

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations				2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53						
3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 10.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	2	4	5	6	7	8	9
		INSP CTIONS DOMESTIC	INSP CTIONS FOREIGN	MEDICAL ERRORS INV HOURS	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZEC	IMPORT SAMPLES TO BE ANALYZED	MISC. HOURS
	<b>TOTAL FIELD</b>	<b>100</b>	<b>26</b>	<b>1824</b>						
NE	HEADQUARTERS	(b)(2)&b(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	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 - NW									
	PACIFIC REGIONAL LAB - SW									
	HOURS PER OPERATION	57.0	60.0							
	TOTAL HOURS	5700	1560	1824						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	6.26	1.71	2.00						

7. REMARKS

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

Domestic Inspections are spread by CDER HFD-332 based upon where inspections are likely to occur.  
Numbers for domestic inspections may change slightly pending CDER assignment.  
Medical errors investigation time is spread evenly to all Districts.  
Foreign Inspections are spread by DEIO ITOB HFC-133.  
Foreign inspections must be reported under foreign operation code 11.



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

4. OBJECTIVES

Through audit procedures determine whether data submitted to FDA in NDAs 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:

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 In Vivo Bioequivalence (Pre-Approval)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	4	5	6	7	8	9
		48001 ANDA INSPEC- TIONS <small>DOMESTIC</small>	48001A NDA INSPEC- TIONS (PDUFA) <small>DOMESTIC</small>	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>36</b>	<b>34</b>							
NE	HEADQUARTERS	(b)(2)&b(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION		65.1	75.6							
TOTAL HOURS		2344	2570							
CONVERSION FACTOR		910	910							
TOTAL OPERATIONAL FTEs		2.58	2.82							

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) 49%, PDUFA 48001A (NDA) 51%.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE  
Foreign Inspections  
NEW PACs Added 48001,A; 48808; 48811D,E; 48811D

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 4.6			
R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	4	5	6	7	8	9
		FOREIGN 48001A NDA INSPEC- TIONS (PDUFA)	FOREIGN 48001 ANDA INSPEC- TIONS (PRE-APPR)	FOREIGN AIDS RELIEF NDA & A NDA INSPEC- TIONS **	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>30</b>	<b>12</b>	<b>21</b>						
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION	70.7	58.3	65.0						
	TOTAL HOURS	2121	700	1365						
	CONVERSION FACTOR	910	910	910						
	TOTAL OPERATIONAL FTEs	2.33	0.77	1.50						

7. REMARKS

**\* Planned inspections include: PAC 48001,A In Vivo Bioequivalence, PAC 48811 Clinical Investigators, 48808 GLPs (PDUFA) and NEW 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): PACs 48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigator. ALL PEPFAR Resources are planned under PAC 48001D. 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:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

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

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

6. FIELD OBLIGATIONS  
Conduct 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:  
 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 Good Laboratory Practices (PDUFA)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48							
3. PROGRAM/ASSIGNMENT CODE(S) 48808			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 NAT'L EXPERT INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	50	615							
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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	88.0								
	TOTAL HOURS	4400	615							
	CONVERSION FACTOR	910	910							
	TOTAL OPERATIONAL FTEs	4.84	0.68							

9. REMARKS

Resources planned for Inspections may also be used for DSCs.

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

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE <b>Institutional Review Board (IRB); Radioactive Drug Research Committee (RDRC)</b>	2. PPS PROJECT NAME/NUMBER <b>Bioresearch Monitoring: Human Drugs - 48</b>
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) <b>Human Drugs</b>	d. INDUSTRY/PRODUCT CODE(S) <b>60 , 61</b>
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board (PDUFA), Radioactive Drug Research Committee (PDUFA)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48
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3. PROGRAM/ASSIGNMENT CODE(S) 48809; 48809A	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 I R B INSPECTIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>145</b>								
	HEADQUARTERS	(b)(2)&b(7)								
NE	REGIONAL STAFF	(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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	57.1								
	TOTAL HOURS	8280								
	CONVERSION FACTOR	910								
	TOTAL OPERATIONAL FTES	9.10								

7. REMARKS

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

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE  
Sponsors, Contract Research Organizations, & Monitors

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

3. PROGRAM TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  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:  
 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  
Clinical Investigators

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

3. PROGRAM TYPE:  COMPLIANCE PROGRAM  PROGRAM CIRCULAR  ASSIGNMENT

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

5. PROGRAM JUSTIFICATION  
Clinical 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:  
 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





## FY 2005

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

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832, 56R359, 56002M*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 132.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	3	7	7	9	9
		INSPECTIONS	INSPECTIONS (Hours)	CHEMISTS INSP CTIONS HOURS	MICRO INSP CTIONS (Hours)	DOMESTIC SAMPLE COLL **	DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	CERTIFICATION HOURS For Audits	MISC HOURS For Team Biologics Therapeutics INV hours
	<b>TOTAL FIELD</b>	1430	755	7574	1538	450	229	40	4800	2730
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	NEW ENGLAND	(b)(2)&b(7)(E)								
	NEW YORK	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	WEAC	(b)(2)&b(7)(E)								
CE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	BALTIMORE	(b)(2)&b(7)(E)								
	CHICAGO	(b)(2)&b(7)(E)								
	CINCINNATI	(b)(2)&b(7)(E)								
	DETROIT	(b)(2)&b(7)(E)								
	MINNEAPOLIS	(b)(2)&b(7)(E)								
	NEW JERSEY	(b)(2)&b(7)(E)								
	PHILADELPHIA FORENSIC CHEM. CTR	(b)(2)&b(7)(E)								
SE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	ATLANTA	(b)(2)&b(7)(E)								
	FLORIDA	(b)(2)&b(7)(E)								
	NEW ORLEANS	(b)(2)&b(7)(E)								
	SAN JUAN REGIONAL LAB	(b)(2)&b(7)(E)								
SW	REGIONAL STAFF	(b)(2)&b(7)(E)								
	DALLAS	(b)(2)&b(7)(E)								
	DENVER	(b)(2)&b(7)(E)								
	KANSAS CITY	(b)(2)&b(7)(E)								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2)&b(7)(E)								
PA	REGIONAL STAFF	(b)(2)&b(7)(E)								
	LOS ANGELES	(b)(2)&b(7)(E)								
	SAN FRANCISCO	(b)(2)&b(7)(E)								
	SEATTLE	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW	(b)(2)&b(7)(E)								
HOURS PER OPERATION		65.0				5.0	38.0	28.0		
TOTAL HOURS		92950	755	7574	1538	2250	8702	1120	4800	2730
CONVERSION FACTOR		910	910	910	910	910	1180	1180	910	910
TOTAL OPERATIONAL FTEs		102.14	0.83	8.32	1.69	2.47	7.37	0.95	5.27	3.00

7. REMARKS

The number of inspections anticipated for drug firms in the high risk category represents 55% of RX drug manufacturers including API manufacturers and sterile drug firms.

(b)(2)&b(7)(E)

Investigational resources include 3 FTEs for transfer of therapeutics from Biologics planned as headquarters positions. Gas firms are under a separate worksheet 56-4 . \*\* DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.

**Use CT PAC 56R845 only when specific CT work is performed. \*56002M Therapeutic Biologic Products PAC**

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1. PROGRAM/ASSIGNMENT TITLE DRUG Process Inspections- Domestic (Gas Manufacturer)				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3. PROGRAM/ASSIGNMENT CODE(S) 56002E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (5.0)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS  MEDICAL GAS *	2 Investigations Hours	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLE ANALYSES	8 IMPORT SAMPLES ANALYSES	9 MISC. HOURS	
	<b>TOTAL FIELD</b>		<b>152</b>								
NE	HEADQUARTERS	(b)(2)&b(7) (E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
	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-SW										
	PACIFIC REGIONAL-NW										
HOURS PER OPERATION		30.0									
TOTAL HOURS		4560									
CONVERSION FACTOR		910									
TOTAL OPERATIONAL FTEs		5.01									

9. REMARKS

\* Total number of planned gas inspections in the Program for 2005

(b)(2)&b(7)(E)

Nationwide there are approximately 4000 gas manufacturers.

There are approximately 285 parent companies with 2200 specific sites where medical gas is manufactured/repacked.

## FY 2005

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Foreign Drug Inspections	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> The field will conduct drug process inspections and maintain profiles of foreign drug manufacturers.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Human Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> All Human Drug Codes
<b>e. EXAM TYPE:</b> <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> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

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 18.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **						
	<b>TOTAL FIELD</b>	195	4670						
NE	HEADQUARTERS	(b)(2)&b(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
HOURS PER OPERATION		60.0							
TOTAL HOURS		11700	4670						
CONVERSION FACTOR		910	910						
TOTAL OPERATIONAL FTEs		12.86	5.13						

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

## FY 2005

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Drug Product Surveillance	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Human Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> Industry Codes: 50, 54-56 and 60-66
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> 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.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

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 28.7		
R E G I O N	6.	1	2	3	3	7	7	7	
	DISTRICT/ SPECIALIZED LABORATORY	CHEMIST ON INSPECTIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLLECTIONS **	DOMESTIC SAMPLE COLLECTIONS (API) ***	DOMESTIC SAMPLES ANALYZED (CHEM) *	DOMESTIC SAMPLES ANALYZED (MICRO) *	DOMESTIC SAMPLES ANALYZED (API) (Chem)	
	<b>TOTAL FIELD</b>	<b>310</b>	<b>950</b>	<b>1150</b>	<b>220</b>	<b>1000</b>	<b>150</b>	<b>220</b>	
NE	HEADQUARTERS	(b)(2)&b(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRI								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION				3.0	4.0	19.0	22.0	19.5	
TOTAL HOURS		310	950	3450	880	19000	3300	4290	
CONVERSION FACTOR		910	910	910	910	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0.34	1.04	3.79	0.97	16.10	2.80	3.64	

9. REMARKS

Work performed under 56008D (Bioassay) and 56008G (Radioactive Drug Sampling) have been discontinued.  
 \*DSAs are assigned by DFS (HFC-140) per lab expertise for specific Drugs.  
 Includes 591(\*\*) and 138(\*\*\*) survey assignments planned by the Center (HFD-330).

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1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56
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3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 41.1
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REGION	DISTRICT/SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW HOURS	IMPORT FILER EVAL. HOURS	REFUSAL Follow-Up HOURS	IMPORT LABEL EXAMS	MAIL/ COURIERS REVIEWS INV HOURS **	IMPORT FIELD EXAMS	IMPORT SAMPLE COLLECTIONS *	IMPORT SAMPLES ANALYZED APIs CHEM	IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	<b>TOTAL FIELD</b>	<b>18295</b>	<b>1593</b>	<b>376</b>	<b>2400</b>	<b>9828</b>	<b>4498</b>	<b>1162</b>	<b>90</b>	<b>60</b>

	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	NEW ENGLAND	(b)(2)&b(7)(E)								
	NEW YORK	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	WEAC	(b)(2)&b(7)(E)								
CE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	BALTIMORE	(b)(2)&b(7)(E)								
	CHICAGO	(b)(2)&b(7)(E)								
	CINCINNATI	(b)(2)&b(7)(E)								
	DETROIT	(b)(2)&b(7)(E)								
	MINNEAPOLIS	(b)(2)&b(7)(E)								
	NEW JERSEY	(b)(2)&b(7)(E)								
	PHILADELPHIA	(b)(2)&b(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	ATLANTA	(b)(2)&b(7)(E)								
	FLORIDA	(b)(2)&b(7)(E)								
	NEW ORLEANS	(b)(2)&b(7)(E)								
SW	SAN JUAN	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	DALLAS	(b)(2)&b(7)(E)								
	DENVER	(b)(2)&b(7)(E)								
PA	KANSAS CITY	(b)(2)&b(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	LOS ANGELES	(b)(2)&b(7)(E)								
PA	SAN FRANCISCO	(b)(2)&b(7)(E)								
	SEATTLE	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LAB - NV	(b)(2)&b(7)(E)								

HOURS PER OPERATION				0.7		0.7	2.7	38.0	25.0
TOTAL HOURS	18295	1593	376	1680	9828	3149	3137	3420	1500
CONVERSION FACTOR	1200	910	910	910	910	910	910	1180	1180
TOTAL OPERATIONAL FTEs	15.25	1.75	0.41	1.85	10.80	3.46	3.45	2.90	1.27

7. REMARKS  
 \* PAC Reporting: Entry Reviews 56R833; Filer Evaluations 99R833; Follow-Up to Refusals 56R824, 63R824 Import Label Reviews, Import Field Exams under PACs 52002, 56008H, 56014/A, 63001; Use CT PAC 56R845 only when specific CT work is performed. Report finished dosage form drugs and APIs collected at the site of entry under 56008H.  
 Some samples will be documentary and will not require analysis. Planned sample analyses do not match planned sample collections as a result.  
 ISCs and ISAs of bulk Drugs/API collected at the docks/point of entry are now planned in the workplan.  
 \*\*Mail entry review time is now planned in the workplan. (Hours for NYK includes 200 hours for Newark Airport.)

## FY 2005

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Drug Quality Reporting System - DQRS NDA-Field Alert Reporting	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Human Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> All Human Drug Codes
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S; T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D (Chem)	IMP O R T S A M P L E S T O B E A N A L Y Z E D	
	<b>TOTAL FIELD</b>	<b>134</b>	<b>300</b>	<b>30</b>				<b>30</b>		
NE	HEADQUARTERS	(b)(2)&b(7)(E)						(b)(2)&b(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		25.0		4.0				35.0		
TOTAL HOURS		3350	300	120				1050		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		3.68	0.33	0.13				0.89		

7. REMARKS

## FY 2005

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Enforcement of the Prescription Drug Marketing Act (PDMA)	<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To provide 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Human Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> All Human Drug Codes
<b>e. EXAM TYPE:</b> <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> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Analysis as directed in CDER/district assignments.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

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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3. 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	2	3	4	5	6	7	8	9
		INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMP O R T S A M P L E C O L L	FIELD E X A M S; T E S T S	IMP O R T F I E L D E X A M S	DOMESTIC S A M P L E S T O B E A N A L Y Z E D (Chem)	IMP O R T S A M P L E S T O B E A N A L Y Z E D	
	<b>TOTAL FIELD</b>	<b>39</b>	<b>910</b>	<b>30</b>				<b>30</b>		
NE	HEADQUARTERS	(b)(2)&b(7)(E)						(b)(2)&b(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		15.0		2.0				11.0		
TOTAL HOURS		585	910	60				330		
CONVERSION FACTOR		910	910	910				1180		
TOTAL OPERATIONAL FTEs		0.64	1.00	0.07				0.28		

7. REMARKS

## FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56D015 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZEC	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)	
	<b>TOTAL FIELD</b>		<b>2730</b>								
NE	HEADQUARTERS		(b)(2)&b (7)(E)								
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
SW	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION										
	TOTAL HOURS		2730								
	CONVERSION FACTOR		910								
	TOTAL OPERATIONAL FTEs		3.00								

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

## FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Project	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS											
	<b>TOTAL FIELD</b>	<b>3655</b>											
NE	HEADQUARTERS	(b)(2)&b (7)(E)											
	REGIONAL STAFF												
	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB												
	WEAC												
CE	REGIONAL STAFF												
	BALTIMORE												
	CHICAGO												
	CINCINNATI												
	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA												
	FORENSIC CHEM. CTR												
SE	REGIONAL STAFF												
	ATLANTA												
	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
	REGIONAL LAB												
SW	REGIONAL STAFF												
	DALLAS												
	DENVER												
	KANSAS CITY												
	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
PA	REGIONAL STAFF												
	LOS ANGELES												
	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LAB - SW												
	PACIFIC REGIONAL LAB - NW												
	HOURS PER OPERATION												
	TOTAL HOURS	3655											
	CONVERSION FACTOR	1205											
	TOTAL OPERATIONAL FTEs	3.03											

7. REMARKS

**FY 2005**

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Forensic Evaluation and Sample Analysis		<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56		
<b>3. PROGRAM TYPE:</b> N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT				
<b>4. OBJECTIVES</b> 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.				
<b>5. PROGRAM JUSTIFICATION</b> 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.				
<b>6. FIELD OBLIGATIONS</b> 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 center Forensic activities PAC 56R838 or OCI PAC 56R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory Evaluations to support the FDA mission. Report time spent on these activities as PODS Operation Code 03, PAC 56R838 Petition Validation, Methods Development, or Forensic Evaluation. Please consult DFS and/or DPEM for additional reporting guidance.				
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b>		<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
<b>b. INSPECTION TYPE:</b>		<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATE	<input type="checkbox"/> DIRECTED
<b>c. PRODUCT(S)</b>		<b>d. INDUSTRY/PRODUCT CODE(S)</b>		
<b>e. EXAM TYPE:</b> N/A <input type="checkbox"/> CHEMICAL		<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> OTHERS <i>(Specify)</i>		
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>				
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>				

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56						
3. PROGRAM/ASSIGNMENT CODE(S) 56R838, 56R831		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						
		5. OPERATIONAL FTE POSITIONS 9.0						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION						
	<b>TOTAL FIELD</b>	<b>10820</b>						
N E	HEADQUARTERS	(b)(2)&b(7)						
	REGIONAL STAFF	(E)						
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
C E	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
S E	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
S W	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
P A	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
P A	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
	HOURS PER OPERATION							
	TOTAL HOURS	10820						
	CONVERSION FACTOR	1205						
	TOTAL OPERATIONAL FTEs	8.98						
7. 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.								



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

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

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



# FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE Fraudulent Drugs	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs-63
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3. PROGRAM/ASSIGNMENT CODE(S)  63001, 63R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS  3.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS; TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
		<b>TOTAL FIELD</b>	<b>51</b>		<b>160</b>				<b>80</b>	
NE	HEADQUARTERS	(b)(2)&b		(b)(2)&b				(b)(2)&b		
	REGIONAL STAFF	(7)(E)		(7)(E)				(7)(E)		
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	28.0		4.0				18.0		
	TOTAL HOURS	1428		640				1440		
	CONVERSION FACTOR	910		910				1180		
	TOTAL OPERATIONAL FTEs	1.57		0.70				1.22		

9. REMARKS  
 \* Not all samples collected will require analysis; most will be collected for documentary and label review.  
  
 Use CT PAC 63R845 only when specific CT work is performed.

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

1. PROGRAM/ASSIGNMENT TITLE Internet Drug Sales	2. PPS PROJECT NAME/NUMBER Health Fraud: Human Drugs - 63
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3. PROGRAM/ASSIGNMENT CODE(S) 63D012, 63D013, 63D014	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc Hours
	<b>TOTAL FIELD</b>		<b>3640</b>							
NE	HEADQUARTERS		(b)(2)&b(7) (E)							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION									
	TOTAL HOURS		3640							
	CONVERSION FACTOR		910							
	TOTAL OPERATIONAL FTEs		4.00							

7. REMARKS  
 A block of hours is planned for monitoring drugs sold over the internet without a RX, unapproved or fraudulent.  
 \* Please report under correct operation; Report internet activities as follows; RX Drugs-- 63D012; OTC Drugs-- 63D013;  
 63D014 GHB/GBL/GD.



FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
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3. PROGRAM/ASSIGNMENT CODE(S) *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS; TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem) Hours	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD							14160		
NE	HEADQUARTERS							(b)(2)&b (7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB-SW									
PACIFIC REGIONAL LAB-NW										
HOURS PER OPERATION										
TOTAL HOURS								14160		
CONVERSION FACTOR								1180		
TOTAL OPERATIONAL FTEs								12.00		

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

**CENTER FOR VETERINARY MEDICINE  
RESOURCE SUMMARY  
FY 2005**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	100.4	30.1	2.4	132.9	173.0	51.9	4.1	229.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	8.7		2.0	10.7	15.0		3.4	18.4
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	91.7	30.1	0.4	122.2	158.0	51.9	0.7	210.6

"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 2005

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

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68					
3. PROGRAM/ASSIGNMENT CODE(S) 68001			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.7		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	1 INSPEC- TIONS (Foreign) ***	1 CHEMIST ON INSP **	3 DOMESTIC SAMPLE COLL			7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>50</b>	<b>50</b>	<b>400</b>	<b>15</b>			<b>15</b>	
NE	HEADQUARTERS	(b)(2)&b(7)(E)						(b)(2)&b(7)(E)	
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
HOURS PER OPERATION		60.3	40.0		3.0			19.4	
TOTAL HOURS		3015	2000	400	45			291	
CONVERSION FACTOR		1000	1000	1000	1000			1180	
TOTAL OPERATIONAL FTEs		3.02	2.00	0.40	0.05			0.25	

9. REMARKS

\*\* Analyst will participate on inspections as necessary.  
 \*\*\* 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".)

**FY 2005**

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    N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Sponsors, Contract Research Organizations, and Monitors	<b>2. PPS PROJECT NAME/NUMBER</b> Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To assure the adherence of sponsors, contract research organizations and monitors to the clinical monitoring regulations specific (21 CFR 511.1 (b)) and to evaluate representative clinical investigators utilized by the sponsor with regard to their adherence to applicable regulations.	
<b>5. PROGRAM JUSTIFICATION</b> As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. Part of this comprehensive program was directed to sponsors, monitors, and clinical investigators under the above stated objective.  Outcome: Assure data integrity and reduce drug development time.	
<b>6. FIELD OBLIGATIONS</b> Conduct inspections of sponsors, contract research organizations, and monitors, identified by the Center in accordance with the guidance set forth in the basic compliance program 7368.810.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Animal Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 67, 68 or 69
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING N/A <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

**FY 2005**

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Clinical Investigators	<b>2. PPS PROJECT NAME/NUMBER</b> Pre-Approval Evaluation of Animal Drugs and Food Additives - 68
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. The program determines the validity of data submitted to FDA by inspecting clinical investigators' records.  Outcome: Assure data integrity and reduce drug development time.	
<b>6. FIELD OBLIGATIONS</b> Conduct inspections of clinical investigators identified by the Center in accordance with the guidance set forth in the basic compliance program 7368.811.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Animal Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 67, 68 or 69
<b>e. EXAM TYPE:</b> N/A <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68						
3. PROGRAM/ASSIGNMENT CODE(S) 68808, 68810, 68811			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.0			
REG ION	6.	1	1	1	3	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	68808 INSPEC- TIONS (GLPs) (SPON/MON) *	INSPEC- TIONS	68811 INSPEC- TIONS (CLINICAL INVEST)	DOMESTIC SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>50</b>		<b>51</b>						
NE	HEADQUARTERS	(b)(2)&b (7)(E)		(b)(2)&b (7)(E)						
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION		58.3		41.0						
TOTAL HOURS		2915		2091						
CONVERSION FACTOR		1000		1000						
TOTAL OPERATIONAL FTEs		2.92		2.09						

9. 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).



## FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE <b>Drug Process and New Animal Drug Inspections/Type A Medicated Articles</b>					2. PPS PROJECT NAME/NUMBER <b>Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</b>					
3. PROGRAM/ASSIGNMENT CODE(S) <b>71001/A/B, 71005/A, 71R841</b>			4. WORK ALLOCATION PLANNED BY <div style="text-align: center;"><input checked="" type="checkbox"/> ORA    <input type="checkbox"/> CENTER</div>			5. OPERATIONAL FTE POSITIONS <div style="text-align: center;"><b>10.9</b></div>				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS	1 NAT'L EXPERTS ON INSP (Hours)	1 CHEM ON INSP (Hours)	1 INSP CTIONS (Foreign)	2 INVESTI GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	7 DOMESTIC SAMPLES TO BE ANALYZED (Micro)	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>220</b>	<b>230</b>	<b>500</b>	<b>10</b>	<b>499</b>	<b>120</b>	<b>60</b>	<b>25</b>	
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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	33.0			40.0		5.5	18.4	21.1	
	TOTAL HOURS	7260	230	500	400	499	660	1104	528	
	CONVERSION FACTOR	1000	1000	1000	1000	1000	1000	1180	1180	
	TOTAL OPERATIONAL FTEs	7.26	0.23	0.50	0.40	0.50	0.66	0.94	0.45	
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										
 <u>Workload Source:</u> FACTS database (registered firms in IND 54,56, 67, and 68 with Status of "Operational" and Workload Obligation of "Yes".) Foreign Inspections Spread by Division of Field Investigations, ORO.										

**FY 2005**

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

1. PROGRAM/ASSIGNMENT TITLE <b>Feed Contaminants - DOMESTIC</b>			2. PPS PROJECT NAME/NUMBER <b>Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</b>								
3. PROGRAM/ASSIGNMENT CODE(S) 71003 A-H *(99R833, 71R833, 71R824)			<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS TOTAL 16.3 DOMESTIC 13.3 IMPORT 3.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS (Dioxin) *	3 DOMESTIC SAMPLES COLL	DOMESTIC SAMPLES COLL Myc 71003C	DOMESTIC SAMPLES COLL Micro 71003E	DOMESTIC SAMPLES COLL Chem 71003A	DOMESTIC SAMPLES COLL Dioxin 71003G	7 DOMESTIC SAMPLES ANALYSIS Myc 71003C	7 DOMESTIC SAMPLES ANALYSIS Micro 71003E	7 DOMESTIC SAMPLES ANALYSIS Chem 71003A	7 DOMESTIC SAMPLES ANALYSIS Dioxin 71003G
	<b>TOTAL FIELD</b>	<b>60</b>	<b>760</b>	<b>220</b>	<b>170</b>	<b>200</b>	<b>170</b>	<b>220</b>	<b>170</b>	<b>200</b>	<b>170</b>
HEADQUARTERS		(b)(2)&b(7)(E)									
REGIONAL STAFF											
NE	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
SW	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
PA	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
SAN FRANCISCO											
SEATTLE											
PACIFIC REGIONAL LAB (SW)											
PACIFIC REGIONAL LAB (NW)											
HOURS PER OPERATION		25.0	4.2					7.7	19.4	5.5	24.0
TOTAL HOURS		1500	3192					1694	3298	1100	4080
CONVERSION FACTOR		1000	1000					1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		1.50	3.19					1.44	2.79	0.93	3.46
9. REMARKS											
* Inspections performed as F/U to violative dioxin samples											
The shaded area breaks out the sample collections and is only a guideline for Districts.											
Workload Source: FACTS database; firms in IND 69-72 with Workload Obligation of "YES" and Firm Status is "Operational".											
Note: Continued on Page 71-7											

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1. PROGRAM/ASSIGNMENT TITLE <b>Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-5</b>		2. PPS PROJECT NAME/NUMBER <b>Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</b>								
3. PROGRAM/ASSIGNMENT CODE(S) <b>71003 A-H *(99R833, 71R833, 71R824)</b>		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS <b>3.0</b>				
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVW HRS	4 IMPORT SAMPLE COLL	IMPORT SAMPLE COLL CHEM	IMPORT SAMPLE COLL MICRO	6 IMPORT FIELD EXAM	8 IMPORT SAMPLE ANALYZED CHEM	8 IMPORT SAMPLE ANALYZED MICRO		
	<b>TOTAL FIELD</b>	<b>1200</b>	<b>175</b>	<b>125</b>	<b>50</b>	<b>500</b>	<b>125</b>	<b>50</b>		
	HEADQUARTERS	(b)(2)&b(7)(E)	(b)(2)&b(7)(E)							
NE	REGIONAL STAFF	(b)(2)&b(7)(E)	(b)(2)&b(7)(E)							
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SW	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)									
HOURS PER OPERATION			2.5			1.0	5.8	10.7		
TOTAL HOURS		1200	438			500	725	535		
CONVERSION FACTOR		1200	1000			1000	1180	1180		
TOTAL OPERATIONAL FTEs		1.00	0.44			0.50	0.61	0.45		
<b>9. REMARKS</b>										
* Dioxin Samples, 71003G, will be analyzed by ARL and Chem Samples, 71003A/B, will follow the distribution of this workplan and Servicing Laboratory Table. Mycotoxin Samples, 71003C, will be analyzed by PRN.										
The shaded area breaks out the sample collections and is only a guideline for Districts.										
Workload Source: FACTS and OASIS databases.										

**FY 2005**

<p>1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing</p>	<p>2. PMS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</p>
<p>3. PROGRAM TYPE:      <input checked="" type="checkbox"/> COMPLIANCE PROGRAM      <input type="checkbox"/> PROGRAM CIRCULAR      <input type="checkbox"/> ASSIGNMENT</p>	
<p>4. OBJECTIVES To determine compliance with GMP elements of registered establishments producing medicated feeds. To determine whether a firm has the appropriate approved applications to make medicated feeds. To initiate appropriate administrative and/or regulatory action.</p>	
<p>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.</p>	
<p>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.</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) Medicated Feeds</p>	<p>d. INDUSTRY/PRODUCT CODE(S) 69</p>
<p>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>)</p>	
<p>f. CHECK THE FOLLOWING ATTRIBUTES Drug analyses (potency) and drug contamination</p>	
<p>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</p>	

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71							
3. PROGRAM/ASSIGNMENT CODE(S) 71004/A		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 * INSPECTIONS MEDICATED FEED ESTABS	1 INSPECTIONS NATIONAL EXPERTS (Hours)			3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES ANALYZED (Micro)	7 DOMESTIC SAMPLES ANALYZED (Chem)	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>258</b>	<b>139</b>			<b>65</b>	<b>15</b>	<b>15</b>	
NE	HEADQUARTERS	(b)(2)&b(7)(E)				(b)(2)&b(7)(E)			
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB (SW) PACIFIC REGIONAL LAB (NW)								
HOURS PER OPERATION		19.0				6.0	44.0	44.0	
TOTAL HOURS		4902	139			390	660	660	
CONVERSION FACTOR		1000	1000			1000	1180	1180	
TOTAL OPERATIONAL FTEs		4.90	0.14			0.39	0.55	0.55	

9. REMARKS

Some inspection time may be used as investigation time where appropriate.  
 Non-potency feed sample analysis should be charged to 71003 A/E. Some samples collected are documentary.  
 There are 359 State Contract inspections and 25 FDA contract audit inspections.  
 The 139 hours of inspections by National Experts equals to 7 Medicated Feed Inspections.

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

## FY 2005

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Illegal Drug Residues in Meat and Poultry	<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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 be partners with FSIS/HACCP on the environment, educational initiatives, and, as necessary, regulatory actions.	
<b>5. PROGRAM JUSTIFICATION</b> FDA is charged with the responsibility to ensure that food is free of adulterants which may render it injurious to health. FDA conducts investigations as a follow-up to USDA residue findings in meat and poultry to identify the source of adulteration and take corrective action to prevent it from re-occurring. This a cooperative program involving FDA, USDA, EPA, and a number of state governments.  Outcome: To provide a safe human food supply.	
<b>6. FIELD OBLIGATIONS</b> To conduct investigations or inspections in accordance with the compliance program requirements based on the Memoranda of Understanding between FDA, USDA and EPA. See CPG 7155a.19. Coordinate state activities with states having MOUs, informal and formal agreements or contracts with FDA to conduct inspections of first time violators.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Meat and Poultry, Animal Feeds and Drugs	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 17, 67, 68, and 69
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Tissue Sample analysis by Denver laboratory when required, including confirmation on USDA CAST samples.	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE 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 INSPECTIONS	2 INVEST-GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)	9 TECHNICAL SUPPORT (HOURS) **	METHODS VALID (HOURS) *
	<b>TOTAL FIELD</b>	225	1000	200	1201	1000		360
NE	HEADQUARTERS	(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			(b)(2)&b(7)(E)
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
SE	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
SW	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
PA	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
PA	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB (SW)							
	PACIFIC REGIONAL LAB (NW)							
HOURS PER OPERATION		35.0		5.0				
TOTAL HOURS		7875	1000	1000	1201	1000		360
CONVERSION FACTOR		1000	1000	1000	1180	1180		1180
TOTAL OPERATIONAL FTEs		7.88	1.00	1.00	1.02	0.85		0.31

9. REMARKS

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

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

\* Additional time for method validation studies.

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

## FY 2005

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

1. PROGRAM/ASSIGNMENT TITLE <b>Ruminant Feed Ban Rule/BSE Program</b>		2. PPS PROJECT NAME/NUMBER <b>Monitoring of Marketed Animal Drugs, Feeds and Devices - 71</b>								
3. PROGRAM/ASSIGNMENT CODE(S) <b>71009, 71R844</b>		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS Domestic 39.7    66.8 Import 27.1					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1. BSE INSPECT- IONS *	3. DOMESTIC SAMPLES COLL	7. DOMESTIC SAMPLES ANALYZED Chem	4. IMPORT SAMPLES COLL	8. IMPORT SAMPLES ANALYZED Chem	2. IMPORT ENTRY REVIEW Hours	2. FILER EVAL Hours	9. OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	<b>3760</b>	<b>900</b>	<b>900</b>	<b>900</b>	<b>900</b>	<b>14280</b>	<b>5100</b>		
NE	HEADQUARTERS	(b)(2)&b (7)(E)	(b)(2)&b(7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LAB (SW)										
PACIFIC REGIONAL LAB (NW)										
HOURS PER OPERATION		7.5	6.0	8.0	5.0	7.4				
TOTAL HOURS		28200	5400	7200	4500	6660	14280	5100		
CONVERSION FACTOR		1000	1000	1180	1000	1180	1200	1000		
TOTAL OPERATIONAL FTEs		28.20	5.40	6.10	4.50	5.64	11.90	5.10		

9. Remarks

\* Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills will 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 allocated based on the inventory of: 1) All BSE firms with a Workload Obligation of "YES" in FACTS; and 2) Renderers feed mills, and protein blenders with a status of "Operational" or "Seasonal" and a Workload Obligation of "NO". Districts should review their inventory of Operational / Seasonal renderers, feed mills, and protein blenders to determine if firms marked with a Workload Obligation of "NO" are properly coded in FACTS.

Planned inspections have been adjusted for state contracts and performance goal coverage.

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**CONTINUATION SHEET**

1. PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program  
71009

2. PPS PROJECT NAME/NUMBER

Monitoring of Marketed Animal Drugs, Feeds and  
Devices - 71

**Inspection Priorities.**

21 CFR §589.2000 pertains to a variety of firms and animal production operations that involve the manufacture, distribution, transportation, and feeding of animal feeds. While the intent of the rule is to ensure that specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources 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 continually expanding the inventory of firms that are potentially subject to this regulation. Districts should work closely with state and other 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/index/bse/RuminantFeedInspections.htm>).



1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71R816	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	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	RESEARCH CENTER RESEARCH CHEM (Hours)					
	<b>TOTAL FIELD</b>	<b>1200</b>		<b>5877</b>					
NE	HEADQUARTERS	(b)(2)&b(7) (E)		(b)(2)&b (7)(E)					
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	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		1200		5877					
CONVERSION FACTOR		1205		1180					
TOTAL OPERATIONAL FTEs		1.00		4.96					

9. Remarks

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



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

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	<b>TOTAL FIELD</b>	<b>875</b>								
	HEADQUARTERS	(b)(2)&b (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION									
	TOTAL HOURS	875								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.73								

9. Remarks

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



1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71V800	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTIGATIONS (Hours)								
	<b>TOTAL FIELD</b>	<b>3000</b>								
NE	HEADQUARTERS	(b)(2)&b (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB (SW)									
	PACIFIC REGIONAL LAB (NW)									
	HOURS PER OPERATION									
	TOTAL HOURS	3000								
	CONVERSION FACTOR	1000								
	TOTAL OPERATIONAL FTEs	3.00								

9. Remarks

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

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

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
RESOURCE SUMMARY  
FY 2005**

PPS NO.	PROJECT TITLE	OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>166.3</b>	<b>44.9</b>	<b>16.4</b>	<b>227.6</b>	<b>285.7</b>	<b>77.5</b>	<b>30.8</b>	<b>394.0</b>
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	85.6	39.4	11.1	136.1	145.4	68.0	21.6	235.0
83	PRODUCT EVALUATION: DEVICES	32.1		4.2	36.3	55.4		7.3	62.7
84	SCIENCE: DEVICES	5.1			5.1	8.8			8.8
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	15.5		0.1	15.6	27.7		0.2	27.9
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	27.5	5.5	1.0	34.0	47.5	9.5	1.7	58.7

"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.



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device Problem Reporting – MDR Follow-up	<b>2. PPS PROJECT NAME/NUMBER</b> Postmarket Assurance: Devices - 81
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> On assignment, follow up on MDR reports either at the medical facility or manufacturer.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Medical Devices	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 73-91
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b> Sterility Performance	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> 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					
3. PROGRAM/ASSIGNMENT CODE(S) 81010			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 0.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS  (1)	2 INVESTI- GATIONS (Hours)  (2)	3 DOMESTIC SAMPLE COLL  (3)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED ENG (4)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (6)	8 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	25	100	3			1	1	1	
	HEADQUARTERS	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
NE	REGIONAL STAFF	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	NEW ENGLAND	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	NEW YORK	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	REGIONAL LAB	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	WEAC	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
CE	REGIONAL STAFF	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	BALTIMORE	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	CHICAGO	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	CINCINNATI	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	DETROIT	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	MINNEAPOLIS	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	NEW JERSEY	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	PHILADELPHIA	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
SE	FORENSIC CHEM. CTR	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	REGIONAL STAFF	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	ATLANTA	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	FLORIDA	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	NEW ORLEANS	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
SW	SAN JUAN	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	REGIONAL LAB	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	REGIONAL STAFF	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	DALLAS	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	DENVER	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
PA	KANSAS CITY	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	REGIONAL LAB	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	REGIONAL STAFF	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	LOS ANGELES	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	SAN FRANCISCO	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	SEATTLE	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&b(7)(E)					(b)(2)&b(7)(E)			
	HOURS PER OPERATION	11.5		5.8			37.0	36.0	20.0	
	TOTAL HOURS	288	100	17			37	36	20	
	CONVERSION FACTOR	950	950	950			1180	1180	1180	
	TOTAL OPERATIONAL FTEs	0.30	0.11	0.02			0.03	0.03	0.02	
9. REMARKS  (1) Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.  (2) Investigational hours for MDR followup at medical facilities.  (3) Includes Documentary samples.  (4) MDR samples to confirm reported defects.  (5) Performance testing of chemical and serological test kits.  (6) Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.										



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Monitoring Devices of Foreign Origin - Import	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> Determine compliance of imported devices with the medical device registration and listing requirements, and other general controls.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> The field will conduct examinations of Form 701 import records for medical devices and ascertain in conjunction with information provided by CDRH whether the manufacturer is listed and the initial distributor is registered with CDRH.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Medical Devices	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 73-91
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> 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						
3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI- GATIONS (Hours)	4 IMPORT FIELD EXAMS -	4 IMPORT SAMPLE COLL (Physical) --	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 IMPORT LABEL EXAM
	<b>TOTAL FIELD</b>		20315	3400		1835	120	60	60	1475
	HEADQUARTERS		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)				
NE	REGIONAL STAFF		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)				
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)				
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)				
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL STAFF		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)				
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)				
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION						0.6	2.2	25.5	25.5	0.3
TOTAL HOURS			20315	3400		1101	264	1530	1530	443
CONVERSION FACTOR			1200	950		950	950	1180	1180	950
TOTAL OPERATIONAL FTEs			16.93	3.58		1.16	0.28	1.30	1.30	0.47
9. REMARKS										
Reporting Guidance:										
- Import Entry Reviews (Electronic and Manual—operation code 14, PAC 82R833);										
- Filer Evaluations (operation code 95, PAC 99R833); and										
- Follow-up to Refusals (PAC 82R824).										
NOTE: Determination of failure to register or list is included in the Entry Review operation.										
Planning Guidance: Any unused resources for Filer Evaluations should be used, if necessary, towards Entry Reviews.										
Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.										
* Import Field Exams to implement performance standard for lead wires and cables.										
** Audit samples for problems other than failure to register or list (eg. special assignment, import alert). Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.										
*** Sterile devices to be tested by USP XX method. Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspection of Medical Device Manufacturers	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To evaluate the manufacturing processes used for general and radiation-emitting medical devices and <i>in vitro</i> diagnostic products, including sterilization. To identify potential problem areas and determine compliance with the GMP and MDR regulations.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Class II and III Devices and all Class I Devices which have been finally classified for one year.	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 73-91
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b> <i>Engineering Samples:</i> Subs/Sample will vary depending on cost, size, etc. Contact Center for guidance if the device presents such problems.	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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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 92.4    [87.3]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	2	2	
		INSPEC- TIONS LEVEL I 82845A	INSPEC- TIONS LEVEL II 82845B	INSPEC- TIONS LEVEL III COMPLIANCE FOLLOWUP 82845C	INSPEC- TIONS FOREIGN	INSPEC- TIONS FOR CAUSE 82845G	INSPEC- TIONS ACCREDITED PERSONS 82845P (1)	INVESTI- GATIONS (Hours) DOMESTIC 82845J (2)	INVESTI- GATIONS (Hours)	INVESTI- GATIONS (Hours)	
	<b>TOTAL FIELD</b>	<b>714</b>	<b>483</b>	<b>100</b>	<b>163</b>	<b>75</b>	<b>135</b>	<b>255</b>		<b>2042</b>	
	HEADQUARTERS	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
NE	REGIONAL STAFF	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	NEW ENGLAND	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	NEW YORK	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	REGIONAL LAB	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	WEAC	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
CE	REGIONAL STAFF	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	BALTIMORE	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	CHICAGO	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	CINCINNATI	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	DETROIT	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	MINNEAPOLIS	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	NEW JERSEY	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	PHILADELPHIA	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	FORENSIC CHEM. CTR	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
SE	REGIONAL STAFF	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	ATLANTA	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	FLORIDA	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	NEW ORLEANS	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	SAN JUAN	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
SW	REGIONAL LAB	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	REGIONAL STAFF	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	DALLAS	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	DENVER	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	KANSAS CITY	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	REGIONAL LAB	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	REGIONAL STAFF	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	LOS ANGELES	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	SAN FRANCISCO	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	SEATTLE	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&b(7)(E)									(b)(2)&b(7)(E)
	HOURS PER OPERATION	34.0	51.0	89.0	65.0	72.0	50.8				
	TOTAL HOURS	24276	24633	8900	10595	5400	6858	255		2042	
	CONVERSION FACTOR	950	950	950	950	950	950	950		950	
	TOTAL OPERATIONAL FTEs	25.55	25.93	9.37	11.15	5.68	7.22	0.27		2.15	

9. REMARKS

**QUALITY SYSTEMS INSPECTION PLANNING**

The workplan reflects the number of operations to be performed in FY 2005 for each district. Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause" inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Any unused resources in those two areas should be reprogrammed into Level 1 and Level 2 inspections. The hours per operation, or inspectional modules, reflect the most recent historical data. Time for 82845S (sterilization) is included in the inspectional modules. Time spent on the QSIT satellites: MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing is averaged into the inspectional module for Level 2 inspections. For additional information regarding inspection strategies refer to the latest Compliance Program. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections.

(1) 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. (2) Accredited Person Audits conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO. For informational purposes: 30 inspections under State Contract will be conducted in DAL-DO; 20 inspections under State Contract will be conducted in DEN-DO for FY 2005.

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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 92.4    [5.1]
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	3	3	3	7	7	7	7	7	9									
		DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR	DOMESTIC SAMPLE COLL MICRO STERILITY	DOMESTIC SAMPLES TO BE ANALYZED CHEM (1)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (2)	DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN BIOINDICATOR	DOMESTIC SAMPLES TO BE ANALYZED MICRO STERILITY	DOMESTIC SAMPLES TO BE ANALYZED ENG	OTHER OPERATIONS (Hours)									
	<b>TOTAL FIELD</b>	89	37	10	18	43	14	6	18										
	HEADQUARTERS	(b)(2)&b(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
PA	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
SEATTLE																			
PACIFIC REGIONAL LABORATORY-SW																			
PACIFIC REGIONAL LABORATORY-NW																			
	HOURS PER OPERATION										5.5	5.5	5.5	32.1	62.0	25.0	25.0	72.0	
	TOTAL HOURS										490	204	55	578	2666	350	150	1296	
	CONVERSION FACTOR										950	950	950	1180	1180	1180	1180	1180	
	TOTAL OPERATIONAL FTEs										0.52	0.21	0.06	0.49	2.26	0.30	0.13	1.10	

9. REMARKS  
 (1) Test Kit or Reagent Testing to support GMP observations (CHEM) at WEAC.  
 (2) Antisera and Products Media Testing to support GMP observations (MICRO) at WEAC; Disinfectant/Cold Sterilant Testing at DEN Lab.  
 Note: Domestic Sample Collections for Contract Sterilizers and/or Bioburden, Bioindicator are to be collected "for cause".

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Determine the extent to which manufacturers of condoms comply with the Device GMP requirements; Assure that both domestic and imported condoms comply with the FDA standards.	
5. PROGRAM JUSTIFICATION The Surgeon General has recommended the use of condoms to reduce the spread of AIDS. Consequently, FDA is committed to assuring that condoms are safe and effective.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct GMP inspections of domestic condom manufacturers and major repackers. Districts will also sample both domestic and imported condoms and conduct tests to assure conformance with the FDA standard.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S) 85
e. EXAM TYPE: <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	3		2	354			2	354	
	HEADQUARTERS	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)				(b)(2)&b(7)(E)		
NE	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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	8.8		3.0	2.5			12.0	13.5	
	TOTAL HOURS	26		6	885			24	4779	
	CONVERSION FACTOR	950		950	950			1180	1180	
	TOTAL OPERATIONAL FTEs	0.03		0.01	0.93			0.02	4.05	

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

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Manufacturers and Importers of Surgical/Examination Gloves	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
<b>3. PROGRAM TYPE:</b> <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> Districts will, upon assignment, conduct GMP inspections of domestic manufacturers. Districts will also sample gloves for testing by the designated laboratories.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 85
<b>e. EXAM TYPE:</b> <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 9.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (PHYSICAL)	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED ENG	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
	<b>TOTAL FIELD</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>1000</b>		<b>1</b>	<b>1</b>	<b>222</b>	<b>778</b>
NE	HEADQUARTERS	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	8.0		6.0	3.0		20.0	13.0	7.4	7.4
	TOTAL HOURS	16		12	3000		20	13	1643	5757
	CONVERSION FACTOR	950		950	950		1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.02		0.01	3.16		0.02	0.01	1.39	4.88

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

(b)(2) & (b)(7)(E)

1. PROGRAM/ASSIGNMENT TITLE BSE Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
3. PROGRAM TYPE: <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To enhance FDA's uniformity in inspection and compliance of BSE firms subject to the regulation and to determine compliance with the BSE regulation.	
5. PROGRAM JUSTIFICATION FDA seeks to protect the public through the development of a comprehensive strategy of education, inspection and enforcement action on industry. These activities were initiated to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) regulations.	
6. FIELD OBLIGATIONS Districts will, upon assignment, conduct inspections of firms whose devices may contain or be exposed to BSE risk material to implement the objectives of this assignment.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE: <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE: <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE BSE Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z005	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INSPEC- TIONS	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>48</b>								
NE	HEADQUARTERS	(b)(2)&b (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	20.0								
	TOTAL HOURS	960								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	1.01								

9. REMARKS  
 Districts will, upon assignment, conduct inspections of firms whose devices may contain, or be exposed to, BSE risk material.

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

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82Z800			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	1 INSP EC T I O N S	2 INVE ST I G A T I O N S (Hours)	3 DOMESTIC SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (3)	9 OTHER OPERATIONS (Hours) METH DEV ENG (4)
	<b>TOTAL FIELD</b>	25		350	12		2	2	2	500
NE	HEADQUARTERS	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL STAFF	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL STAFF	(b)(2)&b(7)(E)		(b)(2)&b(7)(E)			(b)(2)&b(7)(E)			
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		34.0			10.0		50.0	15.0	50.0	
TOTAL HOURS		850		350	120		100	30	100	500
CONVERSION FACTOR		950		950	950		1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.89		0.37	0.13		0.08	0.03	0.08	0.42

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

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

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	DISTRICT RESEARCH CHEM (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)				
	<b>TOTAL FIELD</b>			400	700				
	HEADQUARTERS			(b)(2)&b(7)(E)					
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	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			400	700				
	CONVERSION FACTOR			1205	1180				
	TOTAL OPERATIONAL FTEs			0.33	0.59				

9. REMARKS

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Forensic Evaluation and Sample Analysis	<b>2. PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
<b>3. PROGRAM TYPE:</b> N/A <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> 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.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spend on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. The specific addition of Forensic Evaluation to the Operation Code was new in FY 1999. Please consult the Division of Field Science and/or the Division of Planning, Evaluation, and Management for additional reporting guidance.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> N/A <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> N/A <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b>	<b>d. INDUSTRY/PRODUCT CODE(S)</b> N/A
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82R838	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 0.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	<b>TOTAL FIELD</b>	<b>360</b>								
NE	HEADQUARTERS	(b)(2)&b								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	360								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.30								

9. REMARKS



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Medical Device Premarket Approval and Postmarket Inspections/510(k) Premarket Approval Inspections	<b>2. PPS PROJECT NAME/NUMBER</b> Product Evaluation: Devices - 83
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> <p><b>Medical Device Premarket Approval and Postmarket Inspections:</b> To assure that both prior to and subsequent to approval of a PMA application, the manufacturer has the capability of manufacturing the PMA device in accordance with (1) the conditions specified in the PMA application and (2) the requirements of the device GMP regulation.</p> <p><b>510(k) Premarket Approval Inspections:</b> To assure, prior to approval of the 510(k) for selected devices, that the manufacturer is in compliance with the requirements of the device GMP regulation. To verify that the manufacturer has procedures in place and adequate documentation to support their premarket submission Declarations of Conformity to Standards, and/or their declaration of compliance with design controls.</p>	
<b>5. PROGRAM JUSTIFICATION</b> <p><b>Medical Device Premarket Approval and Postmarket Inspections:</b> Section 515 of the Act requires that devices subject to Premarket Approval must be manufactured in conformance with the requirements of the device GMP regulation. Consequently, no PMA application can be approved until the Center has inspectional evidence that the manufacturer complies with the requirements set forth in the Premarket Approval application.</p> <p><b>510(k) Premarket Approval Inspections:</b> The General Counsel has ruled that compliance with the GMP regulation is one of the elements of device safety which must be considered when reviewing a 510(k) application. This policy is being initially applied to all 510(k)s for preamendment Class III devices. In November 1997, the Federal Food, Drug, and Cosmetic Act (FFDCA) was modified by the FDA Modernization Act (FDAMA) to include Section 205, Device Standards. This section requires FDA to "recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization." After FDA recognizes a standard through publication in the Federal Register, "a person may submit a declaration of conformity in order to meet a premarket submission or other requirement under the FFDCA to which such standard is applicable." The use of standards is applicable to all types of pre-market submissions. These changes became effective on February 20, 1998.</p>	
<b>6. FIELD OBLIGATIONS</b> <p><b>Medical Device Premarket Approval and Postmarket Inspections:</b> The field will conduct pre-approval inspections on assignment and submit an EIR to the Center along with the District's recommendation. The field will be responsible for scheduling (b)(2)&amp;b(7) Under certain conditions, a post-approval inspection will not be necessary. The Center will advise the district when a post-approval inspection is not necessary. <b>510(k) Inspections:</b> On assignment from CDRH, conduct a comprehensive GMP inspection as instructed in the compliance program. Regarding Conformance Standards inspections, conduct inspections based on assignments by the Field Programs Branch: 100% of assignments issued should be completed as high priority. Class II or III devices in the applicable declaration will be covered.</p>	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> All Medical Devices	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 73-91
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>  	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>  	

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections					2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83					
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 11.0			
R E G I O N	6.	1	1	1	1	1	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS PRE- APPROVAL 83001	INSPEC- TIONS POST- APPROVAL 83001A	FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	FOREIGN INSPEC- TIONS POST- APPROVAL 83001A	INSPEC- TIONS MDUFMA USER FEE 83001 (1)	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
<b>TOTAL FIELD</b>		<b>36</b>	<b>67</b>	<b>34</b>	<b>27</b>	<b>86</b>				
HEADQUARTERS		(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		44.0	30.0	50.7	49.4	44.0				
TOTAL HOURS		1584	2010	1724	1334	3784				
CONVERSION FACTOR		950	950	950	950	950				
TOTAL OPERATIONAL FTEs		1.67	2.12	1.81	1.40	3.98				

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) 1 additional FTE in FY 2005 has been planned for Medical Device User Fee and Modernization Act (MDUFMA).

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						
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			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS (GLPs)	1 INSP CTIONS (IRBs)	1 INSP CTIONS (SPON/MON)	1 INSP CTIONS (CLINICAL INVEST) (1)	1 INSP CTIONS (SPON/MON) FOREIGN	1 INSP CTIONS (CLINICAL INVEST) FOREIGN	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>35</b>	<b>30</b>	<b>63</b>	<b>168</b>	<b>2</b>	<b>12</b>			
NE	HEADQUARTERS	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	NEW ENGLAND	(b)(2)&b(7)(E)								
	NEW YORK	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	WEAC	(b)(2)&b(7)(E)								
CE	REGIONAL STAFF	(b)(2)&b(7)(E)								
	BALTIMORE	(b)(2)&b(7)(E)								
	CHICAGO	(b)(2)&b(7)(E)								
	CINCINNATI	(b)(2)&b(7)(E)								
	DETROIT	(b)(2)&b(7)(E)								
	MINNEAPOLIS	(b)(2)&b(7)(E)								
	NEW JERSEY	(b)(2)&b(7)(E)								
	PHILADELPHIA	(b)(2)&b(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	ATLANTA	(b)(2)&b(7)(E)								
	FLORIDA	(b)(2)&b(7)(E)								
	NEW ORLEANS	(b)(2)&b(7)(E)								
SW	SAN JUAN	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	DALLAS	(b)(2)&b(7)(E)								
	DENVER	(b)(2)&b(7)(E)								
PA	KANSAS CITY	(b)(2)&b(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)								
	REGIONAL LAB	(b)(2)&b(7)(E)								
	REGIONAL STAFF	(b)(2)&b(7)(E)								
	LOS ANGELES	(b)(2)&b(7)(E)								
PA	SAN FRANCISCO	(b)(2)&b(7)(E)								
	SEATTLE	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&b(7)(E)								
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&b(7)(E)								
HOURS PER OPERATION		82.0	52.0	87.0	79.0	35.0	68.0			
TOTAL HOURS		2870	1560	5481	13272	70	816			
CONVERSION FACTOR		950	950	950	950	950	950			
TOTAL OPERATIONAL FTEs		3.02	1.64	5.77	13.97	0.07	0.86			
9. REMARKS										
1) 2 FTE are planned to provide for the FY 2005 Congressional Budget Medical Device Review FTE increase. The additional resources will enable FDA to conduct pre-approval inspections for device manufacturers and to thereby meet premarket performance goals committed to under the Medical Device User Fee and Modernization Act (MDUFMA) legislation.										



1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
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3. PROGRAM TYPE:    N/A        COMPLIANCE PROGRAM        PROGRAM CIRCULAR        ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE:    N/A        COMPREHENSIVE        ABBREVIATED        DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation					2. PPS PROJECT NAME/NUMBER Science: Devices - 84					
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 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
	<b>TOTAL FIELD</b>									775
NE	HEADQUARTERS								(b)(2)&b(7)(E)	
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION										
TOTAL HOURS									775	3540
CONVERSION FACTOR									1180	1180
TOTAL OPERATIONAL FTEs									0.66	3.00

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

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

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

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

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

5. PROGRAM JUSTIFICATION  
Research

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

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

b. INSPECTION TYPE: N/A  COMPREHENSIVE  ABBREVIATED  DIRECTED

c. PRODUCT(S)

d. INDUSTRY/PRODUCT CODE(S)

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ORA/Center Directed Research Projects					2. PPS PROJECT NAME/NUMBER Science: Devices - 84				
3. PROGRAM/ASSIGNMENT CODE(S) 84R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 1.4			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)				
	<b>TOTAL FIELD</b>				<b>1660</b>				
NE	HEADQUARTERS				(b)(2)&b(7) (E)				
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS					1660				
CONVERSION FACTOR					1180				
TOTAL OPERATIONAL FTEs					1.41				

9. REMARKS



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Mammography Facilities Inspection Program	<b>2. PPS PROJECT NAME/NUMBER</b> Mammography Quality Standards Act (MQSA) Authority - 85
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To inspect certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA); To bring uncertified facilities into compliance with MQSA.	
<b>5. PROGRAM JUSTIFICATION</b> 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.	
<b>6. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Mammography equipment	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 90
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	

1. PROGRAM/ASSIGNMENT TITLE 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 15.6 [7.9]				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC- TIONS 85014 (1)	1 INSP EC- TIONS 85014F (2)	1 INSP EC- TIONS 85014 (3)	1 INSP EC- TIONS 85014 (4)	1 INSP EC- TIONS FOREIGN 85014 (5)	2 INVESTI- GATIONS (Hours) 85014A (6)	2 INVESTI- GATIONS (Hours) 85014 (7)	9 OTHER OPERATIONS (Hours) 85014C (8)	9 OTHER OPERATIONS (Hours) 85014 (9)
	<b>TOTAL FIELD</b>	216	36	122	33	15	2266	50	468	2900
	HEADQUARTERS	(b)(2)&b(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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		8.0	11.0	8.0	8.0	8.0				
TOTAL HOURS		1728	396	976	264	120	2266	50	468	2900
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1160
TOTAL OPERATIONAL FTEs		1.49	0.34	0.84	0.23	0.10	1.95	0.04	0.40	2.50
9. REMARKS <b>RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE &amp; COORDINATION HOURS</b> 1) Inspection of Certified Mammography Facilities not covered by the states. 2) Follow-up Inspections. 3) Federal Facility Inspections (does not include VHA Facility inspections). 4) VHA Facility Inspections. 5) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries. 6) Audit Investigations. 7) Investigations of Uncertified Mammography Facilities. 8) Compliance Activities. 9) Technical Assistance and Coordination Activities.										

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1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program				2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85						
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 15.6 [7.7]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS 85014F (10)	2 INVESTI- GATIONS (Hours) 85014F (11)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) 85014 (12)
	<b>TOTAL FIELD</b>		72	6965						
	HEADQUARTERS	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	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	11.0								
	TOTAL HOURS	792	6965							1200
	CONVERSION FACTOR	1160	1160							1200
	TOTAL OPERATIONAL FTEs	0.68	6.00							1.00

9. REMARKS  
**RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS**  
 10) Follow-up Inspection after warning letter  
 11) Inspection Follow-Up Activities (Non-Warning Letter).  
 12) Technical Assistance and Coordination Activities: RRHRs.



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

1. PROGRAM/ASSIGNMENT TITLE Optical Electronic Products				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
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 6.7    [5.2]			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S  86001 (1)	1 INSP EC T I O N S F O R E I G N  86001 (2)	1 INSP EC T I O N S  86002 (3)	2 INVEST I G A T I O N S (Hours) 86001 (4)	2 INVEST I G A T I O N S (Hours) 86002	3 DOMEST I C S A M P L E C O L L 86001	3 DOMEST I C S A M P L E C O L L 86002	5 FIELD E X A M S/ T E S T S 86001 (5)	5 FIELD E X A M S/ T E S T S 86002 (6)
	<b>TOTAL FIELD</b>	<b>133</b>	<b>5</b>	<b>7</b>	<b>1147</b>	<b>90</b>	<b>6</b>	<b>3</b>	<b>97</b>	<b>100</b>
	HEADQUARTERS	(b)(2)&b(7)(E)								
N E	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
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										
S W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
P A	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		18.4	52.4	13.8			3.0	8.0	6.2	3.2
TOTAL HOURS		2447	262	97	1147	90	18	24	601	320
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		2.58	0.22	0.10	1.21	0.09	0.02	0.03	0.63	0.34
9. Remarks <b>Inspection of Manufacturers of Laser Products:</b> 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. <b>Sunlamps and Sunlamp Products:</b> 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).										

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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 6.7    [1.5]						
R E G I O N	6.	1	2	3	4	5	6	7	9	9		
	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours) 86001 (7)	OTHER OPERATIONS (Hours) 86002		
	<b>TOTAL FIELD</b>								<b>1215</b>	<b>220</b>		
NE	HEADQUARTERS								(b)(2)&b(7)(E)			
	REGIONAL STAFF											
	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
WEAC												
CE	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
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											1215	220
CONVERSION FACTOR											950	950
TOTAL OPERATIONAL FTEs											1.28	0.23

**Inspection of Manufacturers of Laser Products:**

7) To include all other activities such as technical assistance, coordination, and training.

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

1. PROGRAM/ASSIGNMENT TITLE X-Ray Surveillance Programs				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. PROGRAM/ASSIGNMENT CODE(S) 86003, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 11.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S 86003	1 INSP EC T I O N S 86004	2 INVEST I G A T I O N S (Hours) 86003	2 INVEST I G A T I O N S (Hours) 86004	5 FIELD EXAMS/ TESTS 86003	5 FIELD EXAMS/ TESTS 86004	5B AUDITS 86003	8 IMP O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours) 86003
	<b>TOTAL FIELD</b>	<b>18</b>	<b>27</b>	<b>1029</b>	<b>227</b>	<b>916</b>	<b>285</b>	<b>88</b>		<b>4121</b>
	HEADQUARTERS	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
NE	REGIONAL STAFF	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	NEW ENGLAND	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	NEW YORK	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	REGIONAL LAB	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	WEAC	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
CE	REGIONAL STAFF	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	BALTIMORE	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	CHICAGO	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	CINCINNATI	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	DETROIT	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	MINNEAPOLIS	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	NEW JERSEY	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	PHILADELPHIA	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
FORENSIC CHEM. CTR	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)	
SE	REGIONAL STAFF	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	ATLANTA	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	FLORIDA	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	NEW ORLEANS	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	SAN JUAN	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
SW	REGIONAL LAB	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	REGIONAL STAFF	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	DALLAS	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	DENVER	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	KANSAS CITY	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	REGIONAL LAB	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	REGIONAL STAFF	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	LOS ANGELES	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	SAN FRANCISCO	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	SEATTLE	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&b(7)(E)								(b)(2)&b(7)(E)
HOURS PER OPERATION		19.0	10.0			3.0	4.9	4.0		
TOTAL HOURS		342	270	1029	227	2748	1397	352		4121
CONVERSION FACTOR		950	950	950	950	950	950	950		950
TOTAL OPERATIONAL FTEs		0.36	0.28	1.08	0.24	2.89	1.47	0.37		4.34

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. (b)(2)&b(7)(E)

2) Investigation hours are for review of assembler reports.

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

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

Sources of 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**  
**2005 WORKPLAN FOR FIELD COMPLIANCE TESTING**  
**OF DIAGNOSTIC X-RAY SYSTEMS**  
**(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2005)**

**NEW ENGLAND DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
CT	(b)(2)&b(7)(E)				
ME					
MA					
NH					
RI					
VT					
<b>Total</b>					

**NEW YORK DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
NY	(b)(2)&b(7)(E)				

**BALTIMORE DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
DC	(b)(2)&b(7)(E)				
MD					
VA					
WV					
<b>Total</b>					

**CHICAGO DISTRICT**

	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
<b>State</b> IL	(b)(2)&b(7)(E)				

**CINCINNATI DISTRICT**

	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
<b>State</b> KY OH <b>Total</b>	(b)(2)&b(7)(E)				

**DETROIT DISTRICT**

	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
<b>State</b> IN MI <b>Total</b>	(b)(2)&b(7)(E)				

**MINNEAPOLIS DISTRICT**

	<b>Number Systems Installed</b>	<b>Partner- ship Tests</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
<b>State</b> MN ND SD WI <b>Total</b>	(b)(2)&b(7)(E)				

**NEW JERSEY DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
NJ	(b)(2)&b(7)(E)				

**PHILADELPHIA DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
DE	(b)(2)&b(7)(E)				
PA					
<b>Total</b>					

**ATLANTA DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
GA	(b)(2)&b(7)(E)				
NC					
SC					
<b>Total</b>					

**FLORIDA DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
FL	(b)(2)&b(7)(E)				

**NEW ORLEANS DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AL	(b)(2)&b(7)(E)				
LA					
MS					
TN					
<b>Total</b>					

**SAN JUAN DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
PR	(b)(2)&b(7)(E)				

**SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AR	(b)(2)&b(7)(E)				
OK					
TX					
<b>Total</b>					

**SW REGIONAL STAFF (STATES IN DENVER DISTRICT)**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CO	(b)(2)&b(7)(E)				
NM					
UT					
WY					
<b>Total</b>					

**SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
IA	(b)(2)&b(7)(E)				
KS					
NE					
MO					
<b>Total</b>					

**LOS ANGELES DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AZ	(b)(2)&b(7)(E)				
CA					
<b>Total</b>					

**SAN FRANCISCO DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
CA	(b)(2)&b(7)(E)				
HI					
NV					
<b>Total</b>					

**SEATTLE DISTRICT**

State	Number Systems Installed	Partner- ship Tests	FDA Tests	FDA F/U	Audits
AK	(b)(2)&b(7)(E)				
ID					
MT					
OR					
WA					
<b>Total</b>					

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Compliance Testing of Electronic Products at WEAC	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
<b>3. PROGRAM TYPE:</b> <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
<b>4. OBJECTIVES</b> To assure, through laboratory testing, that electronic products meet the FDA performance standards.	
<b>5. PROGRAM JUSTIFICATION</b> 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).	
<b>6. FIELD OBLIGATIONS</b> 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.	
<b>7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:</b> <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
<b>b. INSPECTION TYPE:</b> <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
<b>c. PRODUCT(S)</b> Microwaves, TV Receivers, Diagnostic X-Ray Equipment, Mercury Vapor/Sunlamp, Ultrasonic Therapy Equipment	<b>d. INDUSTRY/PRODUCT CODE(S)</b> 96MS, 94VS, 94DS, 95US, 97US
<b>e. EXAM TYPE:</b> <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS ( <i>Specify</i> )	
<b>f. CHECK THE FOLLOWING ATTRIBUTES</b>	
<b>g. SPECIAL EQUIPMENT, METHODS, AND HANDLING</b>	



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

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 5.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 ENTRY REVIEW (Hours)	2 FILER EVAL (Hours)	2 INVESTI- GATIONS (Hours)	2 ENTRY REVIEW (Hours)	4 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>			4654	1420			200		
NE	HEADQUARTERS		(b)(2)&b(7)(E)				(b)(2)&b(7)(E)			
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION							0.60			
TOTAL HOURS			4654	1420			120			
CONVERSION FACTOR			1200	950			950			
TOTAL OPERATIONAL FTEs			3.88	1.49			0.13			

9. REMARKS

**Reporting Guidance:**

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

**Investigation Hours Based On:**

- **Import Entry Review Hours (Electronic and Paper):**
  - MAY 1, 2003 - APRIL 30, 2004 Electronic Entry Review Hours Reported Under 86R833;
  - MAY 1, 2003 - APRIL 30, 2004 Entry Review Investigation Hours (Operation 14) Reported Under 86007.
- **Import Filer Evaluation Hours:**
  - MAY 1, 2003 - APRIL 30, 2004 Total Hours Reported in PODS; These hours are multiplied by 6.7% (Rad Health's Percentage of the Total PODS Hours).

**Note-Import Follow-Up To Refusal Hours:**

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

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

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86				
3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 6.6			
R E G I O N	6.	1	2	3	4	9	9	9	9
	DISTRICT/ SPECIALIZED LABORATORY	INSP EC T I O N S	INVEST I G A T I O N S (Hours)	DOMESTIC S A M P L E C O L L	IMPOR T S A M P L E C O L L	TECHNICAL A S S I S T A N C E (Hours) RRHR	TECHNICAL A S S I S T A N C E (Hours) CSO	MISC (Hours) DENT	MISC (Hours) RRHR
	TOTAL FIELD					86009 1200	86009 925	* 86008 750	** 86008 4800
	HEADQUARTERS					(b)(2)&b(7)(E)			
N E	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
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								
S W	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
P A	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION								
	TOTAL HOURS					1200	925	750	4800
	CONVERSION FACTOR					1200	950	1180	1200
	TOTAL OPERATIONAL FTEs					1.00	0.97	0.64	4.00
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
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9. Remarks

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

\* This block of time provides laboratory support for the DENT program; this include the following activities:  
 a) reading exposed personnel radiation monitors (i.e. badges) from participating agencies;  
 b) calibrating and checking the accuracy of DENT survey kits upon request.

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

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

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

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

**FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):**

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

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