FY15 ORA Annual Work Plan Summary

Our vision for work planning is built on 4 objectives:

- **Risk-informed**: Decisions about how to allocate limited resources are informed by risk to the public health and the analysis of available data on the public health impact of field activities.
- **Accurate**: Sources of data, queries, and analysis used to make risk-based decisions are validated and verified by all relevant stakeholders.
- **Flexible**: Move towards a work planning process that is more efficient and less constrained by factors such as geography, organizational structure, annual budget cycles, PAC codes, and IT.
- **Transparent**: All stakeholders share and understand process and assumptions, and have access to the real-time tracking of work plan implementation.

We are pleased to introduce a new management team to implement this vision:

- **John "Chuck" Hassenplug**, Director, Division Planning, Evaluation, and Management (DPEM)
- **Sarah Pichette**, Chief, Work Planning Branch (WPB)
- **Kristen Kamas**, Acting Chief, Program Evaluation Branch (PEB)

In the FY15 ORA Annual Work Plan, we are incorporating many new approaches and tools with these four key objectives in mind.

Risk-informed

- We conducted a study to best determine how we can begin to apply risk to inform our work plan resource allocations. Historically, resources were allocated among districts by previous year's "reviewed-line" volume for entry review, investigations and field exams. Manual edits were made based input from the Division of Import Operations and the field. For FY15, after considering a range of options, we chose to use the PREDICT recommendation to review, which is based on either a hold flag or a risk percentile rank above 60. After analyzing risk gradients and evaluating the impact to each district, we applied 100% risk-informed allocations for food and medical device field and label exams.
- We conducted and provided CDRH with an extensive analysis of the current Condom and Glove surveillance program to inform their decision on whether or not to continue the surveillance program in its current state or reallocate the resources. The result was a reallocation of the 6 FTE to the medical device import program, allowing PREDICT and the districts to target the risk-based work.

Accurate

- The WPB analysts carefully reviewed the feedback and comments we received from the Field Committees and the field on the Draft Work Plans. In several instances, after

conducting additional analysis, the data supported the districts' concerns and the recommended changes were made before finalizing the work plan.
- Working with the Office of Regulatory Science and CFSAN, we adjusted the module time for analysis of allergen samples from 6 hours/operation to 24 hours/operation to account for new methodology and the actual time the tests require in the laboratory. Module times are usually based on a 2-year average of the time reported by investigators and analysts in FACTS. Reporting needs to be as accurate as possible to ensure that planned work can be accomplished by the Field.

Flexible

- The FY15 ORA Annual Work Plan is now available exclusively online. This will allow greater flexibility for making modifications supported by legitimate changes in priorities, resources, or risks throughout the year.
- WPB participated in an effort with CVM to develop a multi-year outlook by program to inform work planning. Our goal is to work towards developing multi-year outlooks for all program areas.
- In the coming year, we will be developing separate work plans for Imports, Laboratories, and the BIMO program to make planning for these cross-cutting easier to implement. All of these elements are currently included with the individual program work plans.
- We will be providing many additional work planning tools, including GIS and risk modeling, throughout the coming months to inform decision making, monitor progress, adapt and adjust to changes in risk, inventories, priorities, and emerging public health situations.

Transparent

- The FY15 ORA Annual Work Plan is now available online immediately improving accessibility and providing a repository and quick links to additional work planning resource tools and documents.
- The current Accomplishment Dashboard provides a real-time tool for tracking planned vs. accomplished work by Region, District, Program, and Operation. Suggested edits or comments on the dashboard should be directed to ORAWorkplan@fda.hhs.gov.
- Together with ORM, we are undertaking studies to better define our work force, track their accomplishments through enhanced time reporting, and improve the "on-board" report to make it easier to complete and use to inform resource allocation decisions.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) PACs 41002B,C,D	Human Cellular, Tissue and Gene Therapies - 41

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

4. OBJECTIVES

To determine through inspections if HCT/P establishments engaged in the recovery, processing, packaging, storage, labeling, and distribution of HCT/Ps, and donor screening and testing, including laboratories that perform donor testing for relevant communicable disease agents and diseases, and microbiology laboratories that perform testing for microorganisms on HCT/Ps, are in compliance with the regulations in 21 CFR Parts1270 and 1271, promulgated under the section 361 of the Public Health Service Act. To assure through inspections that HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing.

C.P.7341.002 - Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
(covers HCT/Ps recovered on or after 5/25/2005)
C.P.7341.002A - Inspection of Tissue Establishments (covers human tissue recovered before 5/25/2005)

5. PROGRAM JUSTIFICATION

Human cells, tissues, and cellular & tissue-based products (HCT/Ps) are important products for medical treatment. Monitoring the recovery, processing, and storage of HCT/Ps and the testing and screening of the donors is critical to assure consumer protection from unsuitable products which may endanger public health.

6. FIELD OBLIGATIONS

ORA will perform the inspections, prepare EIRs, and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), and recommend administrative/regulatory actions when appropriate.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57 K; 57 M; 57L; 57 J; 57 Q; 57 R; 57 S; 57 T; All Other HCT/Ps N.E.C. 57 P 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 GLPs (Nonclinical Lab), IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA) PACS 41808-41811	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41

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

4. OBJECTIVES

GLPs: To assure compliance with Good Laboratory Practices (GLPs) regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.

IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by Institutional Review Boards (IRBs) Regulations (21 CFR 56, 21 CFR 50).

Spon/Mon/CROs: To assess the adherence of Sponsors, Monitors, and Contract Research Organizations (Spon./Mon./CROs) to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies.

Clinical Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of Clinical Investigators with the relevant regulations (21 CFR 312 and 812).

5. PROGRAM JUSTIFICATION

GLPs: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.

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

Spon/Mon/CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.

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

6. FIELD OBLIGATIONS

GLPs: Conduct inspections and forward reports to the assigning office in CBER. IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward report(s) to the assigning CBER office.
Spon/Mon/CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office.
Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed.

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)
Biologics	57 / 99 99 is used for products N.E.C.

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspection of Cell and Gene Therapy Products PACs 41848A,F,G & 41848B,C,D	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41

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

4. OBJECTIVES

To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which cell and gene therapy products are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.

5. PROGRAM JUSTIFICATION

Cell and gene therapy products are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.

6. FIELD OBLIGATIONS

ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a biennial basis. Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(Device Specific)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks PACs 42001F,G,H	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42

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

4. OBJECTIVES

To assure blood and blood products are safe, effective, and adequately labeled by conducting inspections of the following establishments as required by law, to determine the level of compliance and adherence with applicable Federal regulations: a) Licensed and Unlicensed (Registered) Blood Establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products; (b) Blood Donor Centers which collect blood and ship to the Blood Banks of which they are a part; (c) Laboratories that perform testing on blood products and donors, e.g. donor screening for communicable disease agents (HIV 1 and 2, Hepatitis B and C, HTLV I and II, Syphilis) and supplemental testing on reactive tests (HIV Western Blot, HCV RIBA); (d) Laboratories that perform Quality Control Testing for licensed blood establishments, e.g., platelet Quality Control (Q.C.) GMP evaluation to determine the level of competency and adherence to contractual agreements with the licensed establishments.

5. PROGRAM JUSTIFICATION

Blood and Blood Products are vitally important products in medical treatment. Monitoring the collection of whole blood and the processing, manufacturing, and preparation of products derived from human blood assures consumer protection from defective products which may endanger public health.

6. FIELD OBLIGATIONS

ORA will perform the inspections, prepare EIRs, and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Blood and Blood Products	57 D

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 Inspection of Source Plasma Establishments PACs 42002A,F,G	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42

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

4. OBJECTIVES

To determine through inspections if Source Plasma establishments are operating in compliance with applicable regulations to assure donor protection and to assure that Source Plasma is safe, effective, and adequately labeled.

5. PROGRAM JUSTIFICATION

The collection of Source Plasma as source material for further manufacturing into products used in the prevention and treatment of disease is of immeasurable value to the consumer.

Through this program the Agency can accomplish its objectives of donor protection and product safety, purity, and potency.

6. FIELD OBLIGATIONS

ORA will perform inspections, prepare and submit certain specified EIRs to the Center for Biologics Evaluation and Research (CBER), issue Warning Letters, and recommend administrative/regulatory actions when appropriate. Joint inspections with CBER personnel may be performed.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [X] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Source Plasma	57 D

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Imported CBER-Regulated Products PACs 42007, 41/42/45R824, 42R833, 99R833	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42

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

4. OBJECTIVES

1) Determine if import entries comply with the requirements of appropriate Federal regulations.
2) Assure that import entries declared as Import for Export are CBER approved pursuant to section 801(d)(4) of FD & C Act.
3) Detain all import entries not in compliance with applicable regulations, including 21 CFR 600-680 and 1271.

5. PROGRAM JUSTIFICATION

In 1995, a Blood Working Group (consisting of personnel from CBER and ORA) reviewed cases in which imported blood and blood components were identified as being illegally distributed in domestic commerce. Analysis of available information identified a need for a compliance program to clarify existing CBER procedures for the importation of blood products and ensure consistent handling of imported blood products by the Field.

In 2005 new regulations for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) became effective.

6. FIELD OBLIGATIONS

To review electronic line entries or examine entry documentation for imported biological products offered for entry into the United States.

To determine whether biological products offered for import are licensed or unlicensed; and to conduct investigations as necessary and determine whether an entry is in compliance with Federal Regulations.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biological Products	57

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
Inspection of Licensed *In Vitro* Diagnostic (IVD) Devices PACs 42008A,F,G	Blood and Blood Products - 42

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

4. OBJECTIVES

To evaluate the manufacturing process for licensed *in vitro* diagnostic products which are used in relation to blood bank practices, including their instrumentation and software, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, the applicable regulations, including the Quality System Regulations (21 CFR 820), *In Vitro* Diagnostic Products Regulations (21 CFR 809), Biologics Regulations (21CFR Part 600-680), and with standards and commitments made in license applications and/or supplements.

5. PROGRAM JUSTIFICATION

In Vitro Diagnostic Kits are important tools in medical treatment and blood and plasma donor screening. This program enables the Agency to continue to protect the public health by assuring safety, purity, potency, and efficacy of blood and plasma products.

6. FIELD OBLIGATIONS

Conduct comprehensive inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a biennial basis. Inspections will be conducted by a Team Biologics Member and may include a District Representative and /or a Product Specialist from CBER.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
In Vitro Diagnostic Products accordance with the stated objective.	57

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(Device Specific)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA) PACs 42808, 42809, 42810, 42811	Blood and Blood Products - 42

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

4. OBJECTIVES

IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by Institutional Review Boards (IRBs) Regulations (21 CFR 56, 21 CFR 50).

Spon./Mon./CROs: To assess the adherence of Sponsors, Monitors, and Contract Research Organizations (Spon./Mon. /CROs) to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies.

Clinical Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of Clinical Investigators with the relevant regulations (21 CFR 312 and 812.

GLPs: To assure compliance with Good Laboratory Practices (GLPs) regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.

5. PROGRAM JUSTIFICATION

IRBs: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of biological products are protected.

Spon./Mon./CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.

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

GLPs: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.

6. FIELD OBLIGATIONS

IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward report(s) to the assigning CBER office.
Spon./Mon./CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office.
Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed.
GLPs: Conduct inspections and forward reports to the assigning office in CBER.

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)
Biologics	57 / 99 99 is used for products N.E.C.

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics) PACs 42845A,B,C	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42

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

4. OBJECTIVES

To evaluate the manufacturing processes for those medical devices and *in vitro* diagnostic products regulated by the Center for Biologics Evaluation and Research (CBER) through the use of the Medical Device Authorities (e.g. PMA, 510K) and other generic devices outlined in the October 31, 1991 intercenter agreement between CBER and the Center for Devices and Radiological Health (CDRH).

5. PROGRAM JUSTIFICATION

As described in the October 31, 1991 intercenter agreement, CBER is the focal point for the review and evaluation of several categories of medical devices. Our strategies for inspecting those firms not regulated under the licensing provisions of Section 351 of the Public Health Service Act are Risk Based Inspections. The product categories are primarily in the area of devices used in blood banking and human cell, tissue, and cellular and tissue-based products.

6. FIELD OBLIGATIONS

Conduct inspections pursuant to the instructions in the CDRH Compliance Program - Inspection of Medical Device Manufacturers, CP 7382.845. Report findings/observations to the Center for Biologics Evaluation and Research (CBER). Recommend/initiate regulatory follow-up consistent with the compliance program guidance and Agency policy.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All devices in the product categories transferred to CBER.	81 (Device Categories), 57 Y 99 (*In vivo* + *In vitro* Diagnostic Products

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspections of Plasma Derivatives of Human Origin PACs 42848A-D, F-G	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42

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

4. OBJECTIVES

To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which Plasma Derivatives are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, standards and commitments made in license applications and/or supplements, and applicable regulations.

C.P. 7345.848 - Inspection of Biological Drug Products (CBER)
PAC 42848A - Pre-License Inspection - Plasma Derivatives
PAC 42848F - Level 1 CGMP - Plasma Derivatives
PAC 42848G - Level 2 CGMP - Plasma Derivatives
PAC 42848B -Pre-License Inspection - Recombinant Analogues
PAC 42848C - Level 1 CGMP - Recombinant Analogues
PAC 42848D - Level 2 CGMP - Recombinant Analogues

5. PROGRAM JUSTIFICATION

Plasma Derivatives are products used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.

6. FIELD OBLIGATIONS

ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a biennial basis. Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fractionation Products	57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA) PACs 45808, 45809, 45810, 45811	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

IRBs: To ensure that the rights of human subjects participating in clinical trials are protected through proper oversight by Institutional Review Boards (IRBs) Regulations (21 CFR 56, 21 CFR 50).

Spon./Mon./CROs: To assess the adherence of Sponsors, Monitors, and Contract Research Organizations (Spon./Mon./CROs) to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies.

Clinical Investigators: To assess the reliability and accuracy of the data submitted to FDA in support of a marketing or research permit and to determine the compliance of Clinical Investigators with the relevant regulations (21 CFR 312 and 812).

GLPs: To assure compliance with Good Laboratory Practices (GLPs) regulations (21 CFR 58) and the validity, reliability of the data submitted to FDA used to justify the use of an investigational product in humans.

5. PROGRAM JUSTIFICATION

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

Spon./Mon./CROs: Sections of the FD & C Act and the Public Health Service Act require the submission of reliable, accurate clinical data. The inspectional program assures that proper oversight is maintained over the clinical studies.

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

GLPs: Nonclinical studies of investigation products are the basis for their use in humans. The reliability of the nonclinical data must be established prior to the product's use in humans.

6. FIELD OBLIGATIONS

IRBs: Perform inspections of IRBs which are involved in the review of clinical trials of studies involving biological products and forward reports to the assigning CBER office.
Spon./Mon./CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office.
Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed.
GLPs: Conduct inspections and forward reports to the assigning office in CBER.

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)
Biologics	57 / 99 99 is used for products N.E.C.

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products PACs 45848A,F,G	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

To ensure the safety and effectiveness of biological products by evaluating, through inspections, the conditions under which Licensed Allergenic Products and Unlicensed Allergenic Source Materials are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, Standards and commitments made in license applications and/or supplements, and applicable regulations.

C.P. 7345.848 - Inspection of Biological Drug Products (CBER)
PAC 45848A - Pre-License Inspection - Allergenics
PAC 45848F - Level 1 CGMP - Allergenics
PAC 45848G - Level 2 CGMP - Allergenics

5. PROGRAM JUSTIFICATION

Allergenic Products are biological products which are administered to man for the diagnosis, prevention, or treatment of allergies. The products are manufactured from source materials that may include pollen, insects, mold, food, and animals, used in the prevention and treatment of disease and thus are of immeasurable value to the consumer.

6. FIELD OBLIGATIONS

ORA will perform inspections that assess the adequacy of all significant processes and systems. These inspections should be performed on at least a biennial basis. Inspections will be conducted by a Team Biologics Member, and may include a District Representative and/or a Product Specialist from CBER.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57 G

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 Inspection of Licensed Vaccine Products PACs 45848B,C,D	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45

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

4. OBJECTIVES

To ensure the safety and effectiveness of biological products by determining through inspections, the conditions under which vaccines are manufactured, and to determine their compliance with the Federal Food, Drug, and Cosmetic Act, Standards and commitments made in license applications and/or supplements, and applicable regulations.

C.P. 7345.848 - Inspection of Biological Drug Products (CBER)
PAC 45848B - Pre-License Inspection - Vaccines
PAC 45848C - Level 1 CGMP - Vaccines
PAC 45848D - Level 2 CGMP - Vaccines

5. PROGRAM JUSTIFICATION

Vaccine and Vaccine Related Products are biological products which are administered to man for the diagnosis and prevention of microbial disease and for the therapeutic treatment. Products are manufactured from viral and bacterial organisms and components and may include live attenuated, inactivated, and recombinant vaccines. These products are used in the prevention of childhood diseases and in the treatment, diagnosis, and prevention of diseases and thus are of immeasurable value to the consumer.

6. FIELD OBLIGATIONS

ORA will perform inspections that assess the adequacy of all significant processes and systems. Inspections should be performed on at least a biennial basis. Inspections will be conducted by a Team Biologics Member and may include a District Representative and/or a Product Specialist from CBER.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Biologics	57 H, I

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2015

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	129.8	4.0	7.2	141.0
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	44.0			44.0
42	BLOOD AND BLOOD PRODUCTS	75.6	4.0	3.9	83.5
45	VACCINE AND ALLERGENIC PRODUCTS	10.2		3.3	13.5

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Human Cellular, Tissue and Gene Therapeutics - 41

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**44.0**			**44.0**	
1	Inspection of Human Cells, Tissues and Cellular & Tissue-	41002B,C,D	38.0			38.0	41-2
	Based Products (HCT/Ps)						
2	Bioresearch Monitoring Programs *		5.0			5.0	41-3
	Good Laboratory Practices (Nonclinical Labs)	41808	*				
	Institutional Review Boards	41809	*				
	Sponsors, Monitors, and Contract Research Organizations	41810	*				
	Clinical Investigators *	41811	[5.0]				
3	Inspection of Cell and Gene Therapy Products	41848A,F,G &					
		41848B,C,D	1.0			1.0	41-4
	* All resources are planned under PAC 41811.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Janet Ishimoto 301-827-6220	Harriet R. Gerber 301-796-4396

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Human Cells, Tissues, & Cellular & Tissue-Based Products (HCT/Ps)	Human Cellular, Tissue and Gene Therapies - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41002B, C, D	[X] ORA [ ] CENTER	38.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS (1)	CBER PRIORITY ESTABLISH-MENTS (2)	DOMESTIC INVESTI-GATIONS (HOURS) (3)						
	TOTAL FIELD	**689**	**74**	**1581**						
	HEADQUARTERS	(b) (5), (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		50.1								
TOTAL HOURS		34519		1581						
CONVERSION FACTOR		950		950						
TOTAL OPERATIONAL FTEs		36.34		1.66						

9. REMARKS

(1) - There are no separate resources planned for foreign inspections, use domestic resources if needed.

(2) - Refer to CBER's memo for inspectional priorities. Priority establishment numbers are a subset of the planned inspections.

(3) - Domestic Investigation Hours includes time for Follow-Up Inspections.

C.P. 7341.002 - Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
(covers HCT/Ps recovered on or after 5/25/2005)

C.P. 7341.002A - Inspection of Tissue Establishments (covers human tissue recovered before 5/25/2005)

PAC 41002B Inspection of HCT/Ps-361 Reproductive, for product codes: 57K reproductive tissue

PAC 41002C Inspection of HCT/Ps-361 Hematopoietic Stem Cells, for product codes: 57M hematopoietic stem cells

PAC 41002D Inspections of HCT/Ps-361 All other 361 HCT/Ps, for product codes: 57J musculoskeletal tissue; 57L ocular tissue; 57Q skin; 57R veins and arteries; 57S heart tissue; 57T dura mater; 57 P 99 human tissue, N E.C.

All time spent on AIDS related activities are to be reported under the appropriate compliance program and PAC.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	Human Cellular, Tissue and Gene Therapeutics - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41808-GLPs, 41809-IRBs, 41810-Spon/Mon/CROs, 41811 Clinical Investigators	[X] ORA [ ] CENTER	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS (1)								
	TOTAL FIELD	**40**								
	HEADQUARTERS	(b) (5), (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		118.8								
TOTAL HOURS		4752								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		5.00								

9. REMARKS

(1) - Resources for PACs 41808, 41809, 41810, and 41811 are planned under PAC 41811 Clinical Investigators.
Use above resources for foreign inspections as needed. Report foreign inspections under operation code 11.
Inspections are to be conducted only when assignments are received from CBER.
Report accomplishments under appropriate PAC and operation code.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Cell and Gene Therapy Products (Domestic & Foreign)	Human Cellular, Tissue and Gene Therapeutics - 41

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
41848A,F,G and 41848B,C,D*	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS DOMESTIC (1)								
	TOTAL FIELD	**5**								
	HEADQUARTERS	(b) (5), (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		190.0								
TOTAL HOURS		950								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.00								

9. REMARKS

(1) - Resources for all 41848 PACs are planned under PAC 41848F. Use above resources for domestic and foreign inspections as needed and report time under appropriate PAC and operation code. Report foreign inspections under operation code 11.
Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

* PACs include:
41848A Pre-License Inspection - Somatic Cell and Gene Therapy
41848F Level 1 CGMP Inspection - Somatic Cell and Gene Therapy
41848G Level 2 CGMP Inspection - Somatic Cell and Gene Therapy
41848B Pre-License Inspection - Licensed Hematopoietic Progenitor Cell
41848C Level 1 CGMP Inspection - Licensed Hematopoietic Progenitor Cell
41848D Level 2 CGMP Inspection - Licensed Hematopoietic Progenitor Cell

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Blood and Blood Products - 42

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**75.6**	**4.0**	**3.9**	**83.5**	
1	Inspection of Licensed & Unlicensed Blood Banks	42001F,G,H	49.9			49.9	42-6
	National Experts		2.3		0.3	2.6	
	Inspection of Donor Centers						
	Inspection of Reference Laboratories						
	Inspection of Blood/Plasma Brokers						
	Inspection of Blood Product Contractors						
	Technical Assistance and Coordination *		3.0			3.0	
2	Inspection of Source Plasma Establishments	42002A,F,G	11.9			11.9	42-7
3	Imported CBER - Regulated Products	42007,42R833,		4.0		4.0	42-8
		42R824,99R833					
4	Inspection of Licensed In-Vitro Diagnostic (IVD) Devices	42008A,F,G	1.7		0.6	2.3	42-9
	Regulated by CBER (Team Biologics)						
	Field Investigations		0.4			0.4	
5	Bioresearch Monitoring Programs **		4.4			4.4	42-10
	Good Laboratory Practices (Nonclinical Labs)	42808	*				
	Institutional Review Boards	42809	*				
	Sponsors, Monitors, and Contract Research Organizations	42810	*				
	Clinical Investigators **	42811	[4.0]				
	National Experts	42808, 42811	[0.4]				
		45808, 45811					
6	Inspection of Medical Device Manufacturers	42845A,B,C	0.5			0.5	42-11
7	Inspection of Plasma Derivatives of Human Origin	42848A-D,F,G	1.5		3.0	4.5	42-12
	(Team Biologics)						

* For BLT-DO to assist & coordinate ARC information.

** All domestic & foreign resources are planned under domestic PAC 42811. Foreign resources to cover PPS 41, 42, 45.

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Janet Ishimoto 301-827-6220	Harriet R. Gerber 301-796-4396

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42001F,G,H	[X] ORA [ ] CENTER	55.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours) (2)	TECH ASST & COORDIN-ATION (Hours) OP CODE 92 (3)	DOMESTIC INVESTI-GATIONS & OEI CLEAN UP (4) (Hours)				
	TOTAL FIELD	**900**	**8**	**2210**	**2850**	**3050**				
	HEADQUARTERS	(b) (5), (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		49.3	32.6							
TOTAL HOURS		44370	261	2210	2850	3050				
CONVERSION FACTOR		950	950	950	950	950				
TOTAL OPERATIONAL FTEs		46.71	0.27	2.33	3.00	3.21				

9. REMARKS

All listed resources are planned under PAC 42001F. Resources cover all facilities listed in compliance program.

Blood Bank PAC's: 42001F, Level 1 Inspection, 42001G, Level 2 Inspection, 42001H Donor Center Inspection.

Pre-License Inspections for PPS 41, 42, 45 and Field Investigation Hours are not planned separately; use above resources as needed at district discretion.

All time spent on AIDS related activities are to be reported under the appropriate compliance program and PAC.

(1) - Foreign Blood Bank Inspections were spread by OGROP/ORA/OO/OMPTO/DMPTPO.

(2) - Domestic Investigation time is for National Expert Domestic Investigations and Follow-Up Inspections and may be used as needed for other CBER programs.

(3) - Technical Assistance & Coordination (Hours) are for BLT-DO to assist and coordinate ARC information; report time under operation code 92.

(4) - Domestic Investigation Hours include time for washout inspections and OEI Clean Up Activities.

CBER will lead pre-license and pre-approval inspections.

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Inspections of Source Plasma Establishments	Blood and Blood Products - 42

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
42002A,F,G	[X] ORA [ ] CENTER	11 9

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS (1)								
	TOTAL FIELD	**203**								
	HEADQUARTERS	(b) (5), (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		55 7								
TOTAL HOURS		11307								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		11 90								

9 REMARKS

(1) - Resources may be used for Domestic/Foreign/Follow-up Inspections/Investigations, Domestic Sample Collections as needed
The above resources are planned under PAC 42002F, use resources as needed to accomplish this compliance program
Source Plasma PACs:
42002A Pre-License Inspection,
42002F Level 1 CGMP Inspection,
42002G Level 2 CGMP Inspection

Report operations under appropriate PAC and operation code
All time spent on AIDS related activities are to be reported under the appropriate compliance program and PAC
CBER will perform pre-license and pre-approval inspections

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported CBER-Regulated Products	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42007, 42R833, 42R824, 99R833, 41R824, 45R824	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT INVESTI-GATION HOURS (1)								
	TOTAL FIELD	**3800**								
	HEADQUARTERS	(b) (5), (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		3800								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.00								

9. REMARKS

(1) - All resources are planned under PAC 42007 as import investigation hours.
Planned resources are to cover all import operations, PACs: Entry Review 42R833; Follow-Up to Refusals 41R824, 42R824, 45R824; Filer Evaluation 99R833 operation 95 and any resources needed under compliance program for PAC 42007. Resources also include time for Mail Courier and International Mail Facilities reviews.

Report accomplishments under appropriate PAC and operation code.

Note: C.P. 7342.007 "Imported CBER-Regulated Products," and Addendum "Imported Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" provides product specific guidance.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed In-Vitro Diagnostic (IVD) Devices Regulated by CBER	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42008A,F,G Domestic & Foreign (1)	[X] ORA [ ] CENTER	2.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS	DOMESTIC INVESTI-GATIONS (Hours) (2)						
	TOTAL FIELD	**11**	**4**	**441**						
	HEADQUARTERS	(b) (5), (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		142.4	140.3							
TOTAL HOURS		1566	561	441						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.65	0.59	0.46						

9. REMARKS

(1) No separate resources are planned for Pre-License Inspections, use above resources as needed.
PACs include:
42008A Pre-License Inspection - IVDs;
42008F - Level 1 Inspection - Licensed IVDs;
42008G - Level 2 Inspection - Licensed IVDs.
(2) - Field Investigation time is for district support to Team Biologics. Field investigation hours may be used for any Team Biologics program.

Report accomplishments under appropriate PAC and operation code.
Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42808-GLPs, 42809-IRBs, 42810-Spon/Mon/CROs, 42811 Clinical Investigators	[X] ORA [ ] CENTER	4.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS (1)								
	TOTAL FIELD	**44**								
	HEADQUARTERS	(b) (5), (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		95.0								
TOTAL HOURS		4180								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		4.40								

9. REMARKS

(1) - Resources for PACs 42809, 42810, and 42811 are planned under PAC 42811 Clinical Investigators.
Use above resources for foreign inspections as needed. Report foreign inspections under operation code 11.
Inspections are to be conducted only when assignments are received from CBER.
Report accomplishments under appropriate PAC and operation code.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers (Biologics)	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42845A, B, C (1)	[X] ORA [ ] CENTER	0 5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS								
	TOTAL FIELD	**8**								
	HEADQUARTERS	(b) (5), (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		59.5								
TOTAL HOURS		476								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.50								

9. REMARKS

(1) - All resources are planned under PAC 42845A. No foreign inspections are planned, use above resources as needed.
Report all operations under appropriate PAC and operation code.
PACs include:
42845A Level 1 Inspection;
42845B Level 2 Inspection;
42845C Level 3 Inspection.

Note: Inspections of manufacturers of blood bank software should be reported under this program.
Inventory provided by CBER.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Plasma Derivatives of Human Origin	Blood and Blood Products - 42

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
42848A,F,G; 42848B,C,D Domestic & Foreign (1)	[X] ORA [ ] CENTER	4.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC LICENSED INSPEC-TIONS	FOREIGN LICENSED INSPEC-TIONS							
	TOTAL FIELD	**8**	**13**							
	HEADQUARTERS	(b) (5), (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		178.5	219.0							
TOTAL HOURS		1428	2847							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.50	3.00							

9. REMARKS

(1) - No separate resources are planned for pre-license inspections, use above resources as needed.

All resources are planned under PAC 42848F. PACs include:

42848A Pre-License Inspection - Plasma Derivatives;
42848F Level 1 CGMP Inspection - Plasma Derivative;
42848G Level 2 CGMP Inspection - Plasma Derivatives.
42848B Pre-License Inspection - Recombinant Analogues;
42848C Level 1 CGMP Inspection - Recombinant Analogues;
42848D Level 2 CGMP Inspection - Recombinant Analogues.

Report accomplishments under appropriate PAC and operation code.

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Biologics	Vaccines and Allergenic Products - 45

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**10.2**		**3.3**	**13.5**	
1	Bioresearch Monitoring Programs *		7.0			7.0	45-14
	Good Laboratory Practices (Nonclinical Labs)	45808	*				
	Institutional Review Boards	45809	*				
	Sponsors, Monitors, and Contract Research Organizations	45810	*				
	Clinical Investigators *	45811	[7.0]				
2	Licensed Allergenic Products	45848A,F,G	0.7		0.3	1.0	45-15
	(Team Biologics)						
3	Licensed Vaccine Products	45848B,C,D	2.5		3.0	5.5	45-16
	(Team Biologics)						
	* All resources are planned under PAC 45811.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Janet Ishimoto 301-827-6220	Harriet R. Gerber 301-796-4396

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45808-GLPs, 45809-IRBs, 45810-Spon/Mon/CROs, 45811 Clinical Investigators	[X] ORA [ ] CENTER	7.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS (1)								
	TOTAL FIELD	**61**								
	HEADQUARTERS	(b) (5), (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		109.0								
TOTAL HOURS		6649								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		7.00								

9. REMARKS

(1) - Use above resources for foreign inspections as needed. Report foreign inspections under operation code 11.
Resources for PACs 45809, 45810, and 45811 are planned under PAC 45811 Clinical Investigators.
Inspections are to be conducted only when assignments are received from CBER.
Report accomplishment hours under appropriate PAC and operation code.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Allergenic Products (Post-Market & Pre-License)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45848A,F,G Domestic & Foreign (1)	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS							
	TOTAL FIELD	**5**	**2**							
	HEADQUARTERS	(b) (5), (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		130.0	150.0							
TOTAL HOURS		650	300							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.68	0.32							

9. REMARKS

(1) - Resources are planned under PAC 45848F. Use resources as needed for domestic or foreign inspections, and report under appropriate PAC and operation code. Report foreign inspections under operation code 11.

PACs include:

45848A Pre-License Inspection - Allergenics;

45848F Level 1 CGMP Inspection - Allergenics;

45848G Level 2 CGMP Inspection - Allergenics.

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Licensed Vaccine Products (Post-Market)	Vaccines and Allergenic Products - 45

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
45848B,C,D Domestic & Foreign (1)	[X] ORA [ ] CENTER	5 5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS							
	TOTAL FIELD	**9**	**11**							
	HEADQUARTERS	(b) (5), (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		263.7	259.2							
TOTAL HOURS		2373	2851							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.50	3.00							

9. REMARKS

(1) - Resources are planned under PAC 45848C. Use resources as needed and report under appropriate PAC and operation code.
Report foreign inspections under operation code 11.
PACs include:
45848B Pre-License Inspection - Vaccines;
45848C Level 1 CGMP Inspection - Vaccines;
45848D Level 2 CGMP Inspection - Vaccines.

Team Biologics will perform all post market inspections; CBER will lead pre-license and pre-approval inspections.

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations PAC 46832B, C	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive 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

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign PAC 46832B,C,D	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive 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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
BLA Pre-Approval Inspections/Investigations – Domestic and Foreign, PAC 46832M	New Drug Evaluation - 46

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

4. OBJECTIVES

To verify that BLA applicant has the facilities, equipment, and controls as described in the application, and to verify the integrity of the submitted data. To determine compliance of manufacturing establishments with CGMPs prior to approval of pending BLAs.

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before BLA approvals.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs; specifically, Licensed Biological Therapeutic Drugs	Industry Code: 57

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[X] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE PET NDA Pre-Approval Inspections/Investigations PAC 46832P	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before NDA approvals.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Human Drugs, Including Radioactive 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

Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence (PDUFA) - Domestic PAC 48001.A	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Code: 60, 61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence (PDUFA) - Foreign Inspections PAC 48001,A,D,E	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

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

5. PROGRAM JUSTIFICATION

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

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

6. FIELD OBLIGATIONS

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

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Code: 60, 61

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-Clinical Laboratory) PAC 48808	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Code: 60, 61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Institutional Review Board (IRB); Radioactive Drug Research Committee (RDRC), PAC 48809,A	Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

IRB: To assure compliance and integrity of institutional review boards (21 CFR 50) which provide protection for human subjects of clinical investigations to be submitted to FDA.

RDRC: To assure the quality and integrity of Radioactive Drug Research Committees and assure they are operating in compliance with (21 CFR 361.1).

5. PROGRAM JUSTIFICATION

IRB: Through amendments of the Act, Congress has mandated that FDA has the responsibility to assure that the rights of subjects in the clinical trials of investigational drugs are protected. The inspectional program assures that IRBs protect the safety and welfare of clinical trial subjects and ensures that the informed consent form and the process of obtaining informed consent comply with current regulations.

RDRC: The Nuclear Regulatory Commission and the FDA have decided that certain protocols involving radioactive drugs do not need an IND, but must be reviewed by an institutional RDRC. These protocols are those intended for basic research purposes, not those protocols intended to determine the safety and efficacy of the drug in humans. The RDRC assures that the radiation doses and pharmacological doses are within specified limits. The Division of Scientific Investigations, Office of Compliance, CDER, issues assignments to the districts, reviews all complete EIRs and their classification, and issues letters as needed to RDRCs after such review.

6. FIELD OBLIGATIONS

IRB: Conduct inspections of IRBs which are involved in the review of clinical trials of human drug studies and forward the reports to the Division of Scientific Investigations, CDER.

Assist in presentation of IRB workshops.

RDRC: Conduct inspections of RDRCs and forward the EIRs to the Division of Scientific Investigations, CDER.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Code: 60, 61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, & Monitors PAC 48810	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Code: 60, 61

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Clinical Investigators - Domestic and Foreign PAC 48811, D, F (Follow-Up and Complaints)	2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

Clinical data are submitted to FDA in support of a marketing permit (IND, NDA). The clinical studies that generated the data are evaluated for accuracy, completeness, and regulatory compliance.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[X] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Drugs	Industry Code: 60, 61

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre-Approval Inspections/Investigations PAC 52832,B,C	2. PPS PROJECT NAME/NUMBER 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 application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending ANDAs.
ANDA bulk products are collected for profile analysis.

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before ANDA approvals.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

[ ] BY DISTRICT OFFICE [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 [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre-Approval Inspections/Investigations - Foreign, PAC 52832,B,C,E	Generic Drug Evaluation - 52

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

4. OBJECTIVES

To verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their application. 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 approvals.

6. FIELD OBLIGATIONS

Conduct pre-approval inspections of foreign establishments as requested by 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

1. PROGRAM/ASSIGNMENT TITLE PET ANDA Pre-Approval Inspections/Investigations PAC 52832P	2. PPS PROJECT NAME/NUMBER 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 application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending ANDAs.
ANDA bulk products are collected for profile analysis.

5. PROGRAM JUSTIFICATION

Compliance of manufacturing establishments must be assessed before ANDA approvals.

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED [ ] BY DISTRICT OFFICE [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 [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement of the Adverse Drug Experience Reporting Regulations, PAC 53001A (Dom/For)	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 and Section 760 of the FDCA (21 U.S.C. 379aa. Regulatory and/or administrative follow-up will be coordinated between the field and headquarters in cases where significant following guidances are detected. The Program should also promote voluntary compliance with regulations and guidance by 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). Section 760 of the FDCA applies to nonprescription drug products marketed without an approved application. This part of the Act became effective on December 22, 2007. 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 Compliance Risk Management and Surveillance (DCRMS)/ Office of Compliance/CDER, including recommendations for any indicated regulatory follow-up.
Issue regulatory letters as approved by DCRMS. Notify DCRMS of findings from other inspectional program activities which are relevant to ADE reporting.

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 [ ] 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
Risk Evaluation and Mitigation Strategy (REMS) (PDUFA), PAC 53001C	Postmarketing Surveillance & Epidemiology: Human Drugs - 53

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

4. OBJECTIVES

To provide assignments, guidance and specific instructions to field offices for inspecting drug firms to determine compliance with the Risk Evaluation and Mitigation Strategies (REMS) required under Federal Food, Drug, and Cosmetic Act (FDCA) section 505-1. Regulatory and/or administrative follow-up will be determined by CDER headquarters.

5. PROGRAM JUSTIFICATION

On September 27, 2007, the Food and Drug Administration Amendments Act (FDAAA) (Public Law 110-85) was enacted. Title IX, Subtitle A, section 901 of this statute created new section 505-1 of the FDCA, which authorizes FDA to require a REMS if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug. Section 505-1 applies to applications for approval of prescription drugs submitted under sections 505(b) or 505(j) of the Act and applications submitted under section 351 of the Public Health Service Act. The purpose of this program is to ensure that the required REMS programs are being implemented.

6. FIELD OBLIGATIONS

Conduct inspections and forward EIRs directly to the Division of Risk Management and Surveillance, CDER. There will be no Field- initiated inspections in this program. At this time, all regulatory actions will be determined by CDER headquarters.

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)
Human Drugs	Industry Codes: 54, 55, 56, 57, 59, 60-66, 99

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 Process Inspections PAC 56002A-D, F, H-L	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 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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Drug Inspections PAC 56002A-D,F,I	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
Drug Process Inspections: Inspections of Licensed Biological Therapeutic Drug Products, PAC 56002M	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 licensed biological therapeutic drugs by preventing the marketing of, or removing from the market, violative licensed biological therapeutic drugs 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, Inspections of Licensed Biological Therapeutic Drug Products, is FDA's primary means for evaluating the conditions under which licensed biological therapeutic drugs 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 inspection coverage provided for in the inspectional strategy. CDER will maintain the Biological Product Defect Report system.

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; specifically, Licensed Biological Therapeutic Drugs	Industry Code: 57

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections - PET Domestic PAC 56002P, Q	2. PPS PROJECT NAME/NUMBER 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 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

Investigators are to wear dosimeters and otherwise take special safety precautions as instructed by the IOM and by the inspected establishment.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Product Surveillance PAC 56008A, 56008L, 56008H	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 towards drug products, firms, and countries which pose a heightened risk to the consuming public relative to the risk-based management system.

To obtain information about the identifying characteristics (forensic testing) of APIs from domestic/foreign sources in order to establish a forensic database to evaluate formulation changes and uncover possible counterfeiting.

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED [ ] 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 [ ] ENGINEERING [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 Quality Reporting System - DQRS NDA-Field Alert Reporting, PAC 56021A,B	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 health professionals, consumers and drug product manufacturers.

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)
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
Enforcement of the Prescription Drug Marketing Act (PDMA), PAC 56022	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)
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
Post-Approval Inspections/Investigations (Domestic and Foreign), PAC 56843	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 due to significant process design and control issues 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 associated agency regulatory policies by gathering industry-wide data on changing practices and technology for specific drug products.

5. PROGRAM JUSTIFICATION

The Post-Approval Inspections/Investigations program is designed to detect significant process design and control problems at a drug manufacturer early in a product lifecycle. The post-approval inspection is planned for six to eighteen months after approval/marketing of the drug product or biotech product. Focused objectives for inspections/investigations include issues related to ongoing events and evolving agency priorities, including supplier qualification/materials handling, process validation, and laboratory program stability data, and conformance to the application/license commitments.

6. FIELD OBLIGATIONS

The field will conduct post-approval inspections as assigned by the Center. Inspection assignments will typically include the area that the investigator should focus on during the inspection. The field will also recommend firms to inspect to ensure that the highest risk products are targeted.

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, 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 Pharmacy Compounding Assignments PAC 56D015	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56

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

4. OBJECTIVES

Conduct surveillance, for-cause, and follow-up inspections, and sample collection and analysis, as appropriate, of pharmacy compounders.

5. PROGRAM JUSTIFICATION

Conduct surveillance, follow-up, and for-cause (in response to serious adverse event reports and reports of quality problems) inspections of compounders to identify those in non-compliance with the Act. Continue to take action, including enforcement actions, as appropriate to protect the public health.

6. FIELD OBLIGATIONS

Districts will conduct inspections, collect evidence including samples, and develop cases in accordance with inspection assignments from CDER/OC/OUDLC.

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 [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Outsourcing Facilities Registered under Section 503B PAC 56D017	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56

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

4. OBJECTIVES

Conduct surveillance, for-cause, and follow-up inspections, and sample collection and analysis, as appropriate, of compounders registered as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act.

5. PROGRAM JUSTIFICATION

Conduct required risk-based surveillance, follow-up, and for-cause (in response to serious adverse event reports and reports of quality problems) inspections of registered outsourcing facilities to identify those in non-compliance with the Act. Continue to take action, including enforcement actions, as appropriate to protect the public health.

6. FIELD OBLIGATIONS

Districts will conduct inspections, collect evidence including samples, and develop cases in accordance with inspection assignments from CDER/OC/OUDLC.

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 [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Global Parity Program PAC 56R010	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56

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

4. OBJECTIVES

The Global Parity Initiative is a collaborative effort between CDER and ORA and will include the participation of ten (10) ORA employees in a 3-6 month detail performing training modules and reviewing foreign regulatory authority inspection reports. This program will use domestic inspection resources toward improving our knowledge of foreign manufacturing operations, facilities, and counterpart inspectorates.

5. PROGRAM JUSTIFICATION

The Global Parity Initiative is a new collaboration between CDER and ORA that implements the Commissioner's "Pathway to Global Product Safety and Quality" initiative. Specifically, this program will support our aim to leverage foreign regulatory authority inspections.

6. FIELD OBLIGATIONS

- Identify districts that will benefit from the detail work
- Manage current workload adjustments and leave requests for detailed staff

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	All Human Drug Codes

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [X] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

The hours assigned for inspection report completion can be adjusted as employee efficiency increases.

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 56R838	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56

3. PROGRAM TYPE [N/A] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] 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 [ ] ABBREVIATED [ ] DIRECTED

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

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, and OTC Monographs PAC 63001A, 63D012	2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63

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

4. OBJECTIVES

1) To identify and evaluate OTC drug products and to assure their compliance with specific OTC drug monographs or other regulations;
2) to minimize consumer exposure to health fraud drugs that make fraudulent drug claims for serious disease states, contain hidden drug ingredients, and/or target vulnerable populations.
3) To identify and take appropriate action against health fraud products, as previously described, that are unapproved new and/or misbranded drugs sold in interstate commerce.

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) Health Fraud drugs pose serious risks to consumers and threaten the drug approval process. Moreover, health fraud drugs are illegal because they violate the Federal Food, Drug, and Cosmetic Act (FDCA) in various ways. For example, health fraud drugs are unapproved new drugs under 21 U.S.C §§ 321(p) and 355(a). Health fraud drugs are also misbranded under 21 U.S.C. §352 when such products contain drug ingredients that are not declared on the product labeling or when the labeling contains misleading claims.

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 New Drug (Prescription) Without Approved NDAs PAC 63002	2. PPS PROJECT NAME/NUMBER 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 consistent with the enforcement policy articulated in Compliance Policy Guide (CPG) 440.100 "Marketed Unapproved Drugs."

5. PROGRAM JUSTIFICATION

The Drug Amendments of 1962 to the FD&C Act require that all marketed drug products be safe and effective. However, some drugs are available in the United States that lack the required FDA approval. FDA's Marketed Unapproved Drugs Initiative is aimed at efficiently and rationally bringing all marketed unapproved new drugs into the approval process. The Agency's final guidance, "Marketed Unapproved Drugs—Compliance Policy Guide (CPG)," outlines FDA's enforcement policies in this regard. FDA uses a risk-based enforcement program in order to concentrate its resources on those products that pose the highest threat to public health and without imposing undue burdens on consumers, or unnecessarily disrupting the market. Unapproved new drugs introduced onto the market after September 19, 2011 are subject to immediate enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in the CPG. For unapproved new drugs commercially used or sold as of September 19, 2011, the CPG gives highest enforcement priority to the following:

1) Drugs with potential safety risks, 2) Drugs that lack evidence of effectiveness, 3) Health fraud drugs, 4) Drugs that present direct challenges to the new drug approval and OTC drug monograph systems, 5) Unapproved new drugs that are also violative of the Act in other ways, and 6) Drugs that are reformulated to evade an FDA enforcement action.

6. FIELD OBLIGATIONS

-Assign District Coordinator, whose name shall be supplied to CDER/OC/OUDLC

-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.

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
Shelf Life Extension Projects PAC 88 SHELF	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 of 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.

CENTER FOR DRUG EVALUATION AND RESEARCH
RESOURCE SUMMARY
FY 2015

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	245.3	47.4	153.3	446.0
46	NEW DRUG EVALUATION	10.5		16.0	26.5
48	BIORESEARCH MONITORING HUMAN DRUGS	59.3		30.7	90.0
52	GENERIC DRUG EVALUATION	7.5		16.0	23.5
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	9.1		1.2	10.3
56	DRUG QUALITY ASSURANCE	132.5	47.4	89.4	269.3
63	UNAPPROVED AND MISBRANDED DRUGS	14.4			14.4
88	INTERAGENCY COOPERATIVE ACTIVITIES	12.0			12.0

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	New Drug Evaluation - 46

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**10.5**		**16.0**	**26.5**	
1	NDA Pre-Approval Inspections/Investigations	46832/B/C	9.0			9.0	46-02
	- Domestic (PDUFA)						
2	NDA Pre-Approval Inspections/Investigations	46832/B/C			14.0	14.0	46-03
	- Foreign (PDUFA)						
3	Pre-License Biotech (BLA) - (PDUFA)	46832M	1.0		2.0	3.0	46-04
	Inspections/Investigations - Domestic/Foreign						
4	Positron Emission Tomography (PET) Pre-Approval	46832P	0.5			0.5	46-05
	Inspections/Investigations						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Brian Hasselbalch, (301) 796-3279; Grace McNally, (301) 796-3927	Anita T. McCurdy 301-796-4395

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations - Domestic (PDUFA)	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832, 46832B, 46832C, 46R845	[X] ORA [ ] CENTER	9.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 CHEMIST ON INSPECTIONS (Hours)	3 DOMESTIC SAMPLE COLL CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED PROFILE CHEM					
	TOTAL FIELD	**113**	**703**	**18**	**35**					
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		65.3		7.6	11.8					
TOTAL HOURS		7379	703	137	413					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		7.77	0.74	0.14	0.35					

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
(1) 46832, 46832B, 46832C, 46832D	[X] ORA [ ] CENTER	14.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 CHEMIST ON INSPECTIONS (Hours)							
	TOTAL FIELD	**147**	**4522**							
	HEADQUARTERS	(b) (5), (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 MPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		59.6								
TOTAL HOURS		8761	4522							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		9.22	4.76							

9. REMARKS

(1) - Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pre-Licensed Biotech (BLA) Inspections/Investigations - Domestic and Foreign (PDUFA)	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832M	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic	1 INSPECTIONS Foreign							
	TOTAL FIELD	**8**	**19**							
	HEADQUARTERS	(b) (5), (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		113.3	98.5							
TOTAL HOURS		906	1872							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.95	1.97							

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Positron Emission Tomography (PET) Pre-Approval Inspections/Investigations	New Drug Evaluation - 46

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
46832P	[X] ORA [x] CENTER	0.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS Domestic (1)								
	TOTAL FIELD	**14**								
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	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		33.2								
TOTAL HOURS		465								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.49								

9. REMARKS

(1) - Inspections are to verify that NDA applicant has facilities, equipment, controls, etc. as specified in the application.

PROJECT SUMMARY SHEET

FY 2015

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

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**59.3**		**30.7**	**90.0**	
1	In Vivo Bioequivalence - ANDAs & NDAs	48001, A	10.9			10.9	48-07
	PDUFA (NDAs)		[3.4]				
	Foreign Inspections (In Vivo Bioequivalence,	48001, A;			11.5	11.5	48-08
	GLPs) *	48808					
	(1) Foreign Inspections PEPFAR (AIDS Relief)	48001D, E;					
	(planned under 48001A and 48001)	48808, 48811D					
2	Bioresearch Monitoring						48-09
	Good Laboratory Practices (Non-Clinical Lab)	48808	2.8			2.8	
	National Experts		[0.1]				
	(2) Institutional Review Board	48809, 48809A	10.0			10.0	
	Sponsors, Contract Research Organizations,	48810	6.0		0.6	6.6	
	and Monitors						
3	Clinical Investigators	48811, F	29.6		18.6	48.2	48-10
	National Experts		[0.1]		[2.2]		
	(1) - PEPFAR work is not planned separately, NDA PEPFAR resources are planned under 48001A and ANDA PEPFAR						
	resources are planned under 48001.						
	(2) - Resources in the Radioactive Drug Research Committee (48809A) have been collapsed into Institutional Review Board (48809).						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Paul Okwesili, (301) 796-0173	Anita T. McCurdy 301-796-4395

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
In Vivo Bioequivalence - Pre-Approval (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48001 (ANDAs), 48001A (NDAs)	[X] ORA [ ] CENTER	10.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSPECTIONS (1)	1 48001A NDA INSPECTIONS							
	TOTAL FIELD	**96**	**30**							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		81.5	83.6							
TOTAL HOURS		7824	2508							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		8.24	2.64							

9. REMARKS

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

(1) - Includes 5 GDUFA FTE.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections (NDA - PDUFA; ANDA - PRE-APPROVAL)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48001,A; 48808; 48001D,E, 48811D NDA & ANDA (1)	[X] ORA [ ] CENTER	11.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPECTIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPECTIONS (PRE-APPVL) (2)							
	TOTAL FIELD	**42**	**85**							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		76.8	90.2							
TOTAL HOURS		3226	7667							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		3.40	8.07							

9. REMARKS

(1) - Planned inspections include: 48001,A In Vivo Bioequivalence, 48808 GLPs (PDUFA), PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence, and 48811D PEPFAR Clinical Investigations .

Reporting Guidance:
48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigations.
NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001.
Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs.
Data audit under PEPFAR will be verified by on site inspections.

(2) - Includes 4 GDUFA FTE.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48808, 48809, 48809A, 48810	[X] ORA [ ] CENTER	19.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 GLP INSPEC-TIONS 48808	2 NAT'L EXPERT INVESTI-GATIONS (Hours) 48808 - GLP	1 IRB (1) INSPEC-TIONS 48809, 48809A (2)	1 SPONSOR, CRO, MONITORS INSPEC-TIONS 48810 (3)		1 48810 FOREIGN INSPEC-TIONS (3)		
	TOTAL FIELD	**27**	**142**	**116**	**48**		**6**		
	HEADQUARTERS	(b) (5), (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		94.2		82.2	117.8		99.9		
TOTAL HOURS		2543	142	9535	5654		599		
CONVERSION FACTOR		950	950	950	950		950		
TOTAL OPERATIONAL FTEs		2.68	0.15	10.02	5.95		0.63		

9. REMARKS

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

Planned inspections include Center-initiated and directed assignments that will cover surveillance inspections, and studies associated with IND's and NDA's.

Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-06).

(1) - Institutional Review Board
(2) - 48809A: Resource (1 FTE) for the Radioactive Drug Research Committee (RDRC) is not planned separately. However, please use above resources as needed and report RDRC work under PAC 48809A.
(3) - 48810: Sponsors, Contract Research Organizations, and Monitors also includes resources for any foreign work

Please note: District inspection allocation may be subject to change as a result of CDER's final site selections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Clinical Investigators (PDUFA)	Bioresearch Monitoring: Human Drugs - 48

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
48811, F(1)	[X] ORA [ ] CENTER	48.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC-TIONS 48811	2 NAT'L EXPERT INVESTI-GATIONS (Hours) 48811		1 DOMESTIC INSPEC-TIONS Follow-Up & Complaints 48811F	1 FOREIGN INSPEC-TIONS Follow-Up & Complaints 48811F(1)		1 FOREIGN INSPEC-TIONS 48811		
	TOTAL FIELD	**175**	**118**		**66**	**2**		**184**		
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		103.7			150.0	93.5		94.9		
TOTAL HOURS		18148	118		9900	187		17462		
CONVERSION FACTOR		950	950		950	950		950		
TOTAL OPERATIONAL FTEs		19.10	0.12		10.42	0.20		18.38		

9. REMARKS

(1) - NEW: Report foreign Inspection follow-up and complaints under operation 11 in PAC 48811F.

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Human Drugs	Generic Drug Evaluation - 52

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**7.5**		**16.0**	**23.5**	
1	ANDA Pre-Approval Domestic	52832, B, C	6.0			6.0	52-12
2	ANDA Pre-Approval Inspections/Investigations	52832, B, C, E			16.0	16.0	52-13
	- Foreign						
3	Positron Emission Tomography (PET) Pre-Approval	52832P	1.5			1.5	52-14
	Inspections/Investigations						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Brian Hasselbalch, (301) 796-3279; Grace McNally, (301) 796-3286	Anita T. McCurdy 301-796-4395

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
ANDA Pre - Approval Inspections/Investigations - 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	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAS TO INSPECT	3 DOMESTIC SAMPLE COLL	1 CHEM-ON INSPECTION (Hours)	7 DOMESTIC SAMPLES TO BE ANALYZED BIOTEST CHEM					
	TOTAL FIELD	**79**	**44**	**475**	**37**					
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		54.5	4.5		24.3					
TOTAL HOURS		4306	198	475	899					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		4.52	0.21	0.50	0.76					

9. REMARKS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832, 52832B ,52832C, 52832E	[X] ORA [ ] CENTER	16.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS (1) (2) (Foreign)	1 CHEMIST INSPECTIONS (Hours) (Foreign)	2 INVESTI-GATIONS (Hours)	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED CHEM (3)				
	TOTAL FIELD	**181**	**2503**	**200**	**151**	**74**				
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		57.5			3.0	27.8				
TOTAL HOURS		10408	2503	200	453	2057				
CONVERSION FACTOR		950	950	950	950	1180				
TOTAL OPERATIONAL FTEs		10.96	2.63	0.21	0.48	1.74				

9. REMARKS

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

(2) - Includes 3 GDUFA FTEs.

(3) - NRL analyzes all Profile/Biotest ISCs and methods development ISAs.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Positron Emission Tomography (PET) Pre-Approval Inspections/Investigations	Generic Drug Evaluation - 52

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
52832P	[X] ORA [x] CENTER	1.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDA PET INSPEC-TIONS (1)								
	TOTAL FIELD	**27**								
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	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		53.9								
TOTAL HOURS		1455								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.53								

9. REMARKS

(1) - Inspections are to determine compliance of establishments with GMPs prior to approval of pending ANDAs. ANDA bulk products are collected for profile analysis.

PROJECT SUMMARY SHEET

FY 2015

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 FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**9.1**		**1.2**	**10.3**	
1	Enforcement of the Adverse Drug	53001A	6.9		1.2	8.1	53-16
	Experience Reporting Regulation (Domestic/Foreign)						
2	Experience Reporting Regulation REMS (PDUFA)	53001C	2.2			2.2	53-17

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Tamika White, (301) 796-0310	Anita T. McCurdy 301-796-4395

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001A (1)	[X] ORA [X] CENTER	8.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC-TIONS	1 FOREIGN INSPEC-TIONS							
	TOTAL FIELD	**107**	**15**							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		61.1	76.2							
TOTAL HOURS		6538	1143							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		6.88	1.20							

9. REMARKS

(1) - CDER will issue inspection assignments using a risk based selection model. The field should contact CDER for guidance if a site selection is not from the CDER model.

Please note: District inspection allocations may be subject to change as a result of CDER's final site selections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Risk Evaluation and Mitigation System (REMS)	Postmarketing Surveillance and Epidemiology: Human Drugs - 53

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
53001C	[ ] ORA [X] CENTER	2.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1)								
	TOTAL FIELD	**37**								
	HEADQUARTERS	(b) (5), (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		57.2								
TOTAL HOURS		2116								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		2.23								

9. REMARKS

(1) - Because of the complexity and individuality of each REMS program, contact CDER at least 2 weeks before conducting inspection. Forward EIRs directly to CDER's Division of Safety Compliance (CDER/OC/OSI).

Please note: District inspection allocation may be subject to change as a result of CDER's final site selections.

PROJECT SUMMARY SHEET

FY 2015

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 FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**132.5**	**47.4**	**89.4**	**269.3**	
1	Drug Process Inspections - Domestic	56002, B,D*	39.0			39.0	56-19
2	Foreign Drug Process Inspections	56002, B,D*			40.0	40.0	56-20
3	Drug Process Inspections - Small Volume Parenterals	56002A	14.0		14.0	28.0	56-21
4	Drug Process Inspections - Gas Manufs.	56002E	7.0			7.0	56-22
5	Drug Process Inspections - API Manufs. (Domestic/Foreign)	56002F, L*	4.0		29.9	33.9	56-23
6	Drug Process Inspections - Biotech Manufacturers	56002M	3.5		3.5	7.0	56-24
	Positron Emission Tomography (PET) Pre-Approval	56002P, Q*	2.0			2.0	56-25
7	Inspections/Investigations						
8	Drug Quality Sampling and Testing Program	56008A, L	19.0			19.0	56-26-27
9	Drug Product Surveillance - Import Drugs	56008H***		47.4		47.4	56-28
10	Drug Quality Reporting System - DQRS	56021A, B	5.0			5.0	56-29
11	Enforcement of Rx Drug Marketing Act (PDMA)	56022, A	2.0			2.0	56-30
12	Post-Approval Inspections/Investigations(Domestic/Foreign)	56843	2.0		2.0	4.0	56-31
13	Pharmacy Compounding Assignments	56D015	16.0			16.0	56-32
14	DPI - Global Parity Initiative	56D017	6.0			6.0	56-33
15	DPI - Global Parity Initiative	56R010	2.0			2.0	56-34
16	DPI - OEI Clean Up	56R011	1.0			1.0	56-35
17	Forensic Evaluation and Sample Analysis	56R838****	10.0			10.0	56-36
	* 56002H-L Q (Abbreviated); Additional 56832, 56R359						
	*** 56R824, 56R833, 99R833						
	**** 56R831						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Brian Hasselbalch, (301) 796-3279; Grace McNally, (301) 796-3286	Anita T. McCurdy 301-796-4395

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002, B-D, (4) 56002H, I, J, K, L, 56832, 56R359	[X] ORA [ ] CENTER	39.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 CERTIFICA-TION AUDITS (INV Hours) (1)	1 CHEMIST ON INSPEC-TIONS (Hours)	1 MICRO ON INSPEC-TIONS (Hours)	3 DOMESTIC SAMPLE COLL (2)	3 DOMESTIC SAMPLE COLL (CHEM) (3)	3 DOMESTIC SAMPLE COLL (MICRO) (3)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO
	TOTAL FIELD	**332**	**1900**	**2571**	**1200**	**196**	**156**	**40**	**156**	**33**
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	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		74.1				8.0			36.8	21.7
TOTAL HOURS		24601	1900	2571	1200	1568			5741	716
CONVERSION FACTOR		950	950	950	950	950			1180	1180
TOTAL OPERATIONAL FTEs		25.90	2.00	2.71	1.26	1.65			4.87	0.61

9. REMARKS

(1) - Hours for certification audits support Level II Drug Certification Audits and the Pharmaceutical Inspectorate (PI). Report Certification Audit hours under 56R359.

(2) - DSCs not analyzed are documentary samples.

(3) - 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.

(4) -The following PACS are for Abbreviated Inspections

56002H - ABBREVIATED DRUG PROCESS INSPECTIONS (DPI)

56002J - ABBREVIATED DPI / DRUG REPACKERS AND RELABELLERS

56002K - ABBREVIATED DPI / RADIOACTIVE DRUGS

56002L - ABBREVIATED ACTIVE PHARMACEUTICAL INGREDIENT PROCESS INSPECTIONS

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, B, C, D, 56832, 56R359	[X] ORA [ ] CENTER	40.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSPEC-TIONS (1)	1 CHEMIST ON INSPECTIONS FOREIGN (Hours)							
	TOTAL FIELD	**376**	**5675**							
	HEADQUARTERS	(b) (5), (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		86.0								
TOTAL HOURS		32336	5675							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		34.04	5.97							

9. REMARKS

(1) - Foreign Inspections include the Foreign Cadre inspection time and 2 GDUFA FTEs.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Sterile Drug Process Inspections - (Domestic & Foreign)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002A, 56002I*	[X] ORA [ ] CENTER	28.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC-TIONS	3 DOMESTIC SAMPLE COLL	3 DOMESTIC SAMPLES TO BE ANALYZED					1 FOREIGN INSPEC-TIONS	
	TOTAL FIELD	**109**	**32**	**15**					**131**	
	HEADQUARTERS	(b) (5), (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		115.0	9.2	39.4					101.4	
TOTAL HOURS		12535	294	591					13283	
CONVERSION FACTOR		950	950	1180					950	
TOTAL OPERATIONAL FTEs		13.19	0.31	0.50					13.98	

9. REMARKS

* The following PAC is for Abbreviated Inspections:

56002I - ABBREVIATED DPI / SMALL VOLUME PARENTERALS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002E	[X] ORA [ ] CENTER	7.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS MEDICAL GAS								
	TOTAL FIELD	**222**								
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		30.0								
TOTAL HOURS		6660								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		7.01								

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process Inspections - Active Pharmaceutical Ingredients (APIs) - (Domestic and Foreign)	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002F, 56002L	[X] ORA [ ] CENTER	33.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC-TIONS	1 FOREIGN INSPEC-TIONS (1)							
	TOTAL FIELD	**66**	**446**							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALT MORE									
	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		57.7	63.7							
TOTAL HOURS		3808	28410							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		4.01	29.91							

9. REMARKS

(b) (5), (b) (7)(E)
(b) (5), (b) (7)(E)

PAC 56002L is for Abbreviated Inspections.

(1) - Includes 2 GDUFA FTEs.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002M	[X] ORA [ ] CENTER	7.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC-TIONS			1 FOREIGN INSPEC-TIONS					
	TOTAL FIELD	**28**			**34**					
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		118.2			99.3					
TOTAL HOURS		3310			3376					
CONVERSION FACTOR		950			950					
TOTAL OPERATIONAL FTEs		3.48			3.55					

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Process Inspections - Positron Emission Tomography (PET) Inspections/Investigations	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56002P, 56002Q (2)	[X] ORA [X] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS (1)								
	TOTAL FIELD	**40**								
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		47.9								
TOTAL HOURS		1916								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		2.02								

9. REMARKS

(1) - Inspections are to evaluate the conditions under which drug products are manufactured, tested, packaged and held. Manufacturers are required to adhere to USP <823>; 21 CFR Part 212.

(2) - Report Abbreviated Inspections to PAC 56002Q.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Sampling and Testing Program	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008A, L (1)	[X] ORA [X] CENTER	19.0 [4.7]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI-GATIONS (Hours) 56008A	3 DOMESTIC SAMPLE COLL 56008A	3 DOMESTIC SAMPLE COLL CHEM 56008A	3 DOMESTIC SAMPLE COLL MICRO 56008A	3 DOMESTIC IMPORT SAMPLE COLL 56008L	3 DOMESTIC IMPORT SAMPLE COLL CHEM 56008L	3 DOMESTIC IMPORT SAMPLE COLL MICRO 56008L	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM 56008A	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO 56008A
	TOTAL FIELD	203	81	42	39	123	78	45	44	106
	HEADQUARTERS	(b) (5), (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			6.6			6.4			39.0	18.9
TOTAL HOURS		203	535			787			1716	2003
CONVERSION FACTOR		950	950			950			1180	1180
TOTAL OPERATIONAL FTEs		0 21	0.56			0.83			1.45	1.70

9. REMARKS

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

(1) Reporting Guidance: Report domestic sample collections and sample analyses under 56008A. ALL domestic-import sample collections and sample analyses should be reported under PAC 56008L.

Field exam resources for domestic import survey assignments are planned in field exams under PAC 56008H.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Drug Quality Sampling and Testing Program	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56008A, L (1)	[X] ORA [X] CENTER	19.0 [14.3]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	7 DOM-IMP SAMPLES TO BE ANALYZED CHEM 56008L	7 DOM-IMP SAMPLES TO BE ANALYZED MICRO 56008L	9 METHODS VAL/DEV (Hours) CHEM (2)						
	TOTAL FIELD	247	81	4661						
	HEADQUARTERS	(b) (5), (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		39.2	30.7							
TOTAL HOURS		9682	2487	4661						
CONVERSION FACTOR		1180	1180	1180						
TOTAL OPERATIONAL FTEs		8 20	2.11	3.95						

9. REMARKS

(1) Reporting Guidance: Report domestic sample collections and sample analyses under 56008A.
ALL domestic-import sample collections and sample analyses should be reported under PAC 56008L.

(2) - Methods Validation/Development hours include resources for development activities coordinated through ORS.

Field exam resources for domestic import survey assignments are planned in field exams under PAC 56008H.

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	47.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGATIONS HOURS (1)	6 IMPORT FIELD EXAM HOURS	2 INTERNATIONAL MAIL FACILITY REVIEWS INV HOURS	2 MAIL COURIER REVIEWS INV HOURS	4 IMPORT SAMPLE COLL	8 IMPORT SAMPLES TO BE ANALYZED API CHEM	8 IMPORT SAMPLES TO BE ANALYZED FIN-DOSAGE CHEM	
	TOTAL FIELD	**17508**	**6707**	**8654**	**7625**	**1715**	**746**	**155**	**178**	
	HEADQUARTERS	(b) (5), (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				1.0			2.7	20.1	13.5	
TOTAL HOURS		17508	6707	8654	7625	1715	2014	3116	2403	
CONVERSION FACTOR		1200	950	950	950	950	950	1180	1180	
TOTAL OPERATIONAL FTEs		14.59	7.06	9.11	8.03	1.81	2.12	2.64	2.04	

9. 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.
- Use CT PAC 56R845 when specific CT work is performed.

(1) - Import investigation hours are for 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 .

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	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	2 DQRS FARS INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES TO BE ANALYZED (Hours) CHEM					
	TOTAL FIELD	**55**	**1254**	**32**	**30**					
	HEADQUARTERS	(b) (5), (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		40.7		7.4	41.7					
TOTAL HOURS		2239	1254	237	1251					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		2.36	1.32	0 25	1.06					

9. REMARKS

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 SAMPLES COLL (1)	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM					
	TOTAL FIELD	**30**	**294**	**27**	**34**					
	HEADQUARTERS	(b) (5), (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 MPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		42.5		2.5	11.0					
TOTAL HOURS		1275	294	68	374					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		1.34	0.31	0.07	0.32					

9. REMARKS

(1) - Not all samples collected will require analysis; some will be collected for documentary and label review.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Post-Approval Inspections/Investigations - Domestic and Foreign	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56843	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC-TIONS	1 FOREIGN INSPEC-TIONS							
	TOTAL FIELD	**32**	**59**							
	HEADQUARTERS	(b) (5), (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		59.6	32.5							
TOTAL HOURS		1907	1918							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.00	2.02							

9. REMARKS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56D015	[X] ORA [ ] CENTER	16.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLES COLL	7 DOMESTIC SAMPLES TO BE ANALYZED					
	TOTAL FIELD	**91**	**1330**	**169**	**80**					
	HEADQUARTERS	(b) (5), (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		117.0		6.3	33 2					
TOTAL HOURS		10647	1330	1065	2656					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		11.21	1.40	1.12	2.25					

9. REMARKS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pharmacy Compounding - 503B Outsourcing Facilities	Drug Quality Assurance - 56

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56D017	[X] ORA [ ] CENTER	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS							
	TOTAL FIELD	**49**							
	HEADQUARTERS	(b) (5), (b) (7) (E)							
	REGIONAL STAFF								
	NEW ENGLAND								
NE	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
	BALT MORE								
	CHICAGO								
	CINCINNATI								
CE	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
SE	FLOR DA								
	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		117.0							
TOTAL HOURS		5733							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		6.03							

9. REMARKS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R010	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 Desk Audits INVESTIG-ATIONS (Hours)									
	TOTAL FIELD	**1900**									
	HEADQUARTERS	(b) (5), (b) (7) (E)									
	REGIONAL STAFF										
	NEW ENGLAND										
NE	NEW YORK										
	REGIONAL LAB										
	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	C NCINNATI										
CE	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PH LADELPHIA										
	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										
	PAC FIC REGIONAL LABORATORY-SW										
	PAC FIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION											
TOTAL HOURS		1900									
CONVERSION FACTOR		950									
TOTAL OPERATIONAL FTEs		2.00									

9. REMARKS

The Global Parity Initiative is a collaboration between CDER and ORA that implements the Commissioner's "Pathway to Global Product Safety and Quality" initiative. Specifically, this program will support our aim to leverage foreign regulatory authority inspections. The program will use domestic inspection resources toward improving our knowledge of foreign manufacturing operations, facilities, and counterpart inspectorates. Resources will be assigned to initiate and implement the desk audit program.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
56R011	[X] ORA [ ] CENTER	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 Desk Audits INVESTIG-ATIONS (Hours)								
	TOTAL FIELD	**950**								
	HEADQUARTERS	(b) (5), (b) (7) (E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	C NCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PH LADELPHIA									
	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									
	PAC FIC REGIONAL LABORATORY-SW									
	PAC FIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION										
TOTAL HOURS		950								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		1.00								

9. REMARKS

Investigation hours are to be used to update and maintain the foreign inventory contact information.

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	10.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 FORENSIC CHEM FORENSIC EVALUATION [Hours]
	TOTAL FIELD	**12050**
	HEADQUARTERS	(b) (5), (b) (7)(E)
NE	REGIONAL STAFF	
	NEW ENGLAND	
	NEW YORK	
	REGIONAL LAB	
	WEAC	
CE	REGIONAL STAFF	
	BALT MORE	
	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		12050
CONVERSION FACTOR		1205
TOTAL OPERATIONAL FTEs		10.00

9. 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

FY 2015

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 FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**14.4**			**14.4**	
1	Internet, Health Fraud, & OTC Monographs	63001A,	11.4			11.4	63-38
		63D012					
2	New Drugs Rx Not Covered by Approved NDAs	63002	3.0			3.0	63-39

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
John Pace, (301) 796-3538; Sakineh Walther, (301) 796-3349	Anita T. McCurdy 301-796-4395

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63001A, 63D012	[X] ORA [ ] CENTER	11.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)	3 DOMESTIC SAMPLE COLL (1)					7 DOMESTIC SAMPLES TO BE ANALYZED CHEM	
	TOTAL FIELD	**113**	**1520**	**274**					**199**	
	HEADQUARTERS	(b) (5), (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		36.8		5.4					22.8	
TOTAL HOURS		4158	1520	1480					4537	
CONVERSION FACTOR		950	950	950					1180	
TOTAL OPERATIONAL FTEs		4.38	1.60	1.56					3.85	

9. REMARKS

(1) - 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.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
63002	[X] ORA [ ] CENTER	3.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC-TIONS	2 INVESTI-GATIONS (Hours)							
	TOTAL FIELD	**80**	**200**							
	HEADQUARTERS	(b) (5), (b) (7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
NE	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
	BALT MORE									
	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		33.2								
TOTAL HOURS		2656	200							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		2.80	0.21							

9. REMARKS

PROJECT SUMMARY SHEET

FY 2015

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 FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**12.0**			**12.0**	
1	Shelf Life Extension Projects	*	12.0			12.0	88-41
	*For appropriate project reporting PACs, please refer to the list of Active PACs at:						
	http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/PACMasterList/default.htm#cder.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Donna A. Porter, 301-796-6583	Anita T. McCurdy 301-796-4395

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	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (Hours)
	TOTAL FIELD	**14160**
	HEADQUARTERS	(b) (5), (b) (7)(E)
NE	REGIONAL STAFF	
	NEW ENGLAND	
	NEW YORK	
	REGIONAL LAB	
	WEAC	
CE	REGIONAL STAFF	
	BALT MORE	
	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		14160
CONVERSION FACTOR		1180
TOTAL OPERATIONAL FTEs		12.00

9. 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.

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting – MDR Follow-up PAC 81010	2. PPS PROJECT NAME/NUMBER 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 Monitoring Devices of Foreign Origin - Import PAC 82008	2. PPS PROJECT NAME/NUMBER 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

[ ] COMPREHENSIVE [ ] ABBREVIATED [X] 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 Inspection of Medical Device Manufacturers PAC 82845	2. PPS PROJECT NAME/NUMBER 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 Work planning 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 Center Initiated Assignments PAC 82Z800	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82

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 rapidly. This work plan activity provides resources for Center assignments which can rapidly address potential or emerging problems.

6. FIELD OBLIGATIONS

Conduct inspections and investigations as directed by Center assignments.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

[ ] BY DISTRICT OFFICE [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

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 82R816	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82

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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 82R838	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82

3. PROGRAM TYPE ☐ 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. Please consult DFS and/or the DPEM for additional reporting guidance.

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
Medical Device Premarket Approval and Postmarket Inspections PAC 83001	Product Evaluation: Devices - 83

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

4. OBJECTIVES

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

The field will conduct pre-approval inspections on assignment and submit an EIR to the Center along with the District's recommendation. The field will be responsible for scheduling (b) (5), (b) (7)(E) Under certain conditions, a post-approval inspection will not be necessary. The Center will advise the district when a post-approval inspection is not necessary.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED [ ] BY DISTRICT OFFICE [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 Bioresearch Monitoring PAC 83808, 83809, 83810, 83811	2. PPS PROJECT NAME/NUMBER 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 and Import Operations. 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 Test Method Development and Evaluation PAC 84Z002	2. PPS PROJECT NAME/NUMBER Science: Devices - 84

3. PROGRAM TYPE [ ] 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 [ ] 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 Methods Validation/Development Program PAC 84R816	2. PPS PROJECT NAME/NUMBER Science: Devices - 84

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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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 Mammography Facilities Inspection Program PAC 85014	2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85

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

4. OBJECTIVES

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 follow up inspections to determine whether the facility has complied with the terms of their corrective action plan, based on noncompliance 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.

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
Inspection and Field Testing of Radiation-Emitting Electronic Products PAC 86001, 86002, 86004	Radiation Control and Health Safety Act (RCHSA) Authority - 86

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

4. OBJECTIVES

The objectives of inspections and tests conducted under this program are

- To evaluate an electronic product manufacturer's quality control testing program for its ability to ensure such product compliance and radiation safety;
- To identify certified electronic products which fail to comply with the requirements of applicable performance standards;
- To obtain correction of deficient quality control testing programs and noncompliant products identified by initiating appropriate administrative/regulatory action;
- To provide guidance to manufacturers regarding compliance with the laws and regulations administered by FDA.

5. PROGRAM JUSTIFICATION

Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Manufacturers are responsible for producing products that do not emit hazardous or unnecessary radiation and that comply with all applicable radiation safety performance standards. All electronic product manufacturers must comply with applicable requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. If a mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with Title 21 CFR 1010 and the product must comply with the requirements of the specific standard found in 21 CFR 1020 – 1050. Manufacturers are required to self-certify their own products to be compliant with an applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. EPRC inspections and field tests verify that electronic products comply with performance standards, and that manufacturer quality control testing programs ensure product compliance and radiation safety.

6. FIELD OBLIGATIONS

Field personnel will initiate and schedule inspections of electronic product manufacturers as instructed in Compliance Program 7386.001. CDRH is generally responsible for the final review of inspections and field tests made under this program and for the issuance of letters resulting from inspections and field tests performed by field radiological health staff. Exceptions where the district has direct reference authority are noted in Compliance Program 7386.001. Joint EPRC/medical device (QSIT) inspections may be conducted under both Compliance Program 7386.001 and 7382.845.

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, Sunlamp and sunlamp products Cabinet x-ray products, Televisions and Microwave Ovens	94-RXX, 95-RXX See Compliance Program 7386.001 for complete listing

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

f. CHECK THE FOLLOWING ATTRIBUTES

Specific product inspection and field test checklist or forms, if available, are included as Compliance Program Attachments. These checklists may be used to the extent practicable to record inspection and test observations.

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
Insp. of Manuf. (For and Dom) and Field Compliance Testing of Diag. X-Ray Equipment PAC 86003	Radiation Control and Health Safety Act (RCHSA) Authority - 86

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

4. OBJECTIVES

The objectives of inspections and tests conducted under this program are:

1. To ensure that the regulated products and manufacturer quality control programs conform to EPRC regulations;
2. To identify diagnostic x-ray products which fail to comply with the applicable performance standard requirements;
3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and
4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA.

5. PROGRAM JUSTIFICATION

Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Diagnostic x-ray manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary x-radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Because diagnostic x-ray equipment is also subject to performance standards, the manufacturer must also comply with Title 21 CFR 1010 and the equipment must comply with the specific standards found in 21 CFR 1020.30 – 1020.33. Manufacturers are required to self-certify their products comply with the applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. EPRC inspections and field tests verify that electronic products comply with performance standards, and that the manufacturer's quality control testing program ensures product compliance and radiation safety.

6. FIELD OBLIGATIONS

Field personnel will initiate and schedule inspections of diagnostic x-ray manufacturers and field tests of diagnostic x-ray equipment as instructed in Compliance Programs 7386.003 and 7386.003a. CDRH is generally responsible for the final review of inspections and field tests made under this program and for the issuance of letters resulting from inspections and field tests performed by field radiological health staff. Exceptions where the district has direct reference authority are noted in Compliance Program 7386.003 and 7386.003a. Joint EPRC/medical device (QSIT) inspections may be conducted under both Compliance Programs 7386.003a and 7382.845.

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	94DS---

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Field tests will be performed by consumer safety officers who have received specialized training which includes approximately two weeks of on-the-job training with a qualified auditor.

1. PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC PAC 86006	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority-86

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

4. OBJECTIVES

The objectives of laboratory tests conducted under this program are:

1. To ensure that the regulated products conform to EPRC regulations;
2. To identify products which fail to comply with the applicable performance standard requirements;
3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and
4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA.

5. PROGRAM JUSTIFICATION

Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Electronic product manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Products also subject to performance standards must comply with the specific standards found in 21 CFR 1020 – 1050. EPRC laboratory tests verify that electronic products comply with performance standards at the point of manufacture, and that the manufacturer's quality control testing program ensures product compliance and radiation safety.

6. FIELD OBLIGATIONS

WEAC will test all products in accordance with the appropriate Compliance Program and/or test methods. Products will be identified for testing by both WEAC and CDRH for either routine or for cause testing. WEAC will request samples for direct shipment from manufacturer or distributor of product. WEAC will retain products tested until all compliance actions have been completed or upon notification from CDRH. WEAC will also conduct all foreign inspections for electronic product manufacturers, other than diagnostic x-ray manufacturers. See Compliance Program for joint EPRC/medical device (QSIT) inspections. CDRH is responsible for the final review of inspections and lab tests conducted under this program.

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)
Lasers, sunlamps, mercury vapor lamps, x-ray systems, ultrasound therapy products, televisions, and microwaves.	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 Imported Electronic Products PAC 86007	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86

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

4. OBJECTIVES

1. To ensure that the regulated products conform to EPRC regulations;
2. To identify products which fail to comply with the applicable performance standard requirements;
3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and
4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA.

5. PROGRAM JUSTIFICATION

Electronic product radiation control (EPRC) requirements protect the public from unnecessary exposure to electronic product radiation. Electronic product manufacturers are responsible for producing equipment that do not emit hazardous or unnecessary radiation and that comply with applicable radiation safety performance standards. All electronic product manufacturers must comply with requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. Products also subject to performance standards must comply with the specific standards found in 21 CFR 1020 – 1050. EPRC imports entry reviews verify that electronic products subject to performance standards have been reported to FDA as required.

6. FIELD OBLIGATIONS

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All radiation emitting electronic products that are subject to a performance standard contained in 21 CFR 1020 – 1050.	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 Radiological Health Control Activities PAC 86008, 86009	2. PPS PROJECT NAME/NUMBER 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 HQ annual meetings with CDRH, ORA and other FDA officials. WEAC will provide Laboratory Support for the DENT programs.
Emergency Planning & Response Activities: Provide consultation to states and attend regional emergency planning meetings.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE [ ] 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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2015

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	175.9	58.1	45.0	279.0
81	POSTMARKET ASSURANCE: DEVICES	1.0			1.0
82	COMPLIANCE: DEVICES	102.7	50.0	39.0	191.7
83	PRODUCT EVALUATION: DEVICES	29.1		3.8	32.9
84	SCIENCE: DEVICES	7.9			7.9
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.6			14.6
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	20.6	8.1	2.2	30.9

PROJECT SUMMARY SHEET
FY 2015

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		**1.0**			**1.0**	**1.0**	
1	Medical Device Problem Reporting - MDR	81010	1.0			1.0	1.0	81-3
	Follow-up							

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Thomas P. Gross 301-796-5997	Danita Dyer 301-796-9694

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Medical Device Problem Reporting - MDR Follow-Up 0	Postmarket Assurance: Devices - 81

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
81010	[X] ORA [ ] CENTER	1 0

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS (1)	INVESTI-GATIONS (Hours) (2)	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL STER	DOMESTIC SAMPLE COLL ENG	DOMESTIC SAMPLE ANALYSIS CHEM (3)	DOMESTIC SAMPLE ANALYSIS STER (4)	DOMESTIC SAMPLE ANALYSIS ENG (5)	
	TOTAL FIELD	54	30	1	1	1	1	1	1	
	HEADQUARTERS	(b) (5), (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		16 0		8 0	8 0	8 0	36 0	20 0	37 0	
TOTAL HOURS		864	30	8	8	8	36	20	37	
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180	
TOTAL OPERATIONAL FTEs		0 91	0 03	0 01	0 01	0 01	0 03	0 02	0 03	

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 follow-up

(2) Investigational hours for MDR followup at medical facilities

(3) Performance testing of chemical and serological test kits

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

(5) MDR samples to confirm reported defects

PROJECT SUMMARY SHEET
FY 2015

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 OPERATIONAI FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**102.7**	**50.0**	**39.0**	**191.7**	
1	Monitoring Devices of Foreign Origin - Import	82008 *		50.0		50.0	82-5-6
2	Inspection of Medical Device Manufacturers:		95.1		39.0	134.1	82-7- 9
	GMP Inspections	82845A-S	[94.4]		[39]		
	Accredited Persons Audit Investigations	82845J	[0.2]				
	Accredited Persons Audit Inspections	82845P	[0.5]				
3	Center Initiated Assignments	82Z800	5.3			5.3	82-10
4	Methods Validation/Development Program	82R816	2.0			2.0	82-11
5	Forensic Evaluation & Sample Analysis	82R838	0.3			0.3	82-12
	* In addition to PAC 82008, includes reporting						
	PACs 82R824, 82R833, and 99R833.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Steven Silverman 301-796-5500	Danita Dyer 301-796-9694

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	50.0 [48.25]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	ENTRY REVIEW HOURS	IMPORT INVESTI-GATION HOURS (1)	MAIL COURIER REVIEW HOURS	INTERNATIONAL MAIL FACILITY REVIEW HOURS	IMPORT SAMPLE COLL (Physical) MICRO (2)	IMPORT SAMPLE COLL (Physical) ENG	IMPORT FIELD EXAMS	IMPORT SAMPLE ANALYSIS MICRO (3)	IMPORT SAMPLE ANALYSIS ENG
	TOTAL FIELD	**26008**	**4860**	**2201**	**300**	**103**	**210**	**25652**	**103**	**180**
	HEADQUARTERS	(b) (5), (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	0.4	30.4	30.4
TOTAL HOURS		26008	4860	2201	300	227	462	10261	3131	5472
CONVERSION FACTOR		1200	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		21.67	5.12	2.32	0.32	0.24	0.49	10.80	2.65	4.64

9. REMARKS

(1) Import investigation hours are for 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. Field Exams are planned in a separate column.

(2) Audit samples for problems other than failure to register or list (eg. special assignment, import alert).

(3) Sterile devices to be tested by USP XX method.

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.
FTEs from Condom Assignment (82Z002) and Manufacturers and Importers of Surgical/Examination Gloves (82Z003) were realloacted to this program

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	50.0 [1.77]

6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE ANALYSIS CHEM	IMPORT PRIVATE LAB REVIEW (HOURS)							
TOTAL FIELD	**30**	**1180**							
HEADQUARTERS	(b) (5), (b) (7)(E)								
REGIONAL STAFF									
NEW ENGLAND									
NEW YORK									
REGIONAL LAB									
WEAC									
REGIONAL STAFF									
BALTIMORE									
CHICAGO									
CINCINNATI									
DETROIT									
MINNEAPOLIS									
NEW JERSEY									
PHILADELPHIA									
FORENSIC CHEM. CTR									
REGIONAL STAFF									
ATLANTA									
FLORIDA									
NEW ORLEANS									
SAN JUAN									
REGIONAL LAB									
REGIONAL STAFF									
DALLAS									
DENVER									
KANSAS CITY									
SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB									
REGIONAL STAFF									
LOS ANGELES									
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION	30.4								
TOTAL HOURS	912	1180							
CONVERSION FACTOR	1180	1180							
TOTAL OPERATIONAL FTEs	0.77	1.00							

9. REMARKS

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,H,J,K,P,S,81845R,T,81011	[X] ORA [ ] CENTER	134 1 [128.16]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS LEVEL I DOMESTIC CLASS 1 82845A	INSPEC-TIONS LEVEL I DOMESTIC CLASS 2,3 82845A	INSPEC-TIONS LEVEL II DOMESTIC 82845B	INSPEC-TIONS LEVEL III OMPLIANC DOMESTIC 82845C	INSPEC-TIONS FOREIGN 82845B	INSPEC-TIONS FOR CAUSE DOMESTIC 82845G	INSPEC-TIONS FOR CAUS HIGH RISK DOMESTIC 82845H	INSPEC-TIONS FOR CAUSE HIGH RISK FOREIGN 82845H	INSPEC-TIONS ACCRED PERSONS DOMESTIC 82845P
	TOTAL FIELD	**118**	**574**	**451**	**127**	**514**	**115**	**48**	**49**	**9**
	HEADQUARTERS	(b) (5), (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		39.6	39.6	63.2	112.5	62.8	85 9	97.0	87.0	53.0
TOTAL HOURS		4673	22730	28503	14288	32279	9879	4253	4176	477
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		4.92	23.93	30.00	15.04	33.98	10.40	4.90	4.49	0.50

9. REMARKS

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,H,J,K,P,S,81845R,T,81011	[X] ORA [ ] CENTER	134 1 [2.24]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INVESTI-GATIONS (Hours) 82845B	INVESTI-GATIONS (Hours) A.P. AUDITS MDUFMA 82845J	DOMESTIC SAMPLE COLL 82845C	DOMESTIC SAMPLE COLL ENG 82845C	DOMESTIC SAMPLE COLL MICRO 82845C	DOMESTIC SAMPLE COLL CHEM 82845C	DOMESTIC SAMPLE COLL 82845H	DOMESTIC SAMPLE COLL 82845S	DOMESTIC SAMPLE COLL BIOBURDEN BIOINDIC'R 82845S
	TOTAL FIELD	**1516**	**190**	**42**	**10**	**27**	**7**	**14**	**17**	**10**
	HEADQUARTERS	(b) (5), (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				6.0	4.0	
TOTAL HOURS		1516	190	252				84	68	
CONVERSION FACTOR		950	950	950				950	950	
TOTAL OPERATIONAL FTEs		1.60	0.20	0.28				0.09	0.07	

9. REMARKS

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,H,J,K,P,S,81845R,T,81011	[X] ORA [ ] CENTER	134 1 [3.74]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL STERILITY 82845S	DOMESTIC SAMPLES ANALYSIS ENG 82845C	DOMESTIC SAMPLE ANALYSIS MICRO 82845C	DOMESTIC SAMPLE ANALYSIS CHEM 82845C	DOMESTIC SAMPLE ANALYSIS ENG 82845H	DOMESTIC SAMPLE ANALYSIS BIOBURDEN 82845S	DOMESTIC SAMPLE ANALYSIS STERILITY 82845S		
	TOTAL FIELD	**6**	**10**	**27**	**7**	**14**	**10**	**6**		
	HEADQUARTERS	(b) (5), (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			80.0	62.0	38.0	88.3	25.0	29.5		
TOTAL HOURS			800	1674	266	1236	250	177		
CONVERSION FACTOR			1180	1180	1180	1180	1180	1180		
TOTAL OPERATIONAL FTEs			0.68	1.42	0.23	1.05	0.21	0.15		

9. REMARKS

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

CHEM Sample Analyses: Test Kit or Reagant Testing to support GMP observations at WEAC; Sporicidal and Tuberculocidal at WEAC Lab.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
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	5.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS CENTER-INITIATED 82Z800	DOMESTIC SAMPLE COLL (1) 82Z800	DOMESTIC SAMPLE ANALYSIS CHEM (2) 82Z800	DOMESTIC SAMPLE ANALYSIS TERILITY (3 82Z800	DOMESTIC SAMPLE ANALYSIS MICRO (4) 82Z800	DOMESTIC SAMPLE ANALYSIS ENG 82Z800	OTHER OPER-ATIONS (Hours) ENG (5) 82Z800		
	TOTAL FIELD	**25**	**51**	**4**	**11**	**15**	**11**	**1600**		
	HEADQUARTERS	(b) (5), (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		54.0	8.0	15.0	50.0	50.0	100.0			
TOTAL HOURS		1350	408	60	550	750	1100	1600		
CONVERSION FACTOR		950	950	1180	1180	1180	1180	1180		
TOTAL OPERATIONAL FTEs		1.42	0.43	0.05	0.47	0.64	0.93	1.36		

9. REMARKS

Planned BSE Inspections (82Z005) were cancelled in FY 2008; PAC will remain active for reporting purposes and any Center-Initiated Assignments involving BSE should be reported in PAC 82Z005.

(1) Includes Documentary Samples and Analytical Samples.
(2) Ad Hoc testing of test kits or reagents.
(3) Sterility samples.
(4) Ad Hoc testing of media.
(5) Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	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	METHODS VAL/DEV CHEM (Hours)	METHODS VAL/DEV MICRO (Hours)							
	TOTAL FIELD	**1205**	**1205**							
	HEADQUARTERS	(b) (5), (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

Workload Source: Determined by ORS.

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) (5), (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		360
CONVERSION FACTOR		1205
TOTAL OPERATIONAL FTEs		0.30

9. REMARKS

PROJECT SUMMARY SHEET
FY 2015

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	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**29.1**		**3.8**	**32.9**	
1	Medical Device Premarket Approval and		5.9		2.3	8.2	83-14
	Postmarket Inspections:						
	MDUFMA User Fee	83001	[4.7]				
	PreMarket Approval Inspections	83001			[1.4]		
	Postmarket Approval Inspections	83001A	[1.2]		[0.9]	[1.2]	
2	Bioresearch Monitoring		23.2		1.5	24.7	83-15

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Christy Foreman 301-796-6382	Danita Dyer 301-796-9694

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	8.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPECTIONS MDUFMA USER FEE 83001	FOREIGN INSPECTIONS PRE-APPROVAL 83001	INSPECTIONS POST-APPROVAL 83001A	FOREIGN INSPECTIONS POST-APPROVAL 83001A					
	TOTAL FIELD	**69**	**27**	**37**	**19**					
	HEADQUARTERS	(b) (5), (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		65.0	49.0	31.0	44.0					
TOTAL HOURS		4485	1323	1147	836					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		4.72	1.39	1.21	0.88					

9. REMARKS

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

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

1. PROGRAM/ASSIGNMENT TITLE	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	24.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS DOMESTIC	INSPEC-TIONS FOREIGN							
	TOTAL FIELD	**300**	**19**							
	HEADQUARTERS	(b) (5), (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		73.5	75.5							
TOTAL HOURS		22050	1435							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		23.21	1.51							

9. REMARKS

Device Bioresearch Monitoring inspections should be prioritized according to the following scheme:

-For Cause with 30-day due dates;

-Directed data audit for expedited PMA;

-Directed data audit for non-expedited PMA;

-For Cause with 60-90 day due dates;

-OAI Follow-up (6 months);

-Early Intervention (Probability Sampling, Vulnerable Population, and IDE-based);

-Routine Surveillance.

Please contact Ruth Hinckley (301-796-5658) or Jim Saviola (301-796-5432) with any questions.

PROJECT SUMMARY SHEET
FY 2015

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	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		7.9			7.9	
1	Test Method Development and Evaluation	84Z002	5.9			5.9	84-17
2	Methods Validation/Development Program	84R816	2.0			2.0	84-18

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Dr. Steven Pollack 301-796-2476	Danita Dyer 301-796-9694

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	5.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	OTHER OPERATION (Hours) METH DEV ENG
	TOTAL FIELD	**6962**
	HEADQUARTERS	(b) (5), (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		6962
CONVERSION FACTOR		1180
TOTAL OPERATIONAL FTEs		5.90

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
Methods Validation/Development Program	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84R816	[X] ORA [ ] CENTER	2.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	APPLIED TECHNOLOGY CENTER (Hours) MICRO								
	TOTAL FIELD	**2360**								
	HEADQUARTERS	(b) (5), (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		2360								
CONVERSION FACTOR		1180								
TOTAL OPERATIONAL FTEs		2.00								

9. REMARKS

Workload Source: Determined by ORS.

PROJECT SUMMARY SHEET

FY 2015

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			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**14.5**		**0.1**	**14.6**	
1	Mammography Facilities Inspection Program	85014 A,C,F	14.5		0.1	14.6	85-20-21

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Kate Sheridan 301-8796-5714	Lorraine Boykin 301-796-9694

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	14.6 [9.7]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS 85014 (1)	FOREIGN INSPEC-TIONS 85014	DOMESTIC FED FACIL INSPEC-TIONS 85014	DOMESTIC VHA INSPEC-TIONS 85014	DOMESTIC INSPEC-TIONS FOLLOW-UP 85014F (2)	DOMESTIC INSPEC-TIONS FOLLOW-UP 85014F (3)	AUDIT INVESTI-GATIONS (Hours) 85014A	OTHER OPERA-TIONS (Hours) 85014C (4)	OTHER OPERA-TIONS (Hours) 85014C (5)
	TOTAL FIELD	**530**	**14**	**120**	**50**	**9**	**9**	**2156**	**3182**	**59**
	HEADQUARTERS	(b) (5), (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		4240	112	960	400	99	99	2156	3182	59
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1160
TOTAL OPERATIONAL FTEs		3.66	0.10	0.83	0.34	0.09	0.09	1.86	2.74	0.05

7. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

(1) Certified non-federal Mammography Facility not covered by state contracts

(2) Follow-up Inspections non-compliance inspections.

(3) Follow-up Inspections after Warning Letter.

(4) Compliance Activities: Inspection Follow-Up Activities (Non-Warning Letter).

(5) Compliance Activities: Warning Letters.

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	14.6 [4.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	OTHER OPERATIONS (Hours) 85014C (6)	OTHER OPERATIONS (Hours) 85014C (7)							
	TOTAL FIELD	**4470**	**1200**							
	HEADQUARTERS	(b) (5), (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		4470	1200							
CONVERSION FACTOR		1160	1200							
TOTAL OPERATIONAL FTEs		3.85	1.00							

7. REMARKS

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

(6) Technical Assistance and Coordination Activities: Non-RRHRs.

(7) Techical Assistance and Coordination Activities: RRHRs.

PROJECT SUMMARY SHEET

FY 2015

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			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**20.6**	**8.1**	**2.2**	**30.9**	
1	Inspection and Field Testing of Radiation-Emitting		4.3		0.9	5.2	86-23-24
	Electronic Products:						
	Inspection of Manufacturers of Laser Products	86001	[3.5]		[0.9]	[4.4]	
	Field Implementation of the Sunlamp & Sunlamp Products	86002	[0.3]			[0.3]	
	Performance Standard as Amended						
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	[0.5]			[0.5]	
2	Inspections of Manufacturers (Foreign and Domestic) and	86003	7.7		1.0	8.7	86-25-32
	Field Compliance Testing of Diagnostic X-Ray Equipment						
3	Compliance Testing of Electronic Products at WEAC	86006, A, D, E	2.8		0.3	3.1	86-33
4	Imported Electronic Products	86007 *		8.1		8.1	86-34
5	Radiological Health Control Activities:		5.8			5.8	86-35
	Medical Device and Radiological Health Use Control and	86008	[3.0]			[3.0]	
	Policy Implementation						
	Emergency Planning and Response Activities	86009	[2.0]			[2.0]	
6	OEI Improvement - resources are planned in PACs	86R876	0.8			0.8	
	86001 and 86003						
	* In addition to PAC 86007, includes reporting PACs						
	86R824, 86R833, and 99R833.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deniz Mackey 301-796-5908	Lorraine Boykin 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection and Field Testing of Radiation-Emitting 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, 86004	[X] ORA [ ] CENTER	6.0 [4.3]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS 86001 (1)	FOREIGN INSPEC-TION 86001 (2)	DOMESTIC INSPEC-TIONS 86002 (3)	DOMESTIC INSPEC-TIONS 86004 (4)	INVESTI-GATIONS (Hours) 86001 (5)	INVESTI-GATIONS (Hours) 86004	DOMESTIC SAMPLE DOC 86001	FIELD EXAMS/ TESTS 86001 (6)	FIELD EXAMS/ TESTS 86002 (7)
	TOTAL FIELD	**105**	**30**	**3**	**22**	**350**	**30**	**5**	**75**	**30**
	HEADQUARTERS	(b) (5), (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		17.3	36.0	36.0	20.0			3.0	5.0	4.4
TOTAL HOURS		1817	1080	108	440	350	30	15	375	132
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		1.91	0.92	0.11	0.46	0.37	0.03	0.02	0.39	0.14

7. REMARKS

Laser products (86001): (1) Inspections should be conducted on manufacturers of Class IIIb and Class IV products. Medical laser systems should be highest priority, followed by industrial, and commercial lasers (including laser light shows) or inspections directed based on a for cause request. For medical lasers, a joint QSIT and electronic product radiation control inspection should be conducted. (2) Foreign inspections to be conducted by WEAC Analysts and other EOS Specialists. (5) Investigation Hours- refer to Compliance Program for reporting information. (6) Field tests may be conducted for any laser products located at a user facility, following the same priority scheme as for inspections. (Class IIIb or IV medical, industrial and commercial lasers, including laser light show projectors).

Sunlamps and sunlamp products (86002): (3) Inspectional figures are only for biennial or for cause inspections of manufactures of sunlamp products (e.g. sunlamps, booths, or beds). A joint QSIT and electronic product radiation inspection product radiation control inspection should be conducted. Examination of sunlamp products at a user facility (e.g. tanning parlor, athletic club) are NOT counted as inspections because they are field tests. (7) - Each sunlamp product tested may be counted as a field test, even if located in a single facility. NOTE: RRHR's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

Cabinet x-ray products (86004): (4) Cabinet x-ray manufacturer inspections are to be comprehensive electronic product radiation control inspections. Cabinet x-ray field tests are no longer performed routinely under this program. The hours previously associated with field tests have been reprogrammed to inspections.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection and Field Testing of Radiation-Emitting 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, 86004	[X] ORA [ ] CENTER	6.0 [1.7]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	OTHER OPERATIONS (Hours) 86001 (8)	OTHER OPERATIONS (Hours) 86002 (9)	OEI IMPROVEMENT (Hours) 86R876						
	TOTAL FIELD	750	75	760						
	HEADQUARTERS	(b) (5), (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		750	75	760						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		0.79	0.08	0.80						

7. REMARKS

Laser products (86001):

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

Sunlamps and sunlamp products (86002):

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

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86003	[X] ORA [X] CENTER	8.7 [6.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (2)	DOMESTIC INSPEC-TIONS DIRECTED (3)	DOMESTIC INSPEC-TIONS (4)	INVESTI-GATIONS (Hours) (5)	INVESTI-GATIONS (Hours) (6)	FIELD EXAMS/ TESTS (7)	AUDITS (7)	FIELD EXAMS/ TESTS ENG
	TOTAL FIELD	**52**	**15**	**5**	**18**	**884**	**1051**	**295**	**30**	**50**
	HEADQUARTERS	(b) (5), (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		40.0	65.0	40.0	16.0			3.0	4.0	3.0
TOTAL HOURS		2080	975	200	288	884	1051	885	120	150
CONVERSION FACTOR		950	950	950	950	950	950	950	950	1180
TOTAL OPERATIONAL FTEs		2.19	1.03	0.21	0.30	0.93	1.11	0 93	0.13	0.13

7. REMARKS

(1) - Domestic inspections to be conducted based on the OEI of diagnostic x-ray equipment manufacturers. Joint QSIT and electronic product radiation control inspections should be conducted if possible.

(2) - Foreign inspections should be joint QSIT and electronic product radiation control inspections if possible.

(3) - Directed Inspections based on the OEI of diagnostic x-ray equipment manufacturers.

(4) - Inspections based on the OEI of diagnostic x-ray equipment assemblers.

(5) - Investigation hours for review and planning of activities under columns 1 (Domestic), 2 (Foreign), and 3 (Directed) Inspections.

(6) - Investigation hours for review of 2579 forms (reports of assembly) in preparation for performing field tests and field test follow up activities.

(7) - Field tests and audits are obtained from Attachment A and provided by CDRH's OCER/DMQRP Diagnostic Devices Branch,

(8) - Audits are for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86003	[X] ORA [X] CENTER	8.7 [1.8]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	9 OTHER OPERATIONS (Hours) (8)	9 OEI IMPROVEMENT (Hours) 86R876							
	TOTAL FIELD	**965**	**760**							
	HEADQUARTERS	(b) (5), (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		965	760							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		1.02	0.80							

7. REMARKS

(9) - Coordination/technical assistance hours for field test activities.

ATTACHMENT A - 2015 WORKPLAN
INSPECTIONS OF MANUFACTURERS (FOREIGN AND DOMESTIC) AND FIELD COMPLIANCE TESTING OF DIAGNOSTIC X-RAY EQUIPMENT

NEW ENGLAND DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
CT	(b) (5), (b) (7)(E)			
ME				
MA				
NH				
RI				
VT				
Total				

NEW YORK DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
NY	(b) (5), (b) (7)(E)			

CE REGIONAL STAFF (STATES IN BALTIMORE DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
DC	(b) (5), (b) (7)(E)			
MD				
VA				
WV				
Total				

CE REGIONAL STAFF (STATES IN CHICAGO DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
IL	(b) (5), (b) (7)(E)			

CE REGIONAL STAFF (STATES IN CINCINNATI DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
KY	(b) (5), (b) (7)(E)			
OH				
Total				

CE REGIONAL STAFF (STATES IN DETROIT DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
IN	(b) (5), (b) (7)(E)			
MI				
Total				

CE REGIONAL STAFF (STATES IN MINNEAPOLIS DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
MN	(b) (5), (b) (7)(E)			
ND				
SD				
WI				
Total				

CE REGIONAL STAFF (STATES IN NEW JERSEY DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
NJ	(b) (5), (b) (7)(E)			

CE REGIONAL STAFF (STATES IN PHILADELPHIA DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
DE	(b) (5), (b) (7)(E)			
PA				
Total				

ATLANTA DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
GA	(b) (5), (b) (7)(E)			
NC				
SC				
Total				

FLORIDA DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
FL	(b) (5), (b) (7)(E)			

NEW ORLEANS DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AL	(b) (5), (b) (7)(E)			
LA				
MS				
TN				
Total				

SAN JUAN DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
PR	(b) (5), (b) (7)(E)			

SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AR	(b) (5), (b) (7)(E)			
OK				
TX				
Total				

SW REGIONAL STAFF (STATES IN DENVER DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
CO	(b) (5), (b) (7)(E)			
NM				
UT				
WY				
Total				

SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
IA	(b) (5), (b) (7)(E)			
KS				
NE				
MO				
Total				

LOS ANGELES DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AZ	(b) (5), (b) (7)(E)			
CA				
Total				

SAN FRANCISCO DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
CA	(b) (5), (b) (7)(E)			
HI				
NV				
Total				

SEATTLE DISTRICT

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AK	(b) (5), (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/ASSIGNMENT CODE(S) 86006 A,D,E	4. WORK ALLOCATION PLANNED BY [ ] ORA [X] CENTER	5. OPERATIONAL FTE POSITIONS 3.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPEC-TIONS (1)	DOMESTIC SAMPLE ANALYSIS MICROWAVE 86006A	DOMESTIC SAMPLE ANALYSIS X-RAY WHOLE 86006D	DOMESTIC SAMPLE ANALYSIS NON-MED LASERS 86006E	DOMESTIC SAMPLE ANALYSIS SUN LAMPS 86006E				
	TOTAL FIELD	**5**	**61**	**4**	**42**	**10**				
	HEADQUARTERS	(b) (5), (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		68.0	18.0	345.0	15.0	25.0				
TOTAL HOURS		340	1098	1380	630	250				
CONVERSION FACTOR		1180	1180	1180	1180	1180				
TOTAL OPERATIONAL FTEs		0.29	0.93	1.17	0.53	0.21				

7. REMARKS

(b) (5), (b) (7)(E) For any inspections of radiation-emitting medical device manufacturers, a joint QSIT and electronic product radiation control inspection should be conducted. Instructions for performing inspections are provided in Compliance Program 7386.001, with time reported under PAC 86006.

Report time for specific lab analyses under PAC 86006A, D or E.

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	8.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW (Hours) 86R833	IMPORT INV (Hours) (1)	IMPORT FIELD EXAMS	IMPORT SAMPLE COLL	IMPORT SAMPLE ANALYSIS ENG				
	TOTAL FIELD	**6515**	**1400**	**400**	**50**	**50**				
	HEADQUARTERS	(b) (5), (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				0.7	2.8	17.0				
TOTAL HOURS		6515	1400	280	140	850				
CONVERSION FACTOR		1200	950	950	950	1180				
TOTAL OPERATIONAL FTEs		5.43	1.47	0.29	0.15	0.72				

7. REMARKS

(1) Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations.

Filer Evaluations (operation code 95, PAC 99R833)

Follow-up to Refusals (PAC 86R824).

Laboratory allocations were planned by ORS.

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 0

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	MISC (Hours) RRHR (1)	Emergency Response (Hours) RRHR (2)							
	TOTAL FIELD	**3600**	**2400**							
	HEADQUARTERS	(b) (5), (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		3600	2400							
CONVERSION FACTOR		1200	1200							
TOTAL OPERATIONAL FTEs		3 00	2 00							

7 REMARKS

(1) Miscellaneous hours for RRHR for Federal/State liaison activities includes coordination, technical assistance and other activities for following PAC codes 86002,86003, 86004, 86008 and 86009

(2) RRHR for technical assistance to state and local agencies regarding emergency response planning, reviewing, and evaluating emergency plans related to nuclear power plant

1. PROGRAM/ASSIGNMENT TITLE Imported Acidified & Low Acid Canned Foods PACs 03003,A	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To detain Acidified and Low-Acid Canned Food which are packed in food canning establishments not in compliance with 21 CFR 108, 113, and 114.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

Acidified and Low-Acid Canned Foods continue to be the source of sporadic problems from improper processing (e.g., under-processing, inadequate pH or Aw control, leakage). Inspections of foreign firms have shown many firms (and their products) to be out of compliance with CFR Parts 108, 113, and 114.

The number of foreign AF/LACF firms submitting registration has been increasing significantly each year.

6. FIELD OBLIGATIONS

The Field is responsible for the detention of Acidified and Low-Acid Canned Foods that appear to be improperly processed or packaged through the examination of lots or sample analysis. Additionally, products in this category are detained if they are from firms that do not comply with registration and filing requirements. All import field exams are to routinely include: pH determination, can examination and verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety concerns.

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)
Refer to Compliance Program (7303.003)	03, 04, 09, 12-18, 20-25, 27, 29, 30, 31, 33-41

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

f. CHECK THE FOLLOWING ATTRIBUTES

pH, Water Activity, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic & Imported Cheese & Cheese Products. PACs 03037,B,D	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To conduct inspections of domestic and foreign cheese firms, to examine samples of imported and domestic cheese for microbiological contamination, phosphatase and filth. To take appropriate action on imported lots and domestically produced cheese when violations are encountered.

Inspection and analytical resources have been planned separately for outbreak and emergency operations (PAC 03F813) and foreign inspections (03R233).

5. PROGRAM JUSTIFICATION

Cheese and cheese products have been demonstrated to contain pathogenic microorganisms that can cause human illness. Also, a number of deaths have been associated with the consumption of certain cheeses. Due to continuing microbiological problems associated with cheese and cheese products, the Compliance Program covers domestic and imported cheese and cheese products for microbiological as well as phosphatase and filth analysis.

6. FIELD OBLIGATIONS

The field is requested to conduct inspections of domestic and foreign cheese manufacturers and, as necessary, sample collections and analyses to document & support inspectional findings. The field is also requested to conduct sample collections and analyses of imported cheese focusing on soft cheese as high priority. Refer to the instructions in the Compliance Program regarding the collection of domestic samples not resulting from inspections.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Hard and soft cheeses.	12

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

f. CHECK THE FOLLOWING ATTRIBUTES

Salmonella , *Listeria* , *E. coli* , *Enterotoxigenic E. Coli* (ETEC), *Enterohemmorhagic E. Coli* EHEC 0157:H7 - *S. aureus,* Phosphatase, and Filth.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified & Low-Acid Canned Foods PAC 03803A	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To determine if the firms comply with 21 CFR, Part 108, 113 and 114 and other requirements of the FD&C Act.
To perform inspections to ensure compliance of interstate marketing of acidified and low-acid canned foods.

A continued priority will remain with out–of–compliance firms and special situation firms (e.g. newly registered, firms operating under Emergency Permit, etc.). Please refer to the compliance program for instructions.

5. PROGRAM JUSTIFICATION

Low-Acid Canned Foods: Inspections conducted in prior year's programs have demonstrated that the degree of compliance with low-acid canned food regulations relate directly to the degree of freedom from hazard to consumers found in the food produced. High risk industry segments, identified under previous programs, as well as re-inspection of the remaining portions of the industry are needed to establish and maintain compliance with the low-acid canned food regulations.

Acidified Foods: The program is needed to ensure that the acidified food industry's degree of freedom from public health hazard continues and to monitor industry's compliance with the acidified food regulations. To identify needed regulatory action to prevent hazard to health and identify any problem areas which need emphasis in future programs.

6. FIELD OBLIGATIONS

Special situation firms are to be inspected according to the instructions in the Compliance Program (see program). State contract inspections are to be used to increase firm coverage under this program.

State inspections may be conducted in addition to the number of inspections assigned per District. Resources include coverage of food security issues (see IOM) at domestic processors.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Compliance Program.	02-11, 13-41, 45-46, 50

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

f. CHECK THE FOLLOWING ATTRIBUTES

Water Activity, pH, Salinity, Soluble Solids, Headspace Gas Analysis by GC, Heat Resistance Determination.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic Food Safety PACs 03803,B,C,D,E	Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To assure that domestic establishments involved in the production, storage and distribution of food products are in compliance with the FD&C Act and regulations promulgated under the Act.

Non-clinical Good Laboratory Practices inspections, which will be directed by CFSAN, with the appropriate District will also be covered by the resources planned in this program. Utilize available state contract inspections to augment district coverage under this program.

Also, resources needed for inspections of domestic firms for FDA E.U. certification will be taken from this program. Food security issues are to be covered during all inspections (See IOM).

5. PROGRAM JUSTIFICATION

Domestic products, as well as imported products in domestic commerce, must comply with the provisions of the FD&C Act and regulations promulgated under the Act. FDA is charged with the responsibility of assuring that foreign and domestic manufacturers produce these products under current Good Manufacturing Practices.

6. FIELD OBLIGATIONS

To conduct domestic and foreign inspections, focusing on high-risk firms with additional program resources to provide coverage consistent with priorities and objectives of the compliance program. Districts with state contract food inspections are to utilize them in program coverage of high-risk and non-high-risk firms. Resources provided for sample collections and analyses are projections based on recent data, and not absolute work plan obligations.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All Food Products (except Industry Code 12, 16)	All human food codes (use appropriate product codes)

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

f. CHECK THE FOLLOWING ATTRIBUTES

Filth, Decomposition and Microbiological Contamination (See Compliance Program)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - General PACs 03819,A,B,C	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To examine imported foods to determine if they are in compliance with the requirements of the FD&C Act and the regulations promulgated under this Act. To prevent the entry into the United States of imported foods that are found to be out of compliance, and to pursue appropriate regulatory remedies, including compliance actions as well as proactive strategies, (e.g., DWPE, other broad-based actions) to ensure that future entries of products are in compliance.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C Act and the regulations/action level guidelines, concerning microbiological contamination and filth related to health hazards and disease vectors. FDA must assure that such products found to be adulterated or misbranded are removed from the marketplace. Articles offered for import are subject to refusal of admission into the U.S., if they appear to contain a poisonous and deleterious substance, which may render them injurious to health, or are not in compliance with the FD&C Act, PHS Act, and regulations promulgated there under.

6. FIELD OBLIGATIONS

To conduct activities directed by CFSAN, identified through compliance programs, assignments, and import alerts and bulletins. To conduct import field examinations of products most likely to be out of compliance. To collect samples for determination of microbiological contamination, filth, disease vector, or decomposition.

Districts should emphasize priority products from CFSAN's Import Risk-Based Priorities List posted on the intranet and deemphasize coverage of products that are not consistent with priorities noted in the list.

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)
All Food Products	All applicable food codes except Industry Code 12, 16, 40, 41

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

f. CHECK THE FOLLOWING ATTRIBUTES

Microbiological Contamination, Filth, and Decomposition (See Compliance Program)

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish and Fishery Products Inspection Program PACs 03842,B,C,D,H	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To ensure that domestic establishments involved in the production, storage and distribution of fish and fishery products are in compliance with the Fish and Fishery Products (Seafood) HACCP Regulation as well as the FD&C Act and other regulations promulgated under the Act.

Inspections and analytical resources have been planned separately for outbreak and emergency response (03R839).

5. PROGRAM JUSTIFICATION

FDA is responsible for assuring that manufacturers produce these products under the current Good Manufacturing Practices, the Seafood HACCP Regulation, and the FD&C Act.

6. FIELD OBLIGATIONS

HACCP verification samples are not to be routinely collected.
Collection of environmental samples may be conducted at Ready-To-Eat (RTE) firms. CFSAN will issue separate instructions for collecting environmental samples.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Domestic Fish and Fishery Products	16

e. EXAM TYPE [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [X] OTHERS ***(PSP, ASP, Standards, Economic Deception, Labeling)***

f. CHECK THE FOLLOWING ATTRIBUTES

Refer to the Fish & Fishery Products Hazards & Controls Guidance Manual (most recent edition) for hazards associated with each specific seafood product.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Import Seafood Program PACs 03844,B,C,D,H	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To ensure a safe and wholesome imported seafood supply in the U. S., by enforcing importer compliance with the seafood HACCP regulation, and to direct coverage of imported seafood products, in order to determine their compliance with the FD&C Act and regulations promulgated under the Act.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the FD&C Act and its regulations. The Agency approach incorporates both sample collection/analysis and HACCP review by investigators, specially trained in HACCP, of importers' records for safety. The HACCP review is conducted to ensure that each importer has and is using verification procedures for ensuring that the seafood they offer for import was processed in accordance with the HACCP Regulation.

6. FIELD OBLIGATIONS

The field will continue to collect samples from import lots. It is important that the field base their sampling on the priorities as listed in the current compliance program. Equally important is that products be analyzed for the health hazard as identified in the HACCP Guide. For example, raw shrimp should be analyzed for undeclared sulfites, not for micro. Note: Raw seafood is to be analyzed for MICRO only if it is known that the particular lot of seafood is to be consumed raw.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	16

e. EXAM TYPE [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [X] OTHERS ***(PSP, ASP, Standards, Labeling)***

f. CHECK THE FOLLOWING ATTRIBUTES

Refer to the Fish & Fishery Products Hazards & Controls Guidance Manual (most recent edition) for hazards associated with each specific seafood product.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program PACs 03847,H	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To ensure that domestic and imported juice processing establishments are in compliance with the Juice HACCP Regulations as well as the FD&C Act and other regulations promulgated under the Act.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

The Juice HACCP regulation was adopted to ensure safe and sanitary processing of fruit and vegetable juices after reports of many outbreaks of foodborne illnesses, some of which directly affected children.

FDA is responsible for assuring that juice processing firms establish and implement the principles of HACCP. HACCP plans must include a minimum five-log pathogen reduction process control (or performance standard) for juices that are not thermally processed concentrates or that are not shelf-stable according to the regulation. The collection of verification samples will be conducted to help validate the firm's HACCP plans.

6. FIELD OBLIGATIONS

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Juice Products	20-22, 24, 25

e. EXAM TYPE [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[X] MICROANALYTICAL [X] OTHERS ***(Importer Verification of HACCP)***

f. CHECK THE FOLLOWING ATTRIBUTES

Refer to Compliance Program

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program

1. PROGRAM/ASSIGNMENT TITLE Environmental Sampling PAC 03F830	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

Inspectional approach for inspecting certain high risk food manufacturers will include the collection of environmental samples from areas in the plant where bacteria may be surviving and able to grow to high numbers under certain conditions.

High risk firms will be targeted for environmental sampling as identified by CFSAN and the instructions provided to the field through special assignments developed in coordination with ORA.

5. PROGRAM JUSTIFICATION

The purpose for environmental sampling is to determine whether harmful bacteria are present in the food processing environment in high risk food plants and thus present a risk of product contamination.

6. FIELD OBLIGATIONS

The field will be requested to conduct inspections and perform environmental sampling in firms identified by CFSAN through special assignments coordinated with ORA.

The inspections will be conducted by a team which will include an investigator and a microbiologist, if possible.

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)
To be specified in assignments	To be provided in assignments

e. EXAM TYPE

[ ] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

To be specified in assignments.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Refer to assignments and to DDFI Food Bulletins #30 and #32 for equipment and special instructions.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 03R816	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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
Outbreak and Emergency Response PACs 03R839, 04R839	Foodborne Biological Hazards - 03 Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

Conduct follow-up investigations, inspections, sample collections, and analyses related to outbreak and illness attributed to microbiological contamination of food products.

Follow-Up to Reportable Foods Registry reports and Food Defense Assignments are also planned under this category.

5. PROGRAM JUSTIFICATION

Each year the field expends increasing amounts of resources to follow-up on reports of outbreaks and illnesses linked to contaminated food products. Resources are set aside in the work plan specifically to conduct emergency operations associated with these investigations.

6. FIELD OBLIGATIONS

Based on directives issued by CFSAN and ORA, Districts will be requested to conduct investigations and collect documents and samples needed to determine whether a link exists between a reported illness or outbreak and a specific product or firm.

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)
To be specified in assignments.	To be specified in assignments.

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

To be specified in assignments.

1. PROGRAM/ASSIGNMENT TITLE Food Defense PAC 03R845	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03

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

4. OBJECTIVES

To maintain food defense preparedness by means of joint CFSAN/ORA field assignments, FDA collection and analysis of proficiency samples for the Food Emergency Response Network, providing resources for general laboratory preparedness activities including instrument, reagent, and standards maintenance, and related activities. Maintain and expand food defense alertness to the food industry.

Resources for Food Defense are planned under PAC 03F813 (Responsive Investigative/Laboratory Operations).

5. PROGRAM JUSTIFICATION

A secure food supply is considered part of the nation's infrastructure. FDA, along with other federal agencies, is responsible for responding to threats to the security of the food supply. The resources and activities planned under this program will help the Agency maintain a necessary state of readiness to respond to threats and activities planned for periods of heightened alert, as well as initiate and/or maintain food defense alertness to expanding industry groups.

6. FIELD OBLIGATIONS

Actual emergency and code-red alert status activities, when needed, will be directed jointly by CFSAN and ORA, and the Field will be instructed on planned work that will be halted. Food Defense Assignments, cleared by CFSAN and ORA, are to be carried out expeditiously.

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)
All Food Products	All food industry/ product codes.

e. EXAM TYPE

[X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [X] ENGINEERING

[X] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

To be directed by assignment and protocols jointly developed by CFSAN and ORA.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Industrial Chemicals in Domestic and Imported Foods PACs 04004A,D	Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To sample and analyze domestic and imported foods for pesticide residues to determine compliance with EPA residue for imports and Warning Letters for domestic growers.

There is an ongoing emphasis on dioxins to obtain comprehensive data of background levels of dioxin in a variety of foods. This information will help the Agency determine ways to reduce exposure to dioxin.

5. PROGRAM JUSTIFICATION

The food supply requires monitoring for both pesticides and industrial chemicals to protect the public health. The residue data obtained are also used to estimate dietary exposure for risk assessments performed by the Agency and EPA as well as by other national and international organizations.

6. FIELD OBLIGATIONS

Emphasis on pesticide/commodity combinations with high exposure residue potential, especially foods of dietary significance & foods consumed in large amounts by infants and young children. See compliance program for detailed commodity emphasis. CFSAN plans on issuing a sample collection schedule at the beginning of each fiscal year focusing on violations and problem areas detected in recent years by FDA monitoring available foreign pesticide usage data and data provided by USDA's Pesticide Data Program. Dioxin collections will be handled by bi-annual collection schedules issued by CFSAN. Dioxin investigation assignments and follow-up sampling may be used by CFSAN under this program when unusually high dioxin levels are found.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
	02-41, 45-47, 50, 52, 54

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

f. CHECK THE FOLLOWING ATTRIBUTES

Pesticides and industrial chemicals as directed by compliance program.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See compliance program, PAM, IOM, etc.

1. PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood PAC 04018	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To sample and analyze selected imported and domestic aquaculture seafood products. To determine the presence of unapproved chemical compounds such as drugs or antifungals and to initiate regulatory actions against lots which contain unapproved chemical compounds.

5. PROGRAM JUSTIFICATION

Worldwide trends are toward increased dependence upon cultured fish and shellfish produced under environmentally controlled conditions. Many of the countries producing much of the aquaculturally grown species allow the usage of drugs which are illegal in the United States. International conditions, as such, mandate the monitoring of aquaculture products for illegal drug residues. In addition, the use of drugs on a national scope in aquaculture has been reported. Samples collected are intended to assess the current situation regarding drug residues in domestic and imported seafood products and to initiate regulatory action when warranted.

6. FIELD OBLIGATIONS

Districts will collect and analyze domestic and import samples of aquaculture seafood products specified in the program's FY 15 Collection Schedule. This schedule may be updated throughout the fiscal year if warranted by new trends in regulatory findings and/or as additional validated methods are ready to implement. As a budget relief, two agent analyses should be run per sample for all products except crab, provided the second agent is one of interest for that product. Individual subsample analyses will only be required for crab and shrimp samples being analyzed for Chloramphenicol and Nitrofurans. All of the remaining samples will be a composite of 12 sub-samples. Refer to the FY 15 Collection Schedule for additional instruction.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Seafood Products	16

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

Unapproved drugs per the Compliance Program and the Collection Schedule.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic) PACs 04019A,B,C	Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To determine the incidence and levels of lead, arsenic, cadmium, mercury and other toxic elements of significance and radionuclides in domestic and imported foods (including seafood). Also, to determine incidence and levels of lead and cadmium in food ware and to take regulatory action against any food or foodware found to contain levels of toxic elements or radionuclides of regulatory significance.

5. PROGRAM JUSTIFICATION

The continuing monitoring of domestic and imported foods (including seafood) for toxic elements and radionuclides as necessary to determine the occurrence of toxic elements and radionuclides in the U.S. food supply that may pose a health hazard and to take regulatory action to remove those products from human food channels. Also, this monitoring will provide additional data on background levels of toxic elements and radionuclides in foods that will assist in identifying unusual levels that may be of health significance for follow up regulatory action.

6. FIELD OBLIGATIONS

Foods that may be significant sources of lead in children are candy, chocolate/cocoa, and seafood. These products are to be sampled and analyzed for the presence of toxic elements in accordance with instructions in the "Toxic Element" Program and assignments (to be issued). CFSAN will issue collection schedules and direct other FY 15 food work. Specific foods collected near domestic nuclear power plants are to be analyzed for radionuclides. Foods imported from countries potentially affected by radioactive contamination will be sampled and analyzed for radionuclides. The Program should be maintained to keep expertise and proficiency in this area. Surveillance activities will be reported under, and credited to the Program PAC.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All human food products. Ceramic food ware.	All food codes except 53.

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [X] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

Lead, cadmium, mercury and other toxic elements as directed. Domestic - tritium, 90 Sr & gamma ray emitters; IMPORTS; 134 Cs, 137 Cs, 90 Sr

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Radiochemical analysis capability. (Available only at WEAC). Graphite furnace atomic absorption with Zeeman background correction.

1. PROGRAM/ASSIGNMENT TITLE Total Diet Study PAC 04839	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04

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

4. OBJECTIVES

To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/gender groups through analyses of table-ready foods. In addition, to observe differences or trends in the intake of these chemicals and to investigate unusual findings. To monitor radionuclide levels in foods. Selected nutrients are analyzed under the Selected Nutrients in Food Survey, PAC 21839.

5. PROGRAM JUSTIFICATION

The continuing study has provided valuable information on dietary intakes of residues and nutrients and has often been used to gauge intakes in ready-to-eat foods. EPA relies on the data for hazard assessment in special review and other proceedings. Portions of the Total Diet samples are used for other analysis (e.g., radionuclides, selected nutrients, pesticides, industrial chemicals, and toxic elements). Additionally, selected Total Diet Study foods are analyzed for dioxins under the pesticide program by ARL.

6. FIELD OBLIGATIONS

The collection and analysis of four market baskets each consisting of three separate samplings of approximately 280 food items are to be collected from three locales in the region over a five week period. KAN-DO lab will analyze Total Diet samples for pesticides, industrial chemicals, toxic elements, and selected nutrients. WEAC will analyze all foods from two market baskets for radionuclides.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Various Human Foods	All Human Food Codes

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [X] OTHERS ***(SPECIFY)*** ***Moisture Content***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 04R816	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04

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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 04R838	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04

3. PROGRAM TYPE ☐ 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 04R838 or OCI PAC 04R831. Conduct operation 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 04R838; Petition Validation, Methods Development or Forensic Evaluation.

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

b. INSPECTION TYPE ☐ COMPREHENSIVE ☐ ABBREVIATED ☐ DIRECTED

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

e. EXAM TYPE ☐ CHEMICAL ☐ MICROBIOLOGICAL ☐ PHYSICAL ☐ ENGINEERING ☐ MICROANALYTICAL ☐ OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

Unapproved drugs per the Compliance Program

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods PAC 07001	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07

3. PROGRAM TYPE [x] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [ ] ASSIGNMENT

4. OBJECTIVES

To collect and analyze domestic and import samples of food products to determine the occurrence and levels of aflatoxins, fumonisins, deoxynivalenol (DON), ochratoxin, and patulin. To remove from interstate commerce, or detain upon entry, those foods that contain aflatoxins and patulin at levels judged to be of regulatory significance. Regulatory action for fumonisin, DON, and ochratoxin will be considered on a case by case basis until formal enforcement levels are established. Data from current monitoring will be used to establish enforcement levels.

5. PROGRAM JUSTIFICATION

Mycotoxins are metabolic products of specific molds commonly found on foods, some (the aflatoxins) of which are hepatocarcinogens in a number of animal species, and until proven otherwise must be assumed to be carcinogenic. The FDA, in conjunction with other agencies and the food industries, has devised and will continue to improve on practical programs for ensuring minimum exposure of the population to mycotoxins without jeopardizing the food supply.

Descriptions of the following specific mycotoxins included in this program are located in the Mycotoxins in Domestic and Imported Foods compliance program (C.P. 7307.001).

1. Aflatoxins
2. Patulin
3. Deoxynivalenol (DON)
4. Fumonisins (Fumonisin FB1, FB2 and FB3)
5. Ochratoxin A

6. FIELD OBLIGATIONS

The field will conduct follow-up investigations, that may be requested by CFSAN, and collect and analyze samples of domestic and imported products as directed by the compliance program.

Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
See Attachment "A" C.P. 7307.001 for list of Products.	See Attachment "A" C.P. 7307.001 for list of Product Codes.

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program (C.P.) 7307.001

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 07R816	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07

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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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 Imported Foods - Food and Color Additives PACs 09006A,B	2. PPS PROJECT NAME/NUMBER Food and Color Additives - 09

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

4. OBJECTIVES

To direct examination of imported food products to determine their compliance with the Federal Food, Drug and Cosmetic Act (the Act) and regulations with respect to food and color additives, and to detain those entries found to be in violation of the Act.

5. PROGRAM JUSTIFICATION

Imported products must comply with the provisions of the Act and implementing regulations for food and color additives. The compliance program directs sample collections and label review of imported foods for unapproved or undeclared food additives, and for non-permitted or undeclared color additives.

6. FIELD OBLIGATIONS

Districts should conduct label reviews, collect and analyze imported foods for potential food and color additive violations and take appropriate regulatory actions when violations are found.

Import Field Exams: See remarks section on the ORA work plan sheet form 2621a under PAC 09F810.

Surveillance activities planned under this program may be pre-empted by enforcement initiative agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the Program PAC, unless otherwise directed.

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All human foods	All food codes (Industry 16 and 13)

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

f. CHECK THE FOLLOWING ATTRIBUTES

Unapproved or undeclared food additives, and non-permitted or undeclared color additives.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program PAC 18002	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18

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

4. OBJECTIVES

To provide guidance, support, and assistance to the federal, state, tribal, and local agencies that have regulatory control over the retail segment of the food industry with the goal of reducing the occurrence of risk factors implicated in foodborne illnesses. This program will address the promotion of the Voluntary National Retail Food Regulatory Program Standards, National Food Safety needs at retail level, CFSAN directed National Food Security Projects and will continue to provide technical assistance and the standardization of state and other federal officials.

5. PROGRAM JUSTIFICATION

There are more than 3,000 federal, tribal, state, and local regulatory food control agencies which together represent the regulatory resource through which federal food policy is implemented at the retail level. This segment totals more than one million commercial and institutional food establishments, locations, and operations.

Each year the Centers for Disease Control and Prevention's Annual Report shows that a major percentage of foodborne outbreaks, where mishandling of food is implicated, occur in retail food establishments. Therefore, an important part of FDA's mission is to provide assistance to federal, tribal, state, and local regulatory agencies with control over this segment of the food industry.

6. FIELD OBLIGATIONS

Provide technical assistance to federal, tribal, state, and local regulatory food agencies. Provide technical assistance to CFSAN and Headquarters in the preparation of position papers. Conduct periodic baseline and follow-up studies to measure trends on the occurrence of foodborne illness risk factors nationwide in selected food service and retail food establishment. Promote the adoption of retail program standards. Provide training on the provisions of FDA Food Code, HACCP, Facility Plan Review, the Egg Rule and other topics as may be needed by regulatory personnel. Provide support to state and local agencies during emergency situations and special events impacting retail food safety.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Human Foods	Inspections: 51 NY

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

f. CHECK THE FOLLOWING ATTRIBUTES

A major goal in this program is the reduction in the occurrence of CDC identified risk factors associated with foodborne illness in retail establishments and the national promotion of Food Code Interventions.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Work assigned in this program is to be conducted by persons who are Center standardized in the application of the relevant retail establishments Food Code provisions and related program documents.

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program PAC 18003	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18

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

4. OBJECTIVES

To implement FDA's responsibility under the Public Health Service Act, 42 USC 214; 42 USC 243; and 42 USC 246a and the Memorandum of Understanding (MOU) between FDA and the National Conference on Interstate Milk Shipments. This responsibility includes all Grade "A" dairy products processing plants, and all dairy farms supplying raw milk to these plants.

5. PROGRAM JUSTIFICATION

This program will promote a uniform, safe, and wholesome supply of Grade "A" Milk and Milk products throughout the United States. This program enables FDA to exert influence on the application of Uniform Sanitary Standards for Grade "A" Milk produced in the United States. This program provides a mechanism for reciprocity between states, thereby eliminating the need for costly duplicative inspection across jurisdictional lines. Without this program, FDA would have direct responsibility for duplicative inspection across jurisdictional lines. Without this program, FDA would have direct responsibility for inspecting Grade "A" Milk products moving in Interstate commerce. This program also provides a mechanism for promoting greater sanitation uniformity of all dairy products. Due to the increasing consumer interest in chemical contaminants in the food supply, the perception and the potential for animal drug residues in milk and dairy products has become an important issue. This program will place additional emphasis toward continuous vigilance in maintaining a safe wholesome milk supply that is free of illegal animal drug residues.

6. FIELD OBLIGATIONS

To promote the adoption, implementation and enforcement of the uniform technical guidelines, administrative procedures and regulatory standards provided in the Pasteurized Milk Ordinance (PMO) and related documents through provision of technical assistance and consultation; conduct check ratings of IMS listed shippers and audits of listed single service facilities; participation in regional seminars, state workshops and other training courses and evaluate state programs to measure effectiveness in maintaining adequate level of conformity with the PMO and related documents.

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)
Grade "A" Milk and Milk Products, (Cheese, Butter, Dry Milk and Frozen Dessert - when produced in IMS Plants)	09, 12, 13,14

e. EXAM TYPE [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

Listeria, Yersinia, Salmonella, Coliform and animal drug residues in milk and milk products.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Work assigned in this program is to be conducted by persons who are standardized in the use of the Grade "A" Pasteurized Milk ordinance and related documents and in the case of non-IMS products, persons trained to conduct GMP inspections.

1. PROGRAM/ASSIGNMENT TITLE Molluscan Shellfish Evaluation PAC 18004	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18

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

4. OBJECTIVES

Evaluate the shellfish sanitation program of ISSC participating states and the 5 nations with whom the Agency has MOU in place with regard to the sanitary control of shellfish intended for interstate and overseas commerce under the cooperative arrangements for the federal-state National Shellfish Sanitation Program (NSSP). Provide standardization, technical assistance, training evaluation of state and international shellfish control programs.

5. PROGRAM JUSTIFICATION

Shellfish, by virtue of their habitat, physiological characteristics, and the manner in which they are consumed, require specialized comprehensive sanitary control measures to ensure the safety of human consumption. The management of the program requires a cooperative federal-state effort as defined in the National Shellfish Sanitation Program (NSSP). Consumption of raw or partially cooked shellfish presents a high risk factor to a portion of the population, and requires specialized health control measures to oversee. FDA is committed to improving the safety of molluscan shellfish through the NSSP, a program of newly developed safety controls. These initiatives are the direct result of Congressional and public comments directed toward the establishment of a "level playing field" for both domestic and international producers of molluscan shellfish. These program improvements are intended to provide improved shellfish safety through improved program criteria, procedures, and technical support under the NSSP. FDA is committed to improved safety of shellfish through program enhancement activities. FDA has committed support to the NSSP both administratively and technically through an MOU with ISSC.

6. FIELD OBLIGATIONS

Provide technical assistance and training to states and foreign programs in the prevention of shellfish-borne illness and enforcement of appropriate public health controls. Oversee national standardization program for inspecting shellfish processing plants and evaluation of state and foreign shellfish growing areas. Participate in the evaluation of national shellfish control programs in countries applying to import molluscan shellfish into the U.S.

Program time has been allocated for each Regional Shellfish Specialist to hold one regional workshop. Regional workshops provide the opportunity for the specialists to exchange information and provide technical assistance and guidance to their state.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Fresh and fresh frozen molluscan shellfish	52B, 16E

e. EXAM TYPE

[ ] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Work assigned in this program is to be conducted by persons who are Center Standardized in the application of the NSSP MO.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Interstate Travel Program - Conveyances and Support Facilities PAC 18029	Technical Assistance: Food and Cosmetics - 18

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

4. OBJECTIVES

To inspect and investigate passenger conveyances to certify and approve sanitary systems on conveyances and approve their watering points, their support facilities and their food sources based on the Public Health Service Act, the Food, Drug and Cosmetic Act, regulations, program guidance, Food Code, and in cooperation with the regulated industry and cooperating third party organizations. Also, to identify risk factors related to environmental conditions or management practices that may lead to foodborne illnesses, waterborne illnesses, and the transmission of communicable diseases. The program includes administrative compliance and regulatory actions as appropriate to ensure conformance with the public health principles embodied in the Acts and their regulations. The goals of the program are to cooperate with the regulated industries, trade associations, and others to promote voluntary compliance and to coordinate activities with FAA, CDC, DOT, EPA, Department of Homeland Security (USCG, TSA) and other domestic and foreign government health officials to ensure the protection of the traveling public, and crew member of conveyances under construction and in operation and at related watering points, caterers, commissaries and servicing area on conveyances.

5. PROGRAM JUSTIFICATION

This program directs agency efforts in fulfilling Public Health Service Act responsibilities delegated to the Commissioner of Food and Drugs [21 CFR 5.10(a)(2) and (4)]. Sections 311, 361, and 368 of the Act address federal-state cooperation, the controls of communicable disease, and penalties of noncompliance. The agency also bases the Interstate Travel Program, in part, on provisions of the Federal Food, Drug and Cosmetic Act and related regulations. The United States must comply with the updated International Health Regulations (IHR 2005) as of July 17, 2007 that protect the health of people around the world. As one of the competent authorities, FDA as an agency is responsible for monitoring baggage, cargos, containers, conveyances, and goods so that they are maintained free from sources of infection or contamination including vectors and reservoirs. There are specific requirements for ships and aircraft and delivery of food and water to affected conveyances.

6. FIELD OBLIGATIONS

The field is to perform the operations assigned in the ORA Workplan, conduct comprehensive inspections of food operations and support facilities, initiate administrative or regulatory actions as needed to ensure compliance, support the maintenance of official classification list of FDA's approved support facilities, establish and maintain technical expertise in support of the National Interstate Travel Program. Also, to cooperate with other agencies, organizations, and industry toward achieving program objectives and to maintain effective communication between CFSAN and ORA Headquarters regarding significant program issues and 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)
Human food, water, and waste; conveyance environmental conditions	Inspections/Investigations: Industry 51, All food codes including water 29W (Y30).

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

f. CHECK THE FOLLOWING ATTRIBUTES

Food & water surv. & contamination, mostly Micro analysis. Chem analysis; heavy metals in water "FOR CAUSE" basis e.g. lead, cadmium, copper in portable water systems at new support facilities & conveyances after construction or major renovation.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Catering point inspections will be conducted by persons standardized in the use of FDA's Food Code and procedures established for the Interstate Travel Program.

1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import PAC 21002	2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21

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

4. OBJECTIVES

To obtain information regarding the manufacturing processes and quality assurance programs employed by domestic and foreign manufacturers of medical foods.

To collect and analyze domestic and imported medical foods to assure that they are properly formulated and labeled and free from microbial contaminants.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

Medical foods are formulated to be consumed or administered enterally under the supervision of a physician and are intended for specific dietary management of specific disease or condition with distinctive nutritional requirements, based on recognized scientific principles established by medical evaluation. The products are often used for life support and are subject to compositional errors and microbiological contamination. In addition to four infant deaths in 1986, there have been a number of medical food recalls associated with compositional deviations and under processing.

Foreign inspections of medical foods firms are also planned in this program. Investigational time to determine the admissibility of imported lots of medical foods are planned under PAC 03F810. Resources are planned in this program for collection and analysis of samples collected from these imported lots.

6. FIELD OBLIGATIONS

Districts will conduct inspections and collect samples at compliance program directed firms. The Atlanta Center for Nutrient Analysis (ACNA) will perform all nutrient analyses. Southeast Regional Laboratory (SRL), Microbiology Branch will perform microbiological analyses. Food security issues are to be covered during all inspections. CFSAN/OC/DFPG will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.

Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.

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)
Medical Foods	41G[][] Use appropriate product identification number

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

f. CHECK THE FOLLOWING ATTRIBUTES

Nutrient declarations. Micro exam for *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus, Bacillus cereus, Escherichia coli* and Aerobic Plate Count (APC).

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See compliance program.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Domestic and Import NLEA Nutrient Sample/Analysis and General Food Labeling Program PAC 21005	Food Composition Standard Labeling and Economics-21

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

4. OBJECTIVES

To determine the compliance of domestic and imported food product labels with regulations promulgated under the Federal Food Drug and Cosmetic Act; including the Nutrition Labeling and Education Act (NLEA) and the Food Allergen Labeling and Consumer Protection Act (FALCPA). This objective is to be accomplished by reviewing labels of domestic and imported food products and by collecting compliance and surveillance samples for label review and analyses to assure: (1) that the nutrition label is in compliance with the regulations in Title 21 Code of Federal Regulations 101.9; (2) that labeled nutrient content and health claims are made in a manner that complies with applicable regulations; (3) that the label complies with FALCPA; and (4) that all labels include all required label elements.

5. PROGRAM JUSTIFICATION

All domestic and imported foods must disclose the presence of any ingredient that is or contains protein derived from one of the 8 major food allergens so that individuals with allergies will be able to easily identify the presence of substances that they must avoid. In addition, most food products in interstate commerce must list trans fat in the nutrition label. The FD&C Act also mandates other required label information and valid nutrient content and health claims to provide useful information that assists consumers in selecting foods that promote good health and weight management. Continuous monitoring of food labels is necessary to ensure that consumers are provided with truthful information that they need to select foods that are appropriate for their specific dietary needs and health maintenance.

6. FIELD OBLIGATIONS

Districts will review import and domestic product labels for compliance with FALCPA, NLEA, and other mandatory label requirements by conducting field exams. Districts will collect labels that do not appear to comply with FDA's food labeling laws and regulations for review by the district's compliance branch. Physical samples will be collected for lab analyses as follows: (1) compliance samples that do not appear to qualify for labeled health or nutrient content claims (see C.P. Area of Emphasis #5); and (2) surveillance samples collected for general nutrient analyses.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

b. INSPECTION TYPE

[ ] COMPREHENSIVE [ ] ABBREVIATED [ ] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All food products (except vitamins/minerals)	02-41

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [X] OTHERS ***(Label Reviews)***

f. CHECK THE FOLLOWING ATTRIBUTES

Label review and nutrient analyses as appropriate, focus should be given to allergen and trans fat labeling.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Samples for nutrient analyses to be sent to SRL/ACNA. See compliance program for details.

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import PAC 21006	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21

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

4. OBJECTIVES

To ensure compliance with the Infant Formula Act and regulations promulgated there under by inspection of domestic and foreign manufacturers of infant formula and collection and analysis of infant formula samples.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

Serious infant health problems arising from inadequate nutrient content of infant formula prompted Congress to pass the Infant Formula Act of 1980. This inspection and analysis program assures adherence to the provisions of the Act. Violations and recalls over the past several years (and the continuing keen interest by Congress, as evidenced in part by the 1986 amendments to the Act) indicate the need for continued compliance monitoring. The large number of applications for approval of the formulas exempt from the Act requires expansion of oversight activities into this area.

Additional resources have been budgeted to allow annual inspection and sample collection from infant formula firms. Inspections of foreign infant formula are planned in this program. Investigation time to determine admissibility of import lots of infant formula from foreign manufacturers are planned under PAC 03F810. Resources are planned in this program for collection and analysis of samples collected from these imported lots.

6. FIELD OBLIGATIONS

Districts will conduct inspections and collect samples. Atlanta Center for Nutrient Analysis (ACNA) will perform nutrient analyses and label reviews. Southeast Regional Laboratory, Microbiology Branch will perform microbiological analyses. CFSAN/OC/DFPG will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year. Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed. Food security issues (see IOM) are to be covered during all inspections.

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)
Infant Formula	40C

e. EXAM TYPE

[X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [X] OTHERS ***(Label Reviews)***

f. CHECK THE FOLLOWING ATTRIBUTES

Nutrients as required by the Act. Micro exam for *Listeria monocytogenes, Salmonella, Staphylococcus aureus, Bacillus cereus, Escherichia coli* , Aerobic Plate Count (APC).

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import PAC 21008	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21

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

4. OBJECTIVES

To ensure compliance with the Dietary Supplement Health and Education Act and regulations promulgated there under by inspections of dietary supplement manufacturers both domestic and foreign. Dietary supplements of both domestic and import origin will be collected and analyzed for nutrient content vs. label declarations. All non-exempt dietary supplements must comply with the Supplement Facts Labeling requirements of the Act. Compliance with these requirements will be determined by domestic and import field exams and documentary sample collections.

Resources for foreign inspections are planned under PAC 03R233.

5. PROGRAM JUSTIFICATION

Dietary supplements are a special class of products consisting of such dietary ingredients as vitamins, minerals, amino acids, glandulars, herbs, and other botanicals. These products are subject to specific safety and labeling requirements. This program provides instructions to FDA district offices regarding inspections, import investigations, sample collections and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994.

Investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on labels and supplements being marketed with claims to treat diseases.

6. FIELD OBLIGATIONS

Field obligations include inspections, domestic and import investigations, sample collections and analyses of dietary ingredients in dietary supplements.

Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC, unless otherwise directed.

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)
Dietary supplements	54

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

f. CHECK THE FOLLOWING ATTRIBUTES

Analyze selected nutrients and compare with levels declared on product label.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See compliance program.

1. PROGRAM/ASSIGNMENT TITLE Selected Nutrients in Food Survey -Total Diet PAC 21839	2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21

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

4. OBJECTIVES

To monitor the mineral nutrients in foods from typical American diets. To identify mineral and vitamin nutrient intake trends. To provide baseline data on mineral nutrient and vitamin intake for intervention studies and other nutrition studies. To function as an important component in the National Nutrition Monitoring System.

5. PROGRAM JUSTIFICATION

Congress has given the Secretaries of DHHS and USDA a mandate to set up a National Nutrition Monitoring System (NNMS). The current Selected Nutrients in Food Survey is an important segment of the NNMS that provides the only continuous analysis of nutrient minerals in the American food supply. This permits identification of trends in nutrient intake over time as well as information on the general nutritional status of the population at any point in time.

6. FIELD OBLIGATIONS

KAN-DO will analyze Total Diet Study foods from all market baskets for the nutrients identified below in 7F, and all TDS foods from one market basket annually for moisture.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

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

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

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Various foods as required by the Total Diet Studies Program	37, 40

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

f. CHECK THE FOLLOWING ATTRIBUTES

Manganese, iodine, calcium, copper, iron, magnesium, phosphorus, potassium, sodium and water.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 21R816	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21

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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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 Cosmetics: Domestic and Import PAC 29001	2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29

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

4. OBJECTIVES

To determine by inspection, sample collection, and label exam if domestic cosmetic manufacturing or repacking establishments, and cosmetics offered for importation, comply with regulations enforced by the Food and Drug Administration.

To initiate corrective action when violations of the FD & C Act are identified.

5. PROGRAM JUSTIFICATION

Both domestically manufactured and imported products must be: 1) safe under intended conditions of use, 2) properly labeled, and 3) not otherwise adulterated or misbranded under the provisions of the Act. Major safety concerns associated with cosmetics involve microbial contamination of eye-area products and the use of non-approved color additives. Many cosmetic violations also involve products which fail to comply with the labeling regulations of 21 CFR 701.

6. FIELD OBLIGATIONS

Districts will conduct inspections, perform import field exams, collect and analyze samples for non-permitted ingredients, conduct microbiological analyses and perform evaluations for labeling compliance. Food & Cosmetic security issues (see IOM 5.4.1.4.1) are to be covered during all inspections.

Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to the Program PAC unless otherwise directed.

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 Cosmetic Products	53

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

f. CHECK THE FOLLOWING ATTRIBUTES

Non-permitted ingredients (including color additives), microbiological/contaminants, labeling statement.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

See Compliance Program.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
RESOURCE SUMMARY
FY 2015

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	851.2	473.6	49.5	1374.3
3	FOODBORNE BIOLOGICAL HAZARDS	608.1	359.6	49.5	1017.2
4	PESTICIDES AND CHEMICAL CONTAMINANTS	103.7	69.3		173.0
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	15.2	7.2		22.4
9	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		7.8		7.8
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	75.5			75.5
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	36.7	21.6		58.3
29	COLOR AND COSMETICS TECHNOLOGY	12.0	8.1		20.1

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Foodborne Biological Hazards- 03

3. NO	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**608.1**	**359.6**	**49.5**	**1017 2**	
1	Foodborne Biological Hazards	03F810 *	183.6	350.7		534 2	03-2-7
2	Domestic High Risk Inspections	03F811 *	164.1			164 1	03-8
3	Domestic Non-High Risk Inspections	03F812 *	68.3			68 3	03-9
4	CFSAN Environmental Sampling Assignments	03F830 *	24.5			24 5	03-10
5	Foreign Foods Inspections	03R233 *			49.5	49 5	03-11
6	Responsive Investigative/Laboratory Operations	03F813 *	167.6	9.0		176.6	03-12-14
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Kristen Kamas 301-796-4391

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F810	[X] ORA [X] CENTER	534 2 [111 2]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW (Hours) (1)			EXPORTER CERTIFI-CATION ACTIVITIES (2)	IMPORTER INSPECTION (3)	IMPORT INVESTI-GATIONS HOURS	DOMESTIC SAMPLE COLL EMERG TREND PRODUCE	DOMESTIC SAMPLE COLL PILOT CHEESE 03F860 (4)	DOMESTIC SAMPLE COLL PILOT AVOCADO 03F860 (4)
	TOTAL FIELD	**96804**			**100**	**553**	**12350**	**375**	**240**	**240**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION					18 0	17 2		6 0	7 0	6 0
TOTAL HOURS		96804			1800	9512	12350	2250	1680	1440
CONVERSION FACTOR		1200			950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		80 67			1 89	10 01	13 00	2 37	1 77	1 52

7 REMARKS

NOTE: PAC 03F810 is for planning purposes only Accomplished work must be reported against the appropriate program or assignment PAC Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS

(1) - Import Entry Review Hours: Resources for these activities cover all Import Food Programs Includes time for International Mail Facility and Express Courier Review hours

(2) - Exporter certification column to be used for EU activities (dairy/gelatin assignments)

(3) - Inspections of Importers are to ascertain if the importer has complied with Seafood HACCP Regulations, not to perform filer inspections

(4) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), Raw Milk Cheese, Cucumber, Cilantro, Shell Eggs, and Tree Nuts, are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot CFSAN will issue a memo with instructions for sample collection/analyses Report time under PAC 03F860 - CFSAN Surveillance Sampling Program

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F810	[X] ORA [ ] CENTER	534 2 [57 5]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL PILOT SPROUTS 03F860 (1)	DOMESTIC SAMPLE COLL PILOT EGGS 03F860 (1)	DOMESTIC SAMPLE COLL PILOT TREE NUTS 03F860 (1)	DOMESTIC SAMPLE COLL PILOT CILANTRO 03F860 (1)	DOMESTIC SAMPLE COLL PILOT CUCUMBER 03F860 (1)	IMPORT SAMPLE COLL PILOT CHEESE 03F860 (1)	IMPORT SAMPLE COLL PILOT AVOCADO 03F860 (1)	IMPORT SAMPLE COLL PILOT CILANTRO 03F860 (1)	IMPORT SAMPLE COLL PILOT CUCUMBER 03F860 (1)
	TOTAL FIELD	800	3000	1600	640	640	560	560	960	960
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		6 0	8 0	6 0	6 0	6 0	2 0	3 0	3 0	3 0
TOTAL HOURS		4800	24000	9600	3840	3840	1120	1680	2880	2880
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		5 05	25 26	10 11	4 04	4 04	1 18	1 77	3 03	3 03

7 REMARKS

(1) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), Raw Milk Cheese, Cucumber, Cilantro, Shell Eggs, and Tree Nuts, are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot CFSAN will issue a memo with instructions for sample collection/analyses Report time under PAC 03F860 - CFSAN Surveillance Sampling Program

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F810	[X] ORA [ ] CENTER	534 2 [114 6]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY		IMPORT SAMPLE COLL EMERG TREND PRODUCE	IMPORT SAMPLE COLL SEAFOOD 03844	IMPORT SAMPLE COLL IMPORT FOODS 03819	SCREENING STATION SAMPLE COLLECTION (1)	FIELD EXAMS (2)	IMPORT FIELD EXAMS (3)	DOMESTIC SAMPLE ANALYSIS FILTH CHEM	DOMESTIC SAMPLE ANALYSIS EMERG TREND PRODUCE MICRO
	TOTAL FIELD		**625**	**3300**	**3752**	**300**	**1520**	**156943**	**364**	**375**
	HEADQUARTERS		(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION			3 0	2 8	2 3	3 0	1 0	0 5	14 8	13 0
TOTAL HOURS			1875	9240	8630	900	1520	78472	5387	4875
CONVERSION FACTOR			950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs			1 97	9 73	9 08	0 95	1 60	82 60	4 57	4 13

7 REMARKS

(1) - Resources for Port Everglades Screening Station in FLA-DO Collections
(2) - LACF/AF Field Exams are to include pH and canned seam evaluation
(3) - New for FY15, Import Field Exams were allocated based on the number of import lines that PREDICT recommended to review; previously field exams were allocated based on the reviewed-line volume
Import Field Exam time can also be used for Histamine detection kit pilot
All routine Import Field Exam activities conducted during an exam, including reconciliation exams, label reviews, container integrity, source country and intentional adulteration exams are to be reported as a single Import Field Exam
Only in the event of a pre-determined "for cause" counterterrorism exam, or in the event counterterrorism suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc)

NOTE: Laboratory allocations were planned by ORS

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F810	[X] ORA [ ] CENTER	534 2 [99 1]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	SCREENING STATION SAMPLE ANALYSIS MICRO (Hours) (1)	DOMESTIC SAMPLE ANALYSIS PILOT CHEESE MICRO (2)	DOMESTIC SAMPLE ANALYSIS PILOT AVOCADO MICRO (2)	DOMESTIC SAMPLE ANALYSIS PILOT SPROUTS MICRO (2)	DOMESTIC SAMPLE ANALYSIS PILOT EGGS 03F860 (2)	DOMESTIC SAMPLE ANALYSIS PILOT TREE NUTS 03F860 (2)	DOMESTIC SAMPLE ANALYSIS PILOT CILANTRO 03F860 (2)	DOMESTIC SAMPLE ANALYSIS PILOT CUCUMBER 03F860 (2)	IMPORT SAMPLE ANALYSIS PILOT CUCUMBER 03F860 (2)
	TOTAL FIELD	**300**	**240**	**240**	**800**	**3000**	**1600**	**640**	**640**	**960**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		11 0	21 8	13 0	13 0	15 0	13 0	13 0	13 0	13 0
TOTAL HOURS		3300	5232	3120	10400	45000	20800	8320	8320	12480
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		2 80	4 43	2 64	8 81	38 14	17 63	7 05	7 05	10 58

7 REMARKS

(1) - Resources for Port Everglades Screening Station in FLA-DO Analyses

(2) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), Raw Milk Cheese, Cucumber, Cilantro, Shell Eggs, and Tree Nuts, are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot CFSAN will issue a memo with instructions for sample collection/analyses Report time under PAC 03F860 - CFSAN Surveillance Sampling Program

NOTE: Laboratory allocations were planned by ORS

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F810	[X] ORA [ ] CENTER	534 2 [83 3]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE ANALYSIS PILOT CHEESE MICRO (1)	IMPORT SAMPLE ANALYSIS PILOT AVOCADO MICRO (1)	IMPORT SAMPLE ANALYSIS PILOT CILANTRO MICRO (1)	IMPORT SAMPLE ANALYSIS SEAFOOD 03844 CHEM	IMPORT SAMPLE ANALYSIS SEAFOOD 03844 MICRO	IMPORT SAMPLE ANALYSIS FILTH/HIST CHEM (2)	IMPORT SAMPLE ANALYSIS EMERG TREND PRODUCE MICRO	IMPORT SAMPLE ANALYSIS IMPORT FOOD 03819 CHEM	IMPORT SAMPLE ANALYSIS IMPORT FOOD 03819 MICRO
	TOTAL FIELD	560	560	960	3000	300	1163	625	1014	3752
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		16 0	13 0	13 0	4 9	8 3	7 0	13 0	6 7	7 8
TOTAL HOURS		8960	7280	12480	14700	2490	8141	8125	6794	29266
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		7 59	6 17	10 58	12 46	2 11	6 90	6 89	5 76	24 80

7 REMARKS

NOTE: Laboratory allocations were planned by ORS

(1) - Collections and Sample Analyses of Avocados, Sprouts (Seeds, Spent Water, and Finished Product), Raw Milk Cheese, Cucumber, Cilantro, Shell Eggs, and Tree Nuts, are to establish baseline prevalence of selected pathogens for the microbiological surveillance sampling pilot CFSAN will issue a memo with instructions for sample collection/analyses Report time under PAC 03F860 - CFSAN Surveillance Sampling Program

(2) - Time can also be used for Histamine detection kit pilot

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F810	[X] ORA [ ] CENTER	534 2 [68 5]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	LEVEL II AUDITORS CERTI-FICATION (Hours) (1)	APPLIED TECH CENTER MICRO 03R816 (Hours)	METHODS VAL/DEV MICRO 03R816 (Hours)	PRIOR NOTICE REVIEW (Hours) (2)	OP CODE 92 PRIVATE LAB REVIEW IMPORT (Hours) (3)	BETTER PROCESSING SCHOOL TRAINING (Hours) (4)	CONTRACT MANAGE-MENT (Hours) 03R843 (5)		
	TOTAL FIELD	**1600**	**4720**	**7230**	**32400**	**11800**	**760**	**18050**		
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION										
TOTAL HOURS		1600	4720	7230	32400	11800	760	18050		
CONVERSION FACTOR		950	1180	1205	1200	1180	950	950		
TOTAL OPERATIONAL FTEs		1 68	4 00	6 00	27 00	10 00	0 80	19 00		

7 REMARKS

(1) - Level II Auditors Certification Time: These hours are to provide auditors the time to evaluate/train other investigators trying to maintain Level II Certification District allocation was based on the current on board staffing provided by DHRD

(2) - Resources in Headquarters are for review of prior notices at the Division of Food Defense Targeting (DFDT) formally known as the Prior Notice Center

(3) - Private Laboratory Review Time is planned under PAC 03R320 Accomplished work must be reported against the appropriate Private Lab PAC Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field

(4) - Resources are for the attendance at Better Processing Schools (BPS)

(5) - Time planned for Contract management includes resources to conduct audits Report Foods State Contract Inspection Audit time under operation 13 (Investigation Operations) PAC 03R843 NOTE: Non-operational FTE's, i e supervisors, should not report contract management time

NOTE: Laboratory allocations were planned by ORS

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Domestic High Risk Inspections	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F811	[X] ORA [ ] CENTER	164 1

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	FDA FSMA HIGH RISK INSPECTIONS (1) (2)			NON-FSMA EGG FARM INSPECTIONS (3)					
	TOTAL FIELD	**3474**			**400**					
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		40 6			37 2					
TOTAL HOURS		141044			14880					
CONVERSION FACTOR		950			950					
TOTAL OPERATIONAL FTEs		148 47			15 66					

7 REMARKS

NOTE: PAC 03F811 is for planning purposes only Accomplished work must be reported against the appropriate program or assignment PAC Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Domestic Non-High Risk Inspections	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F812	[X] ORA [ ] CENTER	68 3

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	FDA NON-HIGH RISK FSMA INSPECTIONS (1)								
	TOTAL FIELD	**2626**								
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		24 7								
TOTAL HOURS		64862								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		68 28								

7 REMARKS

NOTE: PAC 03F812 is for planning purposes only Accomplished work must be reported against the appropriate program or assignment PAC Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS

(b) (5), (b) (7)(E)
(b) (5), (b) (7)(E)

(b) (5), (b) (7)(E)

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
CFSAN Environmental Sampling Assignments	Foodborne Biological Hazards - 03

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
03F830	[X] ORA [X] CENTER	24 5

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	ENV SAMPLE EGG RULE INSP (Hours) (1)	ENV SAMPLE NTENSIFIED INSP (Hours) (2)	ENV SAMPLE MEXICAN CHEESE INSP (Hours) (3)	ENV LAB ANALYST MICRO (Hours)					
	TOTAL FIELD	**10000**	**5000**	**5000**	**4107**					
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION										
TOTAL HOURS		10000	5000	5000	4107					
CONVERSION FACTOR		950	950	950	1180					
TOTAL OPERATIONAL FTEs		10 53	5 26	5 26	3 48					

7 REMARKS

NOTE: PAC 03F830 is for planning purposes only Accomplished work must be reported against the appropriate program or assignment PAC Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS

CSO time to include inspections and sample collections Report hours utilized under the appropriate operation and PAC code

(1) - Estimated (b firms - Comprehensive Inspections for the Egg Rule Assignment

(2) - Estimated (firms

(3) - Estimated (firms

Hours based on estimated 75 hours per inspection and 25 hours per sample collection

Additional time for inspections is included under the High Risk Inspections Program, planned separately

Above numbers are estimates only- assignment parameters and district inventories will dictate the final number of firms to be covered

Environmental sampling to follow-up on Outbreaks and Emergency Response activities is planned separately (See Responsive Investigative/Laboratory Operations Sheet)

NOTE: Laboratory allocations were planned by ORS

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Foods Inspections	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R233	[X] ORA [ ] CENTER	49.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPECTIONS INCLUDES CADRE (1)
	TOTAL FIELD	1200
	HEADQUARTERS	(b) (5), (b) (7)(E)
NE	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	PRL-SW	
PA	PRL-NW	
HOURS PER OPERATION		39.2
TOTAL HOURS		47040
CONVERSION FACTOR		950
TOTAL OPERATIONAL FTEs		49.52

7. REMARKS

NOTE: PAC 03R233 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) - Foreign Inspections planned in HQ are for Foreign Food Cadre.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Responsive Investigative/Laboratory Operations	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F813	[X] ORA [X] CENTER	176.6 [110.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	EMERGING ISSUES INSPECTIONS (1)		DOMESTIC INVESTI-GATIONS CSO (Hours)	OUTBREAK EMERGENCY RESPONSE CSO (Hours) (2)	ENVIRON-MENTAL SAMPLE CSO F/U	EMERGING ISSUES INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL SEAFOOD 03842	DOMESTIC SAMPLE COLL JUICE HACCP 03847	DOMESTIC SAMPLE COLL LACF/AF 03803A
	TOTAL FIELD	**235**		**15200**	**33535**	**208**	**25882**	**280**	**75**	**209**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		24.7				100.0		7.6	6.5	7.4
TOTAL HOURS		5805		15200	33535	20800	25882	2128	488	1547
CONVERSION FACTOR		950		950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		6.11		16.00	35.30	21.89	27.24	2.24	0.51	1.63

7. REMARKS

NOTE: 03F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues, OAI follow-ups. Accomplished work must be reported against the appropriate program or assignment PAC. Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

Report inspections and analyses against the appropriate PAC (e.g. 03R266 Listeria Emergency, or another PAC to be created in response to a future emergency).

Also, report related inspections and analyses in response to pesticides and chemical contaminants against the appropriate PAC (e.g. 04R078 Deep Water Horizon Water Spill Activities, or another PAC to be created in response to a future emergency).

(1) - Includes time for Registration Verification and BIMO Inspections (Inspections total; (GLP, (Human Subjects Protection, (IRB, and (additional of the above categories).

(2) - Includes investigational hours for all domestic investigations, follow-up to RFR-RCR, and Food Defense Assignments. District allocations are based on 3 year accomplishment data.

NOTE: The FY14 assignments not specified in the workplan that will be extended into FY 15 can use resources from Emerging Issues or Outbreaks and Emergency Response for these assignments.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Responsive Investigative/Laboratory Operations	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F813	[X] ORA [ ] CENTER	176.6 [43.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL FOOD SAFETY	DOMESTIC SAMPLE COLL EMERGING ISSUES	IMPORT SAMPLE COLL LACF/AF 03003A	EMERGING ISSUES IMPORT FIELD EXAM	DOMESTIC LAB ANALYST EMERGING ISSUES MICRO (Hours)	DOMESTIC LAB ANALYST EMERGING ISSUES CHEM (Hours)	DOMESTIC LAB ANALYST OUTBREAK EMERG. MICRO (Hours)	DOMESTIC LAB ANALYST OUTBREAK EMERG. CHEM (Hours)	DOMESTIC SAMPLE ANALYSIS ENV F/U MICRO
	TOTAL FIELD	**1822**	**789**	**1087**	**1273**	**3658**	**3540**	**3505**	**4600**	**208**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		9.8	9.1	1.9	0.3					11.1
TOTAL HOURS		17856	7180	2065	382	3658	3540	3505	4600	2309
CONVERSION FACTOR		950	950	950	950	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		18.80	7.56	2.17	0.40	3.10	3.00	2.97	3.90	1.96

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Responsive Investigative/Laboratory Operations	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F813	[X] ORA [ ] CENTER	176.6 [21.8]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE ANALYSIS JUICE HACCP 03847H MICRO	DOMESTIC SAMPLE ANALYSIS LACF/AF 03803A MICRO	DOMESTIC SAMPLE ANALYSIS FOOD SAFETY CHEM	DOMESTIC SAMPLE ANALYSIS FOOD SAFETY MICRO	DOMESTIC SAMPLE ANALYSIS SEAFOOD 03842 MICRO	IMPORT SAMPLE ANALYSIS LACF/AF 03003A MICRO	OEI COORDI-NATION HOURS 03R876		
	TOTAL FIELD	**75**	**80**	**176**	**455**	**280**	**1087**	**1900**		
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		10.4	10.3	13.1	14.5	18.6	7.0			
TOTAL HOURS		780	824	2306	6598	5208	7609	1900		
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	950		
TOTAL OPERATIONAL FTEs		0.66	0.70	1.95	5.59	4.41	6.45	2.00		

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Pesticides and Chemical Contaminants - 04

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**103.7**	**69.3**		**173.0**	
1	Pesticides and Chemical Contaminants	04F810 *	82.0	69.3		151.3	04-16-19
2	Total Diet Study	04839	21.7			21.7	04-20
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Kristen Kamas 301-796-4391

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04F810	[X] ORA [X] CENTER	151.3 [19.4]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL PESTICIDE 04004A	DOMESTIC SAMPLE COLL GAME MEAT ASSIGN (1)	DOMESTIC SAMPLE COLL CHEMO 04018	DOMESTIC SAMPLE COLL TOXIC ELE 04019A	DOMESTIC SAMPLE COLL DIOXINS	DOMESTIC SAMPLE COLL RADIO-NUCLIDES 04019C (2)	DOMESTIC SAMPLE COLL PILOT COOKIES 04F860 (3)	SCREENING STATION SAMPLE COLL 04004U	IMPORT SAMPLE COLL TOXIC ELEMENTS 04019A
	TOTAL FIELD	1050	75	150	725	80	100	600	300	1275
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		4.7	4.0	8.3	5.6	4.7	2.0	6.0	3.0	2.2
TOTAL HOURS		4935	300	1245	4060	376	200	3600	900	2805
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		5.19	0.32	1.31	4 27	0.40	0.21	3.79	0.95	2.95

7. REMARKS

NOTE: PAC 04F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) - Please refer to the EU-Audit specific CFSAN assignment for collection of multiple subs per sample and distribution of those subs to the different servicing labs for different analyses.

(2) - CFSAN spread DSC's based on location of nuclear power plants. See compliance program for collection details. This includes time for radionuclide testing of domestic seafood under the Toxic Elements / Radionuclides Compliance Program.

(3) - Collections and Sample Analyses of Cookies for allergen analysis are to establish baseline prevalence of allergens for the chemical surveillance sampling pilot. CFSAN will issue a memo with instructions for sample collection/analyses. Report time under PAC 04F860 - CFSAN Surveillance Sampling Program. Includes time for sample collection and label.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04F810	[X] ORA [X] CENTER	151.3 [28.6]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLL RADIO-NUCLIDES 04019C	IMPORT SAMPLE COLL PESTICIDES 04004A	IMPORT SAMPLE COLL CHEMO 04018	IMPORT SAMPLE COLL PILOT COOKIES 04F860 (4)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAM (5)	SCREENING STATION SAMPLE ANALYSIS CHEM (6)	DOMESTIC SAMPLE ANALYSIS ALLERGENS IN COOKIES 04F860 (4)	DOMESTIC SAMPLE ANALYSIS PESTICIDE 04004A
	TOTAL FIELD	**100**	**3300**	**1053**	**150**	**25**	**6406**	**300**	**600**	**1050**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		2.0	1.7	2.4	3.0	4.4	0.4	5.0	20.0	5.7
TOTAL HOURS		200	5610	2527	450	110	2562	1500	12000	5985
CONVERSION FACTOR		950	950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.21	5.91	2.66	0.47	0.12	2.70	1.27	10.17	5.07

7. REMARKS

(4) - Collections and Sample Analyses of Cookies for allergen analysis are to establish baseline prevalence of allergens for the chemical surveillance sampling pilot. CFSAN will issue a memo with instructions for sample collection/analyses.
Report time under PAC 04F860 - CFSAN Surveillance Sampling Program. Includes time for sample collection and label.

(5) - Import Field Exams are for Toxic Elements in Foodware (PAC 04019B)

(6) - Resources for Port Everglades Screening Station in FLA-DO Analyses.

Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04F810	[X] ORA [X] CENTER	151.3 [63.4]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE ANALYSIS RADIO-NUCLIDES 04019C	DOMESTIC SAMPLE ANALYSIS DIOXIN 04004D (7)	DOMESTIC SAMPLE ANALYSIS CHEMO 04018	DOMESTIC SAMPLE ANALYSIS TOXIC ELEMENTS 04019A	DOMESTIC SAMPLE ANALYSIS GAME MEAT CHEM (8)	IMPORT SAMPLE ANALYSIS PESTICIDE 04004A	IMPORT SAMPLE ANALYSIS RADIO-NUCLIDES 04019C	IMPORT SAMPLE ANALYSIS TOXIC ELEMENTS 04019A	IMPORT SAMPLE ANALYSIS ALLERGENS IN COOKIES 04F860 (9)
	TOTAL FIELD	**100**	**620**	**150**	**725**	**75**	**3300**	**100**	**1275**	**150**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		4.5	30.4	19.0	14.2	43.0	7.0	4.6	9.9	20.0
TOTAL HOURS		450	18848	2850	10295	3225	23100	460	12623	3000
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.38	15.97	2.42	8.72	2.73	19.58	0.39	10.70	2.54

7. REMARKS

Laboratory allocations were planned by ORS.

(7) - These samples include the (game meat samples from the EU assignment that will be analyzed for dioxin in addition to chemical contaminants. These (EU samples are NOT separate collections.

(8) - Game meat samples need several different types of contaminant analyses. The numbers in this column capture pesticides, vet drug residues, and metal analyses. Dioxin analyses on these samples are captured under "Domestic Samples to be Analyzed Dioxin 04004D" column.

(9) - Collections and Sample Analyses of Cookies for allergen analysis, are to establish baseline prevalence of allergens for the chemical surveillance sampling pilot. CFSAN will issue a memo with instructions for sample collection/analyses. Report time under PAC 04F860 - CFSAN Surveillance Sampling Program. Includes time for sample collection and label.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04F810	[X] ORA [X] CENTER	151.3 [39.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE ANALYSIS CHEMO 04018	APPLIED TECH-NOLOGY CENTER CHEM (Hours)	METHODS VAL/DEV CHEM (Hours)	IMPORT PRIVATE LAB REVIEW OP CODE 92 (Hours) CHEM (10)	FORENSICS (Hours)				
	TOTAL FIELD	**1050**	**5900**	**4820**	**2360**	**14460**				
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		19.0								
TOTAL HOURS		19950	5900	4820	2360	14460				
CONVERSION FACTOR		1180	1180	1205	1180	1205				
TOTAL OPERATIONAL FTEs		16.91	5.00	4.00	2.00	12.00				

7. REMARKS

Laboratory allocations were planned by ORS.

(10) - Private Laboratory Review Time is planned under PAC 04R320. Accomplished work must be reported against the appropriate Private Lab PAC. Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Total Diet Study	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04839	[ ] ORA [X] CENTER	21.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL (TOTAL) (DIET) (1)	DOMESTIC SAMPLE ANALYSIS CHEM (2)	DOMESTIC SAMPLE ANALYSIS RADIO-NUCLIDE (3)						
	TOTAL FIELD	**48**	**1207**	**2**						
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		27.8	15.2	2800.0						
TOTAL HOURS		1334	18346	5600						
CONVERSION FACTOR		950	1180	1180						
TOTAL OPERATIONAL FTEs		1.40	15.55	4.75						

7. REMARKS

(1) - Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over a four week period and involves 3 districts. Four market baskets are planned annually.

(2) - Represents the total number of food items analyzed for various attributes. VOC analyses will no longer be conducted on TDS foods.

(3) - All TDS food items from two market baskets analyzed by WEAC for selected radionuclides.

Laboratory allocations were planned by ORS.

PROJECT SUMMARY SHEET

FY 2015

1 PROGRAM CATEGORY	2 PPS PROJECT NAME/NUMBER
Food and Cosmetics	Molecular Biology & Natural Toxins - 07

3 NO	4 FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5 PROGRAM ASSIGNMENT CODE	6 OPERATIONAL FTE			7 TOTAL OPERATIONAL FTEs	8 PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**15.2**	**7.2**		**22.4**	
1	Mycotoxins in Domestic and Import Foods	07001,07R816	15 2	7 2		22 4	07-22

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Lorraine B Boykin 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mycotoxins in Domestic and Import Foods	Molecular Biology & Natural Toxins - 07

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
07001, 07R816	[X] ORA [X] CENTER	22.4

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	DOMESTIC SAMPLE ANALYSIS CHEM	IMPORT SAMPLE ANALYSIS CHEM	METHOD VAL/DEV CHEM (Hours) 07R816	APPLIED TECHN-OLOGY CTR MICRO (Hours) 07R816	APPLIED TECHN-OLOGY CTR CHEM (Hours) 07R816		
	TOTAL FIELD	**800**	**800**	**800**	**800**	**1205**	**600**	**4130**		
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		6.0	2.2	7.5	7.9					
TOTAL HOURS		4800	1760	6000	6320	1205	600	4130		
CONVERSION FACTOR		950	950	1180	1180	1205	1180	1180		
TOTAL OPERATIONAL FTEs		5.05	1.85	5.08	5.36	1.00	0.51	3.50		

7. REMARKS

Laboratory allocations were planned by ORS.

PROJECT SUMMARY SHEET

FY 2015

1 PROGRAM CATEGORY	2 PPS PROJECT NAME/NUMBER
Food and Cosmetics	Food & Color Additive Petition Review & Policy Development - 09

3 NO	4 FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5 PROGRAM ASSIGNMENT CODE	6 OPERATIONAL FTE			7 TOTAL OPERATIONAL FTEs	8 PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL			**7.8**		**7.8**	
1	Food and Color Additive Petition Review & Policy	09F810*		7 8		7 8	09-24
	Development						
	* These PACS are for planning purposes only						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Lorraine B Boykin 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Food & Color Additive Petition Review & Development	Food & Color Additive Petition Review & Policy Development - 09

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
09F810	[X] ORA [ ] CENTER	7.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE FOOD ADDITIVES COLL	IMPORT SAMPLE COLOR ADDITIVES COLL	IMPORT SAMPLE ANALYSIS FOOD ADD CHEM	IMPORT SAMPLE ANALYSIS COLOR ADD CHEM					
	TOTAL FIELD	**310**	**500**	**310**	**500**					
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		1.7	1.7	12.6	7.1					
TOTAL HOURS		527	850	3906	3550					
CONVERSION FACTOR		950	950	1180	1180					
TOTAL OPERATIONAL FTEs		0.55	0.89	3.31	3.01					

7. REMARKS

NOTE: PAC 09F810 is for planning purpose only. Accomplished work must be reported against the appropriate program or assignment PAC. Please see the Reporting Guidance for a listing of compliance programs and corresponding reporting PACs.

Laboratory allocations were planned by ORS.

PROJECT SUMMARY SHEET

FY 2015

1 PROGRAM CATEGORY	2 PPS PROJECT NAME/NUMBER
Food and Cosmetics	Technical Assistance: Food and Cosmetics -18

3 NO	4 FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5 PROGRAM ASSIGNMENT CODE	6 OPERATIONAL FTE			7 TOTAL OPERATIONAL FTEs	8 PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**75.5**			**75.5**	
1	Technical Assistance - Food and Cosmetics	18F810*	11 5			11 5	18-26
2	Retail Food Protection - State Program	18002	27 0			27 0	18-27-28
3	(NCIMS) Milk Safety Program	18003	21 0			21 0	18-29-30
4	Molluscan Shellfish Evaluation	18004	16 0			16 0	18-31-32
	* These PACS are for planning purposes only						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC						
	Please see the Reporting Guidance for a listing of						
	compliance programs and corresponding PACs						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Lorraine B Boykin 301-796-4393

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Technical Assistance - Food and Cosmetics	Technical Assistance- Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
See Remarks Section	[ ] ORA [X] CENTER	11 5

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	NON-FSMA HIGH RISK AIRCRAFT WATERING PT INSPECTIONS (1)	NON-AIRLINE WATERING POINTS INSPECTIONS	CONVEYANCE IN OPERATION INSPECTIONS	DOMESTIC SAMPLE COLL FOR CAUSE CHEM	DOMESTIC SAMPLE COLL SURV. MICRO	DOMESTIC SAMPLE ANALYSIS CHEM	DOMESTIC SAMPLE ANALYSIS MICRO		
	TOTAL FIELD	**500**	**160**	**50**	**20**	**180**	**20**	**180**		
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		12 5	12 5	16 0	4 4	4 4	10 0	5 6		
TOTAL HOURS		6250	2000	800	88	792	200	1008		
CONVERSION FACTOR		950	950	950	950	950	1180	1180		
TOTAL OPERATIONAL FTEs		6 58	2 11	0 84	0 09	0 83	0 17	0 85		

7 REMARKS

NOTE: PAC 18F810 is for planning purposes only Accomplished work must be reported against the appropriate program or assignment PAC Please see the Reporting Guidance for listing of compliance programs and corresponding reporting PACs

Districts allocations were planned by CFSAN

Servicing area inspections and any other related work not specifically addressed in the workplan can be taken from this program

(1) These planned resources do not include conveyance construction inspections or High Risk FSMA inspections of conveyance caterers (which are included in the FSMA High Risk Inspection category)

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Retail Food Protection - State Program	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
18002	[ ] ORA [X] CENTER	27 0 [19 9]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL FOOD PROG STAND-ARDS SUPP FOR JURISDICTION (1)	STANDARD-IZATION ITP,CDC,IHS STATE & LOCAL) (2)	RE-STANDARD IZATION (ITP,STATE &LOCAL) (3)	TEAM LEADER SCI/ NATIONAL (4)	NATIONAL TEAM WORK GROUP (5)	REGIONAL SEMINARS (6)	NATL. RETAIL FOOD PROG STANDARDS ENROLLMENT OF NEW JURIS (7)	TECHNICAL ASSISTANCE (8)	CONFERENCE FOR FOOD PROTECTION COMMITTEE WORK
	TOTAL FIELD	**4505**	**2352**	**2528**	**1200**	**2160**	**1620**	**568**	**7915**	**1080**
	HEADQUARTERS	(b) (5), (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										
TOTAL HOURS		4505	2352	2528	1200	2160	1620	568	7915	1080
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3 75	1 96	2 11	1 00	1 80	1 35	0 47	6 60	0 90

7 REMARKS

NOTE: All resources are planned in hours

(1) Includes time for meetings, consultations, conference calls, and any other direct contact with jurisdictions currently enrolled in the program standards to facilitate their continuous improvement in meeting the standards criteria

(2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting inspections

(3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections

(4) Time allocated for team leaders for retail food program planning, development, and coordination

(5) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards and initiatives of national importance

(6) Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the Annual Regional Retail Food Seminars

(7) Includes time from meetings, presentations, workshops, conference calls and other direct contact with jurisdiction to facilitate their enrollment in the program standards

(8) Includes providing assistance to external partners in interpreting and applying FDA's guidance and regulations and the effective use of interventions, inspection and enforcement to reduce the occurrence of foodborne illness risk factors at the retail level

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Retail Food Protection - State Program	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
18002	[ ] ORA [X] CENTER	27 0 [7 1]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (9)	DHRD TRAINING COURSE WORKSHOP (10)	REGIONAL NON-DHRD TRAINING/ COURSES WORKSHOPS (11)	RETAIL FOOD PROG TRACKING DATABASE PILOT (12)	FDA FOOD-BORNE ILL-NESSES RISK ACTOR STUD DATA COLL (13)	FDA FOOD BORNE ILL-NESSES RISK FACTOR STUDY WORKGROUP (14)			
	TOTAL FIELD	**1080**	**2240**	**1279**	**1080**	**1344**	**1450**			
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION										
TOTAL HOURS		1080	2240	1279	1080	1344	1450			
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200			
TOTAL OPERATIONAL FTEs		0 90	1 87	1 07	0 90	1 12	1 21			

7 REMARKS

(9) Time allocated for the presentation and distribution of FDA materials related to food defense Also, includes Specialist activities elated to CFSAN priority assignments in response to National Food Safety needs

(10) Includes support provided to DHRD in the development and delivery of DHRD training courses on topics such as the Food Code, Preparation for Standardization, Managing Retail Food Safety (HACCP), Conducting Risk-Based Inspections, Special Processes at Retail, Foodborne Illness Investigations, Plan Review, Trace-back Investigations, Regulations of Temporary Food Establishments

(11) Includes development and delivery of regionally-coordinated training courses and workshops offered to state, tribal and local partners, excluding workshops related to program standards

(12) Includes updating and maintaining a database of retail food protection program information related to state/local/tribal jurisdictions, ncluding information regarding enrollment in the FDA Voluntary National Retail Food Regulatory Program Standards

(13) Includes the collection and reporting of data from on-site assessments of roughly (b full service and (b fast food restaurant facilities as part of a 10 year FDA study to assess the control of foodborne illness risk factors at the retail level

(14) Includes time of workgroup members responsible for developing the data collection tools, analyzing data and drafting a report on the occurrence of foodborne risk factors in the different retail facility types

(15) Includes preliminary work on issues/position papers development and attendance at Conference for Food Protection Biennial Meeting

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
(NCIMS) Milk Safety Program	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
18003	[ ] ORA [X] CENTER	21 0 [17 2]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	CHECK RATING PLANT (1)	CHECK RATING TRANSFER AND RECEIVING (1)	CHECK RATING BTU (1)	SINGLE SERVICE AUDITS (1)	STATE SAMPLING SURVEILL-ANCE OFF. CERTIFCA-TION (2)	STATE MILK SANITATION RATING OFF CERTIFICA-TION (2)	STATE PROGRAM EVALUATION (3)	TECHNICAL ASSISTANCE	RMS STANDARDI-ZATION (4)
	TOTAL FIELD	**164**	**32**	**289**	**68**	**56**	**36**	**17**	**51**	**15**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		24 0	12 0	20 0	8 0	24 0	40 0	120 0	90 0	40 0
TOTAL HOURS		3936	384	5780	544	1344	1440	2040	4590	600
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		3 28	0 32	4 82	0 45	1 12	1 20	1 70	3 83	0 50

7 REMARKS

(1) Check ratings of plants, Receiving Stations and Transfer Stations(RS/TS) every 3 years; Bulk Tank Units(BTU) every 4 years; and Single-Service Container/Closure Manufacturers every 5 years

(2) Activities include the initial (including Hazard Analysis Critical Control Point (HACCP) if applicable), and continuous certification of State Rating Officers and Sampling Surveillance Officers

(3) State Program Evaluations conducted of 1/3 of the states and Puerto Rico every 3 years

(4) Activities include the initial CFSAN Standardization (including joint inspections and Group Exercise) for Regional Milk Specialists (RMSs)

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
(NCIMS) Milk Safety Program	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
18003	[ ] ORA [X] CENTER	21 0 [3 8]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	NCIMS (5)	9 TRAINING GIVEN (6)	9 FSMA (7)	9 NATIONAL TEAM (8)					
	TOTAL FIELD	**21**	**33**	**21**	**27**					
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		80 0	40 0	10 0	50 0					
TOTAL HOURS		1680	1320	210	1350					
CONVERSION FACTOR		1200	1200	1200	1200					
TOTAL OPERATIONAL FTEs		1 40	1 10	0 18	1 13					

7 REMARKS

(5) National Conference on Interstate Milk Shipments(NCIMS) holds their conference every other year

(6) Activities include the Regional Milk Seminar, DHRD training courses, Regional Training/ Workshops, and RMS Teaching Cadres

(7) Includes time for presentation and distribution of Food Safety Modernization Act(FSMA) guidance document for dairy products to the state regulatory agencies during check ratings, routine field work, and state program assessments Presentations may be made at local meetings and included in training sessions for all segments of the regulatory and industry community Coordination of FSMA field activities

(8) Activities include the National Steering Team Meetings and conference calls and time for team leader activities (2 RMSs with additional 150 hours each identified)

FY 2015 ORA WORKPLAN

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Molluscan Shellfish Evaluation	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
18004	[ ] ORA [X] CENTER	16 0 [13 0]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION (1)	CONTROL OF HARVEST (2)	VIBRO SPECIES MANAGEMENT (Hours) (3)	TECHNICAL ASSISTANCE (Hours) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	CENTER INTIATIVES & LAB EVALUATIONS (7)	PLANT EVALUATION (8)	STANDARDIZATION & RE-STANDARDIZATION (9)
	TOTAL FIELD	**174**	**19**	**2532**	**3474**	**6**	**2**	**9**	**203**	**12**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		20 0	90 0			200 0	180 0	40 0	10 0	40 0
TOTAL HOURS		3480	1710	2532	3474	1200	360	360	2030	480
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200	1200	1200	1200
TOTAL OPERATIONAL FTEs		2 90	1 43	2 11	2 90	1 00	0 30	0 30	1 69	0 40

7 REMARKS

(1) Time is allocated for planning, field evaluations, file reviews to determine state program conformity to the requirements of National Shellfish Sanitation Program (NSSP) Model Ordinance (MO)

(2) Time is allocated for planning, field evaluations, file reviews, growing area data reviews

(3) Activities include mangement, technical assistance and evaluation of state shellfish programs

(4) Includes interpretations and consultation on NSSP MO requirements

(5) Activities include planning, field evaluations, file reviews and report writing for countries with Memorandum of Understanding (MOU) or agreements with FDA

(6) Includes time for shellfish program planning, development and coordination

(7) Time allocated for CFSAN priority assignments in response to national shellfish safety and lab evaluations

(8) Includes time for planning field evaluations of processing plants, file reviews, and final report writing

(9) Standardization conducted every 5 years for all FDA and state standardization officers Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA Shellfish Standardization Officers(SSOs)

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Molluscan Shellfish Evaluation	Technical Assistance: Food and Cosmetics - 18

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
18004	[ ] ORA [X] CENTER	16 0 [3 0]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	9 NATIONAL TEAM WORKSHOP (10)	9 TRAINING WORKSHOPS (11)	9 REGIONAL SEMINARS (12)	9 FOOD DEFENSE COORDINATION (13)	9 ISSC COMMITTEE (14)	9 FSMA WORKGROUP (15)			
	TOTAL FIELD	**14**	**19**	**20**	**11**	**15**	**14**			
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		40 0	30 0	30 0	20 0	90 0	20 0			
TOTAL HOURS		560	570	600	220	1350	280			
CONVERSION FACTOR		1200	1200	1200	1200	1200	1200			
TOTAL OPERATIONAL FTEs		0 47	0 48	0 50	0 18	1 13	0 23			

7 REMARKS

(10) Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, initiatives of national importance

(11) Includes training workshops coordinated and delivered by the specialists

(12) Includes time for the Regional Shellfish Specialists to attend regional shellfish conferences

(13) Time allocated for presentation and distribution of the Food Producers, Processors, and Transporter: Food Security Preventive Measures Guidance to the state regulatory agencies and industries during field work and state program evaluations

(14) Time allocated for the specialists to attend the biennial Interstate Shellfish Sanitation Conference to address program related issues and new ISSC proposals

(15) Time is allocated for participating and/or providing information to the workgroups for the Food Safety Modernization Act

(b) (5), (b) (7)(E)

PROJECT SUMMARY SHEET

FY 2015

1 PROGRAM CATEGORY	2 PPS PROJECT NAME/NUMBER
Food and Cosmetics	Food Composition, Standards, Labeling and Economics - 21

3 NO	4 FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5 PROGRAM ASSIGNMENT CODE	6 OPERATIONAL FTE			7 TOTAL OPERATIONAL FTEs	8 PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**37.7**	**21.6**		**58.3**	
1	Food Composition, Standards, Labeling and Economics	21F810*	37 7	21 6		58 3	21-34-37
	*These PACS are for planning purposes only						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Lorraine B Boykin 301-796-4393

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics	Food Composition, Standards, Labeling and Economics - 21

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
21F810	[X] ORA [X] CENTER	58 3 [18 2]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLE COLL MEDICAL FOODS 21002	DOMESTIC SAMPLE COLL ECONO 21003	DOMESTIC SAMPLE COLL NLEA 21005	DOMESTIC SAMPLE COLL INFANT FORMULA 21006	DOMESTIC SAMPLE COLL DIETARY SUPPL 21008	DOMESTIC SAMPLE COLL SEAFOOD SPEC SUB 21842	DOMESTIC SAMPLE COLL GLUTEN FREE (1)	IMPORT SAMPLE COLL MEDICAL FOODS 21002	IMPORT SAMPLE COLL ECONO 21004
	TOTAL FIELD	**30**	**200**	**340**	**28**	**333**	**100**	**250**	**8**	**200**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		7 1	10 1	6 1	7 4	6 4	7 6	6 0	1 3	10 1
TOTAL HOURS		213	2020	2074	207	2131	760	1500	10	2020
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		0 22	2 13	2 18	0 22	2 24	0 80	1 58	0 01	2 13

7 REMARKS

NOTE: PAC 21F810 is for planning purposes only Accomplished work must be reported against the appropriate program or assignment PAC Please see the Reporting Guidance for a listing of compliance programs and corresponding PACs

For PAC 21008 ~
Domestic Sample Collections may be collected at packers/repackers, distributors or warehouse if number of samples collected cannot be collected during the inspections

(1) Allergen Assignment

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics	Food Composition, Standards, Labeling and Economics - 21

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
21F810	[X] ORA [X] CENTER	58 3 [11 5]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	4 IMPORT SAMPLE COLL NLEA 21005	4 IMPORT SAMPLE COLL INFANT FORMULA 21006	4 IMPORT SAMPLE COLL DIETARY SUPPL 21008	4 IMPORT SAMPLE COLL GLUTEN FRE (1)	5 DOMESTIC FIELD EXAMS	6 IMPORT FIELD EXAMS (2)	7 DOMESTIC SAMPLES TO BE ANALYZED MED FOODS CHEM 21002	7 DOMESTIC SAMPLES TO BE ANALYZED MED FOODS MICRO 21002	7 DOMESTIC SAMPLES TO BE ANALYZED ECONO CHEM 21003
	TOTAL FIELD	**910**	**15**	**713**	**100**	**2400**	**11209**	**21**	**12**	**200**
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		2 1	3 5	2 0	3 0	1 0	0 5	89 5	27 0	24 1
TOTAL HOURS		1911	53	1426	300	2400	5605	1880	324	4820
CONVERSION FACTOR		950	950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs		2 01	0 06	1 50	0 32	2 53	5 90	1 59	0 27	4 08

7 REMARKS

NOTE: Laboratory allocations were planned by ORS

(1) Allergen Assignment

(2) There should be no more than one Import Field Exam per line entry for this compliance program and PAC All routine field exam activities including reconciliation exams, label reviews, container integrity, source country and intentional adulteration exams are to be as a single Import Field Exam

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics	Food Composition, Standards, Labeling and Economics - 21

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
21F810	[X] ORA [X] CENTER	58 3 [21 5]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC SAMPLES TO BE ANALYZED NLEA CHEM 21005	7 DOMESTIC SAMPLES TO BE ANALYZED INFANT FOR CHEM 21006	7 DOMESTIC SAMPLES TO BE ANALYZED INFANT FOR MCRO 21006	7 DOMESTIC SAMPLES TO BE ANALYZED DIETARY SUP CHEM 21008	7 DOMESTIC SAMPLES TO BE ANALYZED TDS CHEM 21839	7 DOMESTIC SAMPLES ANALYZED SEAFOOD SPEC SUB CHEM 21842	7 DOMESTIC SAMPLES ANALYZED GLUTEN FRE CHEM (1)	8 IMPORT SAMPLES TO BE ANALYZED MED FOODS CHEM 21002	8 IMPORT SAMPLES TO BE ANALYZED ECONO CHEM 2100
	TOTAL FIELD	**340**	**18**	**8**	**206**	**1040**	**100**	**250**	**8**	**200**
	HEADQUARTERS	(b) (5), (b) (7)(E)								
NE	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	PRL-SW									
PA	PRL-NW									
HOURS PER OPERATION		14 6	133 9	27 4	18 8	2 0	13 0	20 0	83 5	24 1
TOTAL HOURS		4964	2410	219	3873	2080	1300	5000	668	4820
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		4 21	2 04	0 19	3 28	1 76	1 10	4 24	0 57	4 08

7 REMARKS

NOTE: Laboratory allocations were planned by ORS

(1) Allergen Assignment

1 PROGRAM/ASSIGNMENT TITLE	2 PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics	Food Composition, Standards, Labeling and Economics - 21

3 PROGRAM/ASSIGNMENT CODE(S)	4 WORK ALLOCATION PLANNED BY	5 OPERATIONAL FTE POSITIONS
21F810	[X] ORA [X] CENTER	58 3 [7 1]

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	8 IMPORT SAMPLES TO BE ANALYZED NLEA CHEM 21005	8 IMPORT SAMPLES TO BE ANALYZED INFANT FOR CHEM 21006	8 IMPORT SAMPLES TO BE ANALYZED DIETARY SUP CHEM 21008	8 IMPORT SAMPLES ANALYZED GLUTEN FRE CHEM (1)	9 METHODS VAL/DEV CHEM (Hours)	9 APPLIED TECHN-OLOGY CENTER CHEM (Hours)			
	TOTAL FIELD	**125**	**15**	**114**	**100**	**1205**	**1180**			
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		8 5	81 9	14 8	20 0					
TOTAL HOURS		1063	1229	1687	2000	1205	1180			
CONVERSION FACTOR		1180	1180	1180	1180	1205	1180			
TOTAL OPERATIONAL FTEs		0 90	1 04	1 43	1 69	1 00	1 00			

7 REMARKS

NOTE: Laboratory allocations were planned by ORS

(1) Allergen Assignment

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Colors and Cosmetics Technology - 29

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**12.0**	**8.1**		**20.1**	
1	Cosmetics: Domestic and Imports	29001; 29R833;	12.0	8.1		20.1	29-39-40
		29R824;					
		99R833					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Monali Yajnik 240-402-1616	Kristen Kamas 301-796-4391

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics: Domestic and Imports	Colors and Cosmetics - 29

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
29001, 29R833, 29R824, 99R833	[X] ORA [ ] CENTER	20 1 [14.2]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPECT-IONS	DOMESTIC INSPECT-IONS TATTOO ASSIGN-MENT	DOMESTIC TARGETED INSPECTION (1)	DOMESTIC SAMPLE COLL TATTOO ASSIGN-MENT	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS (2)	DOMESTIC SAMPLE ANALYSIS TATTOO ASSIGNMENT (Micro)	DOMESTIC SAMPLE ANALYSIS (Micro)
	TOTAL FIELD	75	30	25	600	60	500	1600	600	60
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		17.9	17.9	17.9	2.9	2.9	1.9	0.7	13.0	18.6
TOTAL HOURS		1343	537	448	1740	174	950	1120	7800	1116
CONVERSION FACTOR		950	950	950	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		1.41	0.57	0.47	1.83	0.18	1.00	1 18	6.61	0.95

7. REMARKS

(1) - Targeted firms list will be communicated through OFFO.

(2) - There should be no more than one Import Field Exam per line entry for this compliance program and PAC.
All routine field exam activities including reconciliation exams, label reviews, container integrity, source country and intentional adulteration exams are to be reported as a single Import Field Exam.

Only in the event of a pre-determined "for cause" counterterrorism exam, or in the event counterterrorism suspicions are raised while conducting routine work requiring follow-up, should an additional exam and time be reported under the CT PAC 29R845. See IOM Section 5.4.1.4.1. for additional information on Food and Cosmetic Securities Activities.

Note: If the Center initiates any assignments to follow up on drug claims on cosmetics, the field resources will be used from this program.

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics: Domestic and Imports	Colors and Cosmetics - 29

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
29001, 29R833, 29R824, 99R833	[X] ORA [ ] CENTER	20.1 [5.9]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE ANALYSIS (Chem)	IMPORT SAMPLE ANALYSIS (Micro)							
	TOTAL FIELD	**250**	**250**							
	HEADQUARTERS	(b) (5), (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									
	PRL-SW									
	PRL-NW									
HOURS PER OPERATION		11.6	16.1							
TOTAL HOURS		2900	4025							
CONVERSION FACTOR		1180	1180							
TOTAL OPERATIONAL FTEs		2.46	3.41							

7. REMARKS

NOTE: Laboratory allocations were planned by ORS.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Regulated Tobacco Products - Domestic and Import PACs 96R800, 96T800, 96R824, 96R833	Tobacco - 96

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

4. OBJECTIVES

To assess compliance with the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, and its implementing regulations, ORA will use a Tobacco Cadre of approximately five investigators who will report to a supervisor in ORA headquarters, to:

1. inspect registered establishments engaged in the manufacture, preparation, compounding, or processing of regulated tobacco products; and
2. conduct investigations of tobacco product manufacturers.

The Tobacco Cadre will conduct inspections, investigations, and sample collections to support Center-initiated administrative and/or enforcement action when violations are observed.
ORA district staff will review imported tobacco products. SRL and FCC will support CTP enforcement actions with method development and sample analysis.

5. PROGRAM JUSTIFICATION

The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act requires the agency to conduct inspections at least once during a two-year period.

6. FIELD OBLIGATIONS

CTP plans to issue inspection and investigation assignments as needed in lieu of any compliance program(s) during the fiscal year to cover all statutory and regulatory provisions in effect. CTP anticipates approximately half the universe of registered tobacco establishments to be inspected during the fiscal year. Further, CTP anticipates the collection of domestic samples for laboratory analysis to either support enforcement actions or to ensure compliance with certain provisions in effect.
CTP plans to develop import alerts and assignments as needed.

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)
Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco	All tobacco codes

e. EXAM TYPE

[X] CHEMICAL [ ] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [X] OTHERS ***(Label, Labeling, Advertising Reviews)***

f. CHECK THE FOLLOWING ATTRIBUTES

Cigarette, cigarette tobacco, components/parts/accessories labeled with flavor; "low," "light," "mild" descriptors for all tobacco products. Labeling/promo info requested in assignments. Tobacco paper/flavor analysis & other tests as specified by CTP.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Liquid chromatography/triple quadrupole mass spec (LC/MS-MS); Gas Chromatography/flame-ionization-detector and mass spec (GC/FID/MS); GC/MS; GC/MS-MS, e-cigarette smoking machines, PCR machines, among other instruments.

CENTER FOR TOBACCO
RESOURCE SUMMARY
FY 2015

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	25.2	2.8		28.0
96	REGULATED TOBACCO PRODUCTS: DOMESTIC AND IMPORT	25.2	2.8		28.0

PROJECT SUMMARY SHEET

FY 2015

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Tobacco	Tobacco- 96

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**25.2**	**2.8**		**28.0**	
1	Regulated Tobacco Products: Domestic and Import	96R800,96T800	25.2	2.8		28.0	96-2
		96R824,96R833					

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Tara Goldman 301-796-6197	Kristen Kamas 301-796-4391

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	
Regulated Tobacco Products: Domestic and Import	Tobacco - 96	
3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
96R800, 96T800, 96R824, 96R833	[X] ORA [ ] CENTER	28.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	PRE-APPROVAL INSPEC-TIONS DOMESTIC (1)	INSPEC-TIONS DOMESTIC (2)	INSPEC-TIONS ASSIGN-MENTS DOMESTIC (1)	INVESTI-GATIONS (Hours) (3)	IMPORT INVESTI-GATIONS (Hours) (4)	IMPORT ENTRY REVIEW (Hours)	DOMESTIC SAMPLE COLL (5)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (Hours)	METHODS VAL/DEV CHEM (Hours) (6)
	TOTAL FIELD	5	55	10	722	1500	1500	30	11906	12159
	HEADQUARTERS	(b) (5), (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		55.0	55.0	55.0				6.0		
TOTAL HOURS		275	3025	550	722	1500	1500	180	11906	12159
CONVERSION FACTOR		950	950	950	950	950	1200	950	1180	1205
TOTAL OPERATIONAL FTEs		0.29	3.18	0.58	0.76	1.58	1.25	0.19	10.09	10.09

7. REMARKS

(1) - The Domestic Pre-Approval and Inspection Assignment columns represent the Center's potential need for Inspections. There may not be any Pre-Approval Inspections conducted in the FY.

(2) - FDA is required to inspect each registered facility at least once in a two year period.

Note 1: A tobacco cadre which reports to ORA HQ will conduct all tobacco inspections and investigations.
Note 2: Inspectional module includes time for label exams to be conducted on inspections. Please refer to the Assignment Memo when issued for more detailed guidance.

(3) - Represents assignments that include complaint follow-up, smokeless free sample events, and other similar investigative assignments.

(4) - Includes Import Assignments for Label Exams.

(5) - Represents samples that may be collected during an Inspection, Investigation, or Sample Assignments.

(6) - The total hours allocated for FCC equal 6.5 FTEs and SRL equals 13.67 FTEs. Validation hours may be used for analysis as needed. FCC work should be reported under PAC 96R831.

1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections PACs 68001, 68001G	2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs & Food Additives - 68

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

4. OBJECTIVES

To assure that manufacturing, testing, packing and/or labeling facilities (New Animal Drug Applications, NADAs; Abbreviated New Animal Drug Applications, ANADAs; Generic Investigational New Animal Drugs, JINADs; Investigational New Animal Drugs, INADs) comply with current good manufacturing practices (cGMPs) as a condition of drug approval.

Outcome: Increase the number of cooperative activities related to this program.

5. PROGRAM JUSTIFICATION

Inspections are necessary to determine whether a facility identified in an animal drug application whether NADA, ANADA, JINAD, or INAD, has the capability to manufacture, test, pack, or label a drug (including the active ingredient) according to cGMPs and has provided all necessary information in the application. Firms should be inspected only when CVM issues an assignment. The type of application (NADA, ANADA, JINAD, or INAD) will dictate the priority of inspection.

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 Office of New Animal Drug Evaluation (ONADE) Program Manager according to the procedures outlined for field reporting requirements in the compliance program.

Outcome: Field laboratories on an assignment basis, will validate methodology submitted with NADA, ANADA, INAD, and JINAD applications.

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)
Animal Drugs, Type A Medicated Feed Articles	57, 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
Good Laboratory Practice (Non-clinical Laboratory) PACs 68808, G	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 and 69

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
Sponsors, Contract Research Organizations, and Monitors PACs 68810, G	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 regulations (21 CFR 511.1) New Animal Drugs for investigational use.

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 [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
Animal Drugs	67, 68 and 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 Clinical Investigators PACs 68811, G	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 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, and 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
Animal Drug Manufacturing Inspections Type A Medicated Articles PACs 71001, A, B, 71005, A	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 approved and unapproved finished dosage form products and 21 CFR 226 for the Type A Medicated Articles. To obtain accurate listing and labeling information for animal 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 approved New Animal Drug Application (NADA)/Abbreviated New Animal Drug Application (ANADA).

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 safety and effectiveness of animal drugs.

6. FIELD OBLIGATIONS

The field will conduct CGMP inspections of registered animal drug establishments.

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 Animal Drug Dosage forms and Type A Medicated Articles. Medicated feeds or blocks are not included.	54, 56, 60-66, 67, 68

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

f. CHECK THE FOLLOWING ATTRIBUTES

Purity, identity, potency, decomposition

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants PACs 71003 A,B,C,E,G-K	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.	54 and 69-72

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

f. CHECK THE FOLLOWING ATTRIBUTES

Mycotoxins, Pesticides, Industrial Chemicals, Metals, Microbiologicals, Antibiotics and Dioxins.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing PACs 71004, A	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 an approved license to make certain medicated feeds.

5. PROGRAM JUSTIFICATION

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

Outcome: Ensure the safety and effectiveness of 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 [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING

[X] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Illegal Drug Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods PAC 71006	Monitoring of Marketed Animal Drugs, Feeds and Device - 71

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

4. OBJECTIVES

To minimize consumers' exposure to food adulterated with illegal drug residues.
To ensure the proper use of drugs in food producing animals.
To obtain compliance through voluntary and/or regulatory actions.
To conduct inspections to determine and document the source and cause of illegal drug residues and/or shipment of adulterated food and/or drug(s).
To capture on-farm husbandry and veterinary drug practices for program analysis, identification of educational needs, and policy development.

5. PROGRAM JUSTIFICATION

The Food and Drug Administration (FDA) has the responsibility to enforce the Federal Food, Drug, and Cosmetic Act (The Act). Within FDA, the Center for Veterinary Medicine (CVM) is responsible for approving new animal drugs and establishing residue tolerances. The intent of this program is to conduct inspections when an illegal drug residue has been identified. This program covers all animal derived foods such as meat, game meat, poultry, aquacultured seafood, shell eggs, milk, and honey. This is a cooperative program involving FDA, United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and a number of state governments.

Outcome: To minimize consumers' exposure to food adulterated with illegal dug residues, and to ensure the proper use of drugs in food producing animals.

6. FIELD OBLIGATIONS

To conduct inspections in accordance with the Compliance Program, CVM Assignments, and the Memoranda of Understanding (MOU) between FDA, USDA, and EPA. Coordinate state activities with states having MOUs, informal and formal agreements or state contracts with FDA to conduct inspections at establishments below the Risk Score Threshold for FDA inspections.

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)
milk, eggs, aquacultured seafood, meat, poultry, honey, animal feeds and drugs	09, 15, 16, 17, 36, 67, 68, 69

e. EXAM TYPE [X] CHEMICAL [X] MICROBIOLOGICAL [ ] PHYSICAL [ ] ENGINEERING [X] 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 BSE/Ruminant Feed Ban Inspections PACs 71009, 71R844, 71R843	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 use of specified animal proteins in ruminant feeds. 21 CFR 589.2000. A second rule 21 CFR 589.2001, prohibits the use of certain cattle origin-materials in all animal feed.

To ensure that specified animal proteins do not enter the U.S. from BSE-at-risk countries.

5. PROGRAM JUSTIFICATION

Bovine Spongiform Encephalopathy (BSE) is the bovine form of a group of uniformly fatal neurological diseases known as Transmissible Spongiform Encephalopathies (TSEs). BSE appears to be spread through the feeding of infected material to cattle. BSE is a public health issue for the U.S. This disease has been linked to the human TSE known as variant Creutzfeldt-Jakob Disease (vCJD), presumably through people consuming ruminant tissues infected with the BSE agent. In addition, BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected.

Outcome: To prevent the establishment and amplification of BSE through feed in the United States.

6. FIELD OBLIGATIONS

To conduct inspections, investigations, and sample collections/analyses to implement this program. All firms that handle animal feed and feed ingredients that may contain 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.

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)
All feeds and feed ingredients	67-72

e. EXAM TYPE

[X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING

[ ] MICROANALYTICAL [ ] OTHERS ***(SPECIFY)***

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program PAC 71R816	2. PPS PROJECT NAME/NUMBER 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

Validated analytical methods are essential to support enforcement activities.

6. FIELD OBLIGATIONS

Conduct activities under this program as directed by the Office of Regulatory Science.

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

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

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

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis PAC 71R838	2. PPS PROJECT NAME/NUMBER 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
Center Initiated Assignments, Pandemic Preparedness PAC 71V800	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

CENTER FOR VETERINARY MEDICINE
RESOURCE SUMMARY
FY 2015

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	TOTAL	121.9	20.2	4.6	146.7
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	6.9		2.7	9.6
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	115.0	20.2	1.9	137.1

PROJECT SUMMARY SHEET

FY 2015

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			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**6.9**		**2.7**	**9.6**	
1	NADA Pre-Approval Inspection	68001, 68001G	1.5		2.3	3.8	68-2
2	Bioresearch Monitoring		5.4		0.4	5.8	68-3
	(Pre-Market) GLP	68808, 68808G	[2.7]		[0.2]	[2.9]	
	* (Pre-Market) Spon/Mon/Con	68810,68810G					
	(Pre-Market) Clinical Investigators	68811,68811G	[2.7]		[0.2]	[2.9]	

* PAC 68810 is planned under PAC 68808.

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Jeremy Robbi 240-276-9227	Harriet R. Gerber 301-796-4396

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, 68001G	[X] ORA [X] CENTER	3.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPEC-TIONS	DOMESTIC INSPEC-TIONS	CHEMIST ON INSP (Hours) (1)						
	TOTAL FIELD	**30**	**10**	**850**						
	HEADQUARTERS	(b) (5), (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		75.0	55.0							
TOTAL HOURS		2250	550	850						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		2.37	0.58	0.89						

7. REMARKS

(1) - Hours are planned for analysts to participate on inspections as needed.

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.

Resources for the Generic Animal Drug Pre-Approval Inspections, PAC 68001G, are planned under 68001.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
GLPs Sponsor-Monitors-CROs, 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,G; 68810,G; 68811,G	[X] ORA [ ] CENTER	5.8

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS 68808 (1)	DOMESTIC INSPEC-TIONS 68811 (2)	FOREIGN INSPEC-TIONS 68810 (3)	FOREIGN INSPEC-TIONS 68811 (3)					
	TOTAL FIELD	**30**	**44**	**2**	**3**					
	HEADQUARTERS	(b) (5), (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		85.0	58.0	90.0	60.0					
TOTAL HOURS		2550	2552	180	180					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		2.68	2.69	0.19	0 19					

7. REMARKS

(1) - PAC 68808 includes resources for PACs 68808G Generic Good Laboratory Practices and 68810G Generic Sponsors, Monitors, & Contract Research Organizations

(2) - PAC 68811 includes resources for PAC 68811G Generic Clinical Investigators.

(3) - Foreign Inspections, Operation Code 11, are for Sponsor/Monitors (PAC 68810) and Clinical Investigators (PAC 68811).

Inspections planned using assignment and accomplishment data.

Inspections are to be conducted based on CVM issued assignments.

All Inspections should be reported under the appropriate PAC.

PROJECT SUMMARY SHEET

FY 2015

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			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**115.0**	**20.2**	**1.9**	**137 1**	
1	Animal Drug Manufacturing Inspections	71001	10.5	0.1	1.7	12 3	71-5
2	Feed Contaminants*	71003A-K	27.4	8.9		36 3	71-6-8
3	Feed Manufacturing	71004,A	5.0		0.2	5 2	71-9
4	Illegal Drug Residues in Meat and Poultry	71006,M	36.5			36 5	71-10
5	Ruminant Feed Ban Rule (BSE) Program**	71009,71R843	16.2	11.2		27.4	71-11-13
6	High Risk Feed Inspection Pilot Assignment (FSMA)	71V030	7.2			7 2	71-14
7	Methods Validation/Development Program	71R816	5.0			5.0	71-15
8	Forensic Evaluation and Sample Analysis	71R838	1.0			1.0	71-16
9	Center Initiated Assignments***	71V800	6.2			6 2	71-17
	*Includes 3.0 FTE's for selected research projects						
	**Includes PACs: 71R833, 71R844, 99R833, and 71R824						
	***Includes a pool of resources to investigate adverse events						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Jeremy Robbi 240-276-9227	Harriet R. Gerber 301-796-4396

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Animal Drug Manufacturing Inspection/ 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
PACs 71001, A, B, 71005, A	[X] ORA [X] CENTER	12.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPEC-TIONS (1)	DOMESTIC INSPEC-TIONS (2)	CHEM ON INSPEC (Hours)	INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL (3)	DOMESTIC SAMPLE COLL CHEM	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM	
	TOTAL FIELD	**33**	**205**	**600**	**250**	**50**	**20**	**100**	**20**	
	HEADQUARTERS	(b) (5), (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		49.0	40.0			7.0		0.8	35.0	
TOTAL HOURS		1617	8200	600	250	350		80	700	
CONVERSION FACTOR		950	950	950	950	950		950	1180	
TOTAL OPERATIONAL FTEs		1.70	8.63	0.63	0.26	0.37		0.08	0.59	

7. REMARKS

(1) - Foreign Inspections spread by the Office of Medical Products and Tobacco Operations.

(2) - Inspections include product defects and adverse drug reaction follow up.

(3) - Some samples collected will be documentary samples and not analyzed. The shaded area is a subset of the 50 Domestic Sample Collections.

Resources for Type A Medicated Articles Program (71005/A) are planned under PAC 71001.

Workload Source: CVM allocated the number of Domestic Inspections to districts based on their risk model for ranking firms.

Laboratory allocations were planned by the Office of Regulatory Science.

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,B,C,E,G-K	[X] ORA [ ] CENTER	36.3 [6.9]

REGION	DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL TOTAL	DOMESTIC SAMPLE COLL METALS 71003B	DOMESTIC SAMPLE COLL Myco 71003C	DOMESTIC SAMPLE COLL Micro 71003E (2) (a)	DOMESTIC SAMPLE COLL Chem 71003A	DOMESTIC SAMPLE COLL Dioxin 71003G (b)	DOMESTIC SAMPLE COLL Antibiotics 71003K (3)
	TOTAL FIELD	**37**	**1260**	**963**	**105**	**338**	**100**	**250**	**150**	**20**
	HEADQUARTERS	(b) (5), (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		35.0		4.2						
TOTAL HOURS		1295	1260	4045						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		1.36	1.33	4.26						

7. REMARKS

The shaded area is a subset of the total Domestic Sample Collections.

(1) - Inspections performed as follow up to violative samples and as needed for surveillance.

(2) - DSC Micro 71003E - 100 official sample collections and 400 analyses- analyze for four microorganisms (*Salmonella, Listeria* monocytogenes, EHEC enterohemorrhagic E. coli and STEC Shiga toxin-producing strains of E. coli) per official sample.

(3) - DSC Antibiotics 71003K, antiobotics in ethanolic byproducts used in feeds/ingredients is being discontinued in FY15. The last 20 samples collected in FY15 will be sent to CVM's Office of Research for analysis.

Two Center-issued Assignments are expected in FY15:

a. A Micro assignment under 71003E will be issued for raw pet food diets.

b. A 60 sample dioxin assignment, and inspection/collection assignments (approximately 90 samples) will issue pursuant to USDA 5 year Dioxin survey.

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,B,C,E,G-K	[X] ORA [ ] CENTER	36.3 [20.5]

REGION	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC SAMPLES TO BE ANALYZED Metals 71003B	DOMESTIC SAMPLES TO BE ANALYZED Myco 71003C	DOMESTIC SAMPLES TO BE ANALYZED Micro 71003E (4)		DOMESTIC SAMPLES TO BE ANALYZED Chem 71003A (5)	DOMESTIC SAMPLES TO BE ANALYZED Dioxin 71003G (6)		METHODS VAL/DEV CONTAM ID CHEM (Hours) 71003A (7)	METHODS VAL/DEV MICRO (Hours) 71003E
	TOTAL FIELD	**105**	**672**	**400**		**250**	**150**		**2360**	**1180**
	HEADQUARTERS	(b) (5), (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		18.0	11.0	13.0		6.6	30.0			
TOTAL HOURS		1890	7392	5200		1650	4500		2360	1180
CONVERSION FACTOR		1180	1180	1180		1180	1180		1180	1180
TOTAL OPERATIONAL FTEs		1.60	6.26	4.41		1.40	3.81		2.00	1.00

7. REMARKS

(4) - DSA Micro 71003E - 100 official sample collections and 400 analyses- analyze for four microorganisms (Salmonella, Listeria monocytogenes, EHEC enterohemorrhagic E. coli and STEC Shiga toxin-producing strains of E. coli) per official sample.

(5) - DSA Chem 71003A to include Pesticides, Industrial Chemicals and Filth (240 samples for Pesticides & Industrial Chemicals plus 10 Filth samples for FY15).

(6) - DSA Dioxin samples will be used for two assignments, 60 samples for a dioxin sampling assignment and 90 samples for a collection assignment to be issued pursuant with the USDA 5 year Dioxin survey.

(7) - 1.25 FTE will be devoted for Methods Validation/Development for aflatoxins in DDGs, and the remaining 0.75 FTE for T-2 toxin and other trichothecene mycotoxins in animal feed.

Laboratory allocations were planned by the Office of Regulatory Science.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Feed Contaminants- Import	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,B,C,E,G-K	[X] ORA [X] CENTER	36.3 [8.9]

REGION	DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLL	IMPORT SAMPLE COLL Chem & Others (8)	IMPORT SAMPLE COLL Micro 71003E (9)		IMPORT FIELD EXAMS	IMPORT SAMPLES TO BE ANALYZED Chem	IMPORT SAMPLES TO BE ANALYZED Micro (9)	IMPORT SAMPLES TO BE ANALYZED Metals	IMPORT SAMPLES TO BE ANALYZED Myco
	TOTAL FIELD	**790**	**440**	**350**		**300**	**300**	**350**	**25**	**95**
	HEADQUARTERS	(b) (5), (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									
	FLORIDA									
SE	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
SW	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION		2.5				0.6	7.0	12.0	18.0	11.0
TOTAL HOURS		1975				180	2100	4200	450	1045
CONVERSION FACTOR		950				950	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		2.08				0.19	1.78	3.56	0.38	0.89

7. REMARKS

The shaded area is a subset of the total Import Sample Collections.

(8) - ISC Chem and Others: 300 Import Sample Collections are for Chem, 95 Import Samples are for Myco, 20 Import Samples will be collected for antibiotics to be sent to CVM's Office of Research as investigative samples, and 25 Import Samples will be collected for Metals (new for FY 15).

(9) - ISC Micro 71003E, sample collections are for pig ears, pet treats, and pet foods as well as other animal feed ingredients.

Laboratory allocations were planned by the Office of Regulatory Science.

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 [X] CENTER	5.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPEC-TIONS	DOMESTIC INSPEC-TIONS	DOMESTIC SAMPLE COLL (1)	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLES TO BE ANALYZED CHEM				
	TOTAL FIELD	**4**	**141**	**60**	**15**	**15**				
	HEADQUARTERS	(b) (5), (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		50.0	28.0	7.8		25.0				
TOTAL HOURS		200	3948	468		375				
CONVERSION FACTOR		950	950	950		1180				
TOTAL OPERATIONAL FTEs		0.21	4.16	0.49		0.32				

7. REMARKS

(1) - Domstic Sample Collections are allocated for 15 physical samples and 45 documentary samples.

The shaded area is a subset of the Total Domestic Sample Collections.

There are 278 State Contract inspections. Report time for these contract inspections under PAC 71S004.

Note: CVM provided the inspection spread based on their risk model for ranking firms.

Laboratory allocations were planned by the Office of Regulatory Science.

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, M	[X] ORA [X] CENTER	36.5

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL (1)		METHODS VAL/DEV CHEM (Hours)	TECH SUPPORT (Hours) (2)			
	TOTAL FIELD	**500**	**6500**	**930**		**360**	**1900**			
	HEADQUARTERS	(b) (5), (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		39.0		7.0						
TOTAL HOURS		19500	6500	6510		360	1900			
CONVERSION FACTOR		950	950	950		1180	950			
TOTAL OPERATIONAL FTEs		20.53	6.84	6.85		0.31	2.00			

7. REMARKS

CVM will issue FACTS assignments to request Federal inspections when the risk score of the residue reported by FSIS exceeds the annually calculated budget-defined risk-informed threshold.

(1) - Documentary samples collected during inspections.

(2) - Tech support hours include supporting State Activities under Illegal Residues in Meat & Poultry and time for Tissue Residue Monitors.

Laboratory spreads were planned by the Office of Regulatory Science.

Note: CVM spread Inspections and Sample Collections based on their risk model for ranking residue violations in this program.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71009, 71R844, 71R843 (99R833, 71R833, 71R824)	[X] ORA [X] CENTER	27.4 [24.3]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours) (2)	IMPORT ENTRY REVIEW (Hours) (3)	IMPORT INVESTI-GATIONS (Hours) (4)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED CHEM (5)	DOMESTIC SAMPLES TO BE ANALYZED MICRO (5)
	TOTAL FIELD	**800**	**1000**	**8440**	**1530**	**640**	**200**	**3200**	**425**	**215**
	HEADQUARTERS	(b) (5), (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		8.5				4.0	2 5	0.4	6.0	4.0
TOTAL HOURS		6800	1000	8440	1530	2560	500	1280	2550	860
CONVERSION FACTOR		950	950	1200	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		7.16	1.05	7.03	1.61	2.69	0.53	1.35	2.16	0.73

7. REMARKS

(1) - Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills should be inspected annually and other establishment types handling or not handling prohibited material should be inspected as specified on page 71-13.

(2) - Domestic Investigation Hours are to be used for OEI Improvement with a focus on searching for new firms that fall under the high risk category. Report CVM State Contract Inspection Audit time under PAC 71R843 Operation Code 13.

(3) - Reporting Guidance: Import Entry Review (Electronic and Manual- Operation Code 14, PAC 71R833); includes time for Mail Courier review.

(4) - Import Investigation Hours are for Filer Evaluations (Op Code 95, PAC 99R833), Follow-Up to Refusals (PAC 71R824), and other operations as required by the district to cover program priorities. Report accomplishements under the appropriate operation and PACs.

(5) - Domestic Sample Analysis Planned Hours are split 2/3 Chem and 1/3 Micro, however laboratories may use planned time for either type of analysis as needed.

Laboratory allocations were planned by the Office of Regulatory Science.

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71009, 71R844, 71R843 (99R833, 71R833, 71R824)	[X] ORA [X] CENTER	27.4 [3.1]

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLES TO BE ANALYZED CHEM	TECHNICAL SUPPORT (Hours) (6)							
	TOTAL FIELD	**200**	**2248**							
	HEADQUARTERS	(b) (5), (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		4.3								
TOTAL HOURS		860	2248							
CONVERSION FACTOR		1180	950							
TOTAL OPERATIONAL FTEs		0.73	2.37							

7. REMARKS

(6) - Technical support hours include supporting state activities under the Ruminant Feed Ban Regulation and supporting state activities under the Feed Manufacturing Program, PAC 71004. These hours also include resources for audits of state contract inspections.

Laboratory allocations were planned by the Office of Regulatory Science.

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

9. Remarks

Inspection Priorities.

The first inspectional priority under this program is to inspect those firms that have a violative history classifed by the FDA as "Official Action Indicated" or OAI. These inspections should be conducted with the intent that regulatory action will be pursued should the firm be unwilling or unable to take immediate actions to correct the violations. 21 CFR 589.2000 and 589.2001 address a wide variety of firms and animal product operations that involve the manufacture, distribution, transportation, and feeding of animals. 21 CFR 589.2000 prohibits the feeding of specific mammalian proteins to ruminant animals, 21 CFR 589.2001 prohibits the use of specific cattle-origin tissues in the feed of all animals, including pet food. As a result, the regulations have broad applications, including at operations that do not involve ruminant feeds or the feeding of ruminant animals. Inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with regulations be encountered. CVM has developed a mathematical system for priotitizing inspections, which ORA has used the last several years to help with the annual work-planning. The following list of firm/industry types generally describes our priorities, in descending order:

- Follow-up to OAI inspections
- Firms with a violative history
- Firms that manufacture prohibited material or use prohibited material in their manufacturing (renderers, protein blenders, and feed mills)
- Renderers
- Protein Blenders
- Commercial feed mills (licensed and unlicensed)
- Pet food/livestock feed salvage operations
- Haulers/transporters of animal feeds
- Animal feed distributors/retailers
- On-farm feed manufacturers (with ruminant and non-ruminant animals, or only ruminants)
- Ruminant feeders
- On-farm feed manufacturers (no ruminants on the farm premises)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
High Risk Feed Inspection Pilot Assignment (FSMA)	Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
71V030	[X] ORA [ ] CENTER	7.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	HIGH RISK INSPEC-TIONS (1)
	TOTAL FIELD	**228**
	HEADQUARTERS	(b) (5), (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		30.0
TOTAL HOURS		6840
CONVERSION FACTOR		950
TOTAL OPERATIONAL FTEs		7.20

7. REMARKS

(1) - The field can expect a high risk feed inspection pilot assignment related to manufacturing practices to inspect such firms as salvagers, pet food/LACF manufacturers, unlicensed medicated/unmedicated feed mills, and feed ingredient manufacturers, all flagged with a risk identifier.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation	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	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (HOURS)	APPLIED ECHNOLOG CENTER CHEM (HOURS)							
	TOTAL FIELD	**1205**	**4720**							
	HEADQUARTERS	(b) (5), (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		1205	4720							
CONVERSION FACTOR		1205	1180							
TOTAL OPERATIONAL FTEs		1.00	4.00							

7. REMARKS

Workload Source - Determined by Office of Regulatory Science.

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	1.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL FIELD	**1205**								
	HEADQUARTERS	(b) (5), (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		1205								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		1.00								

7. REMARKS

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 [X] CENTER	6.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INVESTI-GATIONS (Hours)	DOMESTIC LAB ANALYST CHEM (Hours)							
	TOTAL FIELD	**4946**	**1145**							
	HEADQUARTERS	(b) (5), (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		4946	1145							
CONVERSION FACTOR		950	1180							
TOTAL OPERATIONAL FTEs		5.21	0.97							

7. REMARKS

Investigational and analytical resources include time for investigating pet turtle establishments and inspecting pharmacies that compound animal products. Resources also may be applied to sample collections and analyses when investigating adverse events.

Workload based on Feed Manufacturing, Feed Contaminants and Animal Drug Manufacturing program inventories.

Note: Laboratory allocations were planned by Office of Regulatory Science (ORS).