

samples. All drug samples in the possession or control of each manufacturer's and distributor's representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record, as specified in paragraph (d)(1) of this section. In addition, manufacturers and distributors shall reconcile the results of the physical inventory with the most recently completed prior physical inventory and create a report documenting the reconciliation process, as specified in paragraph (d)(2) of this section.

(1) The inventory record is required to identify all drug samples in a representative's stock by the proprietary or established name, dosage strength, and number of units.

(2) The reconciliation report is required to include:

(i) The inventory record for the most recently completed prior inventory;

(ii) A record of each drug sample shipment received since the most recently completed prior inventory, including the sender and date of the shipment, and the proprietary or established name, dosage strength, and number of sample units received;

(iii) A record of drug sample distributions since the most recently completed inventory showing the name and address of each recipient of each sample unit shipped, the date of the shipment, and the proprietary or established name, dosage strength, and number of sample units shipped. For the purposes of this paragraph and paragraph (d)(2)(v) of this section, "distributions" includes distributions to health care practitioners or designated hospital or health care entity pharmacies, transfers or exchanges with other firm representatives, returns to the manufacturer or authorized distributor, destruction of drug samples by a sales representative, and other types of drug sample dispositions. The specific type of distribution must be specified in the record;

(iv) A record of drug sample thefts or significant losses reported by the representative since the most recently completed prior inventory, including the approximate date of the occurrence and the proprietary or established

name, dosage strength, and number of sample units stolen or lost; and

(v) A record summarizing the information required by paragraphs (d)(2)(ii) through (d)(2)(iv) of this section. The record must show, for each type of sample unit (i.e., sample units having the same established or proprietary name and dosage strength), the total number of sample units received, distributed, lost, or stolen since the most recently completed prior inventory. For example, a typical entry in this record may read "50 units risperidone (1 mg) returned to manufacturer" or simply "Risperidone (1 mg)/50/returned to manufacturer."

(3) Each drug manufacturer or authorized distributor of record shall take appropriate internal control measures to guard against error and possible fraud in the conduct of the physical inventory and reconciliation, and in the preparation of the inventory record and reconciliation report.

(4) A manufacturer or authorized distributor of record shall carefully evaluate any apparent discrepancy or significant loss revealed through the inventory and reconciliation process and shall fully investigate any such discrepancy or significant loss that cannot be justified.

(e) *Lists of manufacturers' and distributors' representatives.* Each drug manufacturer or authorized distributor of record who distributes drug samples by means of representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored.

§ 203.32 Drug sample storage and handling requirements.

(a) *Storage and handling conditions.* Manufacturers, authorized distributors of record, and their representatives shall store and handle all drug samples under conditions that will maintain their stability, integrity, and effectiveness and ensure that the drug samples are free of contamination, deterioration, and adulteration.

(b) *Compliance with compendial and labeling requirements.* Manufacturers, authorized distributors of record, and their representatives can generally comply with this section by following

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the compendial and labeling requirements for storage and handling of a particular prescription drug in handling samples of that drug.

§ 203.33 Drug sample forms.

A sample request or receipt form may be delivered by mail, common carrier, or private courier or may be transmitted photographically or electronically (i.e., by telephoto, wirephoto, radiophoto, facsimile transmission (FAX), xerography, or electronic data transfer) or by any other system, provided that the method for transmission meets the security requirements set forth in § 203.60(c).

§ 203.34 Policies and procedures; administrative systems.

Each manufacturer or authorized distributor of record that distributes drug samples shall establish, maintain, and adhere to written policies and procedures describing its administrative systems for the following:

(a) Distributing drug samples by mail or common carrier, including methodology for reconciliation of requests and receipts;

(b) Distributing drug samples by means other than mail or common carrier including the methodology for:

(1) Reconciling requests and receipts, identifying patterns of nonresponse, and the manufacturer's or distributor's response when such patterns are found;

(2) Conducting the annual physical inventory and preparation of the reconciliation report;

(3) Implementing a sample distribution security and audit system, including conducting random and for-cause audits of sales representatives by personnel independent of the sales force; and

(4) Storage of drug samples by representatives;

(c) Identifying any significant loss of drug samples and notifying FDA of the loss; and

(d) Monitoring any loss or theft of drug samples.

§ 203.35 Standing requests.

Manufacturers or authorized distributors of record shall not distribute drug samples on the basis of open-ended or standing requests, but shall

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require separate written requests for each drug sample or group of samples. An arrangement by which a licensed practitioner requests in writing that a specified number of drug samples be delivered over a period of not more than 6 months, with the actual delivery dates for parts of the order to be set by subsequent oral communication or electronic transmission, is not considered to be a standing request.

§ 203.36 Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party record-keeping.

(a) *Responsibility for creating and maintaining forms, reports, and records.* Any manufacturer or authorized distributor of record that uses a fulfillment house, shipping or mailing service, or other third party, or engages in a comarketing agreement with another manufacturer or distributor to distribute drug samples or to meet any of the requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

(b) *Responsibility for producing requested forms, reports, or records.* A manufacturer or authorized distributor of record that contracts with a third party to maintain some or all of its records shall produce requested forms, reports, records, or other required documents within 2 business days of a request by an authorized representative of FDA or another Federal, State, or local regulatory or law enforcement official.

§ 203.37 Investigation and notification requirements.

(a) *Investigation of falsification of drug sample records.* A manufacturer or authorized distributor of record that has reason to believe that any person has falsified drug sample requests, receipts, or records, or is diverting drug samples, shall:

(1) Notify FDA, by telephone or in writing, within 5 working days;

(2) Immediately initiate an investigation; and

(3) Provide FDA with a complete written report, including the reason for