

Program Description Reports
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Center for Food Safety & Applied Nutrition
PROGRAM DESCRIPTIONS
FY2011

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1. PROGRAM/ASSIGNMENT TITLE Imported Acidified & Low Acid Canned Foods		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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.			
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 and source country (including container integrity, signs of intentional adulteration, etc); and traditional safety concerns. See the full program for more detail.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Refer to Compliance Program (7303.003)		d. INDUSTRY/PRODUCT CODE(S) 03-04, 09, 12-18, 20-25, 27, 29, 30-31, 33-41	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES pH, water activity, salinity, soluble solids.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program			

1. PROGRAM/ASSIGNMENT TITLE Domestic & Imported Cheese & Cheese Products		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To conduct inspections of domestic and foreign soft 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 03R839).			
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 guidance in the Compliance Program regarding the collection of domestic samples not resulting from inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Hard and soft cheeses.		d. INDUSTRY/PRODUCT CODE(S) 12	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Salmonella, Listeria, E. coli, Enterotoxigenic E. Coli (ETEC), Enterohemorrhagic 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		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 annual 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 guidance.			
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 Firms in compliance and that have not registered new products nor significantly changed a current process, may be inspected on a 3-year frequency. Special situation firms are to be inspected according to the guidance in the compliance program (see program). It is estimated that (b) (7)(E) FDA inspections are needed to fulfill program obligations in FY 11. 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. See full program for more detail.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) See Compliance Program.		d. INDUSTRY/PRODUCT CODE(S) 16, 20-22, 24-25, 27, 35, 37, 38, 40-41	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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 Domestic Food Safety		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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. Resources to conduct foreign inspections of food establishments are also planned here. 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. Resources from this program may be directed to monitor chicken eggs for Salmonella Enteritidis and for follow-up Assignments. 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 other firms. Resources provide for sample collections and analyses are projections based on recent data, and not absolute workplan obligations.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Food Products (except Industry Code 12, 16)		d. INDUSTRY/PRODUCT CODE(S) 02-11, 13-15, 17-41, 45-46, 50, 54	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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.	
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. Districts should deemphasize coverage of products that are not consistent with priorities noted in the list. See full Program for more details.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products (except Industry Code 12, 16, 40,41)	d. INDUSTRY/PRODUCT CODE(S) 02-09, 13-15, 17-39, 45-54
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES 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		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 operations (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 As in FY 10, High Risk Potential Products (HRPP) processors whose last inspection was NAI, can be considered for a 2-year inspection cycle. An exception would be if the firm added a new high risk seafood product to their line since the last inspection. 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. See full program for more detail.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Domestic Fish and Fishery Products		d. INDUSTRY/PRODUCT CODE(S) 16	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>PSP, ASP, Standards, Economic Deception, Labeling</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fisheries 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	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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.	
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. It is equally important 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. See full program for more detail.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Seafood Products	d. INDUSTRY/PRODUCT CODE(S) 16
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (PSP, ASP, Standards, Labeling)	
f. CHECK THE FOLLOWING ATTRIBUTES Refer to the Fish & Fisheries 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	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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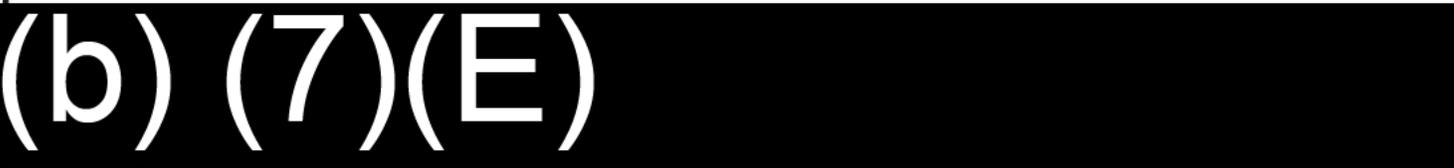
3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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.

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



See full program for more detail.

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

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Juice Products	d. INDUSTRY/PRODUCT CODE(S) 20-22, 24, 25
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL 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 Imported and Domestic Micro Assignments		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected types of produce of domestic and foreign origin for pathogenic microorganisms as needed and directed by CFSAN assignments.			
5. PROGRAM JUSTIFICATION The number of illnesses and deaths related to foodborne illness, due to the presence of microbial pathogens have reached an unacceptably high level in the U.S. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. Produce continues to be one of the major contributors to outbreaks.			
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the FY 11 produce assignments issued by CFSAN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Fresh fruits and vegetables as specified in the assignment.		d. INDUSTRY/PRODUCT CODE(S) 20-22, 24-25	
e. EXAM TYPE CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Presence (and for specified pathogens, quantity) of microbial pathogens listed in the assignment.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Environmental Sampling		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) To be specified in assignments		d. INDUSTRY/PRODUCT CODE(S) To be provided in assignments	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES To be specified in assignments.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Refer to assignments and to DFI Food Bulletins #30 and #32 for equipment and special instructions			

1. PROGRAM/ASSIGNMENT TITLE Unspecified Foreign Inspections/Assessments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted to take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety Inspections are conducted and planned under the appropriate domestic compliance program. An additional block of resources are set aside as reserve for as yet unidentified foreign inspections.	
5. PROGRAM JUSTIFICATION As part of the Agency's strategy of focusing on risk based firms FDA plans to work with foreign governments and Federal partners to ensure that foods produced in foreign facilities meet the U.S. safety requirements.	
6. FIELD OBLIGATIONS ORA/DFI shall plan inspections of foreign firms recommended by CFSAN in so far as contacting the firms and foreign governments a working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN for review and classification. See full program for more detail.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection	d. INDUSTRY/PRODUCT CODE(S) 02-50, 54
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES Check appropriate domestic compliance program for details.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Resources for samples collected as part of infant formula or medical food foreign inspections are planned under those programs.	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR 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 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 Workplan 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 BY BOTH

b. INSPECTION TYPE
 COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) To be specified in assignments.	d. INDUSTRY/PRODUCT CODE(S) To be specified in assignments.
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
 To be specified in assignments.

1. PROGRAM/ASSIGNMENT TITLE Contract Management		2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct an effective state contract inspection program, augmenting regulatory inspections conducted by Agency investigators. To perform audits of inspections by states that are under contract to FDA to conduct food inspections.			
5. PROGRAM JUSTIFICATION Over 10,000 food inspections are anticipated to be contracted out in FY 11 by FDA to the states. The Agency needs to conduct appropriate oversight and management of the contracted inspections.			
6. FIELD OBLIGATIONS To effectively manage contract inspection program for participating states within the district. Inspections should be planned by the field. Report under Operation Code 13 (Domestic Investigation). Audits are not considered inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input checked="" type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products		d. INDUSTRY/PRODUCT CODE(S) 02-41, 45-46, 50	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING			
<input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Following DFSR guidance.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Food Defense	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To maintain food defense preparedness by means of joint CFSAN/ORAs 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.	
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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Food Products	d. INDUSTRY/PRODUCT CODE(S) All food industry/ product codes.
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES To be directed by assignment and protocols jointly developed by CFSAN and ORA.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING To be directed by assignment and protocols jointly developed by CFSAN and ORA.	

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To sample and analyze domestic and imported foods for pesticide residues to determine compliance with EPA residue tolerances and FDA enforcement levels. To take enforcement action when violations are detected, including DWPE 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 and 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			
<input type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER	
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All human foods		d. INDUSTRY/PRODUCT CODE(S) All human food codes	
e. EXAM TYPE			
<input checked="" type="checkbox"/> CHEMICAL		<input type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
		<input type="checkbox"/> ENGINEERING	
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> OTHERS (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		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 11 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 11 Collection Schedule for additional instruction.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Seafood Products		d. INDUSTRY/PRODUCT CODE(S) 16	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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 Toxic Elements in Food, Foodware, and Radionuclides in Foods (Import and Domestic)		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 foodware 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 seafoods) 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 11 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human food products. Ceramic foodware.		d. INDUSTRY/PRODUCT CODE(S) 02-41, 52A	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (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	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine the levels of occurrences and dietary intakes of selected pesticides, industrial chemicals, and toxic elements by various age/sex 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Various Human Foods	d. INDUSTRY/PRODUCT CODE(S) All Human Food Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Moisture Content</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Chemical Contaminants	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected food products of domestic and foreign origin for chemical contaminants as directed by CFSAN field assignments. Assignments are anticipated for perchlorate in foods, contaminants in honey, and general pesticides and toxic elements in dietary supplements. Selected TDS samples will be analyzed for perchlorate in foods.	
5. PROGRAM JUSTIFICATION Monitoring of foods for suspected chemical contaminants is necessary to ensure a safe food supply. Perchlorates and furan have recently been identified as suspect contaminants and monitoring is required to provide the Agency with incidence and level data to properly evaluate their presence in the food supply. Contaminants like fluoroquinilone and nitrofurans have been detected in imported honey. Sample collection and analysis of imported honey will continue as directed by the "Import Bulletin." There are concerns regarding pesticides and toxic elements in dietary supplements yet there are minimal monitoring data available to the Agency for these products.	
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the assignment(s) issued by CFSAN. 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Selected human foods and dietary supplements	d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignments
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES Chemical contaminants as directed by CFSAN field assignments.	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by the assignments.	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES Forensic evaluation and forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.			
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.			
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of Investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Seafood Products		d. INDUSTRY/PRODUCT CODE(S)	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Unapproved drugs per the Compliance Program			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Conduct follow-up investigations, inspections, sample collections and analyses related to outbreaks and illness attributed to pesticide or chemical contamination of food products. Follow-up to Reportable Food Registry reports 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 workplan specifically to conduct the 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 and/or firm.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
d. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES To be specified in assignments	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Mycotoxins in Domestic and Import Foods		2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 FB ₁ , FB ₂ and FB ₃) 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) See Attachment "A" C.P. 7307.001 for list of Products.		d. INDUSTRY/PRODUCT CODE(S) See Attachment "A" C.P. 7307.001 for list of Product Codes.	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Aflatoxins, Fumonisins (Fumonisin FB ₁ , FB ₂ and FB ₃), Deoxynivalenol (DON), Ochratoxin A, and Patulin.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program (C.P.) 7307.001			

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Molecular Biology and Natural Toxins - 07
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3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives		2. PPS PROJECT NAME/NUMBER Food and Color Additives - 09	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 workplan sheet form 2621a under PAC 09006A,B. 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All human foods		d. INDUSTRY/PRODUCT CODE(S) All food codes	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Review</i>)			
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	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM TYPE 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 BY BOTH

b. INSPECTION TYPE

COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Foods	d. INDUSTRY/PRODUCT CODE(S) Inspections: 51 NY
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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		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Grade "A" Milk and Milk Products, (Cheese, Butter, Dry Milk and Frozen Dessert - when produced in IMS Plants)		d. INDUSTRY/PRODUCT CODE(S) 09,13,14	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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	2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3. PROGRAM TYPE	<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR	<input type="checkbox"/> ASSIGNMENT
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4. OBJECTIVES

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

<input type="checkbox"/> BY DISTRICT OFFICE	<input type="checkbox"/> BY CENTER	<input checked="" type="checkbox"/> BY BOTH
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b. INSPECTION TYPE

<input type="checkbox"/> COMPREHENSIVE	<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
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c. PRODUCT(S) Fresh and fresh frozen molluscan shellfish	d. INDUSTRY/PRODUCT CODE(S) 16, 52 B, Y
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e. EXAM TYPE

<input type="checkbox"/> CHEMICAL	<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL	<input type="checkbox"/> ENGINEERING
<input type="checkbox"/> MICROANALYTICAL	<input type="checkbox"/> OTHERS (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 Interstate Travel Program - Conveyances and Support Facilities		2. PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 Public Health Service Act, the Food, Drug and Cosmetic (the 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 baggages, 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 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 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human food, water, and waste; conveyance environmental conditions		d. INDUSTRY/PRODUCT CODE(S) Inspections/Investigations: Industry 51, All food codes including water 29W (Y30).	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Food and water surveillance and contamination, mostly micro. with chem. analysis for heavy metals in water on a for cause basis e.g. lead, cadmium, cooper in portable water systems at new support facilities and 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		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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.			
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. Medical foods are identified as "high-risk" foods under the Center's Food Safety Initiatives. Foreign inspections of medical foods firms are also planned in this program. Investigational time to determine the admissibility of imported lots of medical foods firms are planned under PAC 03819. Resources are planned in this program for collection and analyses 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. 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Medical Foods		d. INDUSTRY/PRODUCT CODE(S) 41G[] [] Use appropriate product identification number	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (Label Reviews)			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrient declarations. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> and Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See compliance program.			

1. PROGRAM/ASSIGNMENT TITLE Field Assignments for Economic Fraud		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To collect and analyze selected food products as directed by CFSAN field assignments.			
5. PROGRAM JUSTIFICATION Monitoring of foods for suspected economic deception and food standard deviations is necessary to ensure a safe food supply.			
6. FIELD OBLIGATIONS To collect samples and perform analyses as specified in the assignment(s) issued by CFSAN.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Selected human foods		d. INDUSTRY/PRODUCT CODE(S) As directed by CFSAN assignment(s)	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Review</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES As directed by CFSAN field assignment(s)			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING As directed by CFSAN field assignment(s)			

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA Nutrient Sample/Analysis and General Food Labeling Program		2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 #2); and (2) surveillance samples collected for general nutrient analyses (see C.P. Area of Emphasis #6).			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All food products (except vitamins/minerals)		d. INDUSTRY/PRODUCT CODE(S) 02-41	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
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		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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.			
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. Infant formulas are identified as "high-risk" foods under the Center's Food Safety Initiatives. Additional resources have been budgeted to allow annual inspections and sample collections from infant formula firms. Inspections of foreign infant formula firms are also planned in this program. Investigational time to determine admissibility of import lots of infant formula from foreign manufacturers are planned under PAC 03819. Resources are planned in this program for collection and analyses 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/FPB 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Infant Formula		d. INDUSTRY/PRODUCT CODE(S) 40C	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES Nutrients as required by the Act. Micro exam for <i>Listeria monocytogenes</i> , <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Escherichia coli</i> , Aerobic Plate Count (APC).			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING See Compliance Program.			

1. PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import		2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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.			
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 collection and analyses, and compliance objectives in accordance with the Dietary Supplement Health and Education Act of 1994. The Center has set aside resources for special headquarters initiated assignments to address emerging issues. Investigational and sample collection time is set aside for continued focus on supplements bearing false or misleading claims on their 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Dietary supplements		d. INDUSTRY/PRODUCT CODE(S) 54	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)			
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 .	2. PPS PROJECT NAME/NUMBER Food Composition Standard Labeling and Economics-21
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Various foods as required by the Total Diet Studies Program	d. INDUSTRY/PRODUCT CODE(S) 37, 40
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Reviews</i>)	
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	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM TYPE COMPLIANCE PROGRAM PROGRAM CIRCULAR ASSIGNMENT

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

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

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

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

b. INSPECTION TYPE
 COMPREHENSIVE ABBREVIATED DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Import		2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Cosmetic Products		d. INDUSTRY/PRODUCT CODE(S) 53	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Label Review</i>)			
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 Biologics Evaluation & Research
PROGRAM DESCRIPTIONS
FY2011

PAC CODE	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PAGE NO.
41002B,C,D	Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS)	BI-1
41808, 41809, 41810, 41811	GLPs (Nonclin. Lab), IRBs, Spon/Mon/CROs, Clinical Investigators (PDUFA)	BI-2
42001F,G	Inspection of Licensed and Unlicensed Blood Banks	BI-3
42002F,G	Inspection of Source Plasma Establishments	BI-4
42007, 42R833, 42R824, 99R833, 41R824, 45R824	Imported CBER- Regulated Products	BI-5
42008,A	Inspections of Licensed Viral Marker Test Kits	BI-6
42809, 42810, 42811	IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	BI-7
42845A,B,C	Inspection of Medical Device Manufacturers (Biologics)	BI-8
42848A,F,G	Inspections of Plasma Derivatives of Human Origin	BI-9
45809, 45810, 45811	IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	BI-10
45848A,F,G	Inspection of Licensed Allergenic Products	BI-11
45848B,C,D	Inspection of Licensed Vaccine Products	BI-12

1. PROGRAM/ASSIGNMENT TITLE Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)		2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To determine if human cells, tissue, and cellular & tissue-based product (HCT/P) establishments are in compliance with the regulations (21 CFR, Part 1270 and 1271), promulgated under the Public Health Service Act, Section 361, to assure 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 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 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 and processing 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 and submit EIRs to the Center for Biologics Evaluation and Research (CBER), and recommend administrative/regulatory actions when appropriate.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Biologics		d. INDUSTRY/PRODUCT CODE(S) Reproductive Tissue, 57 K; Hematopoietic Stem Cells, 57 M; 41002D: 57 J, 57 L, 57 O; All Other HCT/Ps N.E.C., 57 P 99	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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)		2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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, Contract Research Organizations (Spon./Mon./CROs), and monitors 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Biologics		d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products N.E.C.	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks		2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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) Licensed Blood Donor Centers which collect blood and ship to the Licensed 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 and submit the 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. Training of field personnel will be coordinated with CBER.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Blood and Blood Products		d. INDUSTRY/PRODUCT CODE(S) 55, 57	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments		2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Source Plasma		d. INDUSTRY/PRODUCT CODE(S) 55, 57	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Imported CBER-Regulated Products	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biological Products	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspections of Licensed Viral Marker Test Kits		2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To evaluate the manufacturing process for licensed <i>in vitro</i> 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), <i>In Vitro</i> 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 <i>In Vitro</i> 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 these 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 Core Team member and may include a District Representative and / or a Product Specialist from CBER.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input checked="" type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) <i>In Vitro</i> Diagnostic Products accordance with the stated Objective.		d. INDUSTRY/PRODUCT CODE(S) 55, 57, 65, & 81 (Device Categories)	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Device Specific</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>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).</p> <p>Spon./Mon./CROs: To assess the adherence of Sponsors, Contract Research Organizations (Spon./Mon./CROs), and monitors to the current regulations (21 CFR 312 and 812) and their oversight of clinical studies.</p> <p>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).</p>	
5. PROGRAM JUSTIFICATION <p>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.</p> <p>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.</p> <p>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.</p>	
6. FIELD OBLIGATIONS <p>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.</p> <p>Spon./Mon./CROs: Conduct inspections as assigned by CBER and forward the report(s) to the appropriate office.</p> <p>Clinical Investigators: Conduct inspections as assigned by CBER and forward report(s) including recommendations for compliance follow-up as needed.</p>	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products N.E.C.
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)		2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To evaluate the manufacturing processes for those medical devices and <i>in vitro</i> 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 strategy for inspecting those firms not regulated under the licensing provisions of Section 351 of the Public Health Service Act are for Biennial Inspection . The product categories are primarily in the area of devices used in blood banking.			
6. FIELD OBLIGATIONS Conduct inspections pursuant to the instructions in the OMD 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 <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) All devices in the product categories transferred to CBER.		d. INDUSTRY/PRODUCT CODE(S) 65 & 81 (Device Categories)	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (<i>Device Specific</i>)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Inspections of Plasma Derivatives of Human Origin	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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.	
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 Core Team member, and may include a District Representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Fractionation Products	d. INDUSTRY/PRODUCT CODE(S) 55, 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE IRBs, Spon./Mon./CROs, Clinical Investigators (PDUFA)		2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES 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, Contract Research Organizations (Spon./Mon./CROs), and monitors 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 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 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.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Biologics		d. INDUSTRY/PRODUCT CODE(S) 57 / 99 99 is used for products N.E.C.	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 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.	
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 single, 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 Core Team member, and may include a District Representative and/or a Product Specialist from CBER.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Biologics	d. INDUSTRY/PRODUCT CODE(S) 57
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products		2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 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.			
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 single, 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 Core Team Member and may include a District Representative and/or a Product Specialist from CBER.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input checked="" type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Biologics		d. INDUSTRY/PRODUCT CODE(S) 57	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

Center for Drug Evaluation & Research

PROGRAM DESCRIPTIONS

FY2011

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

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

1. PROGRAM/ASSIGNMENT TITLE BLA Pre-Approval Inspections/Investigations – Domestic and Foreign		2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To verify that 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All Human Drugs; specifically, Licensed Biological Therapeutic Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 57	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE PET NDA Pre-Approval Inspections/Investigations	2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that NDA applicant has facilities, equipment, controls, etc. so specified in their application. To determine compliance of manufacturing establishments with GMPs prior to approval of pending NDAs.	
5. PROGRAM JUSTIFICATION Compliance of manufacturing establishments must be assessed before NDA approvals.	
6. FIELD OBLIGATIONS Conduct pre-approval establishment inspections as requested by Center for Drug Evaluation and Research.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Human Drugs, Including Radioactive Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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 In Vivo Bioequivalence (PDUFA) - Domestic		2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES Through audit procedures determine whether data submitted to FDA in NDAs and ANDAs are accurate and valid.			
5. PROGRAM JUSTIFICATION Bioequivalence studies are conducted mainly by private and university affiliated contract laboratories. Previous inspections noted deviations from protocols, poor recordkeeping, inadequate controls over test subjects, poor analytical procedures and fraud. Results of bioequivalence inspections have a direct relationship to approvability of NDA and ANDA applications.			
6. FIELD OBLIGATIONS Conduct inspections and forward the reports directly to the Division of Scientific Investigations, CDER, for evaluation and follow-up.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (PDUFA) - Foreign Inspections		2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

1. PROGRAM/ASSIGNMENT TITLE Institutional Review Board (IRB); Radioactive Drug Research Committee (RDRC)		2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES <p>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.</p> <p>RDRC: To assure the quality and integrity of Radioactive Drug Research Committees and assure they are operating in compliance with (21 CFR 361.1).</p>			
5. PROGRAM JUSTIFICATION <p>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.</p> <p>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.</p>			
6. FIELD OBLIGATIONS <p>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.</p> <p>Assist in presentation of IRB workshops.</p> <p>RDRC: Conduct inspections of RDRCs and forward the EIRs to the Division of Scientific Investigations, CDER.</p>			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Sponsors, Contract Research Organizations, & Monitors		2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To assure adherence by sponsors, contract research organizations, and monitors to the regulations (21 CFR 312) and to assess their interaction with clinical investigators and the sponsors development of safety and efficacy data in NDAs.			
5. PROGRAM JUSTIFICATION Sections of the FD&C Act and the Public Health Service Act require the submission of data to FDA ensuring the safety of human drugs, as well as the filing of an Investigational New Drug Application and New Drug Applications. An inspectional program is required to assess compliance with current regulations.			
6. FIELD OBLIGATIONS Conduct inspections of sponsors, contract research organizations, and monitors for the IND/NDAs identified in the assignments. Forward reports directly to the Division of Scientific Investigations, CDER, for final classification, including District recommendations for compliance follow-up.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

4. OBJECTIVES
To assess 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 BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Code: 60, 61
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre-Approval Inspections/Investigations	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To verify that ANDA applicant has facilities, equipment, controls, etc. so specified in their 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE ANDA Pre-Approval Inspections/Investigations - Foreign	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE PET ANDA Pre-Approval Inspections/Investigations	2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52
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3. PROGRAM TYPE 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 BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

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

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING
 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 Enforcement of the Adverse Drug Experience Reporting Regulations		2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To provide assignments, guidance and instructions to field offices for inspecting drug firms to determine compliance with the 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56, 60-66	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Risk Evaluation and Mitigation Strategy (REMS) (PDUFA)	2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance & Epidemiology: Human Drugs - 53
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3. PROGRAM TYPE 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. This subtitle of FDAAA took effect on March 25, 2008, 180 days after enactment of FDAAA. 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 BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 55, 56, 57, 59, 60-66, 99
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Inspectional work is to minimize the consumer's risk of exposure to defective drug products by preventing the marketing of or removing from the market, violative drug products that are observed as a result of inspections performed under this Program.	
5. PROGRAM JUSTIFICATION The international Drug Process Inspection program is FDA's primary means for evaluating the conditions under which foreign drug products are manufactured, tested, packaged and held.	
6. FIELD OBLIGATIONS The field will conduct drug process inspections and maintain profiles of foreign drug manufacturers.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Drug Process Inspections: Inspections of Licensed Biological Therapeutic Drug Products		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs; specifically, Licensed Biological Therapeutic Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Code: 57	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input checked="" type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

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

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

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

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

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

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 Drug Product Surveillance		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To obtain information about the quality of the nation's drug supply through analyses of selected domestic and imported finished dosage form products and active pharmaceutical ingredients (APIs). To direct analytical coverage 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56 and 60-66	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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 Drug Quality Reporting System - DQRS NDA-Field Alert Reporting		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To establish and operate a structured system for accumulating and evaluating data generated by Drug Quality Reporting System (DQRS) a voluntary reporting program, and NDA Field Alert Reports (FARs), a program mandated by 21CFR 314.81 for reporting by drug manufacturers. To maintain a flexible capability for rapid investigations and product corrections of any drug product quality problems ascertained from 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES To 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) All Human Drug Codes	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Analysis as directed in CDER/district assignments.			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations (Domestic and Foreign)	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To 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, stability program and laboratory 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Human Drugs	d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54-56, 60-66
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Pharmacy Compounding Assignments		2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES Monitor, investigate and take regulatory action, (including working jointly with state regulatory officials), on complaints involving pharmacy compounded drug products and pharmacy compounding operations that are in violation of applicable sections of the Federal Food, Drug, and Cosmetic Act (the Act).			
5. PROGRAM JUSTIFICATION FDA ensures the availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. The agency investigates complaints reports of illnesses associated with compounded drug products. The agency will consider regulatory action, where necessary, to protect the public health and address applicable violations of the Act.			
6. FIELD OBLIGATIONS Districts will conduct inspections and investigations, collect evidence, samples and develop cases in accordance with Assignments from CDER/OC/DNDLC.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, 56 and 60-66	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.	
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.	
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic activities PAC 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, and OTC Monographs		2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To identify and evaluate OTC drug products and to assure their compliance with specific OTC drug monographs or other regulations; 2) to detect, investigate and take action against fraudulent drug products that present the public with a direct and indirect health hazard and economic fraud; and, 3) to monitor, investigate and take regulatory action on the illegal promotion, distribution and sales of prescription and non-prescription drug products via the Internet, including illegal off-shore pharmacy operations associated with approved and unapproved drug products promoted for approved and unapproved treatment of diseases.			
5. PROGRAM JUSTIFICATION 1) In the Federal Register of 1/5/72, the Commissioner announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory panels. As a result, final monographs are published (21 CFR Part 330 through Part 358) which establish conditions under which OTC drugs can be generally recognized as safe and effective and not misbranded; 2) to combat the deceptive and misleading sale of fraudulent drug products; and, 3) FDA must monitor the promotion and sale of drug products on the Internet to identify activities which violate the law and pose a risk to the public health.			
6. FIELD OBLIGATIONS The Field conducts inspections and investigations, develops evidence, collects and analyzes samples, evaluates product labeling, performs surveillance activities, and recommends compliance actions concerning OTC drugs, fraudulent drugs and drugs sold on the Internet as set forth in applicable compliance programs and CDER guidance and requests for follow-up.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 50, 54, and 60-66	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE New Drug (Prescription) Without Approved NDAs		2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To establish uniform procedures for removal from the market of all prescription drug products described by FDA to be new drugs not covered by approved New Drug Applications 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. For historical reasons, some drugs are available in the United States that lack the required FDA-approval. In June 2006, the FDA announced a new drug safety initiative to remove unapproved drugs from the market, including a final guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide (CPG)," outlining its enforcement policies aimed at efficiently and rationally bringing all such drugs into the approval process. The 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. For all unapproved drugs, 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/DNDLC. -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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Human Prescription Drugs		d. INDUSTRY/PRODUCT CODE(S) Industry Codes: 54, 56 and 60-66	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

Center for Veterinary Medicine
PROGRAM DESCRIPTIONS
FY2011

PAC CODE	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PAGE NO.
68001	NADA Pre-Approval Inspections	AD-1
68808	Good Laboratory Practice (Non-clinical Laboratory)	AD-2
68810	Sponsors, Contact Research Organizations, and Monitors	AD-3
68811	Clinical Investigators	AD-4
71001	Animal Drug Manufacturing Inspections/Type A Medicated Articles	AD-5
71003	Feed Contaminants	AD-6
71004	Feed Manufacturing	AD-7
71006	Illegal Drug Residues in Meat and Poultry	AD-8
71009	BSE/Ruminant Feed Ban Inspections	AD-9
71R816	Methods Validation/Development Program	AD-10
71R838	Forensic Evaluation and Sample Analysis	AD-11
71V800	Center Initiated Assignments, Pandemic Preparedness	AD-12

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

4. OBJECTIVES

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

Increase the number of cooperative activities related to this program.

5. PROGRAM JUSTIFICATION

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

Outcome: Reduce new animal drug development and review time.

6. FIELD OBLIGATIONS

The Field will conduct NADA Pre-Approval Inspections at domestic and foreign plants in accordance with the assignment. Establishment inspection reports will be submitted to the New Animal Drug Evaluation (NADE) Program Manager (HFV-140) according to the procedures outlined for field reporting requirements in the compliance program.

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) Animal Drugs, Type A Medicated Feed Articles	d. INDUSTRY/PRODUCT CODE(S) 57, 67, 68
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

Petition validation work.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practice (Non-clinical Laboratory)		2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives 68	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections of facilities and non-clinical laboratories engaged in the collection of data to determine whether the GLP regulations (21 CFR 58) are followed. To take appropriate action whenever a situation involving a serious violation of the GLPs is encountered or when fraud or other deliberate falsifications of test data has occurred.			
5. PROGRAM JUSTIFICATION FDA requires that extensive animal and other types of testing be carried out before approving new animal drug applications or animal food petitions. The FDA's reliance on the basic accuracy of data submitted is essential to the review and approval of Agency-regulated products. The submission of faulty, erroneous, or distorted data increases the potential for wrong decisions and makes it difficult, if not impossible, to draw conclusions regarding the health hazards of the tested product. Outcome: Assure data integrity and reduce drug development time.			
6. FIELD OBLIGATIONS ORA will perform the inspections and submit EIRs in accordance with established procedures set forth in the basic compliance program 7368.808.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input checked="" type="checkbox"/> BY CENTER	
		<input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input checked="" type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Animal Drugs		d. INDUSTRY/PRODUCT CODE(S) 67,68 and 69	
e. EXAM TYPE			
<input type="checkbox"/> CHEMICAL		<input checked="" type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
		<input type="checkbox"/> ENGINEERING	
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

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

b. INSPECTION TYPE
 COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S)
 Animal Drugs

d. INDUSTRY/PRODUCT CODE(S)
 667, 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		2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives 68	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assess through audit procedures (21 CFR 511.1 (b)) whether data submitted by clinical investigators to FDA in a specific clinical study are substantiated by records.			
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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Animal Drugs		d. INDUSTRY/PRODUCT CODE(S) 67, 68, and 69	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Animal Drug Manufacturing Inspections Type A Medicated Articles	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To assure that registered animal drug establishments manufacture animal drugs in compliance with CGMPs 21 CFR 211 for 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All Animal Drug Dosage forms and Type A Medicated Articles. Medicated feeds or blocks are not included.	d. INDUSTRY/PRODUCT CODE(S) 54, 56, 60-66, 67, 68
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES Purity, identity, potency, decomposition	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Feed Contaminants		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To monitor domestic and imported animal feed and feed ingredients to prevent widespread contamination of the nation's food supply. Increase the number of cooperative activities related to this program.			
5. PROGRAM JUSTIFICATION The use of contaminated feed ingredients has resulted in adulterated animal feeds and in economic losses to producers and processors when food-producing animals consume adulterated feeds. A hazard to human health may result from subsequent deposition of residues in meat, poultry, eggs, fish and dairy products. These foods constitute a significant portion of the human diet and fraud. Outcome: Prevention or containment of potential human or animal health hazard.			
6. FIELD OBLIGATIONS To conduct inspections and investigations and sample collections/analysis to implement this program. Both finished feed and feed ingredients for major food animals will be collected for analysis. Field activities will cover misuse, industrial accidents, diversion of seed grain to feed use, industrial by-product conversion to feed and similar activities.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER	
		<input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE			
<input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	
		<input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Complete animal feeds and feed ingredients.		d. INDUSTRY/PRODUCT CODE(S) 54 and 69-72	
e. EXAM TYPE			
<input checked="" type="checkbox"/> CHEMICAL		<input checked="" type="checkbox"/> MICROBIOLOGICAL	
		<input type="checkbox"/> PHYSICAL	
		<input type="checkbox"/> ENGINEERING	
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> OTHERS (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	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To determine compliance with GMP elements of registered establishments producing medicated feeds. To determine whether a firm has the appropriate approved applications to make medicated feeds. To initiate appropriate administrative and/or regulatory action.	
5. PROGRAM JUSTIFICATION Under Sec. 510(h) of the Act, the Agency is obligated to inspect registered medicated feed establishments. Outcome: Ensure the 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) Medicated Feeds	d. INDUSTRY/PRODUCT CODE(S) 69
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Illegal Drug Residues in Meat and Poultry		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To conduct inspections when illegal residues are reported to FDA by the USDA's Food Safety and Inspection Service. To collect milk samples under the CVM milk sampling assignment. To initiate regulatory sanctions against those firms causing tissue or milk residues. To reduce future residues in edible animal tissues. FDA will partner with FSIS and will develop educational initiatives, and, as necessary, regulatory actions.			
5. PROGRAM JUSTIFICATION FDA is charged with the responsibility to ensure that food is free of adulterants which may render it injurious to health. FDA conducts inspections as a follow-up to USDA residue findings in meat and poultry to identify the source of adulteration and take corrective action to prevent it from re-occurring. This is a cooperative program involving FDA, USDA, EPA, and a number of state governments Outcome: To provide a safe human food supply.			
6. FIELD OBLIGATIONS To conduct inspections and collect milk samples in accordance with the compliance program requirements and sample assignments based on the Memoranda of Understanding (MOU) between FDA, USDA, and EPA. Coordinate state activities with states having MOUs, informal and formal agreements or contracts with FDA to conduct inspections and collect milk samples at establishments below the Risk Score Threshold for FDA inspections.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Meat and Poultry, Animal Feeds and Drugs		d. INDUSTRY/PRODUCT CODE(S) 16, 17, 67, 68, and 69	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input checked="" type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES To enhance the FDA's uniformity in inspection and compliance of firms subject to the regulation prohibiting the 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 containing ruminant-based material are the subject of this program. To provide guidance concerning the importation of animal feeds and feed ingredients from BSE at-risk countries, in accordance with Import Alert #99-25. See full program for more detail.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) All feeds and feed ingredients		d. INDUSTRY/PRODUCT CODE(S) 67-72	
e. EXAM TYPE <input checked="" type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input checked="" type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices 71
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

4. OBJECTIVES

To 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)
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e. EXAM TYPE

CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (*SPECIFY*)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

Center for Devices & Radiological Health
PROGRAM DESCRIPTIONS
FY2011

PAC CODE	FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	PAGE NO.
81010	Medical Device Problem Reporting - MDR Follow-up	DE-1
82008	Monitoring Devices of Foreign Origin - Import	DE-2
82845	Inspection of Medical Device Manufacturers	DE-3
82Z002	Condom Assignment	DE-4
82Z003	Manufacturers and Importers of Surgical/Examination Gloves	DE-5
82Z800	Center Initiated Assignments	DE-6
82R816	Methods Validation/Development Program	DE-7
82R838	Forensic Evaluation and Sample Analysis	DE-8
83001	Medical Device Premarket Approval and Postmarket Inspections	DE-9
83808, 83809, 83810, 83811	Bioresearch Monitoring	DE-10
84Z002	Test Method Development and Evaluation	DE-11
84R816	Methods Validation/Development Program	DE-12
85014	Mammography Facilities Inspection Program	DE-13
86001, 86002, 86004	Inspection and Field Testing of Radiation-Emitting Electronic Products	DE-14
86003	Inspection of Manufacturers (Foreign and Domestic) & Field Compliance Testing of Diagnostic X-Ray Equipment	DE-15
86006	Compliance Testing of Electronic Products at WEAC	DE-16
86007	Imported Electronic Products	DE-17
86008, 86009	Radiological Health Control Activities	DE-18

1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting – MDR Follow-up		2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81	
3. PROGRAM TYPE		<input checked="" type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
<input type="checkbox"/> 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			
<input type="checkbox"/> BY DISTRICT OFFICE		<input checked="" type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
b. INSPECTION TYPE			
<input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	<input checked="" type="checkbox"/> DIRECTED
c. PRODUCT(S) All Medical Devices		d. INDUSTRY/PRODUCT CODE(S) 73-91	
e. EXAM TYPE			
<input checked="" type="checkbox"/> CHEMICAL		<input checked="" type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL
<input type="checkbox"/> MICROANALYTICAL		<input checked="" type="checkbox"/> ENGINEERING	
<input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES Sterility Performance			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING Engineering Samples: Subs/sample will vary depending on cost, size, etc. Contact Center for guidance.			

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

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

5. PROGRAM JUSTIFICATION

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

6. FIELD OBLIGATIONS

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

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED

BY DISTRICT OFFICE BY CENTER BY BOTH

b. INSPECTION TYPE

COMPREHENSIVE ABBREVIATED DIRECTED

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

CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING

MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

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

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

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

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program		2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82	
3. PROGRAM TYPE		<input type="checkbox"/> COMPLIANCE PROGRAM	<input type="checkbox"/> PROGRAM CIRCULAR
		<input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.			
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.			
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED			
<input type="checkbox"/> BY DISTRICT OFFICE		<input type="checkbox"/> BY CENTER	<input type="checkbox"/> BY BOTH
b. INSPECTION TYPE			
<input type="checkbox"/> COMPREHENSIVE		<input type="checkbox"/> ABBREVIATED	<input type="checkbox"/> DIRECTED
c. PRODUCT(S)		d. INDUSTRY/PRODUCT CODE(S)	
e. EXAM TYPE			
<input type="checkbox"/> CHEMICAL		<input type="checkbox"/> MICROBIOLOGICAL	<input type="checkbox"/> PHYSICAL
<input type="checkbox"/> MICROANALYTICAL		<input type="checkbox"/> ENGINEERING	
		<input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis		2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82	
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT			
4. OBJECTIVES Forensic evaluation and Forensic sample analysis activities are to provide sound scientific support for the investigations of the Office of Criminal Investigations. This includes sample analysis of physical samples related to incidents of tampering, counterfeiting, fraud, adulteration and other violations of the FD&C and related Acts so that the findings are suitable to be presented as technical evidence in a court of law. It also includes forensic evaluation of methods and the generation of scientific data to identify, characterize, and assess the public health impact of possible adulterants, or intentional violation of the law regarding regulated products to assist FDA in its public health mission.			
5. PROGRAM JUSTIFICATION Incidents of tampering, fraud, and adulteration with known and potentially harmful substances make it clear that FDA needs to be able to conduct sample analyses to reliably determine the chemical identity of suspected substances and support its findings in the courts. FDA's unique public health mission makes it interested in types of forensic evaluation and method studies for which there are few customers and few external funding sources. To protect the public health FDA needs to continue to develop an arsenal of techniques which will permit it to determine the nature and source of risks through criminal investigations.			
6. FIELD OBLIGATIONS Appropriate scientific analysis of official physical samples in support of investigations are to be performed so that the findings are suitable to be presented in a court of law. The time spent on these activities is to be reported as PODS Operation Code 41 or 43, domestic or import sample analysis under the appropriate Forensic Activities PAC 82R838 or OCI PAC 82R831. Conduct operations supporting methods refinement, development, or general forensic studies that may be applied to laboratory evaluations to support the FDA mission. Report the time spent on these activities as PODS Operation Code 03, PAC 82R838: Petition Validation, Methods Development, or Forensic Evaluation. Please consult DFS and/or the DPEM for additional reporting guidance.			
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S)		d. INDUSTRY/PRODUCT CODE(S)	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections	2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83
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3. PROGRAM TYPE 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) (7)(E) (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 BY CENTER BY BOTH

b. INSPECTION TYPE COMPREHENSIVE ABBREVIATED DIRECTED

c. PRODUCT(S) All Medical Devices	d. INDUSTRY/PRODUCT CODE(S) 73-91
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e. EXAM TYPE CHEMICAL MICROBIOLOGICAL PHYSICAL ENGINEERING
 MICROANALYTICAL OTHERS (SPECIFY)

f. CHECK THE FOLLOWING ATTRIBUTES

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

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

1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 <input type="checkbox"/> BY DISTRICT OFFICE <input checked="" type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) To be assigned	d. INDUSTRY/PRODUCT CODE(S) 73-91
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
3. PROGRAM TYPE <input type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input checked="" type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES Develop new and/or improved methodology in support of regulatory analysis.	
5. PROGRAM JUSTIFICATION Validated analytical methods are essential to support enforcement activities.	
6. FIELD OBLIGATIONS Conduct activities under this program as directed by the Division of Field Science.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (<i>SPECIFY</i>)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

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

1. PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of inspections and tests conducted under this program are <ul style="list-style-type: none"> • 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input checked="" type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED	
c. PRODUCT(S) Lasers and laser products, Sunlamp and sunlamp products Cabinet x-ray products, Televisions and Microwave Ovens	d. INDUSTRY/PRODUCT CODE(S) 94-RXX, 95-RXX See Compliance Program 7386.001 for complete listing
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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 Inspection of Manufacturers (For and Dom) and Field Compliance Testing of Diagnostic X-Ray Equipment		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S) Diagnostic X-Ray Equipment		d. INDUSTRY/PRODUCT CODE(S) 94DS---	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (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		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority-86	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM		<input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> ASSIGNMENT	
4. OBJECTIVES The objectives of laboratory tests conducted under this program are: <ul style="list-style-type: none"> 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input checked="" type="checkbox"/> DIRECTED			
c. PRODUCT(S) Lasers, sunlamps, mercury vapor lamps, x-ray systems, ultrasound therapy products, televisions, and microwaves.		d. INDUSTRY/PRODUCT CODE(S) 96MS, 94VS, 94DS, 95US, 97US	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input checked="" type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products	2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 imports entry reviews verify that electronic products subject to performance standards have been reported to FDA as required.	
6. FIELD OBLIGATIONS The district import program manager will monitor all entries of electronic products for which performance standards are in effect and whether reports for imported products are contained in FDA databases. Any products which have been determined to be noncompliant with the performance standard or which have not been reported to CDRH will be detained. NOTE: only those products subject to performance standards are subject to import detention. All information gathered as a result of these activities will be furnished to the Office of Communication, Education and Radiation Programs (OCER)/Division of Mammography and Radiological Health Programs (HFZ-240) in accordance with the compliance program.	
7a. SELECTION OF ESTABLISHMENTS TO BE COVERED <input checked="" type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input type="checkbox"/> BY BOTH	
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED	
c. PRODUCT(S) All radiation emitting electronic products that are subject to a performance standard contained in 21 CFR 1020 – 1050.	d. INDUSTRY/PRODUCT CODE(S) 94-97
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)	
f. CHECK THE FOLLOWING ATTRIBUTES	
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING	

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities		2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86	
3. PROGRAM TYPE <input checked="" type="checkbox"/> COMPLIANCE PROGRAM <input type="checkbox"/> PROGRAM CIRCULAR <input type="checkbox"/> 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 <input type="checkbox"/> BY DISTRICT OFFICE <input type="checkbox"/> BY CENTER <input checked="" type="checkbox"/> BY BOTH			
b. INSPECTION TYPE <input type="checkbox"/> COMPREHENSIVE <input type="checkbox"/> ABBREVIATED <input type="checkbox"/> DIRECTED			
c. PRODUCT(S)		d. INDUSTRY/PRODUCT CODE(S) Emergency Planning & Response Activities: 94YN-99	
e. EXAM TYPE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PHYSICAL <input type="checkbox"/> ENGINEERING <input type="checkbox"/> MICROANALYTICAL <input type="checkbox"/> OTHERS (SPECIFY)			
f. CHECK THE FOLLOWING ATTRIBUTES			
g. SPECIAL EQUIPMENT, METHODS, AND HANDLING			