLE					26				
	PACIFIC REGIONAL LABORATORY-SW									457
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION					2.6	2.6			6.7	6.7
TOTAL HOURS					585	1768			1508	4556
CONVERSION FACTOR					950	950			1180	1180
TOTAL OPERATIONAL FTEs					0.62	1.86			1.28	3.86

9. REMARKS
 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).

NWE-DO, NYK-DO, and CHI-DO Import Samples are for ENG Analysis; remaining districts Import Samples are for CHEM analysis.

1. PROGRAM/ASSIGNMENT TITLE BSE Assignment/Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES
 BSE: To enhance FDA's uniformity in inspection and compliance of BSE firms subject to the regulation and to determine compliance with the BSE regulation.

Center Initiated Assignments: Investigate emerging problems not covered by specific programs and develop approaches for dealing with such problems.

5. PROGRAM JUSTIFICATION
 BSE: 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.

Center Initiated Assignments: 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
 BSE: Districts will, upon assignment, conduct inspections of firms whose devices may contain or be exposed to BSE risk material to implement the objectives of this assignment.

Center Initiated Assignments: 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)
 Center Initiated Assignments: All Devices

d. INDUSTRY/PRODUCT CODE(S)
 Center Initiated

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

f. CHECK THE FOLLOWING ATTRIBUTES
 Center Initiated Assignments: Sterility/Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE BSE Assignment, Center Initiated Assignments					2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z005, 82Z800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 1.7			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	3	7	7	7	8	9
		INSPEC- TIONS BSE (1) 82Z005	INSPEC- TIONS CENTER- INITIATED 82Z800	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL (2) 82Z800	DOMESTIC SAMPLES TO BE ANALYZED CHEM (3) 82Z800	DOMESTIC SAMPLES TO BE ANALYZED STERILITY(4) 82Z800	DOMESTIC SAMPLES TO BE ANALYZED MICRO (5) 82Z800	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours) METH DEV ENG (6) 82Z800
	TOTAL FIELD	10	22		14	1	2	2		400
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	2		1					
	NEW YORK	1	1		1					
	REGIONAL LAB									
	WEAC					1	2	2		400
CE	REGIONAL STAFF									
	BALTIMORE	1	1							
	CHICAGO		1		3					
	CINCINNATI		1		1					
	DETROIT		1							
	MINNEAPOLIS	1	1		1					
	NEW JERSEY	1	1		1					
	PHILADELPHIA		1							
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA	1	1		1					
	FLORIDA		1		1					
	NEW ORLEANS		1							
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS	1	1		1					
	DENVER	1	1							
	KANSAS CITY		1							
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1	3		1					
	SAN FRANCISCO	1	2		2					
	SEATTLE		1							
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		20.0	36.0		10.0	15.0	50.0	50.0		
TOTAL HOURS		200	792		140	15	100	100		400
CONVERSION FACTOR		950	950		950	1180	1180	1180		1180
TOTAL OPERATIONAL FTEs		0.21	0.83		0.15	0.01	0.08	0.08		0.34

9. REMARKS
 (1) BSE Inspections (82Z005):Districts will, upon assignment, conduct inspections of firms whose devices may contain, or be exposed to, BSE risk material.
 (2) Includes Documentary Samples and Analytical Samples.
 (3) WEAC--Ad Hoc testing of test kits or reagents.
 (4) WEAC--Sterility samples.
 (5) WEAC--Ad Hoc testing of media.
 (6) WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM TYPE: N/A COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

5. PROGRAM JUSTIFICATION
Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS
Conduct activities under this program as directed by the Division of Field Science.

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
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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 Methods Validation/Development Program			2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82R816		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV MICRO (Hours)	METHODS VAL/DEV CHEM (Hours)						
	TOTAL FIELD	1205	1205						
N E	HEADQUARTERS								
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC	1205	1205						
C E	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
S E	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
P A	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
LOS ANGELES									
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS		1205	1205						
CONVERSION FACTOR		1205	1205						
TOTAL OPERATIONAL FTEs		1.00	1.00						

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related Acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize, and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. The specific addition of Forensic Evaluation to 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 Medical Device Premarket Approval and Postmarket Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that both prior to and subsequent to approval of a PMA application, the manufacturer has the capability of manufacturing the PMA device in accordance with (1) the conditions specified in the PMA application and (2) the requirements of the device GMP regulation.	
5. PROGRAM JUSTIFICATION Section 515 of the Act requires that devices subject to Premarket Approval must be manufactured in conformance with the requirements of the device GMP regulation. Consequently, no PMA application can be approved until the Center has inspectional evidence that the manufacturer complies with the requirements set forth in the Premarket Approval application.	
6. FIELD OBLIGATIONS The field will conduct pre-approval inspections on assignment and submit an EIR to the Center along with the District's recommendation. The field will be responsible for scheduling post-approval inspections to occur approximately 8 months following approval of the PMA. Under certain conditions, a post-approval inspection will not be necessary. The Center will advise the district when a post-approval inspection is not necessary.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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 11.2
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E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	6	7	8	9
		INSP CTIONS PRE- APPROVAL 83001	INSP CTIONS POST- APPROVAL 83001A	FOREIGN INSP CTIONS PRE- APPROVAL 83001	FOREIGN INSP CTIONS POST- APPROVAL 83001A	INSP CTIONS MDUFMA USER FEE 83001	IMP ORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMP ORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	20	65	32	27	99				
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	2	7	4	3	10				
	NEW YORK	1	3			4				
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		2			2				
	CHICAGO		1	3	3	2				
	CINCINNATI	1	2			3				
	DETROIT		1			2				
	MINNEAPOLIS	2	7	4	3	11				
	NEW JERSEY	1	3	3	3	5				
	PHILADELPHIA	1	3			4				
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	1	2			4				
	FLORIDA	1	4	3	3	5				
	NEW ORLEANS	1	2			3				
	SAN JUAN	1	2	2	3	3				
	REGIONAL LAB									
PA	REGIONAL STAFF									
	DALLAS	1	3	3	3	4				
	DENVER	1	2			3				
	KANSAS CITY		1			2				
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	3	12	6	3	20				
	SAN FRANCISCO	2	6	4	3	9				
	SEATTLE	1	2			3				
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		48.2	30.2	50.7	49.4	48.2				
TOTAL HOURS		964	1963	1622	1334	4772				
CONVERSION FACTOR		950	950	950	950	950				
TOTAL OPERATIONAL FTEs		1.01	2.07	1.71	1.40	5.02				

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.

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
3. PROGRAM TYPE: <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure the quality, reliability and integrity of data and information supporting device applications (PMAs, 510(k)s or IDEs) and their claims of safety and effectiveness; To ensure that human subjects taking part in clinical trials involving medical devices are protected from undue hazard or risk; To coordinate, implement and enforce the provisions of the Agency's Application Integrity Policy (AIP) for medical devices; To enforce the prohibition against promotion and/or commercialization of investigational devices.	
5. PROGRAM JUSTIFICATION Congress has mandated that the Agency maintain close surveillance of bioresearch activities done in support of application. CDRH issues assignments and provides inspectional/investigational support documents for transmission to the field through ORA's Office of Enforcement (HFC-230). The Center reviews and evaluates all Establishment Inspection Reports (EIRs) from the field and is responsible for the final classification of all bioresearch monitoring inspection reports and the issuance of all associated correspondence.	
6. FIELD OBLIGATIONS To conduct inspections, investigations and other activities related to the bioresearch monitoring programs or the Agency's Application Integrity Policy for medical devices and to submit EIRs to the Center for review, evaluation and final classification. The field is encouraged to review and initially classify inspection reports generated under the bioresearch monitoring program. However, final classification authority rests with the Center and decisions will be communicated promptly to the field.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73Z, 74Z and 94Z, 95Z
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>Specify</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Bioresearch Monitoring (Pre-Market)	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM/ASSIGNMENT CODE(S) 83808, 83809, 83810, 83811	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 25.3
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REG I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	4	5	6	7	8	9
		INSP E C T I O N S D O M E S T I C	INSP E C T I O N S F O R E I G N	D O M E S T I C S A M P L E C O L L	I M P O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	I M P O R T F I E L D E X A M S	D O M E S T I C S A M P L E S T O B E A N A L Y Z E D	I M P O R T S A M P L E S T O B E A N A L Y Z E D	O T H E R O P E R A T I O N S (Hours)
	TOTAL FIELD	300	10							
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND	16	1							
	NEW YORK	18	1							
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	16	1							
	CHICAGO	10								
	CINCINNATI	19								
	DETROIT	19								
	MINNEAPOLIS	14								
	NEW JERSEY	5								
	PHILADELPHIA	13	1							
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA	15	1							
	FLORIDA	17	1							
	NEW ORLEANS	17								
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS	26	2							
	DENVER	9	1							
	KANSAS CITY	10								
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES	38								
	SAN FRANCISCO	18	1							
	SEATTLE	20								
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	77.5	77.5							
	TOTAL HOURS	23250	775							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	24.47	0.82							

9. REMARKS
 Device Bioresearch Monitoring inspections should be prioritized according to the following scheme:
 1) For Cause with 30-day due dates;
 2) Directed data audit for expedited PMA;
 3) Directed data audit for non-expedited PMA;
 4) For Cause with 60-90 day due dates;
 5) OAI Follow-up (6 months);
 6) Early Intervention (Probability Sampling, Vulnerable Population, and IDE-based)
 7) Routine Surveillance.

Please contact Matthew Tarosky at (240) 276-0243 with any questions.

P, IRB, Sponsor/Monitor, and Clinical Investigator Inspections have been consolidated for planning purposes, with a column for Domestic and Foreign inspections. Continue to report time against PACs 83808 (GLP), 83809 (IRB), 83810 (Sponsor/Monitor), and 83811 (Clinical Investigator), depending on the type of inspection.

1. PROGRAM/ASSIGNMENT TITLE
Test Method Development and Evaluation

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

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

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

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

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

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
To be assigned

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation					2. PPS PROJECT NAME/NUMBER Science: Devices - 84					
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.7				
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	9 OTHER OPERATIONS (Hours)	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	TOTAL FIELD									800
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC								800	3590
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									
PA	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
LOS ANGELES										
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION										
TOTAL HOURS									800	3590
CONVERSION FACTOR									1180	1180
TOTAL OPERATIONAL FTEs									0.68	3.04

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
Methods Validation/Development Program

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

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

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

5. PROGRAM JUSTIFICATION
Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS
Conduct activities under this program as directed by the Division of Field Science.

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Mammography equipment	d. INDUSTRY/PRODUCT CODE(S) 90
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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 Mammography Facilities Inspection Program				2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85						
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.9 [9.4]			
REG ION	DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2		
		INSPEC- TIONS 85014 (1)	INSPEC- TIONS FOREIGN 85014 (2)	INSPEC- TIONS 85014 (3)	INSPEC- TIONS 85014 (4)	INSPEC- TIONS 85014F (5)	INSPEC- TIONS 85014F (6)	INVESTI- GATIONS (Hours) 85014A (7)	INVESTI- GATIONS (Hours) 85014F (8)	
TOTAL FIELD		213	15	122	31	9	9	2321	5334	
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	46	5	3	1	1	1	154	217	
	NEW YORK			1	3	1	1	154	483	
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE	15		17	2	1	1	110	287	
	CHICAGO			2	1			121		
	CINCINNATI			3	1			143	511	
	DETROIT	13		1				143	252	
	MINNEAPOLIS			9				143	469	
	NEW JERSEY	20		2				66	98	
	PHILADELPHIA FORENSIC CHEM. CTR		5	2	1	1	1	110	154	
SE	REGIONAL STAFF									
	ATLANTA			13	2			132	455	
	FLORIDA		5	6	6	1	1	110	217	
	NEW ORLEANS			8	2	1	1	154	245	
	SAN JUAN REGIONAL LAB	3						55	98	
W	REGIONAL STAFF	110		24	5	2	2	330	735	
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES			11	3	1	1	110	483	
	SAN FRANCISCO	6		10	4			176	420	
	SEATTLE			10				110	210	
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		8.0	8.0	8.0	8.0	11.0	11.0			
TOTAL HOURS		1704	120	976	248	99	99	2321	5334	
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	
TOTAL OPERATIONAL FTEs		1.47	0.10	0.84	0.21	0.09	0.09	2.00	4.60	

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

- 1) Inspection of Certified Mammography Facilities not covered by the states.
- 2) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries.
- 3) Federal Facility Inspections (does not include VHA Facility inspections).
- 4) VHA Facility Inspections.
- 5) Follow-up Inspections.
- 6) Follow-up Inspection after Warning Letter.
- 7) Audit Investigations.
- 8) Inspection Follow-Up Activities (Non-Warning Letter).

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1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program					2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85					
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.9 [5.5]			
R E G I O N	6.	1	2	3	4	5	6	9	9	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	F I E L D E X A M S/ T E S T S	IMP O R T F I E L D E X A M S	O T H E R O P E R A T I O N S (Hours) 85014 (9)	O T H E R O P E R A T I O N S (Hours) 85014 (10)	O T H E R O P E R A T I O N S (Hours) 85014C (11)
	TOTAL FIELD							1200	5162	59
NE	HEADQUARTERS									
	REGIONAL STAFF							200		
	NEW ENGLAND								294	7
	NEW YORK								369	6
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF							400		
	BALTIMORE								250	7
	CHICAGO									
	CINCINNATI								347	
	DETROIT								321	
	MINNEAPOLIS								334	
	NEW JERSEY								150	
	PHILADELPHIA FORENSIC CHEM. CTR								255	6
SE	REGIONAL STAFF							200		
	ATLANTA								363	
	FLORIDA								294	6
	NEW ORLEANS								360	7
	SAN JUAN								89	
	REGIONAL LAB									
N	REGIONAL STAFF							200	910	13
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF							200		
	LOS ANGELES								343	7
	SAN FRANCISCO								255	
	SEATTLE								228	
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS								1200	5162	59
CONVERSION FACTOR								1200	1160	1160
TOTAL OPERATIONAL FTEs								1.00	4.45	0.05

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

9) Technical Assistance and Coordination Activities: RRHRs.
 10) Technical Assistance and Coordination Activities.
 11) Compliance Activities.

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 TYPE:	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

Inspection of Manufacturers of Laser Products:
To determine if laser products are in compliance with the radiation emissions requirement 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 light radiation from sunlamp products. The performance standard for sunlamp products became effective May 7, 1980, and the amended standard on September 7, 1986. Recent studies suggest that exposure to excessive UVA radiation has resulted in malignant melanoma.

6. FIELD OBLIGATIONS

Inspection of Manufacturers of Laser Products: Electro-Optic specialists will initiate and schedule their own inspections of laser manufacturers listed in the compliance program. In addition, the Electro-Optic Specialist will participate on joint CDRH/ORR inspections when such inspections are scheduled by the Center.

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 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
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b. INSPECTION TYPE:

<input checked="" type="checkbox"/>	COMPREHENSIVE	<input type="checkbox"/>	ABBREVIATED	<input checked="" type="checkbox"/>	DIRECTED
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c. PRODUCT(S) Lasers and laser products Sunlamp, suntanning booths, and sunlamp products.	d. INDUSTRY/PRODUCT CODE(S) 95LS-99 95 US-11
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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

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

Caution: laser product *may* 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					
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 4.7		
6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	3	5	5	9	9
	INSP- CTIONS 86001 (1)	INSP- CTIONS FOREIGN 86001 (2)	INSP- CTIONS 86002 (3)	INVEST- IGATIONS (Hours) 86001 (4)	DOMESTIC SAMPLE COLL 86001	FIELD EXAMS/ TESTS 86001 (5)	FIELD EXAMS/ TESTS 86002 (6)	OTHER OPERATIONS (Hours) 86001 (7)	OTHER OPERATIONS (Hours) 86002
TOTAL FIELD	100	5	7	638	5	75	30	1216	75
HEADQUARTERS									
REGIONAL STAFF									
NE	NEW ENGLAND		1	60		7	1	113	9
	NEW YORK	4			30	1	3	56	
	REGIONAL LAB								
	WEAC		5						
	REGIONAL STAFF								
CE	BALTIMORE	3		21		2	2	40	
	CHICAGO	3		1	21	2	1	42	9
	CINCINNATI	3		1	22	3	2	42	15
	DETROIT	5			29	1	4	55	
	MINNEAPOLIS	4			27		4	51	
	NEW JERSEY	3		1	19		2	37	5
	PHILADELPHIA	3			21		2	40	
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF	12		1	80	1	11	153	18
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
Y	REGIONAL STAFF								
	DALLAS	6			30		3	56	
	DENVER	4			31		4	60	
	KANSAS CITY	3		1	17	1	2	33	13
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
PA	LOS ANGELES	17		1	106	1	12	201	6
	SAN FRANCISCO	15			89		10	170	
	SEATTLE	5			35		4	67	
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION	17.2	52.4	13.8		3.0	5.0	3.9		
TOTAL HOURS	1720	262	97	638	15	375	117	1216	75
CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs	1.81	0.22	0.10	0.67	0.02	0.39	0.12	1.28	0.08

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

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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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

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

f. CHECK THE FOLLOWING ATTRIBUTES

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 10.0			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	2	5	5	5B	8	9
		INSP CTIONS 86003	INSP CTIONS 86004	INVEST IGATIONS (Hours) 86003	INVEST IGATIONS (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	8	1030	40	1307	163	30		3225
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND	1	1	39	8	50	9			131
	NEW YORK	2	1	44		56	19	2		143
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE	1		52		66	25	2		164
	CHICAGO	1	1	42	8	53	6			137
	CINCINNATI	1		55		70	9	2		172
	DETROIT			54		68	7	4		168
	MINNEAPOLIS			60		75	5	4		183
	NEW JERSEY			22		28	3			86
PHILADELPHIA	2		44		56	5	2		143	
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		1	83	8	105	10	2		244
	FLORIDA	1	1	79		101		2		236
	NEW ORLEANS	2	1	78		98	3			230
	SAN JUAN			2		2	2			32
W	REGIONAL LAB									
	REGIONAL STAFF	3		222		284		4		670
	DALLAS						12			
	DENVER				8		4			
	KANSAS CITY						3			
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES	1	1	61	8	77	27	2		187
	SAN FRANCISCO	2	1	51		65	8	2		162
	SEATTLE	1		42		53	6	2		137
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		16.0	8.0			3.0	5.2	4.0		
TOTAL HOURS		288	64	1030	40	3921	848	120		3225
CONVERSION FACTOR		950	950	950	950	950	950	950		950
TOTAL OPERATIONAL FTEs		0.30	0.07	1.08	0.04	4.13	0.89	0.13		3.39

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, HFZ 300. 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.

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ATTACHMENT A
2007 WORKPLAN FOR FIELD COMPLIANCE TESTING
OF DIAGNOSTIC X-RAY SYSTEMS
(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2007)

NEW ENGLAND DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CT	90	-	10	1	-
ME	41	-	4	1	-
MA	183	-	20	2	-
NH	46	-	5	1	-
RI	35	-	4	-	-
VT	20	-	2	-	-
Total	415		45	5	

NEW YORK DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NY	466	-	50	6	2

BALTIMORE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DC	26	-	3	-	-
MD	168	-	18	2	2
VA	287	-	31	4	-
WV	66	-	7	1	-
Total	547		59	7	2

CHICAGO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IL	441		48	5	

CINCINNATI DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
KY	188	-	21	2	-
OH	392	-	42	5	2
Total	580		63	7	2

DETROIT DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IN	235	-	25	3	2
MI	331	-	36	4	2
Total	566		61	7	4

MINNEAPOLIS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
MN	252	-	27	3	4
ND	28	-	3	-	-
SD	42	-	4	1	-
WI	305	-	33	4	-
Total	627		67	8	4

NEW JERSEY DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NJ	230		25	3	

PHILADELPHIA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DE	31	-	4	-	-
PA	428	-	47	5	2
Total	459		51	5	2

ATLANTA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
GA	321	-	35	4	2
NC	358	-	39	4	-
SC	193	-	21	2	-
Total	872		95	10	2

FLORIDA DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
FL	833		91	10	2

NEW ORLEANS DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AL	201	-	22	2	-
LA	198	-	22	2	-
MS	109	-	12	1	-
TN	308	-	33	4	-
Total	816		89	9	

SAN JUAN DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
PR	20		2		

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AR	121	-	13	2	-
OK	137	-	15	2	-
TX	1067	-	116	13	4
Total	1325		144	17	4

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CO	195	-	22	2	-
NM	59	-	6	1	-
UT	102	-	11	1	-
WY	21	-	3	-	-
Total	377		42	4	

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IA	150	-	16	2	-
KS	121	-	13	2	-
NE	95	-	10	1	-
MO	270	-	30	3	-
Total	636		69	8	

LOS ANGELES DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AZ	266	-	29	3	-
CA	376	-	40	5	2
Total	642		69	8	2

SAN FRANCISCO DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CA	397	-	43	5	2
HI	34	-	4	-	-
NV	104	-	12	1	-
Total	535		59	6	2

SEATTLE DISTRICT

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AK	33	-	4	-	-
ID	61	-	6	1	-
MT	33	-	4	-	-
OR	108	-	12	1	-
WA	208	-	22	3	2
Total	443		48	5	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
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR 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: BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE: COMPREHENSIVE ABBREVIATED 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: CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*Specify*)

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
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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 3.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	7	7	7	7	7	7	8	9
		FOREIGN INSPECTIONS (PL 90-602 STANDARD)	DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	DOMESTIC SAMPLES TO BE ANALYZED X-RAY SOURCE	DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	14	75	15	4	1	12			
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC	14	75	15	4	1	12			
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
W	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		70.0	23.6	39.0	245.0	120.0	15.0			
TOTAL HOURS		980	1770	585	980	120	180			
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs		0.83	1.50	0.50	0.83	0.10	0.15			

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
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3. PROGRAM TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

To assure that imported electronic products presented for entry into the U.S. are certified to be in compliance with appropriate standards where applicable.

To provide a mechanism through which imported electronic products found to be in noncompliance with FDA regulations can be precluded from introduction into commerce in the United States.

5. PROGRAM JUSTIFICATION

FDA under the authority of Public Law 90-602 conducts program effort to minimize the effects of harmful radiation from electronic products and radiation emitting medical devices. The Act is very specific about restrictions and safeguards concerning such electronic products from foreign countries.

6. FIELD OBLIGATIONS

The district import program manager will monitor all custom entries of electronic products for which performance standards are in effect and determine whether imported models are contained on lists provided by CDRH and that these models are not among those which have been determined to be noncompliant. All information gathered as a result of these activities will be furnished to the Office of Compliance in accordance with the compliance program.

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

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

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

MICROANALYTICAL OTHERS (*Specify*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
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3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 8.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	2	3	4	5	7	8	9
		INSP EC T I O N S	ENT RY R E V I E W (Hours)	IMP O R T I N V H O U R S *	DO M E S T I C S A M P L E C O L L	IMP O R T S A M P L E C O L L	FI E L D E X A M S/ T E S T S	DO M E S T I C S A M P L E S T O B E A N A L Y Z E D	IMP O R T S A M P L E S T O B E A N A L Y Z E D	OT H E R O P E R A T I O N S (Hours)
	TOTAL FIELD		7790	1620						
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND		78	29						
	NEW YORK		527	371						
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE		47	59						
	CHICAGO		234	132						
	CINCINNATI		980	61						
	DETROIT		351	47						
	MINNEAPOLIS		27	31						
	NEW JERSEY									
	PHILADELPHIA		20	56						
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA		116	83						
	FLORIDA		126	118						
	NEW ORLEANS		351	53						
W	SAN JUAN		12							
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT		3204	222						
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES		945	178						
	SAN FRANCISCO		222	97						
	SEATTLE		550	83						
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS			7790	1620						
CONVERSION FACTOR			1200	950						
TOTAL OPERATIONAL FTEs			6.49	1.71						

9. REMARKS

* Import investigation hours are for field exams, filer evaluations, follow-up to refusals, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

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).

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 TYPE: COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

4. OBJECTIVES

Use Control:
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.

Emergency Planning & Response Activities:
To act as a focal point for emergency readiness response planning by States.

5. PROGRAM JUSTIFICATION

Medical Device and Radiological Health Use Control and Policy Implementation:
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.

Emergency Planning & Response Activities:
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

Use Control: 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.

Emergency Planning & Response Activities: Provide consultation to states and attend regional emergency planning meetings.

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

Emergency Planning & Response Activities

b. INSPECTION TYPE: N/A COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) Emergency Planning & Response Activities: 94YN-99
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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 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 5.4
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REGION	6. DISTRICT/SPECIALIZED LABORATORY	1	2	3	4		9 TECHNICAL ASSISTANCE (Hours) RRHR	9 MISC (Hours) DENT	9 MISC (Hours) RRHR
		INSPCTIONS	INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL		86009	86008	86008
	TOTAL FIELD						2400	475	3600
NE	HEADQUARTERS								
	REGIONAL STAFF						400		600
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC							475	
CE	REGIONAL STAFF						800		1200
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF						400		600
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF						400		600
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF						400		600
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS							2400	475	3600
CONVERSION FACTOR							1200	1180	1200
TOTAL OPERATIONAL FTEs							2.00	0.40	3.00

9. REMARKS
 See Continuation Sheet for footnotes, guidance, etc.

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

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

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 will be performed by RRHRs.

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.

