(1) Notify FDA, by telephone or in writing, within 5 working days of becoming aware of a significant loss or known theft;

(2) Immediately initiate an investigation into the significant loss or known theft; and

(3) Provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (b)(1) of this section.

(c) Conviction of a representative. (1) A manufacturer or authorized distributor of record that distributes drug samples shall notify FDA, by telephone or in writing, 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 drug sample or the offer to sell, purchase, or trade a drug sample.

(2) A manufacturer or authorized distributor of record shall provide FDA with a complete written report not later than 30 days after the date of the initial notification.

(d) Selection of individual responsible for drug sample information. A manufacturer or authorized distributor of record that distributes drug samples shall inform FDA in writing within 30 days of selecting the individual responsible for responding to a request for information about drug samples of that individual’s name, business address, and telephone number.

(e) Whom to notify at FDA. Notifications and reports concerning prescription human drugs and biological products regulated by the Center for Drug Evaluation and Research shall be made to the Division of Compliance Risk Management and Surveillance, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Notifications and reports concerning prescription human biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Division of Inspections and Surveillance (HFMD–650), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

§ 203.38 Sample lot or control numbers; labeling of sample units.

(a) Lot or control number required on drug sample labeling and sample unit label. The manufacturer or authorized distributor of record of a drug sample shall include on the label of the sample unit and on the outside container or packaging of the sample unit, if any, an identifying lot or control number that will permit the tracking of the distribution of each drug sample unit.

(b) Records containing lot or control numbers required for all drug samples distributed. A manufacturer or authorized distributor of record shall maintain for all samples distributed records of drug sample distribution containing lot or control numbers that are sufficient to permit the tracking of sample units to the point of the licensed practitioner.

(c) Labels of sample units. Each sample unit shall bear a label that clearly denotes its status as a drug sample, e.g., “sample,” “not for sale,” “professional courtesy package.”

(1) A drug that is labeled as a drug sample is deemed to be a drug sample within the meaning of the act.

(2) A drug product dosage unit that bears an imprint identifying the dosage form as a drug sample is deemed to be a drug sample within the meaning of the act.

(3) Notwithstanding paragraphs (c)(1) and (c)(2) of this section, any article that is a drug sample as defined in section 503(c)(1) of the act and §203.3(i) that fails to bear the label required in this paragraph (c) is a drug sample.

§ 203.39 Donation of drug samples to charitable institutions.

A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients, provided that the following requirements are met:
§ 203.50 Requirements for wholesale distribution of prescription drugs.

(a) Identifying statement for sales by unauthorized distributors. Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

(1) The proprietary and established name of the drug;
(2) Dosage;
(3) Container size;
(4) Date of expiration; and
(5) The name and address of the seller and the authorized distributor of record.

(b) Record of wholesale distribution. Each wholesale distributor shall maintain complete records of the disposition of all manufactured or purchased drug samples, a copy of which shall be retained by the recipient charitable institution for a period of not less than 3 years, containing the following information:

(1) The name, address, and telephone number of the recipient charitable institution;
(2) The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and
(3) The name of the charitable institution donating the drug sample.

(c) Disposal of unsuitable drug samples. Each charitable institution shall dispose of any unsuitable drug sample by destroying it or returning it to the manufacturer. The charitable institution shall maintain complete records of the disposal of all destroyed or returned drug samples.

(d) Inspection of drug samples. Each recipient charitable institution shall prepare at the time of collection or delivery of a drug sample a complete and accurate donation record, a copy of which shall be retained by the recipient charitable institution for at least 3 years, containing the following information:

(1) The name, address, and telephone number of the licensed practitioner (or donating charitable institution);
(2) The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and
(3) The date of the donation.

(e) Wholesale distribution records. Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

(f) Reporting of losses or thefts. Each recipient charitable institution shall conduct, at least annually, an inventory of prescription drug sample stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug sample inventory discrepancies and reconciliation problems shall be investigated by the charitable institution and reported to FDA.

(g) Record of returns and exchanges. Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

(h) Storage of drug samples. Each recipient charitable institution shall store drug samples under conditions that will maintain the sample’s stability, integrity, and effectiveness, and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

(i) Reporting of losses or thefts. Each recipient charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.