

§ 203.1

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

203.39 Donation of drug samples to charitable institutions.

Subpart E—Wholesale Distribution

203.50 Requirements for wholesale distribution of prescription drugs.

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

203.60 Request and receipt forms, reports, and records.

Subpart G—Rewards

203.70 Application for a reward.

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Subpart A—General Provisions

§ 203.1 Scope.

This part sets forth procedures and requirements pertaining to the reimportation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples. Blood and blood components intended for transfusion are excluded from the restrictions in and the requirements of the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

§ 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.

21 CFR Ch. I (4–1–01 Edition)

§ 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:

(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