

(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.

[64 FR 67756, Dec. 3, 1999, as amended at 73 FR 59500, Oct. 9, 2008]

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 part 5, subpart M of this chapter).

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

[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 17292, Apr. 2, 2004]

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

An appeal from an adverse decision by the district office involving insulin-containing drugs or prescription human drugs, other than biological products, may be made to the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. An appeal from an adverse decision by the district office 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 or the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, depending on the Center responsible for regulating the product.

[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 48775, Aug. 11, 2004; 70 FR 14980, Mar. 24, 2005; 74 FR 13112, Mar. 26, 2009]

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:

§ 203.23

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(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 hospitals or health care entities owned or operated by Federal, State, or local governmental units to other hospitals or health care entities owned or operated by Federal, State, or local governmental units.

(g) The sale, purchase, or trade of, or the offer to sell, purchase, or trade blood or blood components intended for transfusion.

(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a health care entity any:

(1) Drug indicated for a bleeding or clotting disorder, or anemia;

(2) Blood collection container approved under section 505 of the act; or

(3) Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative); as long as all of the health care services that the establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested to-

gether with specimens undergoing routine donor testing. Blood establishments relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.

(i) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a health care entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Comprehensive hemophilia diagnostic treatment centers relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.

[64 FR 67756, Dec. 3, 1999, as amended at 73 FR 59500, Oct. 9, 2008]

§ 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 copy of each credit memo to the manufacturer and retains a copy of each credit memo for its records;

(c) Any drugs returned to a manufacturer or wholesale distributor are kept under proper conditions for storage, handling, and shipping, and written documentation showing that proper conditions were maintained is provided