

(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 together 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 to the manufacturer or wholesale distributor to which the drugs are returned.

#### Subpart D—Samples

##### § 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: