CHAPTER 56 – Drug Quality Assurance

SUBJECT:	IMPLEMENTATION DATE
ENFORCEMENT OF THE DRUG SAMPLE DISTRIBUTION REQUIREMENTS OF THE PRESCRIPTION DRUG MARKETING ACT (PDMA)	March 11, 2013
	COMPLETION DATE
	March 11, 2016

DATA REPORTING	
PRODUCT CODES	PROGRAM ASSIGNMENT CODES
50, 54-56, 50, 60-66, inclusive	PAC 56022: All Headquarters and District-initiated assignments

FIELD REPORTING REQUIREMENTS:

Districts should submit via MARCS CMS to CDER Office of Compliance (OC) all recommendations for judicial, administrative, or advisory actions.

Districts should submit an email to the CDER OC Division of Supply Chain Integrity (DSCI) mailbox (CDER-OC-ODSIR-DSCI@fda.hhs.gov) and include "PDMA Information" in the subject heading when any non-violative (NAI or VAI) investigative reports and Establishment Inspection Reports (EIRs) conducted concerning enforcement of the Prescription Drug Marketing Act (PDMA) are available in FACTS or Turbo EIR.

The District should scan and submit to PDMAreports@FDA.HHS.GOV reports received from any source concerning drug sample theft, loss, falsification, or diversion. CDER OC will input the reports into the CDER PDMA database. CDER OC will then refer certain reports to the ORA Office of Criminal Investigations (OCI) for evaluation/follow-up by that office.

The District should routinely update the IOM with the name and phone number for the District's PDMA liaison contact.

DATA REPORTING - Use PAC 56022 for all **assignments** directly generated by headquarters and field offices.

PART I – BACKGROUND

A. GENERAL

This compliance program is an update/replacement for the FDA Compliance Program Guidance Manual 7356.022 *Investigations Performed under the Prescription Drug Marketing Act (PDMA)*, dated January 31, 1991. The purpose of this compliance program is to provide general guidance in conducting investigations of individuals, drug manufacturers, distributors, and other parties that may be involved in prescription drug sample theft, loss, falsification, or diversion.

This program also provides general guidance concerning inspection of firms for compliance with recordkeeping and monitoring systems required under the PDMA. Inspectional guidance in this compliance program is primarily focused on requirements in the PDMA concerning drug samples [*].

B. SUMMARY OF PDMA PROVISIONS

The Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (FDAMA), amended several sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to:

1. ban the reimportation of prescription human drugs manufactured in the U.S., except when reimported by the manufacturer or for emergency medical care with permission of the Secretary;

2. prohibit, with certain exceptions, the sale, purchase, or trade (including the offer to sell, purchase, or trade) of prescription human drugs purchased by hospitals or other health care entities, and of prescription human drugs donated or sold at reduced cost to charitable institutions;

3. ban the sale, purchase, trade, or counterfeiting of drug coupons;

4. **ban the sale, purchase, or trade (including the offer to sell, purchase, or trade) of prescription drug samples;**

5. require state licensing of wholesale distributors of prescription human drugs under Federal guidelines that include minimum standards for storage, handling, and recordkeeping;

6. require unauthorized drug distributors to provide a statement of origin ("pedigree") as part of certain drug sales; and

[*] A separate compliance program may be issued in the future addressing other requirements contained in the PDMA, and guidance on inspections covering aspects such as American Goods Returned, resale of drugs by hospitals or other health care entities, wholesaler registration, and pedigree.

7. **set forth criminal and civil penalties for violations of these provisions.**

Provisions 4 and 7 are relevant to this program. More specifically, PDMA in part regulates the storage, handling and distribution of prescription drug samples by firms via mail, common carrier, and delivery by representatives to licensed practitioners or pharmacies of hospitals or other health care entities. The inspectional aspects of this compliance program are focused on compliance with drug sample provisions.

PART II - IMPLEMENTATION

A. OBJECTIVE

To provide direction and guidance to field personnel who conduct investigations or inspections of individuals or parties who may be involved in prescription drug sample theft, loss, falsification, or diversion.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. **Investigator Qualifications**
   It is recommended that investigators selected to perform these investigations are experienced in drug inspections. It is also recommended that they obtain PDMA training and read the preamble to the final rule and the regulations implementing PDMA prior to the assignment or inspection

2. **Coordination with the Office of Criminal Investigations (OCI)**
   All reports received from any source concerning prescription drug sample theft, loss, falsification, or diversion should be referred to the CDER Division of Supply Chain Integrity (DSCI) for inclusion into the CDER PDMA database. DSCI will determine whether to refer certain reports to OCI Headquarters for evaluation/follow-up by that office. As agreed with OCI, any reports that will not be investigated by that office will be returned to DSCI, who will issue a follow-up assignment to the appropriate district office. The field should not send reports to OCI field offices, unless the local OCI field office has specifically requested them.

3. **Coordination with State Offices and Other Federal Agencies**
   Coordination with local and state offices and with other federal agencies will normally be initiated at the district level. The district offices are responsible for identifying their counterparts in these investigations, and reporting any substantive communications with these other agencies to CDER DSCI.

   When PDMA investigations reveal possible Medicare/Medicaid or Social Security fraud, DSCI should be notified, and DSCI will initiate contact with the local offices of the HHS Inspector General to coordinate follow-up.

4. **Reports**
   All reports received by the districts of suspected prescription drug sample loss, theft, falsification, or diversion should be reported promptly to CDER DSCI. Reporting can be initiated by telephone call, with electronic documents submitted to the PDMA mailbox (PDMAreports@fda.hhs.gov). DSCI will incorporate all reports into the CDER PDMA database to provide background and support for case development.

5. **Assignments**
   All Headquarters assignments will issue from CDER DSCI

6. **Federal-State Relations**
   In many states, the Board of Pharmacy has jurisdiction over investigations involving diversion of prescription drug products. Contact with the state Board of Pharmacy or other appropriate local state authorities will generally be left to the initiative of the individual districts, but discretion should be used with such notification when covert operations are involved.

7. **Program Evaluation**
   Program evaluation will be conducted by CDER DSCI.

PART III – INSPECTIONAL

A. INVESTIGATIONS AND INSPECTIONS - GENERAL

CDER DSCI is designated as the focal point for all potential, emerging, and ongoing routine and directed investigations of prescription drug samples.

The districts will determine if a manufacturer has a drug sampling program. For firms that have drug sample programs, routine inspections should be conducted under this compliance program as part of district-directed workplans. It will be determined by the Districts if the inspections will be conducted at the same time or in conjunction with other inspections (such as CGMP or ADE inspections) or as an independent inspections. In the event that a for-cause inspection is needed, CDER DSCI will furnish guidance through the issuance of specific assignments and discussion of investigational plans.

The FDA may elect to cooperate with manufacturers to investigate certain cases. Information may be shared with the manufacturers with the caveat that information that is proprietary or subject to the Privacy Act is not released.

1. **Undercover Investigations/Purchases**
   Some undercover investigations may identify targets for further follow-up of illegal activities, including obtaining affidavits from non-FDA persons who have acquired drug samples from illicit sources. Before extending the investigation, district management should consult with headquarters contact personnel in CDER DSCI and the ORA Office of Medical Products and Tobacco Operations.

2. **Security and Audit Systems**
   When inspecting a firm's sample distribution security and audit systems, the investigator should question the firm about all programs whereby prescription drug products are distributed at no cost. A prescription drug product may meet the definition of a "sample" under the Act (a unit of drug not intended for sale and intended to promote the sale of the drug product) even if it is not labeled or distributed as a physician/professional sample. Of particular concern is the fact that, if such programs are not monitored through a centralized system, the possibility exists that an individual could exploit the various programs individually to obtain drug products for diversionary purposes without danger of exposure.

   Questions concerning whether any of these programs meet the definition of a sample under the Act should be discussed with the CDER-DSCI.

B. INSPECTION OF PDMA DRUG SAMPLE PROGRAMS

1. **Sales Representatives' Records**
   When the investigation requires the inspection of drug storage facilities maintained by a

drug manufacturer sales representative, use discretion and follow the guidance in IOM 5.1.1.9, "Premises Used for Living Quarters."

While routine inspection of the automobiles of sales representatives is not envisioned, if such an inspection becomes necessary, an inventory should be made of all prescription drug samples at the storage location and in the sales representative's delivery vehicle. Review the sales representative's records of receipt and disbursements for drug samples, and obtain copies as appropriate for comparison to manufacturer/distributor records. Identify missing quantities and note the response provided to explain any inventory discrepancies. Identify the major customers of the drug product samples in the investigation. The use of abbreviated names or "code names" may indicate an attempt to disguise diversion, and may constitute conspiracy under Title 18.

Inspectional coverage should include the following areas:

a. Records of sales representatives should be selected that represent a broad range of employment history with the firm (newly hired to several years of employment).

b. Records of employees terminated by the firm for lack of compliance with PDMA samples and recordkeeping procedures should be included.

2. **Third Parties (see 21 CFR 203.36)**

a. Obtain a copy of an example of a contract between [FIRM] and a third party fulfillment house and a contract sales organization (this does not have to be an executed agreement).

b. If any auditing of the contract firm is done, obtain copies of the audit protocol. Record whether audits are surprise or pre-announced.

3. **Record-keeping (see 21 CFR 203.34 and 203.60; 21 CFR Part 11)**
21 CFR Part 11 is the agency's rule concerning the use of electronic records and electronic signatures to meet the recordkeeping requirements of the laws and regulations enforced by the FDA.

Provided the requirements of Part 11 are met, electronic records, electronic signatures, and handwritten signatures executed to electronic records may be used in place of paper records to comply with the PDMA. Records maintained by firms that do not have to be submitted to FDA may be electronic in whole or in part.

a. Determine if records are kept electronically, on paper, or a combination. If electronic or combination, determine whether the requirements of Part 11, § 203.60, and the August 2003 Guidance for Industry: Part 11: Electronic Records; Electronic Signatures

– Scope and Application [†] are met.

b. Describe the communication procedures between sales force personnel and headquarters departments, e.g., sales representatives and District Managers; between District Managers and Headquarters.

c. Obtain copies of the firm's recordkeeping standard operating procedures (SOPs).

d. Determine if recordkeeping procedures are being followed.

e. How does the firm trace prescription drug sample distribution by lot number down to the requesting practitioner? (21 CFR 203.38)

4. **Sample Storage Requirements (see 21 CFR 203.32)**

a. Determine whether there are any prescription drug product samples that require special storage conditions.

b. Determine how prescription drug sample storage by sales representatives is documented and monitored.

c. Obtain copies of prescription drug sample storage SOPs. (§ 203.34)

5. **Sample Packaging and Distribution (see 21 CFR 203.30, 203.31, 203.35, and 203.38)**

a. Assure that the firm receives sample requests prior to shipping/delivery of samples, and determine if the required information (§ 203.30(b) and (c)) is on the sample request and receipt.

b. If sales representatives record prescription drug sample requests electronically, determine if there is a lock-out feature incorporated into the software to prevent entries into the request form once the licensed practitioner has signed the form. If not, determine how unauthorized changes are detected. (See § 203.30 and Part 11).

c. If prescription drug sample requests are paper documents, determine what procedures the firm has for reviewing requests for falsification or unauthorized entries or deletions (see § 203.34(b)(3) and (d), § 203.37, and § 203.31(d)(3)).

d. Identify the firm's policy on avoiding standing requests for samples (see § 203.35).

e. Determine whether the firm distributes prescription drug samples at pharmaceutical conventions and what guidelines the firm has for compliance with the distribution and

[†] URL as of publication: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

recordkeeping requirements of the PDMA (see § 203.34).

f. Request copies of any additional SOPs pertaining to drug sample and related requirements.

g. Determine how prescription drug samples are packaged and labeled. If the firm uses retail stock packages in sampling, determine how the packages are identified as "samples" (see § 203.38).

6. **Reporting (see 21 CFR 203.37)**
Describe the firm's procedures for timely reporting of:
- Losses (all significant losses)
- Thefts (any)
- Possible diversions (any)
- Convictions
  - Determine if the firm keeps a conviction list, and if so, for what period of time.
  - Determine if all convictions have been reported to FDA. Collect copies of all conviction reports.
- Obtain copies of reporting SOPs.
- Determine the types of analyses the firm performs on their sampling data.
- Determine how a "significant loss" is defined by the firm.

a. **Significant Loss Reports**: FDA has not established any minimum tolerance level for significant losses above which a report is required. Each manufacturer or authorized distributor is expected to establish its own threshold for determining when inventory that cannot be accounted for is significant. This threshold should be derived from each firm's past experience in prescription drug sample distribution and inventory, and should be based on the level of accuracy of the firm's internal audit and security procedures.

The following criteria are to be used as guidance to the regulated industry in determining what constitutes a "significant loss" of samples and is therefore reportable to the Agency:

(i) Frequency of loss above an established, justified baseline which is associated with the same representative, the same carrier, or the same distribution site.

(ii) Any loss associated with diversion activity.

(iii) Any loss associated with falsification of sample inventory or distribution records.

(iv) Any loss associated with theft.

(v) A loss associated with other suspicious circumstances.

(vi) Losses above an established, justified baseline which are associated with

expensive brand-name products.

(vii) Losses above an established, justified baseline which are associated with drugs of abuse.

b. **Reporting Time Frames**: The final regulations establish timeframes for manufacturers and authorized distributors to notify and provide written investigation reports to the FDA concerning prescription drug sample thefts, significant losses, diversion, and falsification of prescription drug sample control records. These requirements are contained in 21 CFR 203.37 and generally require that FDA be notified verbally or in writing within 5 working days, when a manufacturer or authorized distributor becomes aware of an apparent sample theft, loss, diversion or record falsification. This notification is to be followed by a written report of the firm's investigation within 30 days. In complex cases, the 30 day report can be a preliminary report and subsequent update reports submitted every 30 days until the investigation is completed.

c. **Conviction Reports**: A manufacturer or authorized distributor is required to notify FDA, within 30 days of becoming aware of the conviction of one or more of its representatives for a violation of section 503(c)(1) of the Act or any State law involving the sale, purchase, or trade of a prescription drug sample or the offer to sell, purchase, or trade a prescription drug sample. A manufacturer or authorized distributor must provide a written report on the conviction to the FDA within 30 days after the initial notification. Failure to provide such notification and report could subject the manufacturer or authorized distributor to civil money penalties as described under sections 303(b)(3) of the Act.

7. **Donation of prescription drug samples (see 21 CFR § 203.39)**

a. Identify the types of donation, charity, "mission," indigent patient, or other similar programs in which the firm participates.

b. Determine if the firm has SOPs for donation of prescription sample and retail drug products. If so, please request a copy of the SOPs.

c. Determine whether the firm accepts returns from the donor customer if the samples are unusable, and if the firm has inventory controls on the returns (auditing and quarantine procedures).

8. **Audits (see 21 CFR 203.34)**
Development of a prescription drug sample distribution security and audit system is required under § 203.34(b)(3).

a. Obtain copies of firm's prescription drug sample audit and security SOPs. Determine who performs the audits (are they separate from the sales force?).

b. Determine how negative findings are handled.

c. Determine what types of audits are performed; for what reasons and how often (i.e., are the audits random or for cause, are they surprise or pre-announced?).

9. **Inventory (see 21 CFR 203.31 and 203.34(b)(2))**

a. Obtain copies of the firm's SOP for conducting the annual prescription drug sample inventory (§ 203.34(b)(2))

b. Determine if results of inventory are reconciled with most recent previous inventory, and if the required report documenting the reconciliation process has been created (§ 203.31(d)).

c. Verify that the inventory record identifies all drug samples in a representative's stock by the proprietary or established name, dosage strength, and number of units (§ 302.31(d)(1).

d. Identify how the inventory is performed, by whom, and how often. Determine whether inventories are pre-announced or surprise, and which department in the firm makes that determination.

e. Identify which department receives inventory reports.

f. Determine whether reports are automatically sent to an audit quality assurance unit and if the audit quality assurance unit may independently perform an audit.

g. Determine whether records are kept electronically, on paper, or a combination.

h. Determine whether a sales representative's inventory status is available for review at any point in time, and if not, how much lead time is needed.

10. **Practitioner Verification (see 21 CFR 203.30 & 31)**
§§ 203.30 and 203.31 require manufacturers and authorized distributors to verify that the State license or authorization number provided by a licensed practitioner prior to sampling is accurate and current. As noted in the PDMA 1999 preamble, a source outside of the relevant State authority may be used to verify the license or authorization number provided:

a. the manufacturer or authorized distributor confirms that the license information provided by the alternate source is obtained directly from the appropriate State authority (§203.30(a)(2) and §203.31(a)(2)); and

b. the information is updated at least annually by the alternate source to confirm that the licensed practitioner continues to be licensed to prescribe and that the license is in good

standing (64 FR 67720 at 67736-67737).

Re-verification of practitioner State license or authorization numbers should be performed annually by the manufacturer (64 FR 67720 at 67736-67737).

Mid-level practitioners (e.g., nurse practitioners) who are permitted to prescribe under State law may receive prescription drug samples. A mid-level practitioner's authority to request, receive, and dispense prescription drug samples is determined by the limitations placed upon that practitioner's prescribing authority under State law (e.g., co-signing of the prescription by a physician required?).

Obtain copies of firm's SOP for verifying state licensing of practitioners. Determine whether mid-level practitioners are sampled and how verification is performed. Also, identify how much lag time occurs between the first receipt of samples by a practitioner and subsequent receipts of samples based upon verification. Establish whether there are there built-in checks in this process

C. INVESTIGATIONS AND INSPECTIONS - ADDITIONAL

1. **Training Program (not a requirement)**

   a. Determine if the firm has a formal PDMA training program. If so, for informational purposes, collect any documentation or information related to the training program.

   b. Determine if the training is scheduled routinely. Record how the training is documented.

2. **Samples in Pharmacies**

   Under section 503(d) of the FFDCA, prescription drug samples may only be distributed to licensed practitioners or to the pharmacies of hospitals or other health care entities upon the written request of a licensed practitioner. A "health care entity" means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy (21 CFR 203.3(q)). A health care entity cannot simultaneously also be a retail pharmacy.

   If a pharmacy of a health care entity operates as part of the health care entity, it is eligible to receive prescription drug samples from a manufacturer or authorized distributor of record, if the drug samples are obtained pursuant to a written, signed request of a licensed practitioner affiliated with the health care entity. "Affiliation" is interpreted to mean that the requesting practitioner sees patients at the health care entity.

   A retail pharmacy that has no relationship to a health care entity is not permitted to receive prescription drug samples (21 CFR 203.3 and Section 503(d) of the Act).

3. **Starter-Packs**
   Starter packs of solid oral dosage forms are offered in ordinary stock packages, in special packaging in unit-of-use or course-of-treatment sizes, or in special packaging smaller than standard stock packages whose sizes have no relationship to treatment regimens.

   Drug products packaged in "starter packs" may be encountered in investigations. "Starter packs" (also known as stock samples, trade packages, or starter stocks) are prescription drug products distributed without charge by manufacturers or distributors to pharmacists with the intent to place the prescription drugs in stock and sell them at retail. Under the PDMA, a sample is defined as a unit of drug ". . . not intended to be sold . . . and intended to promote the sale of the drug." Although starter packs are provided to pharmacies free of charge, they are not intended to be free samples for the consumer nor are they packaged as such. Since starter packs do not meet both parts of the definition of a sample under the PDMA, *they are not considered to be samples*. However, similarly to stock shipments of prescription drugs, starter packs are subject to regulation as prescription drugs under the FFDCA.

PART IV - ANALYTICAL

No analytical activities are planned under this program.

The collection of physical samples for analysis of drug marketing samples is not generally required under this compliance program; however, this program does not supersede any collection of physical samples required under any other program, e.g. content uniformity. Physical samples should be collected and analyzed under this program only upon written assignment or oral direction from CDER DSCI, district management, or the ORA Office of Regulatory Science.

In the event analyses are required, each district will utilize its designated servicing laboratory for CPGM 7356.002. Consult the Office of Regulatory Science for assistance in placing samples.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

A. GENERAL

The full range of advisory, administrative and judicial sanctions will be utilized in Agency enforcement of the PDMA – from warning letters to criminal prosecutions. (Note that seizures may not be obtained under the PDMA since a drug must be adulterated or misbranded in order to be seized.)

The PDMA requires enforcement of many areas of the commercial domestic drug arena in which FDA has had little prior involvement. In order to achieve consistency in agency enforcement of this program area, ALL proposed administrative and regulatory actions must be submitted to CDER-DSCI for approval.

Given the possibility of criminal and covert activities under this area, urgent cases (those cases in which timeliness is a critical factor) will be coordinated from the beginning among the District Office(s), ORA Office of Operations, ORA Office of Enforcement and Import Operations, CDER DSCI and FDA Office of General Counsel, and it is recommended that the District walk through any resulting regulatory recommendation.

B. VIOLATIONS

DSCI will determine if a significant loss, theft, falsification or other diversion should be reported to OCI. DSCI will refer the report to the field office(s) by investigative assignment if OCI does not pursue the investigation. When the district is the first FDA office to become aware of possible violations of the PDMA provisions, DSCI should be notified immediately. Such possible violations would include reports from state or local authorities of pharmacists or physicians who are allegedly repacking drug samples and selling them in prescriptions, and brand name prescription drugs that are available for sale at below wholesale prices.

Investigational tactics will be left to district discretion. CDER DSCI will furnish guidance through the issuance of specific assignments and discussion of investigational plans for for-cause inspections. The district offices are encouraged to discuss proposed investigational techniques with their local OCI field office.

C. GENERIC DRUG ENFORCEMENT ACT

This law amends the Federal Food, Drug, and Cosmetic Act (FFDCA). Enacted May 13, 1992, the law provides for the mandatory or permissive debarment of individuals convicted of a federal felony or misdemeanor from providing a service in any capacity to a person that has pending or approved drug product applications. In other words, if an individual is found guilty of a felony or misdemeanor violation of the FFDCA concerning the regulation of a drug product, that individual could be permanently or temporarily barred from working in any capacity for a person

who has a pending or approved (A)NDA products (e.g., a drug firm).

The debarment provisions of this Act apply to felony and misdemeanor convictions under the PDMA. When such convictions are obtained, the district should contact the ORA Office of Policy and Risk Management with the conviction information.

Under this Act, a person, whether an individual, corporation, or partnership, may be debarred for violations of the FFDCA, and for violations of Title 18 such as fraud, bribery, falsification, and racketeering. If an individual, such as a sales representative, physician, or pharmacist, is convicted for violations of the PDMA or Title 18 and subsequently debarred, he/she may not provide services in any capacity to a drug firm holding an approved or pending drug application for the period of the debarment.

Under the Generic Drug Enforcement Act a person is considered to have been convicted of a criminal offense if:

1. a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending;

2. a plea of guilty or *nolo contendere* by the person has been accepted by a Federal or state court; or

3. the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program (e.g., pre-trial diversion program) where judgment of conviction has been withheld.

The FDA Debarment List (Drug Product Applications) [‡] is located on the FDA internet.

D. ENFORCEMENT POLICIES

Reports of Theft, Falsification, and Significant Losses of Prescription Drug Samples:

The theft, falsification, and significant loss reports that are referred to the field offices under an accompanying memo by CDER DSCI do not require immediate follow-up investigations. These reports normally include information such as isolated thefts from sales representatives' cars, falsification of practitioner signatures, or losses of sample shipments by common carriers. These reports are referred for district follow-up when performing the subsequent inspection at the reporting firm.

‡ URL as of publication: http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

A. REFERENCES

1. Federal Food, Drug, and Cosmetic Act [§]

   - Section 301(t) [21 U.S.C. 331(t)], for offering to sell, purchase, or trade a drug sample, and distribution of a drug sample
   - Section 303(a) [21 U.S.C. 333(a)], for penalties
   - Sections 303(b)(1),(2),(3),(4)) [21 U.S.C. 333(b)(1),(2),(3),(4)], for penalties for knowingly selling, purchasing, or trading a drug sample, drug sample distribution
   - Section 306 [21 U.S.C. 335a], for debarment
   - Section 503(c) [21 U.S.C. 353(c)], for definition of drug sample, which is a unit of a drug which is not intended to be sold and is intended to promote the sale of the drug
   - Section 503(d) [21 U.S.C. 353(d)], for the definition of distribute, which exempts the providing of a drug sample to a patient by a licensed practitioner, a health care professional acting at the direction and under the supervision of a practitioner, or a pharmacy of a hospital or other health care entity

2. Code of Federal Regulations, Title 21 [**]

   - Sections 203.1, 203.2, and 203.3, which provides the scope of PDMA, the purpose, and definitions;
   - Section 203.30, regarding sample distribution by mail or common carrier;
   - Section 203.31, regarding sample distribution by direct delivery by a representative or detailer;
   - Section 203.32, requirements for drug sample storage and handling;
   - Section 203.33, drug sample forms;
   - Section 203.34, policies and procedures; administrative systems;
   - Section 203.35, prohibition on standing requests;
   - Section 203.36, fulfillment houses, shipping and mailing services, co-marketing agreements, and third-party recordkeeping;
   - Section 203.37, requirements for investigations and notification;
   - Section 203.38, sample lot or control numbers; labeling of sample units;
   - Section 203.39, donation of drug samples to charitable institutions.

---

§ URL: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm

** URL: http://www.gpoaccess.gov/cfr/index.html or http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

3. Other References

   - Guidance for Industry: Part 11: Electronic Records; Electronic Signatures – Scope and Application (http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm, August 2003)
   - FDA Internet website: FDA Debarment List (Drug Product Applications) (http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm, January 2013)

B. PROGRAM CONTACTS

1. Send all inspectional correspondence to:

   Food and Drug Administration
   Center for Drug Evaluation and Research
   Office of Compliance, Drug Integrity and Security Program
   10903 New Hampshire Avenue
   Silver Spring, MD 20993-002

2. For assistance during inspections:

   CDER Office of Compliance
   Ofc. of Drug Integrity, Security and Recalls
   Division of Supply Chain Integrity
   301-796-3130, FAX 301-847-8722

3. For assignment, inspectional or sampling guidance:

   Respective District Office, or

   ORA Office of Medical Products and Tobacco Operations
   12420 Parklawn Drive, ELEM-2136
   Rockville, MD 20857
   301-796-5403, FAX 301-827-4090

4. For debarment or conviction information:

   ORA Office of Policy and Risk Management
   12420 Parklawn Drive, ELEM-4044
   Rockville, MD 20857
   301-796-3820, FAX 301-827-3670

5. For servicing laboratory, testing/methods, and sampling guidance under this program:

   ORA Office of Regulatory Science
   Medical Products and Tobacco Scientific Staff
   Ian (Paul) Mayers, 301-796-6552

PART VII - HEADQUARTERS RESPONSIBILITIES

CDER Office of Compliance:

1. Reviews all Establishment Inspection Reports forwarded by the Districts;
2. Serves as a source of information for the districts regarding compliance with drug sample programs under the Prescription Drug Marketing Act (PDMA);
3. Determines the action to be taken regarding prescription drug sample programs. When appropriate, issues warning letters to all violative firms with a copy to the appropriate district or concurs with district issuance of a warning letter;
4. Monitors the effectiveness of this program;
5. Promptly advises districts of policy and/or significant status changes as they occur.
6. Resolves questions and makes final determinations concerning the applicability of this program to a product or situation.