CHAPTER 56 - DRUG QUALITY ASSURANCE

SUBJECT:	IMPLEMENTATION DATE
DRUG QUALITY SAMPLING AND TESTING (DQST)-HUMAN DRUGS (aka "Drug Surveys") (Formerly entitled the "Drug Product Surveillance Program") (09/23/2011 – Correction made by removing attachment B organizational chart and adding appropriate implementation/completion date, and adding additional PACs)	08/02/2011 (Corr: 09/23/2011) COMPLETION DATE 09/30/2014

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
Industry codes: 50, 54-56, 60-66	56008A - CDER-Initiated (Domestic samples) 56008L - CDER-Initiated (Domestic-Import samples) 56008H – Import Labeling Examinations

FIELD REPORTING REQUIREMENTS

A. DRUG QUALITY SAMPLING AND TESTING (DQST) COORDINATORS

1. Each district and laboratory assigns Drug Quality Sampling and Testing (DQST) Coordinators to monitor the sampling and analysis under this program. The DQST program is commonly referred to as the "Survey Program". When the DQST assignments or "survey assignments" are issued to the field districts, there are "survey numbers" associated with specific product names or a category of products.

2. The Program Manager in CDER's Office of Compliance (OC), Office of Manufacturing and Product Quality (OMPQ), Division of Policy, Collaboration and Data Operations, (DPCDO), Drug Surveillance and Data Reporting Branch (DCDRB) interfaces with the DQST Coordinators via the Field Accomplishment and Compliance Tracking System (FACTS) database. The Program Manager issues DQST "survey" assignments in FACTS, then monitors and provides updated status reports of survey sample collections and testing to the DQST Coordinators via electronic mail on a monthly basis. The DQST Coordinators, investigators, and laboratory personnel use FACTS to report both their sample collections and specific testing results. For tracking purposes, it is important that the DQST Coordinators use the assigned **FACTS Work Request Identification Numbers** associated with specific drug products (designated with unique survey numbers) in order to capture their sample collection and analyses information. Each drug product is assigned a unique survey number (or one survey number pertains to a group of drug products sharing common characteristics) reflecting the fiscal year followed by a number (e.g. 2012-001) and a FACTS

Identification Number is associated with the survey number. Survey numbers are associated with all finished dosage forms, excipients, or active pharmaceutical ingredients (API)s.

3. If samples are unavailable for collection (i.e., the firm no longer manufactures the product or the manufacturing firm has moved from the assigned district), the assigned district should return the assignment to OMPQ/DPCDO/DSDRB utilizing the "return assignment" in FACTS and should provide a list of products available for collection. Each “returned” assignment should include the reason for the return, and if known, the name and address of the new location where samples are available. The assigned district should alert the OMPQ/DPCDO/DSDRB Program Manager via electronic mail to surveyreport@cder.fda.gov so that the Program Manager can re-assign the sample collection to the appropriate district in FACTS [or select a different product for collection].

B. VIOLATIVE SAMPLES (OUT-OF-SPECIFICATION) RESULTS

Immediately notify the OMPQ/DPCDO/DSDRB Program Manager by e-mail to surveyreport@cder.fda.gov, the Division of Field Science (DFS) in the Office of Regional Operations (ORO), and the home district of the manufacturer of any out-of-specification sample results. Send the original worksheets to the home district for follow-up, along with a copy of the summary worksheet to the attention of the DSDRB Program Manager. CDER’s OC may be the home district in certain circumstances. Please check the collection report to identify the appropriate home district.

C. ANALYTICAL RESULTS AND FINDINGS

1. Accurately enter into FACTS all specific analytical results and testing methodology used. In addition to providing the specific analytical results for each test performed, please provide the basic pass/fail results in the “Laboratory Conclusion” field under “Sample Summary”. Also, the following Laboratory Classifications (LC) are to be provided in the Laboratory Report:

   LC 1: In Compliance
   LC 2: Regulatory Action Not Needed
   LC 3: Adverse Findings
   LC 4: No Classification Needed
   LC 5: Sample Not Analyzed or Reviewed

2. The OMPQ/DPCDO/DSDRB Program Manager prepares a summary report of the products sampled and tested for each fiscal year and the DQST Coordinators review the status update information. The summary report includes the number of samples collected and tested for each drug product; the Online Reporting Analysis Decision Support System (ORADSS) accomplishment data for the Program Activity Code (PAC) 56008A (for domestic sampling and testing activities), PAC 56008L (for domestic-import sampling and testing activities), and PAC 56008H (for import labeling examinations); a brief description of out-of-specification sample results along with reported findings of the follow-up conducted by the

home district. More detailed summary reports are being developed and, upon implementation, will be posted at the following URL:

http://inside.fda.gov:9003/CDER/OfficeofCompliance/DivisionofComplianceRiskManagemntSurveillance/ucm254252.htm

These new summary reports will reflect data extracted directly from FACTS relative to the sample collection reports and laboratory reports.

PART I – BACKGROUND

The goal of the Drug Quality and Sampling Testing (DQST) compliance program is to protect the public health by means of sampling and testing domestic and international (domestic-import) drug products in order to minimize exposure to non-compliant and/or poor quality drugs. This is accomplished by means of targeting products (finished dosage forms, APIs, and excipients) for sampling based on risk-based selection criteria and a risk-based model, and then conducting drug quality testing in an effort to monitor and assure the quality of the nation's drug supply. This program, in combination with other quality assurance compliance programs, is an integral part of the Agency's overall post marketing surveillance strategy.

In previous years, survey samples were mainly collected directly from manufacturers, distributors, and wholesalers, and were primarily prescription drugs subject to approved Abbreviated or New Drug applications (A/NDAs). Due to the globalization of pharmaceutical products increasing consumer risk, the types of domestic and international products have expanded under this program to include:

- prescription and over-the-counter (OTC) drugs, excipients, and APIs manufactured or repacked by domestic and international (domestic-import) manufacturers;
- drug products available at pharmacy retailers (including compounded drugs);
- drug products that have approved NDAs or ANDAs;
- unapproved drug products;
- APIs considered at risk for Economically Motivated Adulteration (EMA);
- APIs and excipients considered at risk for melamine and melamine analog adulteration;
- OTC drug products at risk for Diethylene Glycol Adulteration (DEG); and
- Vitamin APIs considered at risk for adulteration

In keeping with DSDRB's effort to strengthen the DQST program, the following strategies are being developed for implementation to enhance the effectiveness of the program:

- refining the existing product selection criteria as well as developing a risk-based model for targeting firms and products with quality issues;
- expanding the techniques for sampling (e.g. sampling at import entry docks) and broadening the scope of testing;
- developing more detailed summary reports of survey findings; and
- improving the timeliness and completeness of sample collection and testing; and
- collaborating and sharing information between Federal Agencies.

PART II – IMPLEMENTATION

A. OBJECTIVES

- To protect the public health through the sampling and testing of domestic and international products to minimize exposure to non-compliant and poor quality drugs;

- To obtain information about the quality of the nation's drug supply by directing coverage of drug products, firms, and countries that are perceived to pose the greatest public health significance risks and to conduct the necessary compliance follow-up for out-of-specification samples.

B. PROGRAM MANAGEMENT INSTRUCTIONS

The Drug Quality Sampling and Testing (DQST) compliance program (CP) is an integral part of FDA's postmarket drug product surveillance activities. All sampling and testing activities should be reported under PAC 56008A (for domestic samples), PAC 56008L (for domestic-import samples). Also, use PAC 56008H for import label examinations.

CP 7356.008 complements other compliance programs - Drug Manufacturing Inspections (7356.002), the Active Pharmaceutical Ingredients (7356.002F), Unapproved New Drugs (Marketed, Human, Prescription Drugs only) (7352.002), and other assignments, such as the Pharmacy Compounding Assignments (PAC 56D015). Use PAC 56002 when conducting drug process inspections for follow-up to out-of-specification (violative) “survey” samples, but use PAC 56008A (for domestic samples) and PAC 56008L (for domestic-import samples) for any investigations related to DQST “survey” products.

Under certain circumstances, CDER may develop study protocols or provide more detailed instructions for sample collections and analyses that supplement this CP. These instructions will be appropriately cleared through the Office of Regulatory Affairs (ORA). Also refer to the instructions in the Investigations Operations Manual (IOM) and ORA’s Laboratory Manual.

Some sample analyses will require method development and validation (e.g., for some unapproved and compounded drug products). Time used for development of methods, and the validation of those methods, for testing samples under this program should be reported under PAC 56008A (for domestic samples) and PAC 56008L (for domestic-import samples).

PART III – INSPECTIONAL

A. GENERAL

This program covers both domestic and international (domestic-import) finished dosage forms, excipients, and APIs. Samples include commercially manufactured or compounded drugs available to consumers through various outlets including wholesalers, distributors, and retail pharmacies.

CDER's DSDRB Program Manager issues a DQST assignment in FACTS at the beginning of each fiscal year and as new information of potentially poor quality drug products (finished dosage forms, APIs or excipients) becomes available, additional assignments will also be issued during the same fiscal year. The total number samples for collection and testing for all the assignments issued during the fiscal year is contingent upon the number of resources allocated in the ORA Workplan for the DQST program.

B. INSPECTIONS

PAC 56008A is used for the resources dealing with sampling and testing of domestic samples and PAC 56008L is used for the resources dealing with sampling and testing of domestic-import samples under this program. PAC 56008A does not include resources for inspection; rather use PAC 56002, Drug Manufacturing Inspections, for inspection resources. Use the appropriate CPs when performing follow-up inspections. Please copy the DSDRB Program Manager on all follow-up inspections. Also, please use PAC 56008H for import labeling examinations.

C. SAMPLE SELECTION

In March/April, the Program Manager in DSDRB solicits drug survey candidate recommendations from CDER and ORA headquarters and FDA district offices based on their intelligence and reported consumer complaints. The risk-based selection criteria list is provided for their reference. Recommendations may include finished products, excipients, and/or APIs. The DSDRB Program Manager provides the list of drug survey candidates to an established committee called the DQST Working Group (WG). The DQST WG consists of representatives from OC, the Office of Generic Drugs, the Office of New Drug Quality Assurance, and DFS. The primary function of the WG is to evaluate and select which recommended products to survey relative to risk-based selection criteria. The goal is to target those products posing the greatest potential public health risk in terms of quality. In addition to using the traditional reference to risk-based criteria, the WG will be using a risk-based computerized model, which is currently being developed, to better assist in evaluating the risk factors of drug survey candidates. Furthermore, the DQST WG will explore different kinds of survey assignments in order to improve the effectiveness of the DQST program. For instance, the WG may choose to survey products with common characteristics, such as drug products having similar preparation methods (e.g., compounding; sterile process) or drug products having a specific use or drug products for targeted populations.

In addition to the solicitation of drug survey candidates, the Program Manager in DSDRB will solicit establishment site recommendations for sampling, based on past history of compliance, elapsed time since last inspection, or because the firm has been recently added in the official establishment inventory. Once the establishments have been identified, using a combination of risk-based criteria and the establishment selection model, the products for collection will be selected following the same procedure previously described under drug survey candidate solicitation.

The DQST survey assignment, concurred by the WG and approved by ORA, is issued at the beginning of the fiscal year. In keeping with resource allocations in the ORA field workplan for PAC 56008A (for domestic samples) and 56008L (for domestic-import samples), separate assignments are staggered throughout the fiscal year.

D. SAMPLE COLLECTION

The sampling and testing assignments, issued by DSDRB in FACTS, reflect the identified drug products, survey numbers assigned to the drug products, dosage forms, strengths, manufacturers and their site addresses, sample sizes, required tests, methodology sources, and sample collection and testing instructions.

Depending upon the assignment issued, sample collection can be conducted by field investigators at a manufacturer, distributor, wholesaler, or import dock entry. In some cases, CDER's OC will collect samples.

Unless specifically requested in the assignment, do not collect interstate (I/S) documentation. Do not collect the 702b portion for these "survey samples" since they will not be considered official samples for regulatory purposes. These samples are flagged as per the IOM as "survey samples". In rare circumstances, CDER will discuss the feasibility of converting an unofficial sample to an official sample with the Investigator.

Follow the IOM instructions for sample identification, sample preparation, and collection report preparation.

As appropriate, districts should request representatives from state boards of pharmacies to accompany FDA Investigators on sample collections at pharmacies. Contact the Office of Unapproved Drugs and Labeling Compliance (OUDLC) in OC for any questions concerning inspections, labeling concerns, or sample collections at pharmacies with state authorities.

1. Instructions for Collecting Finished Dosage Form Drug Products:

- DSDRB will enter the sample collection and analysis assignments into FACTS.
- If the assigned dosage strength is not available for sampling, a different dose strength of the same product should be collected, if available.

- **One lot from each of the identified products** is targeted for sampling. A sample should come entirely from one lot.

- The investigator must check their database sources to determine if the National Drug Code (NDC) number identified in the assignment is correct; if the NDC number is incorrect or missing, the investigator collects the assigned product and notifies the Drug Registration and Listing Team in DCRMS (eDRLS@fda.hhs.gov) with the correct NDC number.

- If the firm reports that they no longer manufacture the product (s) requested in this assignment, the investigator should request the firm to check their current drug listing to ensure that all products are correctly listed with FDA. If the firm finds their listing is incorrect or out of date, they should update their listing as required by 21 CFR Part 207. Questions can be addressed to eDRLS@fda.hhs.gov

- If any samples and/or records are not available at the site listed in the assignment and instead should be collected at a different district, the original district should return the sample assignment to the DSDRB Program Manager in FACTS, stating the correct sampling site and appropriate district under "Comments" if known. The DSDRB Manager, in turn, will re-assign the sample collection assignment to the appropriate district in FACTS.

- If any samples and/or records are not available at the site listed in the assignment and **no other site is available for collection**, the original district should return the sample assignment to the DSDRB Program Manager in FACTS, listing available drug products in the sampling site under "Comments". The DSDRB Manager, in turn, will replace the assignment as needed with a new sample collection request in FACTS.

- If the "Duplicate C/R" function is used when creating collection reports, be sure you duplicate on top of the blank assigned collection report so as to ensure you do not create an Ad Hoc assignment.

- If collection reports are inadvertently entered under Ad Hoc assignments, the investigator should notify DSDRB of the Ad Hoc FACTS assignment number to enable DSDRB to accurately monitor all samples collections under the survey.

- If a different lab is listed to perform chemical and microbiological analysis, when splitting the sample is requested in the assignment, the **Investigator should split the sample** and send the appropriate amounts to the identified laboratories based on the stated sample size guidelines reflected in the assignment. **If in doubt, please call the laboratory as to how much sample is needed for specific testing in analyses**. In some cases, two different laboratories will be assigned to perform chemical and microbiological analysis, but splitting the sample is not requested so the full appropriate sample size needs to be directed to each laboratory.

- Collect the firm's methods, specifications, references (include impurity and active ingredient reference standards) and degradant standards, and Certificates of Analysis, if available, and forward a copy to the analyzing laboratory in the Form FDA 525 envelope, marked "methods". In the event that the firm's methods, specifications, references, degradants, and/or certificates of analysis are not available at the collection site, immediately inform the analyzing laboratory through an e-mail message.

- When the FACTS collection report is created, the "National Sample Distributor" feature may, by default, designate a lab different from that specified in this assignment. If this occurs, the investigator should use the "Override" feature and input the laboratory designated in the assignment.

(a) Sample Size:

The sample size guidelines related to chemistry testing for finished dosage forms and APIs are reflected under "Suggested Sample Size (Chem)" in the assignment.

Refer to the following guidelines for suggested sample size for microbiological testing for finished dosage form products:

- for all products requiring STERILITY testing, collect 48 units of product .

- for all NON-STERILE products (e.g. ointments, creams, etc.) requiring microbiology testing for Microbial limits testing (aka microbial enumeration or testing for specified microorganisms), collect a minimum of 15 units [if the product container size has 30 grams or more] (5 units for either enumeration or specified microorganisms testing, 5 units for the suitability testing, 2 for method development and 3 extra in case of laboratory accident). If the volume of the individual units is less than 30 grams, then collect enough units to total 450 grams.

For products targeted for specialized testing (e.g., degradation, impurities), the sample size may be adjusted by the collecting party to ensure there is sufficient product to conduct the specific tests. Some samples, such as ophthalmic ointments, may contain very small amounts of product. The validated regulatory method (USP, NDA) or the firm's method should indicate sample size needed for analysis.

Supplemental Sample Size Instructions:

Impurities, degradants and related compounds:

Sufficient to perform the analysis (three times by the applicable method) (NOTE: check the official or validated regulatory method or the firm's method as needed

for the required amount.)

NOTE: In the case of a very expensive drug product or standard, the Investigator should contact the DSDRB Manager who will consult with both the DQST WG to determine how vital the analysis is, and with DFS and/or the laboratory to determine the minimum amount required to complete the analyses in an effort to reduce the costs.

Non-compendial reference standards:

Sufficient to perform the analysis (three times by the applicable method) (NOTE: check the official or validated regulatory method or the firm's method as needed for the required amount.)

(b) Methods:

If "dissolution" or "drug release" tests are specified for the sample being collected, please obtain a copy of the firm's methods and specifications or use the compendial methods (USP methodology) for these tests. If USP methods are appropriate, it is unnecessary to obtain the firm's analytical methods.

(c) Records:

The following records should be collected, if applicable, for each finished dosage form sampled:

- Specifications and test methods of analyses used by the firm for each test referenced in Attachment I, if other than USP method.
- If USP method, please provide the USP reference (edition, supplement, page number, and title).
- I/S is not required for sample collection. However, I/S is required as part of the follow-up investigation to any violative samples.

2. Instructions for Collection of APIs:

- The DSDRB Manager has entered the sample collection and analysis assignments into FACTS.

- The firm should collect API samples from the bulk API container to ensure the integrity of the sample. The investigator should observe the sample collection conducted by the firm.

- Collect non-USP methods, specifications, reference/impurity standards, and Certificates of Analysis, if applicable.

- The Investigator should request the firm to collect API samples and references or impurity standards in opaque, non-reactive containers, such as amber glass bottles. API samples should not be collected in Whirl–Pak bags or other plastics unless the firm uses this type of container for storage of the substance. Review the firm's SOPs for any precautionary measures that should be observed when handling/sampling. Be sure to protect light sensitive materials. Either conduct the sampling yourself or observe the firm while they collect samples. If you choose to collect the samples yourself, please use safe procedures with clean utensils in a manner so as not to cause cross contamination.

- API samples should be stored under appropriate storage conditions (e.g., temperature).

Description of Firm Data in the Collection Report:

If an API is collected from a finished dosage form manufacturer, the API manufacturer should be listed as the manufacturer and the finished dosage form manufacturer should be listed as the dealer.

Collect APIs that have been received by the finished dosage form manufacturer within the past 36 months. For lots older than 36 months, the Investigator should identify the firm's proposed outcome for the lot. The Investigator should notify the SPT Manager who will then consult with both the DQST WG and DFS whether the lot should be sampled.

(a) Sample Size:

- Active Ingredients (Chemistry & Microbiological Testing)*
  *(These samples are to be collected by the firm, not the Investigator, to protect the integrity of the sample)
  Powder - 50 grams from stock or 10 grams from the firm's reserve
  Liquid - 100 ml from stock or 100 ml from firm's reserve

- Impurities and related compounds
  Sufficient to perform the analysis three times by the applicable method (NOTE: check the official or validated regulatory method or the firm's method as needed for the required amount.)

- Non-compendial reference standards
  Sufficient to perform the analysis three times by the applicable method (NOTE: check the official or validated regulatory method or the firm's method as needed for the required amount.)

(b) Records:

The following records should be collected by the Investigator for each API sampled by the firm:

- Material Safety Data Sheets;
- Certificate of Analysis for each batch sampled;
- Results of any assay, identification and/or impurity tests performed by the firm on the batches of API sampled (this should include at least one example chromatogram for each of the assay and impurity tests;
- Specifications and methods of analyses used by the firm for each test referenced in Attachment I, if other than USP methods, with a copy of their method validation. If USP method is used, please provide the USP reference (edition, supplement, page number, and title).

E. REPORTING INSTRUCTIONS:

All sampling activities conducted under this program should be reported under PAC 56008A (for domestic samples) and under PAC 56008L (for domestic-import samples).

1. FACTS Reporting Instructions

The collecting district offices should not generate Ad Hoc work assignments for this program, but should use the FACTS work assignment identification numbers issued by the requesting office.

If collection reports are inadvertently entered into FACTS as an Ad Hoc assignment, please inform the DSDRB Program Manager via e-mail to surveyreport@cder.fda.gov, with the Ad Hoc FACTS work assignment identification number or sample number so that its progress can be tracked.

Sampling assignments that cannot be completed should be "Returned by Accomplishing Organization" in FACTS with the **reason noted in the "Remarks" section** (i.e. firm no longer makes the product at the assigned location). If an alternate collection site is discovered, this information should be included under "Remarks", along with an e-mail to surveyreport@cder.fda.gov and DSDRB will issue new operation (s) in FACTS to the new district. If the site is within your district, an attempt should be made to collect samples at the alternate location.

When the FACTS collection report is created, the "National Sample Distributor" feature may, by default, designate a laboratory different from that one specified in the assignment. If this occurs, the Investigator should use the "Override" feature and input the laboratory designated in the assignment.

PART IV – ANALYTICAL

A. SAMPLE ANALYSIS

The assignments specify the methods, tests, and designated laboratories for the drug product. Please utilize validated regulatory methods (USP and/or A/NDA) or as needed, method developed and validated by FDA. Guidance for validation of analytical methods can be found in the ORA Laboratory Manual, Volume II, Section 2, ORA-LAB 5.4.5, Appendix 1 'ORA Validation and Verification Guidance for Human Drug Analytical Methods'.

If specific tests are not listed, the sample should be evaluated using stability-indicating chromatographic methods or other suitable techniques for assay (including specificity), identification, physicochemical characteristics, and purity.

When a chromatographic purity method is not specified in the monograph, the chromatographic purity should be determined using HPLC (i.e. a diode array detector) and/or other suitable techniques.

No Check Analysis is required for any of the required tests for this assignment. No analytical worksheet is required for any of the required tests for this assignment with noted exceptions.

If assay and content uniformity methods are the same, then assay does not need to be accomplished for the original analysis.

For methods validated by FDA labs, refer to the document in the ORA Laboratory Manual: ORA Laboratory Manual Volume II, Section 2, ORA-LAB 5.4.5, Appendix 1 ORA 'Validation and Verification Guidance for Human Drug Analytical Methods'.

If non-USP tests are run for impurities or degradants, please use suitable techniques (NMR, MS-MS, etc) or reference/impurity standards, if available.

If laboratories encounter difficulties or irregularities with a method, an explanation should be incorporated into the worksheet, with immediate follow-up by telephone or e-mail to both DFS and DSDRB. **Any change in the methodology would require a worksheet.**

1. Sample Disposition

All Class I, IV and V samples can be authorized for disposition by the home district's Compliance Branch following their standard procedures for disposing Class I, IV, and V samples, or by the laboratory following standard laboratory disposition procedures found in the LM under Volume III, section 2.9 "Disposition of Samples". For the domestic-import (international) samples, contact CDER (e-mail surveyreport@cder.fda.gov) before you issue

an SDN (Sample Disposition Notice) for these samples as CDER will check with the field laboratory and CDER's Division of Pharmaceutical Analysis (DPA) to confirm that their analysis is complete. Do not SDN Class II and III violative survey samples until the regulatory cases are closed out and CDER gives permission to SDN the sample.

B. ANALYZING LABORATORIES

1. **Field Laboratories:**

   Each FACTS assignment includes the analytical laboratory identified by DFS.

2. **Headquarters Laboratories:**

   Office of Pharmaceutical Science, Office of Testing and Research, Division of Pharmaceutical Analysis, 1114 Market Street, Room 2001, St. Louis, MO 63101

Laboratory analysts must report final analytical results into FACTS as soon as analyses are completed. Specific analytical test results are required.

C. REPORTING INSTRUCTIONS:

All testing activities conducted under this program should be reported under PAC 56008A (for domestic samples) and under PAC 56008L (for domestic-import samples).

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Samples collected under this program are unofficial samples since they are not considered regulatory samples as reflected in the IOM Section 4.1.4. Do not collect the 702b portion when sampling. Do not collect I/S documentation at the time of sampling since these are not regulatory samples.

Drug products manufactured by international manufacturers are considered domestic-import samples. The investigator should follow the IOM, Section 4.1.4.8, to describe these domestic-import samples in the collection report.

Use appropriate compliance programs for follow-up inspections of out-of-specification (violative) samples.

For out-of-specification domestic and international samples, the DSDRB Program Manager coordinates follow-up within OC's OMPQ and OUDLC; ORA's Division of Domestic Field Investigations and Division of Foreign Field Investigations; and the home district, as appropriate. For all out-of-specification samples, the DSDRB Program Manager will issue a follow-up assignment by electronic mail and request the districts to conduct the necessary follow-up investigations and document/report all corrective actions to the DSDRB Program Manager by electronic mail to surveyreport@cder.fda.gov. If extra sampling is necessary, the districts are required to report all specific analytical results in FACTS.

PART VI - PROGRAM CONTACTS AND REFERENCE

A. CONTACTS

1. Office of Regional Operations

- Division of Domestic Field Investigations (DFFI)
  Jim Dunnie
  Telephone: (301) 827-5652

- Division of Foreign Field Investigations
  Jim Dunnie
  Telephone: (301) 827-5652

- Division of Field Science

  Ian Paul Mayers – General Chemistry
  Telephone: (301) 827-3804

  Jennifer Letts – Sterility
  Telephone (301) 796-6318

  Norma Duran – General Microbiology
  Telephone (301) 796-6133

2. CDER

Office of Compliance/Office of Manufacturing and Product Quality
Division of Policy, Collaboration and Data Operations, Drug Surveillance & Data Reporting Branch (OMPQ/DPCDO/DCDRB)

DCDRB Program Manager: Andrea Schaub
Telephone: (301) 796-3225

E-mail: Surveyreport@cder.fda.gov or CDER SURVEY REPORT

B. REFERENCE

Please see FDA intranet for current chart reflecting organizational location of Division of Policy, Collaboration & Data Operations, Drug Surveillance & Data Reporting Branch after reorganization effective June 6, 2011 (PATH: > CDER > OFFICE OF COMPLIANCE > OFFICE OF MANUFACTURING AND PRODUCT QUALITY).

PART VII – CENTER/ORA HEADQUARTER RESPONSIBILITIES

The Office of Compliance, Office of Manufacturing and Product Quality (OMPQ), Division of Policy, Collaboration and Data Operations (DPCDO), Drug Surveillance & Data Reporting Branch (DSDRB) will:

1. solicit drug product recommendations from CDER and ORA headquarters and district offices;
2. solicit drug establishment site recommendations from CDER and ORA headquarters and district offices;
3. collaborate with the DQST WG in identifying drug products and establishment sites for collection and testing for the assignment relative to the resources in the field workplan. Employ the risk survey model to assist in evaluating the risks of the solicited drug products;
4. recommend or specify tests to be performed based on the reason/justification given for sampling;
5. prepare study protocol, if necessary;
6. prepare and issue sampling and testing assignments electronically and via FACTS;
7. if necessary, collect samples, prepare collection reports, and submit samples to laboratories for analysis;
8. re-assign sample collections in FACTS as appropriate;
9. manage and monitor the status of the sample collections and testing via FACTS; and
10. prepare summary results of samples collected and tested and post the summary reports at the following URL:

http://inside.fda.gov:9003/CDER/OfficeofCompliance/DivisionofComplianceRiskManagemntSurveillance/ucm254252.htm

The Division of Field Science (DFS) will:

1. assign the appropriate laboratories, contingent upon their equipment and workload, to the assigned sampling product;
2. resolve analytical issues in consultation with laboratories and to DSDRB; and
3. assure timely completion of analyses.