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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre - Approval Inspections/Inv. Methods Validation - Domestic	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832, B, C	[X] ORA [ ] CENTER	18.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAs TO INSPECT Domestic	1 CHEMIST INSPECT. (Hours) *	2 DOMESTIC INVEST (Hours)	3 DOMESTIC SAMPLE COLL **	3 PROFILE/ PORTION OF DSCs FOR DDA **	7 DOMESTIC SAMPLE ANALYSES PROFILE (Chem) ***	7 BIOTEST (Chem) ***	7 DSAs (METH) (VALID) (Chem) (Hours)	9 MISC. HOURS
	TOTAL FIELD	**137**	**1931**	**1593**	**140**	**(50)**	**45**	**45**	**29**	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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	60.0			5.0		50.0	30.0	105.0	
	TOTAL HOURS	8220	1931	1593	700		2250	1350	3045	
	CONVERSION FACTOR	950	950	950	950		1180	1180	1180	
	TOTAL OPERATIONAL FTEs	8.65	2.03	1.68	0.74		1.91	1.14	2.58	

7. REMARKS

*Includes microbiologists on inspections. ** DSCs for profile/biotest analyses. Includes 50 Profile DSCs to be analyzed by Division of Drug Analysis (HFD-920). *** NRL-analyzes profile/biotest DSCs collected in NE &SE Region; FCC analyzes profile/biotest DSCs collected in CE, SW & PA Regions.
Use CT PAC 52R845 only when specific CT work is performed.

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre-Approval Inspections/Investigations - Foreign	Generic Drug Evaluation - 52

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: [ ] BY DISTRICT OFFICE [X] BY CENTER [x] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [x] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

ANDA Pre - Approval Inspections/Investigations (Methods Validation) - Foreign	2. PPS PROJECT NAME/NUMBER: Generic Drug Evaluation - 52
3. PROGRAM/ASSIGNMENT CODE(S): 52832, 52832B ,52832C, 52832E	4. WORK ALLOCATION PLANNED BY: [X] ORA [ ] CENTER
	5. OPERATIONAL FTE POSITIONS: 11.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS * (Foreign) ++	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS		5 IMPORT SAMPLE COLL ***	6 IMPORT FIELD EXAMS	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST '(Chem) ****	8 IMPORT SAMPLE ANALYSES METH. VALID. ****
	TOTAL FIELD	**62**	**2095**	**1125**		**140**		**70**	**70**	**15**
	HEADQUARTERS	(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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	60.0				3.0		30.0	15.0	50.0
	TOTAL HOURS	3720	2095	1125		420		2100	1050	750
	CONVERSION FACTOR	950	950	950		950		1180	1180	1180
	TOTAL OPERATIONAL FTEs	3.92	2.21	1.18		0.44		1.78	0.89	0.64

7. REMARKS

*** Report as follow: Insps./Chem on Insps. under foreign operation code 11 Pac Code 52832;**

++ PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

Meth. Valid. under PAC 52832; Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C.

** Includes microbiologists on inspections *** Samples are collected at foreign manufacturers.

**** NRL analyzes all Profile/Biotest ISCs and methods Validation ISAs.

Use CT PAC 52R845 only when specific CT work is performed.

PROJECT SUMMARY SHEET

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

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		8.3		1.7	10.0	17.2	
1	Enforcemement of the Adverse Drug	53001A,B,	8.3		1.7	10.0	17.2	2-3
	Expereience Reporting Regulation	53R845,						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ralph J Schmid, HFD-332; 301-827-8929	Anita T. McCurdy, 301-827-1632

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Adverse Drug Experience Reporting Regulations	Postmarketing Surveillance & Epidemiology: Human Drugs - 53

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To provide assignments, guidance and instructions to field offices for inspecting drug firms to determine compliance with the ADE reporting requirements of 21 CFR 310.305,314.80 and 318.98. Regulatory and/or administrative follow-up will be coordinated between the field and headquarters in cases where significant violations of reporting regulations or deficiencies in following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by responsible parties, including applicants, manufacturers, packers and distributors.

5. PROGRAM JUSTIFICATION

The postmarketing adverse drug experience (ADE) regulations (21CFR 310.305,314.80 and 314.98) became effective on August 22, 1985, September 2, 1986 and June 29, 1992 and cover prescription drugs. The regulations also apply to OTC drugs that have approved applications, including those initially marketed as prescription drugs under approved applications (i.e., Rx to OTC switched drugs). The purpose of postmarketing ADE surveillance is to obtain information on rare, latent or long term drug effects not identified during pre-market testing. Accurate, complete, and timely reporting of ADE information is essential to the safety evaluation of marketed drug products. It enables FDA to act when information concerning the use and safety of marketed drug products suggests that new labeling, market withdrawal or other action is required.

6. FIELD OBLIGATIONS

Conduct inspections and forward reports directly to the Division of Prescription Drug Compliance and Surveillance/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up.
Issue regulatory letters as approved by DPDCS. Notify DPDCS of findings from other inspectional program activities which are relevant to ADE reporting.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Adverse Drug Experience Reporting Regulations	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001A, 53001B *	[X] ORA [ ] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS DOMESTIC	1 INSPEC-TIONS FOREIGN	2 INVESTI-GATION	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 MISC. HOURS
	TOTAL FIELD	**138**	**27**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION		57.0	60.0							
TOTAL HOURS		7866	1620							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		8.28	1.71							

7. REMARKS

*Report both Domestic and Foreign inspections 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.
Foreign Inspections are spread by ORA/DFI.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Drug Quality Assurance - 56

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**187.4**	**41.1**	**18.0**	**246.5**	**425.2**	
1	Drug Process Inspections - Domestic	56002A-F, *	134.1			134.1	231.2	2-5
2	Drug Process Inspections - Gas Manufs.	56002E	5.0			5.0	8.6	
3	Foreign Drug Inspections	56002A-F,*			18.0	18.0	31.0	6-7
4	Drug Product Surveillance - Domestic Drugs	56008A,C	25.7			25.7	44.3	8-11
5	Drug Product Surveillance - Import Drugs	56008H****		41.1		41.1	70.8	
6	Drug Quality Reporting System - DQRS	56021A, B	4.0			4.0	7.0	12-13
7	Enforcement of Rx Drug Marketing Act (PDMA)	56022	2.0			2.0	3.4	14-15
8	Pharmacy Compounding Assignments	56D015	4.0			4.0	7.0	16-17
9	ORA/Center Directed Research Project	56R816	3.6			3.6	6.2	18-19
10	Forensic Evaluation and Sample Analysis	56R838*****	9.0			9.0	15.7	20-21
	(*) 56832, 56R359							
	(****) 56R824, 56R833, 99R833							
	(*****)56R831							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Ralph J. Schmid, HFD-330; 301-827-8929	Anita T. McCurdy 301-827-1632

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process Inspections	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Drug Process Inspections - Domestic	2. PPS PROJECT NAME/NUMBER: Drug Quality Assurance - 56	
3. PROGRAM/ASSIGNMENT CODE(S): 56002, A, B, C, D, F 56832, 56R359, 56002M*	4. WORK ALLOCATION PLANNED BY: [X] ORA [X] CENTER	5. OPERATIONAL FTE POSITIONS: 134.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 INSPECTIONS (Hours) *	1 CHEMIST INSPECTIONS (Hours)	1 MICRO INSPEC-TIONS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)	9 CERTIFICATION HOURS For Audits	9 MISC HOURS For Team Biologics Therapeutics INV hours
	TOTAL FIELD	1504	2810	7574	1538	450	229	40	229	40	4800	2730
	HEADQUARTERS	(b)(2) & (b)(7)(E)										
	REGIONAL STAFF											
NE	NEW ENGLAND											
	NEW YORK											
	REGIONAL LAB											
	WEAC											
	REGIONAL STAFF											
	BALTIMORE											
	CHICAGO											
	CINCINNATI											
CE	DETROIT											
	MINNEAPOLIS											
	NEW JERSEY											
	PHILADELPHIA											
	FORENSIC CHEM. CTR											
	REGIONAL STAFF											
	ATLANTA											
	FLORIDA											
SE	NEW ORLEANS											
	SAN JUAN											
	REGIONAL LAB											
	REGIONAL STAFF											
	DALLAS											
SW	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	65.0				5.0			38.0	28.0		
	TOTAL HOURS	97760	2810	7574	1538	2250			8702	1120	4800	2730
	CONVERSION FACTOR	950	950	950	950	950			1180	1180	950	950
	TOTAL OPERATIONAL FTEs	102.90	2.96	7.97	1.62	2.37			7.37	0.95	5.05	2.87

7. REMARKS

* Inspections hours are for additional drug inspections or investigations as needed.

Any new registrants in the high risk categories should be inspected during the first 6 months after registration.

Investigational resources include 3 FTEs for transfer of therapeutics from Biologics planned as headquarters postions.

Gas firms are under a separate worksheet 56-4 . **** DSCs not analyzed are doc. samples. Report Certification Audit hrs under 56R359.

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

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

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
DRUG Process Inspections- Domestic (Gas Manufacturer)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002E	[X] ORA [ ] CENTER	(5.0)

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS MEDICAL GAS *	2 Investigations Hours	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLE ANALYSES	8 IMPORT SAMPLES ANALYSES	9 MISC. HOURS
	TOTAL FIELD	**157**								
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PA	PACIFIC REGIONAL-SW									
	PACIFIC REGIONAL-NW									
	HOURS PER OPERATION	30.0								
	TOTAL HOURS	4710								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	4.96								

9. REMARKS

* Total number of planned gas inspections in the Program for 2006.

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

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Drug Inspections	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Inspectional work is to minimize the consumer's risk of exposure to defective drug products by preventing the marketing of or removing from the market, violative drug products that are observed as a result of inspections performed under this Program.

5. PROGRAM JUSTIFICATION

The international Drug Process Inspection program is FDA's primary means for evaluating the conditions under which foreign drug products are manufactured, tested, packaged and held.

6. FIELD OBLIGATIONS

The field will conduct drug process inspections and maintain profiles of foreign drug manufacturers.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Drug Inspections	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002,A,B,C,D,E,F 56832	[X] ORA [ ] CENTER	18.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS FOREIGN	1 CHEMIST INSPEC-TIONS (Hours) FOREIGN **							
	TOTAL FIELD	**195**	**4670**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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	63.7								
	TOTAL HOURS	12422	4670							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	13.08	4.92							

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 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To obtain information about the quality of the nation's drug supply through analyses of selected domestic and imported finished dosage form products and active pharmaceutical ingredients (APIs).
To direct analytical coverage toward drug products, firms, and countries which pose a heightened risk to the consuming public relative to the risk-based management system.
To obtain information about the identifying characteristics (forensic testing) of APIs from domestic/foreign sources in order to establish a forensic database to evaluate formulation changes and uncover possible counterfeiting.

5. PROGRAM JUSTIFICATION

FDA has the mandate to assure that the nation's drug supply is safe and effective. The Drug Product Surveillance program is FDA's primary means for monitoring the quality of finished drug products and APIs through sampling and analysis.

6. FIELD OBLIGATIONS

To collect samples and perform laboratory examinations. Upon assignment form CDER, conduct inspections to obtain specific information, such as analytical results, production data, and formulation.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

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

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINERING
[X] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Potency, content uniformity, disintegration, dissolution, time release patterns, identification, microbial contamination, and other selected analyses are directed in Drug Surveillance Requests at CDER/District assignments.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance - Domestic Drugs	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008A, C	[X] ORA [X] CENTER	25.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 CHEMIST ON INSPECTIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLLECTIONS	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	3 DOMESTIC SAMPLE COLLECTIONS (API)	7 DOMESTIC SAMPLES ANALYZED (CHEM) *	7 DOMESTIC SAMPLES ANALYZED (MICRO) *	7 DOMESTIC SAMPLES ANALYZED (API) (Chem)
	TOTAL FIELD	**310**	**998**	**955**	**827**	**128**	**220**	**827**	**128**	**220**
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRIC									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION			4.0			4.0	**19.0**	22.0	19.5
	TOTAL HOURS	**310**	998	3820			880	**15713**	2816	4290
	CONVERSION FACTOR	**950**	950	950			950	**1180**	1180	1180
	TOTAL OPERATIONAL FTEs	**0.33**	1.05	4.02			0.93	**13.32**	2.39	3.64

9. REMARKS

*DSAs are assigned by Division of Field Science, ORO per lab expertise for specific Drugs.

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

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance - Imported Drugs	Drug Quality Assurance-56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008H, 56R833, 56R824, 99R833	[X] ORA [ ] CENTER	41.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGATIONS HOURS **		MAIL/ COURIERS REVIEWS INV HOURS	4 IMPORT SAMPLE COLLECT-IONS *	8 IMPORT SAMPLES ANALYZED APIs CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD	**18295**	**9899**		**10260**	**150**	**90**	**60**
	HEADQUARTERS	(b)(2) & (b)(7)(E)			(b)(2) & (b)(7)(E)			
	REGIONAL STAFF							
NE	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
CE	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
SE	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
SW	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					2.7	38.0	25.0
	TOTAL HOURS	18295	9899		10260	405	3420	1500
	CONVERSION FACTOR	1200	950		950	950	1180	1180
	TOTAL OPERATIONAL FTEs	15.25	10.42		10.80	0.43	2.90	1.27

7. REMARKS

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

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

** Import investigation hours are for field exams, filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.
Use CT PAC 56R845 only when specific CT work is performed.

FY 2006

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56021A, 56021B	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	8 IMPORT SAMPLES TO BE ANALYZED	9
	TOTAL FIELD	**100**	**300**	**30**				**30**		
	HEADQUARTERS	(b)(2) & (b)(7)(E)						(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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	25.0		4.0				35.0		
	TOTAL HOURS	2500	300	120				1050		
	CONVERSION FACTOR	950	950	950				1180		
	TOTAL OPERATIONAL FTEs	2.63	0.32	0.13				0.89		

7. REMARKS

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Prescription Drug Marketing Act (PDMA)	Drug Quality Assurance - 56

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To provide general guidance in conducting inspections and investigations of individuals, prescription drug manufacturers, distributors, and other parties that may be involved in the diversion of prescription drug samples, American Goods Returned, or the resale of drugs by hospitals or other health care entities, thereby disrupting legitimate domestic prescription drug distribution channels.

5. PROGRAM JUSTIFICATION

FDA has the mandate to enforce the Prescription Drug Marketing Act amendments to the Federal Food, Drug and Cosmetic Act. These amendments are designed to curtail diversion of prescription drug products from legitimate channels of distribution.

6. FIELD OBLIGATIONS

To follow-up on routine reports referred from CDER during regularly scheduled inspections; upon CDER assignment to perform investigations of possible drug diversion reports; and to collect samples and perform laboratory examinations as appropriate to support regulatory activities.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

Analysis as directed in CDER/district assignments.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Prescription Drug Marketing Act (PDMA)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56022, 56022A	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	8 IMPORT SAMPLES TO BE ANALYZED	
	TOTAL FIELD	**41**	**950**	**34**				**34**		
	HEADQUARTERS	(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									
	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	615	950	68				374		
	CONVERSION FACTOR	950	950	950				1180		
	TOTAL OPERATIONAL FTEs	0.65	1.00	0.07				0.32		

7. REMARKS

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pharmacy Compounding Assignments	Drug Quality Assurance - 56

3. PROGRAM TYPE: ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☒ ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

While the pharmacy compounding law section 503A of the Act was recently struck down by the courts, the agency is still engaged in determining whether or not a pharmacy compounder and its compounded drug products comply with all other applicable sections of the Act. FDA continues to ensure the availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding.

The agency needs to investigate pharmacy-compounding reports of illnesses associated with compounded drug products. In cases where it is determined that exercising the agency's enforcement discretion in regard to pharmacy compounding is not warranted, the agency will consider regulatory action, where necessary, to address applicable violations of the Act.

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATED ☒ DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pharmacy Compounding Assignments	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56D015 *	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	TOTAL FIELD		**3800**							
	HEADQUARTERS		(b)(2) & (b)(7)(E)							
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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									
	TOTAL HOURS		3800							
	CONVERSION FACTOR		950							
	TOTAL OPERATIONAL FTEs		4.00							

7. REMARKS

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

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Project	Drug Quality Assurance - 56

3. PROGRAM TYPE: ☐ COMPLIANCE PROGRAM ☐ PROGRAM CIRCULAR ☒ ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

All research will be distributed in-house and/or published in the referred scientific literature.

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

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATED ☒ DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Project	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R816, 52R816*	[X] ORA [ ] CENTER	3.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEMIST HOURS							
	TOTAL FIELD	**4335**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
CE	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SE	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
SW	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								
	TOTAL HOURS	4335							
	CONVERSION FACTOR	1205							
	TOTAL OPERATIONAL FTEs	3.60							

7.REMARKS

* Resources for 52R816 are planned under 56R816.

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

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Drug Quality Assurance - 56

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

4. OBJECTIVES

Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations.
This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law.
It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.

5. PROGRAM JUSTIFICATION

Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.

6. FIELD OBLIGATIONS

Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic activities PAC 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.

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

b. INSPECTION TYPE: ☐ COMPREHENSIVE ☐ ABBREVIATE ☐ DIRECTED

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

e. EXAM TYPE: N/A ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R838, 56R831	[X] ORA [ ] CENTER	9.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION								
	TOTAL FIELD	**10820**								
	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		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.

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Unapproved and Misbranded Drugs: - Human Drugs - 63

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		12.0			12.0	20.8	
1	Internet, Health Fraud, & OTC Monographs	63001A, 63D012	8.0			8.0	13.8	2-3
2	New Drugs Rx Not Covered by Approved NDAs	63002	4.0			4.0	7.0	4-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
William Nychis HFD-310 301-594-1065	Anita T. McCurdy 301-827-1632

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Internet, Health Fraud, and OTC Monographs	Unapproved and Misbranded Drugs - 63

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To identify and evaluate OTC drug products and to assure their compliance with specific OTC drug monographs or other regulations; 2) to detect, investigate and take action against fraudulent drug products that present the public with a direct and indirect health hazard and economic fraud; and, 3) to monitor, investigate and take regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal off-shore pharmacy operations associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases.

5. PROGRAM JUSTIFICATION

1) In the Federal Register of 1/5/72, the Commissioner announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory panels. As a result, final monographs are published (21 CFR Part 330 through Part 358) which establish conditions under which OTC drugs can be generally recognized as safe and effective and not misbranded; 2) to combat the deceptive and misleading sale of fraudulent drug products; and, 3) FDA must monitor the promotion and sale of drug products on the Internet to identify activities which violate the law and pose a risk to the public health.

6. FIELD OBLIGATIONS

The Field conducts inspections and investigations, develops evidence, collects and analyzes samples, evaluates product labeling, performs surveillance activities, and recommends compliance actions concerning OTC drugs, fraudulent drugs and drugs sold on the Internet as set forth in applicable compliance programs and CDER guidance and requests for follow-up.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Internet, Health Fraud, & OTC Monographs NEW	Unapproved and Misbranded Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63001A, 63D012	[X] ORA [ ] CENTER	8.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVEST-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 Misc. (Hours)
	TOTAL FIELD	**47**	**4775**	**118**				**59**		
	HEADQUARTERS	(b)(2) & (b)(7)(E)						(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	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	30.0		4.0				20.0		
	TOTAL HOURS	1410	4775	472				1180		
	CONVERSION FACTOR	950	950	950				1180		
	TOTAL OPERATIONAL FTEs	1.48	5.03	0.50				1.00		

7. REMARKS

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

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

FY 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
New Drug (Prescription) Without Approved NDAs	Unapproved and Misbranded Drugs - 63

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To establish uniform procedures for removal from the market of all prescription drug products described by FDA to be new drugs not covered by approved New Drug Applications; complete Category VII of Compliance Policy Guide (CPG) 7132c.02 which are not in the earlier categories of this CPG; and any drug products in prior categories remaining for regulatory action.

5. PROGRAM JUSTIFICATION

The Drug Amendments of 1962 to the FD&C Act require that all marketed drug products be safe and effective. Judge June L. Green of the U.S. District Court for the District of Columbia ruled (July 29, 1975) that an approved new drug application for prescription drugs which the FDA has previously declared to be a new drug within the meaning of 21 USA 321(p) is required in order for the drug product to be introduced into interstate commerce. Therefore, those without approved applications must be withdrawn from the market. This compliance program is responsive to this mandate.

6. FIELD OBLIGATIONS

-Assign District Coordinator, whose name shall be supplied to HFD-310.
-Identify all drug products which require regulatory letters and prepare such letters to be signed by the District Director.
-Maintain records of all activities under this program, including a list of drug products voluntarily removed from the market in compliance with the warning letters, products removed by recall, etc.
-Initiate regulatory actions, where appropriate, to assure compliance with program.
Submit monthly report to HFD-310.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Prescription Drugs	Industry Codes: 54, 56, and 60-66

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
New Drugs (Prescription) Without Approved NDAs (NEW)	Unapproved and Misbranded Drugs - 63

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63002	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVEST-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL. *	4 IMPORT SAMPLE COLL.	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 Misc. (Hours)
	TOTAL FIELD	**79**	**950**	**95**						
	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	30.0		5.0						
	TOTAL HOURS	2370	950	475						
	CONVERSION FACTOR	950	950	950						
	TOTAL OPERATIONAL FTEs	2.49	1.00	0.50						

7. REMARKS

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

Report work under New Drugs (Rx) without Approved NDAs (formerly PAC 52002) to PAC 63002.

CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2006

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	94.2	28.7	3.9	126.8	162.7	49.6	6.7	219.0
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	7.2		3.5	10.7	12.5		6.0	18.5
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	87.0	28.7	0.4	116.1	150.2	49.6	0.7	200.5

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

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

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

PROJECT SUMMARY SHEET
FY 2006 ORA WORKPLAN

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

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**7.2**		**3.5**	**10.7**	**18.5**	
1	NADA Pre-Approval Inspections	68001	2.2		3.5	5.7	9.9	2-3
	(National Expert)		(0.1)			(0.1)		
2	Bioresearch Monitoring		5.0			5.0	8.6	4-7
	(Pre-Market) GLP and Spon/Mon/Con	68808*	(2.9)			(2.9)		
	*68810 planned under 68808	68810						
	(Pre-Market) Clinical Investigators	68811	(2.1)			(2.1)		

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deborah A. Cera, (240) 276-9209	Carrie M. Mampilly, (301) 827-1635

1. PROGRAM/ASSIGNMENT TITLE
NADA Pre-Approval Inspections

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure that applicants for New Animal Drug Application (NADA) approvals have the required capabilities to fulfill their NADA commitments to manufacture, process, and pack new animal drugs that are safe and effective for their intended use.

Increase the number of cooperative activities related to this program.

5. PROGRAM JUSTIFICATION

Domestic and foreign plant inspections are necessary to determine whether the establishment can produce the new animal drug in accordance with current good manufacturing practice regulations and comply with the commitments in the NADA. Inspections will be issued by assignment. Priority will be specified by CVM.

Outcome: Reduce new animal drug development and review time.

6. FIELD OBLIGATIONS

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

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

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

Petition validation work.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NADA Pre-Approval Inspections	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68001	[X] ORA [X] CENTER	5.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	1 CHEMIST ON INSP **	1 INSPEC-TIONS (Foreign) ***	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)			
	TOTAL FIELD	**40**	**310**	**47**						
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	46.4		75.3						
	TOTAL HOURS	1856	310	3539						
	CONVERSION FACTOR	1000	1000	1000						
	TOTAL OPERATIONAL FTEs	1.86	0.31	3.54						

7. REMARKS

** Analyst will participate on inspections as necessary.

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

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

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practice (Non-clinical Laboratory)	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To conduct inspections of facilities and non-clinical laboratories engaged in the collection of data to determine whether the GLP regulations (21 CFR 58) are followed. To take appropriate action whenever a situation involving a serious violation of the GLPs is encountered or when fraud or other deliberate falsifications of test data has occurred.

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:
[ ] BY DISTRICT OFFICE [X] BY CENTER [ ] BY BOTH

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure the adherence of sponsors, contract research organizations and monitors to the clinical monitoring regulations specific (21 CFR 511.1 (b)) and to evaluate representative clinical investigators utilized by the sponsor with regard to their adherence to applicable regulations.

5. PROGRAM JUSTIFICATION

As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. Part of this comprehensive program was directed to sponsors, monitors, and clinical investigators under the above stated objective.

Outcome: Assure data integrity and reduce drug development time.

6. FIELD OBLIGATIONS

Conduct inspections of sponsors, contract research organizations, and monitors, identified by the Center in accordance with the guidance set forth in the basic compliance program 7368.810.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Clinical Investigators	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assess through audit procedures (21 CFR 511.1 (b)) whether data submitted by clinical investigators to FDA in a specific clinical study are substantiated by records.

5. PROGRAM JUSTIFICATION

As a result of Senate committee hearings and a GAO investigation, Congress directed FDA to develop and implement a program of inspecting non-clinical laboratories and an intensified program of monitoring clinical investigations. The program determines the validity of data submitted to FDA by inspecting clinical investigators' records.

Outcome: Assure data integrity and reduce drug development time.

6. FIELD OBLIGATIONS

Conduct inspections of clinical investigators identified by the Center in accordance with the guidance set forth in the basic compliance program 7368.811.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, Sponsor-Monitors, Clinical Investigators (Pre-Market)	Pre-Approval Evaluation of Animal Drugs and Food Additives - 68

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
68808, 68810, 68811	[X] ORA [ ] CENTER	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 68808 INSPEC-TIONS (GLPs) (SPON/MON)	1 68811 INSPEC-TIONS (CLINICAL INVEST)							
	TOTAL FIELD	**50**	**51**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	58.3	41.0							
	TOTAL HOURS	2915	2091							
	CONVERSION FACTOR	1000	1000							
	TOTAL OPERATIONAL FTEs	2.92	2.09							

7. REMARKS

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

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

PROJECT SUMMARY SHEET
FY 2006 ORA WORKPLAN

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

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**87.0**	**28.7**	**0.4**	**116.1**	**200.5**	
1	Drug Process and New Animal Drug Inspections	71001/71R841	9.2		0.4	9.6	16.6	2-3
2	Feed Contaminants	71003A-J	11.9	2.2		14.1	24.4	4-7
3	Feed Manufacturing	71004/A	6.1			6.1	10.5	8-9
4	Illegal Drug Residues in Meat and Poultry	71006	12.0			12.0	20.7	10-11
5	Ruminant Feed Ban Rule (BSE) Program*	71009, 71R844	40.3	26.5		66.8	115.4	12-15
6	ORA/Center Directed Research Projects	71R816	5.8			5.8	10.0	16-17
7	Forensic Evaluation and Sample Analysis	71R831/71R838	0.7			0.7	1.2	18-19
8	Center Initiated Assignments	71V800	1.0			1.0	1.7	20-21

*Includes: 71R833, 99R833, and 71R824

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deborah A. Cera, (240) 276-9209	Carrie M. Mampilly, (301) 827-1635

1. PROGRAM/ASSIGNMENT TITLE
Drug Process and New Animal Drug Inspections / Type A Medicated Articles

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21 CFR 211 for dosage form products and 21 CFR 226 for Type A Medicated Articles. To obtain accurate listing and labeling information for veterinary drug establishments. To check and verify the existence and scope of stability testing programs, protocols and commitments, and the validity of storage conditions, testing criteria and methodology together with reporting of results in the Drug Experience Report (DER) as specified in the approval New Animal Drug Application (NADA).

5. PROGRAM JUSTIFICATION

Section 510(h) of the Act obligates the Agency to inspect (pursuant to 704 of the Act) drug establishments required to register with FDA. In addition, it is one of the primary purposes of establishment inspections to assure that the drug product is being manufactured, processed, controlled, etc. under the same conditions as approved and that it maintains the same stability profile as originally demonstrated.

Outcome: Ensure the marketing of safe and effective animal drugs.

6. FIELD OBLIGATIONS

The field will conduct CGMP inspections of registered animal drug establishments. Top priority will be given to establishments which manufacture sterile products.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)
All Animal Drug Dosage forms and Type A Articles. Medicated feeds or blocks, diagnostic aids and devices are not included.

d. INDUSTRY/PRODUCT CODE(S)
56, 60-66, 67-69

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

f. CHECK THE FOLLOWING ATTRIBUTES
Sterility, purity, identify, potency, decomposition

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
N/A

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process and New Animal Drug Inspections / Type A Medicated Articles	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71001 /A /B, 71005 /A, 71R841	[X] ORA [ ] CENTER	9.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	1 NAT'L EXPERTS ON INSP (Hours)	1 CHEM ON INSP (Hours)	1 INSPEC-TIONS (Foreign)	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	DOMESTIC SAMPLE COLL (Micro)	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)	7 DOMESTIC SAMPLES TO BE ANALYZED (Micro)
	TOTAL FIELD	**213**	**210**	**500**	**10**	**235**	**80**	**30**	**15**	**30**	**15**
	HEADQUARTERS										
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
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	33.0			40.0		5.5			18.4	21.1
	TOTAL HOURS	7029	210	500	400	235	440			552	317
	CONVERSION FACTOR	1000	1000	1000	1000	1000	1000			1180	1180
	TOTAL OPERATIONAL FTEs	7.03	0.21	0.50	0.40	0.24	0.44			0.47	0.27

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

9. REMARKS

Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples. Investigational or official samples should be collected as appropriate.
Type A Medicated Articles program (71005 / A is now under 71001); continue to report work to PAC 71005 / A.

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

Workload Source: FACTS database (registered firms in IND 56, 67, 68 with Status of "Operational" and Workload Obligation of "Yes".)
Foreign Inspections spread by Division of Field Investigations, ORO.

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To monitor domestic and imported animal feed and feed ingredients to prevent widespread contamination of the nation's food supply.

Increase the number of cooperative activities related to this program.

5. PROGRAM JUSTIFICATION

The use of contaminated feed ingredients has resulted in adulterated animal feeds and in economic losses to producers and processors when food-producing animals consume adulterated feeds. A hazard to human health may result from subsequent deposition of residues in meat, poultry, eggs, fish and dairy products. These foods constitute a significant portion of the human diet and fraud.

Outcome: Prevention or containment of potential human or animal health hazard.

6. FIELD OBLIGATIONS

To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis.

Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Complete animal feeds and feed ingredients.	69-72

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

f. CHECK THE FOLLOWING ATTRIBUTES
*Mycotoxins, Pesticides, Industrial Chemicals, Metals, and Microbiologicals

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
N/A

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS	
71003 A-J	[X] ORA [X] CENTER	**TOTAL**	**14.1**
		DOMESTIC	11.9
		IMPORT	2.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (Dioxin) *	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLE COLL Metals 71003B	3 DOMESTIC SAMPLE COLL Myco 71003C	3 DOMESTIC SAMPLE COLL Micro 71003E	3 DOMESTIC SAMPLE COLL Chem 71003A	3 DOMESTIC SAMPLE COLL Dioxin 71003G	7 DOMESTIC SAMPLE ANALYSIS Metals 71003B	7 DOMESTIC SAMPLE ANALYSIS Myco 71003C	7 DOMESTIC SAMPLE ANALYSIS Micro 71003E	7 DOMESTIC SAMPLE ANALYSIS Chem 71003A	7 DOMESTIC SAMPLE ANALYSIS Dioxin 71003G
	TOTAL FIELD	15	805	20	250	200	200	135	20	250	200	200	135
	HEADQUARTERS												
	REGIONAL STAFF												
NE	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB												
	WEAC												
	REGIONAL STAFF												
	BALTIMORE												
	CHICAGO												
	CINCINNATI												
CE	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA												
	FORENSIC CHEM. CTR												
	REGIONAL STAFF												
	ATLANTA												
SE	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
SW	DENVER												
	KANSAS CITY												
	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
PA	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LABORATORY-SW												
	PACIFIC REGIONAL LABORATORY-NW												
	HOURS PER OPERATION	20.0	4.2						12.0	7.7	19.4	5.5	19.0
	TOTAL HOURS	300	3381						240	1925	3880	1100	2565
	CONVERSION FACTOR	1000	1000						1180	1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.30	3.38						0.20	1.63	3.29	0.93	2.17

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

9. REMARKS

* Inspections performed as F/U to violative dioxin samples

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

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

NOTE: Continued on Page 71-7

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-5	Monitoring of Marketed Animal Drugs, Feeds and Devices -71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71003 A-J	[X] ORA [X] CENTER	2.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL	4 IMPORT SAMPLE COLL Chem	4 IMPORT SAMPLE COLL Micro	4 IMPORT SAMPLE ANALYSIS Chem	8 IMPORT SAMPLE ANALYSIS Micro				
	TOTAL FIELD	**220**	**155**	**65**	**155**	**65**				
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	2.5			7.5	12.0				
	TOTAL HOURS	550			1163	780				
	CONVERSION FACTOR	1000			1180	1180				
	TOTAL OPERATIONAL FTEs	0.55			0.99	0.66				

9. REMARKS

Dioxin Samples, 71003G, will be analyzed by ARL and chem samples, 71003 A/B, will follow the distibution of this workplan and Servicing Laboratory Table.

Mycotoxin samples, 71003C, will be analyzed by PRN. Mycotoxin and dioxin samples should be collected as necessary.

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

Workload Source: FACTS and OASIS databases.

1. PROGRAM/ASSIGNMENT TITLE
Feed Manufacturing

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To determine compliance with GMP elements of registered establishments producing medicated feeds. To determine whether a firm has the appropriate approved applications to make medicated feeds. To initiate appropriate administrative and/or regulatory action.

5. PROGRAM JUSTIFICATION

Under Sec. 510(h) of the Act, the Agency is obligated to inspect registered medicated feed establishments.

Outcome: Ensure the marketing of safe and effective animal feeds.

6. FIELD OBLIGATIONS

To conduct inspections of registered medicated feed establishments and State audit inspections as needed. Districts will collect and analyze samples when appropriate. Field will coordinate federal/state operations.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)
Medicated Feeds

d. INDUSTRY/PRODUCT CODE(S)
69

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

f. CHECK THE FOLLOWING ATTRIBUTES
Drug analysis (potency) and drug contamination

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Manufacturing	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71004 / A	[X] ORA [ ] CENTER	6.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS FEED ESTABS	1 INSPEC-TIONS NATIONAL EXPERTS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	DOMESTIC SAMPLE COLL (Micro)	7 DOMESTIC SAMPLES ANALYZED (Chem)	7 DOMESTIC SAMPLES ANALYZED (Micro)	1 VSIP INSPEC-TIONS (Hours) *	
	TOTAL FIELD	**243**	**120**	**55**	**15**	**5**	**15**	**5**	**250**	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
NE	NEW YORK									
NE	REGIONAL LAB									
NE	WEAC									
CE	REGIONAL STAFF									
CE	BALTIMORE									
CE	CHICAGO									
CE	CINCINNATI									
CE	DETROIT									
CE	MINNEAPOLIS									
CE	NEW JERSEY									
CE	PHILADELPHIA									
CE	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
SE	ATLANTA									
SE	FLORIDA									
SE	NEW ORLEANS									
SE	SAN JUAN									
SE	REGIONAL LAB									
SW	REGIONAL STAFF									
SW	DALLAS									
SW	DENVER									
SW	KANSAS CITY									
SW	SOUTHWEST IMPORT DISTRICT									
SW	REGIONAL LAB									
PA	REGIONAL STAFF									
PA	LOS ANGELES									
PA	SAN FRANCISCO									
PA	SEATTLE									
PA	PACIFIC REGIONAL LABORATORY-SW									
PA	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	19.0		6.6			44.0	44.0		
	TOTAL HOURS	4617	120	363			660	220	250	
	CONVERSION FACTOR	1000	1000	1000			1180	1180	1000	
	TOTAL OPERATIONAL FTEs	4.62	0.12	0.36			0.56	0.19	0.25	

9. REMARKS

Non-potency feed sample analysis should be charged to 71003 A/E.
There are 348 State Contract inspections.
The 120 hours of inspections by National Experts equals to 6 Medicated Feed Inspections.

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

Shaded area serves as a **guideline** for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis. The remining 35 collected samples are available for documentary sample collection.

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

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

Reduce future residues in edible animal tissues. FDA will be partners with FSIS/HACCP on the environment, educational initiatives, and, as necessary, regulatory actions.

5. PROGRAM JUSTIFICATION

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

Outcome: To provide a safe human food supply.

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Meat and Poultry, Animal Feeds and Drugs	16, 17, 67, 68, 69

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

f. CHECK THE FOLLOWING ATTRIBUTES
Tissue Sample analysis by Denver laboratory when required.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71006	[X] ORA [X] CENTER	12.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED Chem (Hours)	7 DOMESTIC SAMPLES ANALYZED Micro (Hours)	9 METHODS VALID (Hours) *			
	TOTAL FIELD	**245**	**1000**	**200**	**600**	**500**	**360**			
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	35.0		6.0						
	TOTAL HOURS	8575	1000	1200	600	500	360			
	CONVERSION FACTOR	1000	1000	1000	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	8.58	1.00	1.20	0.51	0.42	0.31			

9. REMARKS

Planned analytical time may be converted to methods development per CVM's concurrence. Methods development work will be assigned by CVM.
Sample collections represent FSIS repeat violator samples involving C/R's, no sample analysis.
* Additional time for method validation studies.

Feed and Animal Drug samples are analyzed by Denver Laboratory.

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

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: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] 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 Encephalophy (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, investigations, and sample collections/analyses 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:
[ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)
Animal feeds and feed ingredients

d. INDUSTRY/PRODUCT CODE(S)
67-72

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
N/A

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS		
71009, 71R844 (99R833, 71R833, 71R824)	[X] ORA [X] CENTER	Domestic Import	40.3 26.5	66.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSPECTIONS *	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INVESTIGATION HOURS **	3 DOMESTIC SAMPLE COLLECTIONS	4 IMPORT SAMPLES COLLECTIONS	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES ANALYZED	9 TECHNICAL SUPPORT (HOURS) ***
	TOTAL FIELD	**3760**	**12900**	**7900**	**900**	**900**	**900**	**900**	**1500**
	HEADQUARTERS	(b)(2) & (b)(7)(E)							
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
CE	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
SE	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
SW	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
PA	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	7.5			5.0	2.5	8.0	7.4	
	TOTAL HOURS	28200	12900	7900	4500	2250	7200	6660	1500
	CONVERSION FACTOR	1000	1200	1000	1000	1000	1180	1180	1000
	TOTAL OPERATIONAL FTEs	28.20	10.75	7.90	4.50	2.25	6.10	5.64	1.50

9. REMARKS

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

BSE inspections are allocated based on a weighted inventory of: 1) Renderers, Feed Mills, Protein Blenders who manufacture or process products using prohibited materials requiring annual BSE inspections, Operational, Seasonal, Workload Obligation Yes or No; 2) Renderers, Feed Mills, Protein Blenders, Operational, Seasonal, who only distribute prohibited material or do not handle prohibited material, Workload Obligation Yes or No; 3) All other firms, Workload Obligation Yes, Operational, Seasonal, that handle prohibited material, only distribute prohibited material, or do not handle prohibited material requiring an annual BSE inspection.

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

*** Technical support hours includes supporting state activities under the Ruminant Feed Ban Regulation.

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

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Ruminant Feed Ban Rule/BSE Program	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 includ some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources should be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with the regulations be encountered. Certain higher risk firm types, such as renderers, protein blenders, and feed mills, generally require regular re-inspections, even if the firm did not manufacture with prohibited material at their last inspection. Efforts should also be placed on regulatory agencies in identifying additional firms to be inspected under this program. In the identification, planning, and prioritization of inspections conducted under this program, the following firm / industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- 'For Cause' inspections
- Firms that have a violative history
- Renderers, Protein Blenders, and Feed Mills manufacturing with prohibited materials (Performance Goal Firms)
- Rendering operations (involving any product)
- Protein Blenders (involving any product)
- Commercial feed mills (ruminant feeds involved)
- Commercial feed mills (non-ruminant feeds involved)
- Animal feed distributors/retailers (ruminant feed or feed ingredients involved)
- Pet food/animal feed salvage operations
- Commercial feed mills (pet food manufacturing ONLY)
- Haulers/transporters of animal feeds (ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (non-ruminant feed or feed ingredients involved)
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Mobile feed mixers
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feed or feed ingredients involved)
- Haulers/transporters of animal feeds (no ruminant feed or feed ingredients involved)
- Animal feed distributors/retailers (pet foods ONLY involved)
- On-farm feed mixers (ONLY ruminant OR no ruminant animals on farm premises)

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Research

6. FIELD OBLIGATIONS

All research will be distributed in-house and/or published in the referred scientific literature.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71R816	[X] ORA [ ] CENTER	5.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	RESEARCH CENTER RESEARCH CHEM							
	TOTAL FIELD	**965**	**5900**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	965	5900							
	CONVERSION FACTOR	1205	1180							
	TOTAL OPERATIONAL FTEs	0.80	5.00							

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analyses	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

6. FIELD OBLIGATIONS

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71R838	[X] ORA [ ] CENTER	0.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)
	TOTAL FIELD	**875**
	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 LABORATORY-SW	
	PACIFIC REGIONAL LABORATORY-NW	
	HOURS PER OPERATION	
	TOTAL HOURS	875
	CONVERSION FACTOR	1205
	TOTAL OPERATIONAL FTEs	0.73

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	Monitoring of Marketed Animal Drugs, Feeds and Devices - 71

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

A number of potential or emerging problems which cannot be predicted must be handled. The resources for these Center initiated assignments are planned under this umbrella program.

6. FIELD OBLIGATIONS

Conduct inspections, investigations, sample collections and analyses as directed by Center assignments.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All veterinary products	54, 56, 67-72

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
N/A

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71V800	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI-GATIONS (Hours)								
	TOTAL FIELD	**1000**								
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1000								
	CONVERSION FACTOR	1000								
	TOTAL OPERATIONAL FTEs	1.00								

9. REMARKS

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

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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2006

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs	PROGRAM FTEs			TOTAL PROGRAM FTEs
		DOMESTIC	IMPORT	FOREIGN		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	174.2	50.6	19.3	244.1	299.8	86.3	32.9	419.0
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5	0.9			0.9
82	COMPLIANCE: DEVICES	97.0	40.4	14.2	151.6	165.6	68.9	24.2	258.7
83	PRODUCT EVALUATION: DEVICES	33.3		4.0	37.3	56.8		6.8	63.6
84	SCIENCE: DEVICES	5.1			5.1	8.7			8.7
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.8		0.1	14.9	27.7		0.2	27.9
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	23.5	10.2	1.0	34.7	40.1	17.4	1.7	59.2

"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.

PROJECT SUMMARY SHEET

FY 2006

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Postmarket Assurance: Devices - 81

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		0.5			0.5	0.9	
1	Medical Device Problem Reporting - MDR	81010	0.5			0.5	0.9	2-3
	Follow-up							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Susan N. Gardner 301-594-1708	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Problem Reporting – MDR Follow-up	Postmarket Assurance: Devices - 81

3. PROGRAM TYPE:							
	[X]	COMPLIANCE PROGRAM	[ ]	PROGRAM CIRCULAR	[ ]	ASSIGNMENT

4. OBJECTIVES

Rapidly identify immediate hazards to health;
Identify significant problems by analyzing recurring problems and performing trends analysis;
Provide data on complaints, significant problems and potential hazards so that corrective action can be initiated for hazardous products in the marketplace.

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE:						
	[ ]	COMPREHENSIVE	[ ]	ABBREVIATED	[X]	DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73-91

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

f. CHECK THE FOLLOWING ATTRIBUTES

Sterility Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Problem Reporting - MDR Follow-Up	Postmarket Assurance: Devices - 81

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
81010	[X] ORA [ ] CENTER	0.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1)	2 INVESTI-GATIONS (Hours) (2)	3 DOMESTIC SAMPLE COLL ENG	3 DOMESTIC SAMPLE COLL CHEM	3 DOMESTIC SAMPLE COLL STER	7 DOMESTIC SAMPLES TO BE ANALYZED ENG (3)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (4)	7 DOMESTIC SAMPLES TO BE ANALYZED STER (5)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**23**	**100**	**1**	**1**	**1**	**1**	**1**	**1**	
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	12.1		11.5	11.5	11.5	37.0	36.0	20.0	
	TOTAL HOURS	278	100	12	12	12	37	36	20	
	CONVERSION FACTOR	950	950	950	950	950	1180	1180	1180	
	TOTAL OPERATIONAL FTEs	0.29	0.11	0.01	0.01	0.01	0.03	0.03	0.02	

9. REMARKS

(1) Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.

(2) Investigational hours for MDR followup at medical facilities.

(3) MDR samples to confirm reported defects.

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

(5) Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.

PROJECT SUMMARY SHEET

FY 2006

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Compliance: Devices - 82

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**97.0**	**40.4**	**14.2**	**151.6**	**258.7**	
1	Monitoring Devices of Foreign Origin - Import	82008 *		28.1		28.1	47.9	2-3
2	Inspection of Medical Device Manufacturers:		92.6		14.2	106.8	182.3	4-9
	GMP Inspections	82845ABCGS	(87.3)		(14.2)	(101.5)	(173.3)	
	Accredited Persons Audit Investigations	82845J	(0.3)			(0.3)	(0.5)	
	Accredited Persons Audit Inspections	82845P	(5.0)			(5.0)	(8.5)	
3	Condom Assignment	82Z002		4.3		4.3	7.3	10-11
4	Manufacturers and Importers of Surgical/ Examination Gloves	82Z003	0.1	8.0		8.1	13.9	12-13
5	BSE Assignment	82Z005	0.5			0.5	0.8	14-15
6	Center Initiated Assignments	82Z800	1.5			1.5	2.6	14-17
7	ORA/Center Directed Research Projects	82R816	2.0			2.0	3.4	18-19
8	Forensic Evaluation & Sample Analysis	82R838	0.3			0.3	0.5	20-21

* In addition to PAC 82008, includes reporting PACs 82R824, 82R833, and 99R833.

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Tim Ulatowski 301-594-4692	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Monitoring Devices of Foreign Origin - Import	Compliance: Devices - 82

3. PROGRAM TYPE:						
	[X]	COMPLIANCE PROGRAM	[ ]	PROGRAM CIRCULAR	[ ]	ASSIGNMENT

4. OBJECTIVES

Determine compliance of imported devices with the medical device registration and listing requirements, and other general controls.

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:						
	[X]	BY DISTRICT OFFICE	[ ]	BY CENTER	[ ]	BY BOTH
b. INSPECTION TYPE: N/A	[ ]	COMPREHENSIVE	[ ]	ABBREVIATED	[ ]	DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73-91

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Refer to Compliance Program for procedures to handle initial distributors and/or foreign establishments which are not registered.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Monitoring Devices of Foreign Origin - Import	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82008, 82R824, 82R833, 99R833	[X] ORA [ ] CENTER	28.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 IMPORT INV HOURS *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL (Physical) ENG	4 IMPORT SAMPLE COLL (Physical) MICRO **	8 IMPORT SAMPLES TO BE ANALYZED ENG	8 IMPORT SAMPLES TO BE ANALYZED MICRO ***	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		**23111**	**5663**		**60**	**60**	**60**	**60**	
	HEADQUARTERS		(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									
	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					2.2	2.2	25.5	25.5	
	TOTAL HOURS		23111	5663		132	132	1530	1530	
	CONVERSION FACTOR		1200	950		950	950	1180	1180	
	TOTAL OPERATIONAL FTEs		19.26	5.96		0.14	0.14	1.30	1.30	

9. REMARKS

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

** Audit samples for problems other than failure to register or list (eg. special assignment, import alert).
Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

*** Sterile devices to be tested by USP XX method.
Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

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

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

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

3. PROGRAM TYPE:						
	X	COMPLIANCE PROGRAM		PROGRAM CIRCULAR		ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

The Center's inspectional strategy requires that all manufacturers of Class II and III devices be inspected under the GMP Compliance Program on a biennial basis. FDA selects certain establishments for intensive GMP coverage. Establishments with a history of good GMP systems are subject to less-intensive inspections. All establishments are subject to complaint file reviews to assess compliance with the MDR regulation.

6. FIELD OBLIGATIONS

Under the Quality Systems/GMP strategy, the field should conduct biennial inspections of high-risk device manufacturers and Class III device manufacturers that are not considered to be high risk. The remaining manufacturers (Class III, II, and I devices) should be inspected as each district's resources allow, and scheduled according to the priority outline described in Part II of the compliance program. For more detailed instructions on QSIT/GMP inspections as they relate to device manufacturers, refer to the Workplanning Sheet's Remarks section.

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

b. INSPECTION TYPE:						
	X	COMPREHENSIVE	X	ABBREVIATED		DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Class II and III Devices and all Class I Devices which have been finally classified for one year.	73-91

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845A,B,C,G,J,K,P,S, 81845R,T, 81011	[X] ORA [ ] CENTER	106.8 [101.7]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS LEVEL I DOMESTIC 82845A	1 INSPECTIONS LEVEL II DOMESTIC 82845B	1 INSPECTIONS LEVEL III COMPLIANCE DOMESTIC 82845C	1 INSPECTIONS FOREIGN 82845B	1 INSPECTIONS FOR CAUSE DOMESTIC 82845G	1 INSPECTIONS ACCREDITED PERSONS DOMESTIC 82845P	2 INVESTIGATIONS (Hours) 82845B	2 INVESTIGATIONS (Hours) A.P. AUDITS MDUFMA 82845J
	TOTAL FIELD	**800**	**535**	**107**	**207**	**95**	**95**	**2602**	**255**
	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 LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	HOURS PER OPERATION	34.0	60.0	89.0	65.0	71.0	50.1		
	TOTAL HOURS	27200	32100	9523	13455	6745	4760	2602	255
	CONVERSION FACTOR	950	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	28.63	33.79	10.02	14.16	7.10	5.01	2.74	0.27

9. REMARKS

Quality Systems Inspection Technique (QSIT) Inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause " inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Reprogram any unused resources into Level 1 and 2 inspections.
Inspectional modules include time for 82845S (sterilization), MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections. Investigational Hours resources have also been planned for National Experts (HQ line) and State Contract Monitoring (DAL-DO line).

Foreign inspections include resources for Level I, II, III, and For Cause-related inspections. For planning purposes Foreign inspections will be planned under the Level II inspection PAC (82845B); use the appropriate reporting PAC to record accomplishments associated with these Foreign inspections.

Accredited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program. Accredited Person Audits are conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845A,B,C,G,J,K,P,S, 81845R,T, 81011	[X] ORA [ ] CENTER	106.8 [4.5]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL 82845C	3 DOMESTIC SAMPLE COLL ENG 82845C	3 DOMESTIC SAMPLE COLL MICRO 82845C	3 DOMESTIC SAMPLE COLL CHEM 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C		
	TOTAL FIELD	**96**	**18**	**43**	**18**	**18**	**43**	**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									
	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	6.0				72.0	62.0	32.5		
	TOTAL HOURS	576				1296	2666			
	CONVERSION FACTOR	950				1180	1180	1180		
	TOTAL OPERATIONAL FTEs	0.61				1.10	2.26	0.50		

9. REMARKS

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

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

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

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845A,B,C,G,J,K,P,S, 81845R,T, 81011	[X] ORA [ ] CENTER	106.8 [0.6]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL 82845S	3 DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR 82845S	3 DOMESTIC SAMPLE COLL STERILITY 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN 82845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY 82845S	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**44**	**11**	**6**	**11**	**6**				
	HEADQUARTERS									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	6.0			25.0	25.0				
	TOTAL HOURS	264			275	150				
	CONVERSION FACTOR	950			1180	1180				
	TOTAL OPERATIONAL FTEs	0.27			0.23	0.13				

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

9. REMARKS

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

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

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Condom Assignment	Compliance: Devices - 82

3. PROGRAM TYPE:		COMPLIANCE PROGRAM		PROGRAM CIRCULAR	X	ASSIGNMENT

4. OBJECTIVES

Determine the extent to which manufacturers of condoms comply with the Device GMP requirements; Assure that both domestic and imported condoms comply with the FDA standards.

5. PROGRAM JUSTIFICATION

The Surgeon General has recommended the use of condoms to reduce the spread of AIDS. Consequently, FDA is committed to assuring that condoms are safe and effective.

6. FIELD OBLIGATIONS

Districts will, upon assignment, conduct GMP inspections of domestic condom manufacturers and major repackers. Districts will also sample both domestic and imported condoms and conduct tests to assure conformance with the FDA standard.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		BY DISTRICT OFFICE		BY CENTER	X	BY BOTH
b. INSPECTION TYPE:	X	COMPREHENSIVE		ABBREVIATED		DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Condom Assignment	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z002	[X] ORA [ ] CENTER	4.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL CHEM	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**3**		**2**	**320**			**2**	**320**	
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)				(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	8.8		3.0	2.5			12.0	12.7	
	TOTAL HOURS	26		6	800			24	4064	
	CONVERSION FACTOR	950		950	950			1180	1180	
	TOTAL OPERATIONAL FTEs	0.03		0.01	0.84			0.02	3.44	

9. REMARKS

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

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

3. PROGRAM TYPE:		COMPLIANCE PROGRAM		PROGRAM CIRCULAR	X	ASSIGNMENT

4. OBJECTIVES

Determine the extent to which manufacturers of both surgical and examination gloves comply with the Device GMP requirements; Assure that both domestic and imported gloves comply with the applicable FDA standard.

5. PROGRAM JUSTIFICATION

Healthcare providers rely heavily on gloves to prevent the transmission of the AIDS virus. Consequently, FDA is committed to assure that both surgical and examination gloves comply with published standards.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		BY DISTRICT OFFICE		BY CENTER	X	BY BOTH
b. INSPECTION TYPE:	X	COMPREHENSIVE		ABBREVIATED		DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z003	[X] ORA [ ] CENTER	8.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	3 DOMESTIC SAMPLE COLL ENG	3 DOMESTIC SAMPLE COLL CHEM	4 IMPORT SAMPLE COLL ENG (PHYSICAL)	4 IMPORT SAMPLE COLL CHEM (PHYSICAL)	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)
	TOTAL FIELD	**2**	**1**	**1**	**222**	**778**	**1**	**1**	**222**	**778**
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	8.0	6.0	6.0	2.3	2.3	20.0	13.0	6.6	6.6
	TOTAL HOURS	16	6	6	511	1789	20	13	1465	5135
	CONVERSION FACTOR	950	950	950	950	950	1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs	0.02	0.01	0.01	0.54	1.88	0.02	0.01	1.24	4.35

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	2. PPS PROJECT NAME/NUMBER
BSE Assignment/Center Initiated Assignments	Compliance: Devices - 82

3. PROGRAM TYPE:		COMPLIANCE PROGRAM		PROGRAM CIRCULAR	X	ASSIGNMENT

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

BSE: FDA seeks to protect the public through the development of a comprehensive strategy of education, inspection and enforcement action on industry. These activities were initiated to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) regulations.

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

6. FIELD OBLIGATIONS

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

Center Initiated Assigments: Conduct inspections and investigations as directed by Center assignments.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		BY DISTRICT OFFICE	X	BY CENTER		BY BOTH
b. INSPECTION TYPE:		COMPREHENSIVE		ABBREVIATED	X	DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Center Initiated Assignments: All Devices	Center Initiated

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

f. CHECK THE FOLLOWING ATTRIBUTES

Center Initiated Assignments: Sterility/Performance

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z005, 82Z800	[X] ORA [ ] CENTER	2.0 [1.7]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS BSE (1) 82Z005	1 INSPEC-TIONS CENTER-INITIATED 82Z800	2 INVESTI-GATIONS (Hours) 82Z800	3 DOMESTIC SAMPLE COLL (2) 82Z800	3 DOMESTIC SAMPLE COLL STERILITY 82Z800	3 DOMESTIC SAMPLE COLL MICRO 82Z800	3 DOMESTIC SAMPLE COLL CHEM 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY (3) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4) 82Z800
	TOTAL FIELD	**23**	**19**	**300**	**10**	**2**	**2**	**1**	**2**	**2**
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	20.0	30.0		10.0				50.0	50.0
	TOTAL HOURS	460	570	300	100				100	100
	CONVERSION FACTOR	950	950	950	950				1180	1180
	TOTAL OPERATIONAL FTEs	0.48	0.60	0.32	0.11				0.08	0.08

9. REMARKS

(1) BSE Inspections (82Z005):Districts will, upon assignment, conduct inspections of firms whose devices may contain, or be exposed to, BSE risk material.

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

(3) WEAC--Sterility samples.

(4) WEAC--Ad Hoc testing of media.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z005, 82Z800	[X] ORA [ ] CENTER	2.0 [0.3]

REGION	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 (5) 82Z800	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) METH DEV ENG (6) 82Z800
	TOTAL FIELD							**1**		**400**
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
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							15.0		
	TOTAL HOURS							15		400
	CONVERSION FACTOR							1180		1180
	TOTAL OPERATIONAL FTEs							0.01		0.34

9. REMARKS

(5) WEAC--Ad Hoc testing of test kits or reagents.
(6) WEAC--Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Compliance: Devices - 82

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	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82R816	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	DISTRICT RESEARCH CHEM (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)					
	TOTAL FIELD	**1205**		**1205**						
	HEADQUARTERS	(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)						
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	1205		1205						
	CONVERSION FACTOR	1205		1205						
	TOTAL OPERATIONAL FTEs	1.00		1.00						

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Compliance: Devices - 82

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

4. OBJECTIVES

Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related Acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize, and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.

5. PROGRAM JUSTIFICATION

Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.

6. FIELD OBLIGATIONS

Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. The specific addition of Forensic Evaluation to the Operation Code was new in FY 1999. Please consult the Division of Field Science and/or the Division of Planning, Evaluation, and Management for additional reporting guidance.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: N/A ☐ BY DISTRICT OFFICE ☐ BY CENTER ☐ BY BOTH

b. INSPECTION TYPE: N/A ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

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	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82R838	[X] ORA [ ] CENTER	0.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	**360**								
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	360								
	CONVERSION FACTOR	1205								
	TOTAL OPERATIONAL FTEs	0.30								

9. REMARKS

PROJECT SUMMARY SHEET

FY 2006

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Product Evaluation: Devices - 83

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**33.3**		**4.0**	**37.3**	**63.6**	
1	Medical Device Premarket Approval and		8.8		3.2	12.0	20.5	2-3
	Postmarket Inspections:							
	MDUFMA User Fee	83001	(5.0)			(5.0)	(8.5)	
	PreMarket Approval Inspections	83001	(1.7)		(1.8)	(3.5)	(6.0)	
	Postmarket Approval Inspections	83001A	(2.1)		(1.4)	(3.5)	(6.0)	
2	Bioresearch Monitoring:		24.5		0.8	25.3	43.1	4-5
	Good Laboratory Practices	83808	(2.8)			(2.8)	(4.8)	
	Institutional Review Board Program	83809	(4.1)			(4.1)	(7.0)	
	Sponsors, Contract Research Organizations &	83810	(4.1)		(0.2)	(4.3)	(7.3)	
	Monitors							
	Clinical Investigators	83811	(13.5)		(0.6)	(14.1)	(24.0)	

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Daniel Schultz 301-594-2022	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Premarket Approval and Postmarket Inspections/510(k) Premarket Approval Inspections	Product Evaluation: Devices - 83

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Medical Device Premarket Approval and Postmarket Inspections: To assure that both prior to and subsequent to approval of a PMA application, the manufacturer has the capability of manufacturing the PMA device in accordance with (1) the conditions specified in the PMA application and (2) the requirements of the device GMP regulation.

510(k) Premarket Approval Inspections: To assure, prior to approval of the 510(k) for selected devices, that the manufacturer is in compliance with the requirements of the device GMP regulation. To verify that the manufacturer has procedures in place and adequate documentation to support their premarket submission Declarations of Conformity to Standards, and/or their declaration of compliance with design controls.

5. PROGRAM JUSTIFICATION

Medical Device Premarket Approval and Postmarket Inspections: Section 515 of the Act requires that devices subject to Premarket Approval must be manufactured in conformance with the requirements of the device GMP regulation. Consequently, no PMA application can be approved until the Center has inspectional evidence that the manufacturer complies with the requirements set forth in the Premarket Approval application.

510(k) Premarket Approval Inspections: The General Counsel has ruled that compliance with the GMP regulation is one of the elements of device safety which must be considered when reviewing a 510(k) application. This policy is being initially applied to all 510(k)s for preamendment Class III devices. In November 1997, the Federal Food, Drug, and Cosmetic Act (FFDCA) was modified by the FDA Modernization Act (FDAMA) to include Section 205, Device Standards. This section requires FDA to "recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization." After FDA recognizes a standard through publication in the Federal Register, "a person may submit a declaration of conformity in order to meet a premarket submission or other requirement under the FFDCA to which such standard is applicable." The use of standards is applicable to all types of pre-market submissions. These changes became effective on February 20, 1998.

6. FIELD OBLIGATIONS

Medical Device Premarket Approval and Postmarket Inspections: The field will conduct pre-approval inspections on assignment and submit an EIR to the Center along with the District's recommendation. The field will be responsible for scheduling post-approval inspections to occur approximately 8 months following approval of the PMA. Under certain conditions, a post-approval inspection will not be necessary. The Center will advise the district when a post-approval inspection is not necessary. **510(k) Inspections**: On assignment from CDRH, conduct a comprehensive GMP inspection as instructed in the compliance program. Regarding Conformance Standards inspections, conduct inspections based on assignments by the Field Programs Branch: 100% of assignments issued should be completed as high priority. Class II or III devices in the applicable declaration will be covered.

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

b. INSPECTION TYPE: [X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Medical Devices	73-91

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Premarket Approval and Postmarket Inspections	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83001, A	[X] ORA [ ] CENTER	12.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS PRE-APPROVAL 83001	1 INSPEC-TIONS POST-APPROVAL 83001A	1 FOREIGN INSPEC-TIONS PRE-APPROVAL 83001	1 FOREIGN INSPEC-TIONS POST-APPROVAL 83001A	1 INSPEC-TIONS MDUFMA USER FEE 83001 (1)	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**33**	**67**	**34**	**27**	**99**				
	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 LABORATORY-S									
	PACIFIC REGIONAL LABORATORY-N									
HOURS PER OPERATION		48.2	30.0	50.7	49.4	48.2				
TOTAL HOURS		1591	2010	1724	1334	4772				
CONVERSION FACTOR		950	950	950	950	950				
TOTAL OPERATIONAL FTEs		1.67	2.12	1.81	1.40	5.02				

9. REMARKS

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

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

1) 1 additional FTE in FY 2006 has been planned for Medical Device User Fee and Modernization Act (MDUFMA).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Product Evaluation: Devices - 83

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

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

6. FIELD OBLIGATIONS

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

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

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring (Pre-Market)	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83808, 83809, 83810, 83811	[X] ORA [ ] CENTER	25.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS DOMESTIC	1 INSPEC-TIONS FOREIGN	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**300**	**10**							
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	77.5	77.5							
	TOTAL HOURS	23250	775							
	CONVERSION FACTOR	950	950							
	TOTAL OPERATIONAL FTEs	24.47	0.82							

9. REMARKS

New for FY 2006: GLP, IRB, Sponsor/Monitor, and Clinical Investigator Inspections have been consolidated for planning purposes, with a column for Domestic and Foreign inspections. Continue to report time against PACs 83808 (GLP), 83809 (IRB), 83810 (Sponsor/Monitor), and 83811 (Clinical Investigator), depending on the type of inspection.

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

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

PROJECT SUMMARY SHEET

FY 2006

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Science: Devices - 84

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		5.1			5.1	8.7	
1	Test Method Development and Evaluation	84Z002	3.7			3.7	6.3	2-3
2	ORA/Center Directed Research Projects	84R816	1.4			1.4	2.4	4-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Larry Kessler 301-827-4777	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Test Method Development and Evaluation	Science: Devices - 84

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:		BY DISTRICT OFFICE	X	BY CENTER		BY BOTH
b. INSPECTION TYPE: N/A		COMPREHENSIVE		ABBREVIATED		DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
To be assigned	73-91

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Test Method Development and Evaluation	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84Z002	[ ] ORA [X] CENTER	3.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	9 OTHER OPERATIONS (Hours)	9 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG
	TOTAL FIELD								**800**	**3590**
	HEADQUARTERS								(b)(2) & (b)(7)(E)	
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
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SE	FLORIDA									
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	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS								800	3590
	CONVERSION FACTOR								1180	1180
	TOTAL OPERATIONAL FTEs								0.68	3.04

9. REMARKS

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	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	2. PPS PROJECT NAME/NUMBER
ORA/Center Directed Research Projects	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84R816	[X] ORA [ ] CENTER	1.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DISTRICT RESEARCH CHEM (Hours)	DISTRICT RESEARCH MICRO (Hours)	DISTRICT RESEARCH ENG (Hours)	RESEARCH CENTER RESEARCH MICRO (Hours)					
	TOTAL FIELD				**1660**					
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS				1660					
	CONVERSION FACTOR				1180					
	TOTAL OPERATIONAL FTEs				1.41					

9. REMARKS

PROJECT SUMMARY SHEET

FY 2006

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Mammography Quality Standards Acts (MQSA) Authority - 85

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		14.8		0.1	14.9	27.9	
1	Mammography Facilities Inspection Program	85014 A,C,F	14.8		0.1	14.9	27.9	2-5

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Lynne L. Rice 301-443-2845	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mammography Facilities Inspection Program	Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To inspect certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA);
To bring uncertified facilities into compliance with MQSA.

5. PROGRAM JUSTIFICATION

MQSA (Public Law 102-539) establishes uniform, national quality standards for mammography. It establishes a comprehensive statutory mechanism for certification and inspection of all mammography facilities under the regulatory jurisdiction of the United States. Under the MQSA, only certified facilities that are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation starting October 1, 1994. Operation after that date is contingent on receipt of a certificate from the FDA. The authority to implement the MQSA was delegated by the Secretary of Health and Human Services (HHS) to FDA in June 1993.

6. FIELD OBLIGATIONS

Inspect certified mammography facilities in accordance with procedures specified in the compliance program. Conduct followup inspections to determine whether the facility has complied with the terms of their corrective action plan, based on noncompliances found during a prior inspection. Perform on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections. Conduct investigations of suspected uncertified mammography facilities.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Mammography equipment	90

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
85014 A,C,F	[X] ORA [ ] CENTER	14.9 [10.6]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 85014 (1)	1 INSPEC-TIONS FOREIGN 85014 (2)	1 INSPEC-TIONS 85014 (3)	1 INSPEC-TIONS 85014 (4)	1 INSPEC-TIONS 85014F (5)	1 INSPEC-TIONS 85014F (6)	2 INVESTI-GATIONS (Hours) 85014A (7)	2 INVESTI-GATIONS (Hours) 85014F (8)	
	TOTAL FIELD	**216**	**15**	**119**	**32**	**9**	**9**	**2365**	**6629**	
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	8.0	8.0	8.0	8.0	11.0	11.0			
	TOTAL HOURS	1728	120	952	256	99	99	2365	6629	
	CONVERSION FACTOR	1160	1160	1160	1160	1160	1160	1160	1160	
	TOTAL OPERATIONAL FTEs	1.49	0.10	0.82	0.22	0.09	0.09	2.04	5.71	

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

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

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1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mammography Facilities Inspection Program	Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
85014 A,C,F	[X] ORA [ ] CENTER	14.9 [4.3]

REGION	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) 85014 (9)	9 OTHER OPERATIONS (Hours) 85014 (10)	9 OTHER OPERATIONS (Hours) 85014C (11)
	TOTAL FIELD							**1200**	**3831**	**59**
	HEADQUARTERS							(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS							1200	3831	59
	CONVERSION FACTOR							1200	1160	1160
	TOTAL OPERATIONAL FTEs							1.00	3.30	0.05

9. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

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

PROJECT SUMMARY SHEET

FY 2006

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		**23.5**	**10.2**	**1.0**	**34.7**	**59.2**	
1	Optical Electronic Products:		4.5		0.2	4.7	8.0	2-3
	Inspection of Manufacturers of Laser Products	86001	(4.2)		(0.2)	(4.4)	(7.5)	
	Field Implementation of the Sunlamp & Sunlamp	86002	(0.3)			(0.3)	(0.5)	
	Products Peformance Standard as Amended							
2	X-Ray Surveillance Programs:		10.0			10.0	17.1	4-11
	Field Compliance Testing of Diagnostic X-Ray	86003	(9.0)			(9.0)	(15.4)	
	Equipment							
	Field Compliance Testing of Cabinet X-Ray	86004	(1.0)			(1.0)	(1.7)	
	Equipment							
3	Compliance Testing of Electronic Products	86006, A, B,	3.4		0.8	4.2	7.2	12-13
	at WEAC	D, E						
4	Imported Electronic Products	86007 *		10.2		10.2	17.4	14-15
5	Radiological Health Control Activities:		5.6			5.6	9.5	16-19
	Medical Device and Radiological Health Use	86008	(3.6)			(3.6)	(6.1)	
	Control and Policy Implementation							
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	(3.4)	
	* In addition to PAC 86007, includes reporting							
	PACs 86R824, 86R833, and 99R833.							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Lynne L. Rice 301-443-2845	John Aydinian 301-827-1634

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Optical Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE:						
	X	COMPLIANCE PROGRAM		PROGRAM CIRCULAR		ASSIGNMENT

4. OBJECTIVES

Inspection of Manufacturers of Laser Products:
To determine if laser products are in compliance with the radiation safety emissions and other requirements of the "laser performance standard."

Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended:
To conduct a field enforcement program to determine the compliance of sunlamp and sunlamp products with both the performance standard and Agency issued recommendations.

5. PROGRAM JUSTIFICATION

Inspection of Manufacturers of Laser Products: FDA conducts a program effort to protect the public from the dangerous emission of radiation from laser products. Under the authority of Public Law 90-602 the FDA published a Laser Product Performance Standard designed to control dangerous emissions from these products and is applicable to laser products manufactured after August 2, 1976. In addition, those laser products that are used in medical applications are covered under this Agency's medical device authority.
Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: FDA conducts program efforts to minimize radiation emissions from electronic products and devices that have proven to have harmful biological effects. Under the authority of Public Law 90-602 and the Medical Device Amendments to the Food, Drug and Cosmetic Act, FDA has published a performance standard and separate recommendations designed to control the emission of radiation from sunlamp products. The performance standard for sunlamp products became effective May 7, 1980, and the amended standard on September 7, 1986. Recent studies suggest that exposure to excessive UVA radiation has resulted in malignant melanoma and other skin cancers.

6. FIELD OBLIGATIONS

Inspection of Manufacturers of Laser Products: Field personnel will initiate and schedule their own inspections of laser manufacturers listed in the compliance program. In addition, they will participate on joint CDRH/ORA inspections when such inspections are scheduled by the Center.
Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended: Districts will identify and schedule inspections of sunlamp product manufacturers for compliance with the FD&C Act. Districts will initiate and conduct field testing of products in suntanning facilities per the guidance set out in the compliance program. In addition, in that most states and local radiological health bureaus have no regulation on these products, the field should establish communications with them and offer assistance if they choose to develop such regulations.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:						
		BY DISTRICT OFFICE		BY CENTER	X	BY BOTH
b. INSPECTION TYPE:	X	COMPREHENSIVE		ABBREVIATED	X	DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Lasers and laser products	95LS-99
Sunlamp, suntanning booths, and sunlamp products.	95 US-11

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

f. CHECK THE FOLLOWING ATTRIBUTES

Sunlamp Products: The investigator should use the inspectional Check-List (Review of Product Compliance) located in the compliance program when conducting field tests under this compliance program.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
Caution: laser product *may* be dangerous or hazardous. Only personnel trained on both instrumentation use, as well as type of lasers should test equipment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Optical Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86001, 86002	[X] ORA [X] CENTER	4.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 86001 (1)	1 INSPEC-TIONS FOREIGN 86001 (2)	1 INSPEC-TIONS 86002 (3)	2 INVESTI-GATIONS (Hours) 86001 (4)	3 DOMESTIC SAMPLE COLL 86001	5 FIELD EXAMS/ TESTS 86001 (5)	5 FIELD EXAMS/ TESTS 86002 (6)	9 OTHER OPERATIONS (Hours) 86001 (7)	9 OTHER OPERATIONS (Hours) 86002
	TOTAL FIELD	**99**	**5**	**7**	**639**	**6**	**73**	**27**	**1216**	**75**
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	17.5	52.4	13.8		3.0	5.0	4.3		
	TOTAL HOURS	1733	262	97	639	18	365	116	1216	75
	CONVERSION FACTOR	950	1180	950	950	950	950	950	950	950
	TOTAL OPERATIONAL FTEs	1.82	0.22	0.10	0.67	0.02	0.38	0.12	1.28	0.08

9. Remarks

Inspection of Manufacturers of Laser Products:

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

Sunlamps and Sunlamp Products:

3) Inspectional figures are only for biennial inspections of manufacturers of sunlamp products (to include sunlamps, booth beds, etc.). Inspections are to be conducted in conjunction with a GMP inspection. Examination of booth beds at tanning parlors, athletic clubs, etc. should be reported as field exams and not inspections.
6) The field test of each sunlamp product should be counted as a separate operation.
NOTE: RRHR's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

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

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

Field Compliance Testing of Diagnostic X-Ray Equipment:
To determine if certified dental and medical x-ray diagnostic equipment meet the Federal performance requirement for diagnostic x-ray equipment (21 CFR 1020.30), in order to monitor the compliance of x-ray equipment component manufacturers and assemblers.

Field Compliance Testing of Cabinet X-Ray Equipment:
To determine compliance with the performance standard for cabinet x-ray equipment with respect to radiation emissions under conditions of use.

5. PROGRAM JUSTIFICATION

Field Compliance Testing of Diagnostic X-Ray Equipment:
Under the authority of Public Law 90-602, FDA has published a performance standard designed to control unnecessary radiation associated with diagnostic x-ray equipment. The promulgated standard became effective August 1, 1974, and this authority extends to all diagnostic x-ray equipment manufactured after that date.

Field Compliance Testing of Cabinet X-Ray Equipment:
Under the authority of Public Law 90-602 FDA published a performance for cabinet x-ray equipment which became effective on April 10, 1975, (and on April 25, 1974, for carry-on baggage systems). This performance standard is designed to control the emission levels of radiation from cabinet x-ray systems and baggage x-ray equipment and to assure that radiation exposure will be reduced to, or maintained at, acceptable levels in accessible areas from those systems manufactured after the effective date of the standard. In addition, the standard will have the effect of minimizing incidences of system failure and associated excessive radiation exposure.

6. FIELD OBLIGATIONS

Diagnostic X-Rays: Assemblers will be inspected to ensure their capabilities to properly install diagnostic x-ray components. Field personnel will conduct tests using their discretion as far as site selection except where the CDRH identifies priorities. Equipment at each site will be tested per the instruction of the compliance program. ORA will monitor both State and Federal inspectors to assure quality and consistency in the collected test data. **Cabinet X-Rays**: Districts will conduct record reviews of manufacturers in their inventory to determine locations of cabinet x-ray systems. Identified site locations will be sent to appropriate DDs so they can schedule field tests. Field personnel will conduct tests at locations identified by the district. Each site shall be investigated per the instructions of the compliance program.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Diagnostic X-Ray Equipment Cabinet x-ray and baggage x-ray	94DS--- 94 IS-11 94 IS-21

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
Diagnostic X-Rays: Field tests will be performed by consumer safety officers who have received specialized training which includes approximately two weeks of on-the-job training with a qualified auditor.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86003, 86004	[X] ORA [X] CENTER	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS 86003	1 INSPEC-TIONS * 86004	2 INVESTI-GATIONS (Hours) 86003	2 INVESTI-GATIONS (Hours) 86004	5 FIELD EXAMS/ TESTS 86003	5 FIELD EXAMS/ TESTS 86004	5B AUDITS 86003	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours) 86003
	TOTAL FIELD	**18**	**8**	**1007**	**40**	**952**	**163**	**82**		**4081**
	HEADQUARTERS	(b)(2) & (b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	16.0	8.0			3.0	5.2	4.0		
	TOTAL HOURS	288	64	1007	40	2856	848	328		4081
	CONVERSION FACTOR	950	950	950	950	950	950	950		950
	TOTAL OPERATIONAL FTEs	0.30	0.07	1.06	0.04	3.01	0.89	0.35		4.30

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. 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
2006 WORKPLAN FOR FIELD COMPLIANCE TESTING OF DIAGNOSTIC X-RAY SYSTEMS
(BASED ON PARTNERSHIP AGREEMENTS FOR FY 2006)

NEW ENGLAND DISTRICT

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

NEW YORK DISTRICT

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

BALTIMORE DISTRICT

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

CHICAGO DISTRICT

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

CINCINNATI DISTRICT

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

DETROIT DISTRICT

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

MINNEAPOLIS DISTRICT

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

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					
Total					

ATLANTA DISTRICT

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

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					
Total					

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					
Total					

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					
Total					

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					
Total					

LOS ANGELES DISTRICT

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

SAN FRANCISCO DISTRICT

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

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					
Total					

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Compliance Testing of Electronic Products at WEAC	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE:						
	[X]	COMPLIANCE PROGRAM	[ ]	PROGRAM CIRCULAR	[ ]	ASSIGNMENT

4. OBJECTIVES

To assure, through laboratory testing, that electronic products meet the FDA performance standards.

5. PROGRAM JUSTIFICATION

Public Law 90-602 and subsequent regulations (21 Subchapter J) are intended to safeguard the public from radiation hazards associated with electronic products. The Act specifically authorizes the Secretary to promulgate performance standards imposing additional requirements on specific electronic products of special concern from a radiation safety standpoint. Such performance standards have been issued: Microwave ovens (21 CFR 1030.10); dental, portable and mobile x-ray equipment (21 CFR 1020.30); ultrasonic therapy devices (21 CFR 1050.10); and television receivers (21 CFR 1020.10); sunlamp and mercury vapor lamps (21 CFR 1040.20, 1040.30).

6. FIELD OBLIGATIONS

WEAC will test all products in accordance with the appropriate compliance program circular and submit each report to the Center. WEAC will return equipment to lenders when advised by the Center. In addition, WEAC will advise the Center with the status of all equipment on hand, being tested and returned to lenders. WEAC will conduct inspections to confirm conformance to the Radiological Health Standards Act.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED:						
	[ ]	BY DISTRICT OFFICE	[ ]	BY CENTER	[X]	BY BOTH
b. INSPECTION TYPE:	[ ]	COMPREHENSIVE	[ ]	ABBREVIATED	[X]	DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Microwaves, TV Receivers, Diagnostic X-Ray Equipment, Mercury Vapor/Sunlamp, Ultrasonic Therapy Equipment	96MS, 94VS, 94DS, 95US, 97US

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Compliance Testing of Electronic Products at WEAC	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86006 A,B,D,E	[ ] ORA [X] CENTER	4.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPECTIONS (PL 90-602 STANDARD)	7 DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	7 DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	7 DOMESTIC SAMPLES TO BE ANALYZED X-RAY SOURCE	7 DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	**14**	**70**	**23**	**4**	**1**	**16**			
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	70.0	25.0	43.0	245.0	120.0	11.2			
	TOTAL HOURS	980	1750	989	980	120	179			
	CONVERSION FACTOR	1180	1180	1180	1180	1180	1180			
	TOTAL OPERATIONAL FTEs	0.83	1.48	0.84	0.83	0.10	0.15			

9. REMARKS

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

-Diagnostic X-Ray

Whole - For analysis of entire diagnostic X-Ray systems for compliance;

Source - Leakage test of diagnostic source assembly only.

Foreign Inspections--PL 90-602 Standard Inspections:

Report accomplishments in PAC 86006;

To ensure conformance to Rad Health Standards; to be conducted by Engineering Analyst.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE: [X] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

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

b. INSPECTION TYPE: N/A [ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All electronic products or devices that emit radiation.	94-97

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86007, 86R824, 86R833, 99R833	[X] ORA [ ] CENTER	10.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 ENTRY REVIEW (Hours)	2 IMPORT INV HOURS *	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		**10195**	**1620**						
	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 LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS		10195	1620						
	CONVERSION FACTOR		1200	950						
	TOTAL OPERATIONAL FTEs		8.50	1.71						

9. REMARKS

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

Reporting Guidance:

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM TYPE:						
	[X]	COMPLIANCE PROGRAM	[ ]	PROGRAM CIRCULAR	[ ]	ASSIGNMENT

4. OBJECTIVES

Use Control:
Provide technical assistance to State and Federal radiological health programs implementing FDA use control programs, including DENT (see the compliance program for a more complete statement of objectives and laboratory support); Maintain liaison with State radiological health programs; Provide support for regional training activities and regional videotape library; Promote implementation of programs to optimize radiation exposure; Communicate FDA policies to State and local health agencies.

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

5. PROGRAM JUSTIFICATION

Medical Device and Radiological Health Use Control and Policy Implementation:
Rapidly changing technology requires that the FDA develop use control programs whose effective implementation will require training beyond that possessed by most State radiological health program personnel.

Emergency Planning & Response Activities:
The Agency has been assigned responsibilities by the Federal Emergency Management Agency to review radiological emergency response plans prepared by the States.

6. FIELD OBLIGATIONS

Use Control: RRHRs will maintain liaison and provide technical assistance to State/Federal radiological health program personnel; assist in the planning and presentation of quality assurance training with the region; help select State participants in new use control programs; serve as managers of the regional videotape library; and attend the following meetings: National Conference of State Program Directors; Regional meetings with state and local radiological health agencies; and Rockville, MD HQ annual meetings with CDRH, ORA and other FDA officials. WEAC will provide Laboratory Support for the DENT programs.

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: **Emergency Planning & Response Activities**						
	[ ]	BY DISTRICT OFFICE	[ ]	BY CENTER	[X]	BY BOTH

b. INSPECTION TYPE: N/A						
	[ ]	COMPREHENSIVE	[ ]	ABBREVIATED	[ ]	DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
	Emergency Planning & Response Activities: 94YN-99

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86008, 86009	[ ] ORA [X] CENTER	5.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL		9 TECHNICAL ASSISTANCE (Hours) RRHR 86009		9 MISC (Hours) DENT * 86008	9 MISC (Hours) RRHR ** 86008
	TOTAL FIELD						**2400**		**750**	**3600**
	HEADQUARTERS						(b)(2) & (b)(7)(E)		(b)(2) & (b)(7)(E)	
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS						2400		750	3600
	CONVERSION FACTOR						1200		1180	1200
	TOTAL OPERATIONAL FTEs						2.00		0.64	3.00

9. REMARKS

See Continuation Sheet for footnotes, guidance, etc.

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CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

9. Remarks

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

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

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

This block of time also includes coordination, technical assistance, and other activities performed by RRHRs under the following programs:
- Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended (PAC 86002);
- Field Compliance Testing of Diagnostic X-Ray Equipment (PAC 86003);
- Field Compliance Testing of Cabinet X-Ray Equipment (PAC 86004);
- Medical Device and Radiological Health Use Control and Policy Implementation (PAC 86008);
- Emergency Planning and Response Activities (PAC 86009);

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

FOOTENOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):

Technical Assistance hours will be performed by RRHRs.

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

PROJECT SUMMARY SHEET

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	ICA (Interagency Cooperative Activities) - 88

3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTEs			TOTAL OPERATIONAL FTEs	TOTAL PROGRAM FTEs	8 PAGE
			DOMESTIC	IMPORT	FOREIGN			
	TOTAL		12.0			12.0	20.8	
1	Shelf Life Extension Projects	*	12.0			12.0	20.8	2/3
	*Use appropriate project reporting PACs							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Donna A. Porter, HFC-140; 301-827-2757	Anita T. McCurdy 301-827-1632

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Shelf Life Extension Projects	Interagency Cooperative Activities - 88

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

To develop an effective program for extending the shelf Life of about-to expire drugs and medical devices.

5. PROGRAM JUSTIFICATION

Congress has placed a high priority on maintaining the military in a state of readiness. This includes purchasing and storing for contingency use sufficient quantities of medical products needed to sustain our military forces under wartime conditions. This project is established to assist DOD in reducing the cost of replacement stocks as the stockpiled materials expire.

6. FIELD OBLIGATIONS

Selected laboratories, on assignment from MPQAS.

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

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Environmental chambers used to stress drug products.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Shelf Life Extension Projects	Interagency Cooperative Activities - 88

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
All Appropriate PACs	[X] ORA [ ] CENTER	12.0

REGION	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**		
	HEADQUARTERS							(b)(2) & (b)(7)(E)		
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
CE	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
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	KANSAS									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB-SW									
	PACIFIC REGIONAL LAB-NW									
	HOURS PER OPERATION									
	TOTAL HOURS							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.