Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the ‘‘Physicians Desk Reference’’) for use by medical practitioners, pharmacists, or nurses containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

EFFECTIVE DATE NOTE: At 44 FR 37467, June 26, 1979, §202.1(e)(6) (ii) and (vii) were revised. At 44 FR 74817, Dec. 18, 1979, paragraphs (e)(6) (ii) and (vii) were stayed indefinitely. At 64 FR 400, Jan. 5, 1999, these paragraphs were amended. For the convenience of the user, paragraphs (e)(6) (ii) and (vii), published at 44 FR 37467, are set forth below:

§ 202.1 Prescription-drug advertisements.

(e) * * * *

(ii) Represents or suggests that a prescription drug is safer or more effective than another drug in some particular when the difference has not been demonstrated by substantial evidence. An advertisement for a prescription drug may not, either directly or by implication, e.g., by use of comparative test data or reference to published reports, represent that the drug is safer or more effective than another drug, nor may an advertisement contain a quantitative statement of safety or effectiveness (a) unless the representation has been approved as part of the labeling in a new drug application or biologic license, or (b) if the drug is not a new drug or biologic, unless the representation of safety or effectiveness is supported by substantial evidence derived from adequate and well-controlled studies as defined in §314.111(a)(5)(ii) of this chapter, or unless the requirement for adequate and well-controlled studies is waived as provided in §314.111(a)(5)(ii) of this chapter.

(vii) Suggests, on the basis of favorable data or conclusions from nonclinical studies of a prescription drug, such as studies in laboratory animals or in vitro, that the studies have clinical significance, if clinical significance has not been demonstrated. Data that demonstrate activity or effectiveness for a prescription drug in animal or in vitro tests and have not been shown by adequate and well-controlled clinical studies to pertain to clinical use may be used in advertising except that (a), in the case of anti-infective drugs, in vitro data may be included in the advertisement, if data are immediately preceded by the statement ‘‘The following in vitro data are available but their clinical significance is unknown’’ and (b), in the case of other drug classes, in vitro and animal data that have not been shown to pertain to clinical use by adequate and well-controlled clinical studies as defined in §314.111(a)(5)(ii) of this chapter may not be used unless the requirement for adequate and well-controlled studies is waived as provided in §314.111(a)(5)(ii) of this chapter.

PART 203—PRESCRIPTION DRUG MARKETING

Subpart A—General Provisions

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§ 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

§ 203.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992, except for those sections relating to State licensing of wholesale distributors (see part 205 of this chapter), to protect the public health, and to protect the public against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples.

§ 203.3 Definitions.

(a) The act means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

(b) Authorized distributor of record means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products.

(c) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(d) Blood component means that part of a single-donor unit of blood separated by physical or mechanical means.

(e) Bulk drug substance means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(f) Charitable institution or charitable organization means a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(g) Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(h) Distribute means to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term “distribute” does not include:
§ 203.3

(1) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(2) Providing of a drug sample to a patient by:
   (i) A practitioner licensed to prescribe such drug;
   (ii) A health care professional acting at the direction and under the supervision of such a practitioner; or
   (iii) The pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the act and regulations.

(i) Drug sample means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(j) Drug coupon means a form that may be redeemed, at no cost or at reduced cost, for a drug that is prescribed in accordance with section 503(b) of the act.

(k) Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(l) Electronic signature means any computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature.

(m) Emergency medical reasons include, but are not limited to, transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and fire fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage; but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures.

(n) FDA means the U.S. Food and Drug Administration.

(o) Group purchasing organization means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

(p) Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(q) 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 or any wholesale distributor. A person cannot simultaneously be a “health care entity” and a retail pharmacy or wholesale distributor.

(r) Licensed practitioner means any person licensed or authorized by State law to prescribe drugs.

(s) Manufacturer means any person who is a manufacturer as defined by §201.1 of this chapter.

(t) Nonprofit affiliate means any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in section 501(c)(3) of the Internal Revenue Code of 1954.

(u) Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer’s products for a period of time or for a number of shipments. If
the distributor is not authorized to distribute a manufacturer’s entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.


(w) PDMA means the Prescription Drug Marketing Act of 1987.

(x) Person includes any individual, partnership, corporation, or association.

(y) Prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

(2) Representative means an employee or agent of a drug manufacturer or distributor who promotes the sale of prescription drugs to licensed practitioners and who may solicit or receive written requests for the delivery of drug samples. A detailer is a representative.

(aa) Sample unit means a packet, card, blister pack, bottle, container, or other single package comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or distributor to be provided by a licensed practitioner to a patient in an unbroken or unopened condition.

(bb) Unauthorized distributor means a distributor who does not have an ongoing relationship with a manufacturer to sell or distribute its products.

(cc) Wholesale distribution means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription executed in accordance with section 503(b) of the act;

(7) The distribution of drug samples by manufacturers’ and authorized distributors’ representatives;

(8) The sale, purchase, or trade of blood or blood components intended for transfusion;

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with §203.23; or

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(dd) Wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

EFFECTIVE DATE NOTE: At 65 FR 25639, May 3, 2000, the effective date for §203.3(u) was delayed until Oct. 1, 2001. At 66 FR 12851, Mar. 1, 2001, §203.3(u) was further delayed until Apr. 1, 2002. At 67 FR 6646, Feb. 13, 2002, the effective date was further delayed until Apr. 1, 2003.

Subpart B—Reimportation

§203.10 Restrictions on reimportation.

No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its
manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.

§ 203.11 Applications for reimportation to provide emergency medical care.

(a) Applications for reimportation for emergency medical care shall be submitted to the director of the FDA District Office in the district where reimportation is sought (addresses found in §5.115 of this chapter).

(b) Applications for reimportation to provide emergency medical care shall be reviewed and approved or disapproved by each district office.

§ 203.12 An appeal from an adverse decision by the district office.

An appeal from an adverse decision involving insulin-containing drugs or prescription human drugs, other than biological products, may be made to the Office of Compliance (HFD–300), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. An appeal from an adverse decision involving prescription human biological products may be made to the Office of Compliance and Biologics Quality (HFM–600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852.

Subpart C—Sales Restrictions

§ 203.20 Sales restrictions.

Except as provided in §203.22 or §203.23, no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization.

§ 203.22 Exclusions.

Section 203.20 does not apply to:

(a) The purchase or other acquisition of a drug for its own use by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of the organization.

(b) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control.

(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.

(e) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.

(f) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

§ 203.23 Returns.

The return of a prescription drug purchased by a hospital or health care entity or acquired at a reduced price by or donated to a charitable institution is exempt from the prohibitions in §203.20, provided that:

(a) The hospital, health care entity, or charitable institution documents the return by filling out a credit memo specifying:

(1) The name and address of the hospital, health care entity, or charitable institution;

(2) The name and address of the manufacturer or wholesale distributor from which it was acquired;

(3) The product name and lot or control number;

(4) The quantity returned; and

(5) The date of the return.

(b) The hospital, health care entity, or charitable institution forwards a
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§ 203.30 Sample distribution by mail or common carrier.

(a) Requirements for drug sample distribution by mail or common carrier. A manufacturer or authorized distributor of record may distribute a drug sample to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity, by mail or common carrier, provided that:

(1) The licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record, as set forth in paragraph (b) of this section, before the delivery of the drug sample;

(2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product;

(3) The recipient executes a written receipt, as set forth in paragraph (c) of this section, when the drug sample is delivered; and

(4) The receipt is returned to the manufacturer or distributor from which the drug sample was received.

(b) Contents of the written request form for delivery of samples by mail or common carrier. (1) A written request for a drug sample to be delivered by mail or common carrier to a licensed practitioner is required to contain the following:

(i) The name, address, professional title, and signature of the practitioner making the request;

(ii) The practitioner’s State license or authorization number or, where a scheduled drug product is requested, the practitioner’s Drug Enforcement Administration number.

(iii) The proprietary or established name and the strength of the drug sample requested;

(iv) The quantity requested;

(v) The name of the manufacturer and the authorized distributor of record, if the drug sample is requested from an authorized distributor of record; and

(vi) The date of the request.

(2) A written request for a drug sample to be delivered by mail or common carrier to the pharmacy of a hospital or other health care entity is required to contain, in addition to all of the information in paragraph (b)(1) of this section, the name and address of the pharmacy of the hospital or other health care entity to which the drug sample is to be delivered.

(c) Contents of the receipt to be completed upon delivery of a drug sample. The receipt is to be on a form designated by the manufacturer or distributor, and is required to contain the following:

(1) If the drug sample is delivered to the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner’s designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is delivered to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or health care entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.
§ 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

(a) Requirements for drug sample distribution by means other than mail or common carrier. A manufacturer or authorized distributor of record may distribute by means other than mail or common carrier, by a representative or detailer, a drug sample to a practitioner licensed to prescribe the drug to be sampled or, at the written request of such a licensed practitioner, to the pharmacy of a hospital or other health care entity, provided that:

1. The manufacturer or authorized distributor of record receives from the licensed practitioner a written request signed by the licensed practitioner before the delivery of the drug sample;

2. The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product;

3. A receipt is signed by the recipient, as set forth in paragraph (c) of this section, when the drug sample is delivered;

4. The receipt is returned to the manufacturer or distributor; and

5. The requirements of paragraphs (d) through (e) of this section are met.

(b) Contents of the written request forms for delivery of samples by a representative. (1) A written request for delivery of a drug sample by a representative to a licensed practitioner is required to contain the following:

(i) The name, address, professional title, and signature of the practitioner making the request;

(ii) The practitioner’s State license or authorization number, or, where a scheduled drug product is requested, the practitioner’s Drug Enforcement Administration number;

(iii) The proprietary or established name and the strength of the drug sample requested;

(iv) The quantity requested;

(v) The name of the manufacturer and the authorized distributor of record, if the drug sample is requested from an authorized distributor of record; and

(vi) The date of the request.

(2) A written request for delivery of a drug sample by a representative to the pharmacy of a hospital or other health care entity is required to contain, in addition to all of the information in paragraph (b) of this section, the name and address of the pharmacy of the hospital or other health care entity to which the drug sample is to be delivered.

(c) Contents of the receipt to be completed upon delivery of a drug sample. The receipt is to be on a form designated by the manufacturer or distributor, and is required to contain the following:

1. If the drug sample is received at the address of the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner’s designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

2. If the drug sample is received by the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or health care entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(d) Inventory and reconciliation of drug samples of manufacturers’ and distributors’ representatives. Each drug manufacturer or authorized distributor of record that distributes drug samples by means of representatives shall conduct, at least annually, a complete and accurate physical inventory of all drug 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 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)(i) 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 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, 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 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 and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (a)(1) of this section.
§ 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:

(b) Significant loss or known theft of drug samples. A manufacturer or authorized distributor of record that distributes drug samples or a charitable institution that receives donated drug samples from a licensed practitioner shall:

(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 shall be made to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852.
§ 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) Number of containers;
(5) The drug’s lot or control number(s);
(6) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
(7) The date of each previous transaction.

(b) The drug origin statement is subject to the record retention requirements of §203.60 and must be retained by all wholesale distributors involved in the distribution of the drug product, whether authorized or unauthorized, for 3 years.

(c) Identifying statement not required when additional manufacturing processes are completed. A manufacturer that subjects a drug to any additional manufacturing processes to produce a different drug is not required to provide to a purchaser a statement identifying the previous sales of the component drug or drugs.

(d) List of authorized distributors of record. Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record.

(1) Each manufacturer’s list of authorized distributors of record shall specify whether each distributor listed thereon is authorized to distribute the manufacturer’s full product line or only particular, specified products.

(2) Each manufacturer shall update its list of authorized distributors of record on a continuing basis.

(3) Each manufacturer shall make its list of authorized distributors of record available on request to the public for inspection or copying. A manufacturer may impose reasonable copying charges for such requests from members of the public.

EFFECTIVE DATE NOTE: At 65 FR 25639, May 3, 2000, the effective date for §203.50 was delayed until Oct. 1, 2001. At 66 FR 12851, Mar. 1, 2001, §203.50 was further delayed until Apr. 1, 2002. At 67 FR 6666, Feb. 13, 2002, the effective date was further delayed until April 1, 2003.

Subpart F—Request and Receipt Forms, Reports, and Records

§203.60 Request and receipt forms, reports, and records.

(a) Use of electronic records, electronic signatures, and handwritten signatures executed to electronic records. (1) Provided the requirements of part 11 of this chapter are met, electronic records, electronic signatures, and handwritten signatures executed to electronic records may be used as an alternative to paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA, PDA, or this part.

(2) Combinations of paper records and electronic records, electronic records and handwritten signatures executed on paper, or paper records and electronic signatures or handwritten signatures executed to electronic records, may be used to meet any of the record and signature requirements of PDMA, PDA, or this part, provided that:

(i) The requirements of part 11 of this chapter are met for the electronic records, electronic signatures, or handwritten signatures executed to electronic records; and

(ii) A reasonably secure link between the paper-based and electronic components exists such that the combined records and signatures are trustworthy and reliable, and to ensure that the signer cannot readily repudiate the signed records as not genuine.

(b) Maintenance of request and receipt forms, reports, records, and other documents created on paper. Request and receipt forms, reports, records, and other documents created on paper may be maintained on paper or by photographic imaging (i.e., photocopies or microfiche), provided that the security
§ 203.70 and authentication requirements described in paragraph (c) of this section are followed. Where a required document is created on paper and electronically scanned into a computer, the resulting record is an electronic record that must meet the requirements of part 11 of this chapter.

(c) Security and authentication requirements for request and receipt forms, reports, records, and other documents created on paper. A request or receipt form, report, record, or other document, and any signature appearing thereon, that is created on paper and that is maintained by photographic imaging, or transmitted electronically (i.e., by facsimile) shall be maintained or transmitted in a form that provides reasonable assurance of being:

(1) Resistant to tampering, revision, modification, fraud, unauthorized use, or alteration;

(2) Preserved in accessible and retrievable fashion; and

(3) Available to permit copying for purposes of review, analysis, verification, authentication, and reproduction by the person who executed the form or created the record, by the manufacturer or distributor, and by authorized personnel of FDA and other regulatory and law enforcement agencies.

(d) Retention of request and receipt forms, reports, lists, records, and other documents. Any person required to create or maintain reports, lists, or other records under PDMA, PDA, or this part, including records relating to the distribution of drug samples, shall retain them for at least 3 years after the date of their creation.

(e) Availability of request and receipt forms, reports, lists, and records. Any person required to create or maintain request and receipt forms, reports, lists, or other records under PDMA, PDA, or this part shall make them available, upon request, in a form that permits copying or other means of duplication, to FDA or other Federal, State, or local regulatory and law enforcement officials for review and reproduction. The records shall be made available within 2 business days of a request.

§ 203.70 Application for a reward.

(a) Reward for providing information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample. A person who provides information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample, or the offer to sell, purchase, or trade a drug sample, in violation of section 503(c)(1) of the act, is entitled to one-half the criminal fine imposed and collected for such violation, but not more than $125,000.

(b) Procedure for making application for a reward for providing information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample. A person who provides information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample, or the offer to sell, purchase, or trade a drug sample, in violation of section 503(c)(1) of the act, may apply for a reward by making written application to:

(1) Director, Office of Compliance (HFD–300), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; or

(2) Director, Office of Compliance and Biologics Quality (HFM–600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, as appropriate.

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Sec. 205.1 Scope.
205.2 Purpose.
205.3 Definitions.
205.4 Wholesale drug distributor licensing requirement.
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