

## Food and Drug Administration, HHS

## § 606.3

reporting applicable to all approved biological products.

### § 601.94 Promotional materials.

For biological products being considered for approval under this subpart, unless otherwise informed by the agency, applicants must submit to the agency for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

### § 601.95 Termination of requirements.

If FDA determines after approval under this subpart that the requirements established in §§ 601.91(b)(2), 601.92, and 601.93 are no longer necessary for the safe and effective use of a biological product, FDA will so notify the applicant. Ordinarily, for biological products approved under § 601.91, these requirements will no longer apply when FDA determines that the postmarketing study verifies and describes the biological product's clinical benefit. For biological products approved under § 601.91, the restrictions would no longer apply when FDA determines that safe use of the biological product can be ensured through appropriate labeling. FDA also retains the discretion to remove specific postapproval requirements upon review of a petition submitted by the sponsor in accordance with § 10.30 of this chapter.

## PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

### Subpart A—General Provisions

Sec.  
606.3 Definitions.

### Subpart B—Organization and Personnel

606.20 Personnel.

### Subpart C—Plant and Facilities

606.40 Facilities.

### Subpart D—Equipment

606.60 Equipment.

606.65 Supplies and reagents.

### Subpart E [Reserved]

### Subpart F—Production and Process Controls

606.100 Standard operating procedures.

606.110 Plateletpheresis, leukapheresis, and plasmapheresis.

### Subpart G—Additional Labeling Standards for Blood and Blood Components

606.120 Labeling, general requirements.

606.121 Container label.

606.122 Circular of information.

### Subpart H—Laboratory Controls

606.140 Laboratory controls.

606.145 Control of bacterial contamination of platelets.

606.151 Compatibility testing.

### Subpart I—Records and Reports

606.160 Records.

606.165 Distribution and receipt; procedures and records.

606.170 Adverse reaction file.

606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

SOURCE: 40 FR 53532, Nov. 18, 1975, unless otherwise noted.

### Subpart A—General Provisions

#### § 606.3 Definitions.

As used in this part:

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

(b) *Unit* means the volume of blood or one of its components in a suitable volume of anticoagulant obtained from a single collection of blood from one donor.

## § 606.20

(c) *Component* means that part of a single-donor's blood separated by physical or mechanical means.

(d) *Plasma for further manufacturing* means that liquid portion of blood separated and used as material to prepare another product.

(e) *Plasmapheresis* means the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor.

(f) *Plateletpheresis* means the procedure in which blood is removed from a donor, a platelet concentrate is separated, and the remaining formed elements are returned to the donor along with a portion of the residual plasma.

(g) *Leukapheresis* means the procedure in which blood is removed from the donor, a leukocyte concentrate is separated, and the remaining formed elements and residual plasma are returned to the donor.

(h) *Facilities* means any area used for the collection, processing, compatibility testing, storage or distribution of blood and blood components.

(i) *Processing* means any procedure employed after collection, and before or after compatibility testing of blood, and includes the identification of a unit of donor blood, the preparation of components from such unit of donor blood, serological testing, labeling and associated recordkeeping.

(j) *Compatibility testing* means the procedures performed to establish the matching of a donor's blood or blood components with that of a potential recipient.

(k) *Distributed* means:

(1) The blood or blood components have left the control of the licensed manufacturer, unlicensed registered blood establishment, or transfusion service; or

(2) The licensed manufacturer has provided Source Plasma or any other blood component for use in the manufacture of a licensed biological product.

(l) *Control* means having responsibility for maintaining the continued safety, purity, and potency of the product and for compliance with applicable product and establishment standards,

## 21 CFR Ch. I (4–1–16 Edition)

and for compliance with current good manufacturing practices.

[40 FR 53532, Nov. 18, 1975, as amended at 64 FR 45370, Aug. 19, 1999; 65 FR 66635, Nov. 7, 2000; 66 FR 1835, Jan. 10, 2001; 66 FR 40889, Aug. 6, 2001; 72 FR 45886, Aug. 16, 2007]

EFFECTIVE DATE NOTE: At 80 FR 29894, May 22, 2015, § 606.3 was amended by revising paragraphs (a) and (c), effective May 23, 2016. For the convenience of the user, the revised text is set forth as follows:

### § 606.3 Definitions.

\* \* \* \* \*

(a) *Blood* means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

\* \* \* \* \*

(c) *Blood component* means a product containing a part of human blood separated by physical or mechanical means.

\* \* \* \* \*

## Subpart B—Organization and Personnel

### § 606.20 Personnel.

(a) [Reserved]

(b) The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the procedures or control operations they perform, the necessary training or experience, and adequate information concerning the application of pertinent provisions of this part to their respective functions.

(c) Persons whose presence can adversely affect the safety and purity of the products shall be excluded from areas where the collection, processing,

## Food and Drug Administration, HHS

## § 606.60

compatibility testing, storage or distribution of blood or blood components is conducted.

[40 FR 53532, Nov. 18, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11014, Mar. 26, 1990; 62 FR 53538, Oct. 15, 1997]

### Subpart C—Plant and Facilities

#### § 606.40 Facilities.

Facilities shall be maintained in a clean and orderly manner, and shall be of suitable size, construction and location to facilitate adequate cleaning, maintenance and proper operations. The facilities shall:

(a) Provide adequate space for the following when applicable:

(1) Private and accurate examinations of individuals to determine their suitability as blood donors.

(2) The withdrawal of blood from donors with minimal risk of contamination, or exposure to activities and equipment unrelated to blood collection.

(3) The storage of blood or blood components pending completion of tests.

(4) The quarantine storage of blood or blood components in a designated location pending repetition of those tests that initially gave questionable serological results.

(5) The storage of finished products prior to distribution.

(6) The quarantine storage, handling and disposition of products and reagents not suitable for use.

(7) The orderly collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.

(8) The adequate and proper performance of all steps in plasmapheresis, plateletpheresis and leukapheresis procedures.

(9) The orderly conduction of all packaging, labeling and other finishing operations.

(b) Provide adequate lighting, ventilation and screening of open windows and doors.

(c) Provide adequate, clean, and convenient handwashing facilities for personnel, and adequate, clean, and convenient toilet facilities for donors and personnel. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

(d) Provide for safe and sanitary disposal for the following:

(1) Trash and items used during the collection, processing and compatibility testing of blood and blood components.

(2) Blood and blood components not suitable for use or distribution.

EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.40(a)(1) was amended by removing “suitability” and adding in its place “eligibility”, effective May 23, 2016.

### Subpart D—Equipment

#### § 606.60 Equipment.

(a) Equipment used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be maintained in a clean and orderly manner and located so as to facilitate cleaning and maintenance. The equipment shall be observed, standardized and calibrated on a regularly scheduled basis as prescribed in the Standard Operating Procedures Manual and shall perform in the manner for which it was designed so as to assure compliance with the official requirements prescribed in this chapter for blood and blood products.

(b) Equipment that shall be observed, standardized and calibrated with at least the following frequency, include but are not limited to:

Equipment	Performance check	Frequency	Frequency of calibration
Temperature recorder ....	Compare against thermometer .....	Daily .....	As necessary.
Refrigerated centrifuge ..	Observe speed and temperature .....	Each day of use	Do.
Hematocrit centrifuge ....	.....	.....	Standardize before initial use, after repairs or adjustments, and annually. Timer every 3 mo.
General lab centrifuge ...	.....	.....	Tachometer every 6 mo.
Automated blood-typing machine.	Observe controls for correct results .....	Each day of use.	
Hemoglobinometer .....	Standardize against cyanmethemoglobin standard.	.....do.	

Equipment	Performance check	Frequency	Frequency of calibration
Refractometer .....	Standardize against distilled water .....	.....do.	As necessary.
Blood container scale ....	Standardize against container of known weight.	.....do .....	
Water bath .....	Observe temperature .....	.....do .....	Do.
Rh view box .....	.....do .....	.....do .....	Do.
Autoclave .....	.....do .....	Each time of use	Do.
Serologic rotators .....	Observe controls for correct results .....	Each day of use	Speed as necessary.
Laboratory thermometers.	.....	.....	Before initial use.
Electronic thermometers	.....	.....	Monthly.
Vacuum blood agitator ..	Observe weight of the first container of blood filled for correct results.	Each day of use	Standardize with container of known mass or volume before initial use, and after repairs or adjustments.

(c) Equipment employed in the sterilization of materials used in blood collection or for disposition of contaminated products shall be designed, maintained and utilized to ensure the destruction of contaminating microorganisms. The effectiveness of the sterilization procedure shall be no less than that achieved by an attained temperature of 121.5 °C (251 °F) maintained for 20 minutes by saturated steam or by an attained temperature of 170 °C (338 °F) maintained for 2 hours with dry heat.

[40 FR 53532, Nov. 18, 1975; 40 FR 55849, Dec. 2, 1975, as amended at 45 FR 9261, Feb. 12, 1980; 57 FR 11263, Apr. 2, 1992; 57 FR 12862, Apr. 13, 1992]

#### § 606.65 Supplies and reagents.

All supplies and reagents used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be stored in a safe, sanitary and orderly manner.

(a) All surfaces coming in contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product. All final containers and closures for blood and blood components not intended for transfusion shall be clean and free of surface solids and other contaminants.

(b) Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling. Such examination shall include inspection for breakage of seals, when indicated, and abnormal discoloration.

Where any defect is observed, the container shall not be used, or, if detected after filling, shall be properly discarded.

(c) Representative samples of each lot of the following reagents or solutions shall be tested on a regularly scheduled basis by methods described in the Standard Operating Procedures Manual to determine their capacity to perform as required:

Reagent or solution	Frequency of testing
Anti-human globulin .....	Each day of use.
Blood grouping reagents .....	Do.
Lectins .....	Do.
Antibody screening and reverse grouping cells.	Do.
Hepatitis test reagents .....	Each run.
Syphilis serology reagents ....	Do.
Enzymes .....	Each day of use.

(d) Supplies and reagents that do not bear an expiration date shall be stored in such a manner that the oldest is used first.

(e) Supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer.

(f) Items that are required to be sterile and come into contact with blood should be disposable whenever possible.

[40 FR 53532, Nov. 18, 1975, as amended at 59 FR 23636, May 6, 1994]

### Subpart E [Reserved]

### Subpart F—Production and Process Controls

#### § 606.100 Standard operating procedures.

(a) In all instances, except clinical investigations, standard operating procedures shall comply with published

additional standards in part 640 of this chapter for the products being processed; except that, references in part 640 relating to licenses, licensed establishments and submission of material or data to or approval by the Director, Center for Biologics Evaluation and Research, are not applicable to establishments not subject to licensure under section 351 of the Public Health Service Act.

(b) Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures shall include, but are not limited to, descriptions of the following, when applicable:

(1) Criteria used to determine donor suitability, including acceptable medical history criteria.

(2) Methods of performing donor qualifying tests and measurements, including minimum and maximum values for a test or procedure when a factor in determining acceptability.

(3) Solutions and methods used to prepare the site of phlebotomy to give maximum assurance of a sterile container of blood.

(4) Method of accurately relating the product(s) to the donor.

(5) Blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood removed from the donor.

(6) Methods of component preparation, including any time restrictions for specific steps in processing.

(7) All tests and repeat tests performed on blood and blood components during manufacturing.

(8) Pretransfusion testing, where applicable, including precautions to be taken to identify accurately the recipient blood samples and crossmatched donor units.

(9) Procedures for investigating adverse donor and recipient reactions.

(10) Storage temperatures and methods of controlling storage temperatures for all blood products and reagents as

prescribed in §§ 600.15 and 610.53 of this chapter.

(11) Length of expiration dates, if any, assigned for all final products as prescribed in § 610.53 of this chapter.

(12) Criteria for determining whether returned blood is suitable for reissue.

(13) Procedures used for relating a unit of blood or blood component from the donor to its final disposition.

(14) Quality control procedures for supplies and reagents employed in blood collection, processing and pretransfusion testing.

(15) Schedules and procedures for equipment maintenance and calibration.

(16) Labeling procedures, including safeguards to avoid labeling mixups.

(17) Procedures of plasmapheresis, plateletpheresis, and leukapheresis, if performed, including precautions to be taken to ensure reinfusion of a donor's own cells.

(18) Procedures for preparing recovered plasma, if performed, including details of separation, pooling, labeling, storage, and distribution.

(19) Procedures under §§ 610.46 and 610.47 of this chapter:

(i) To identify previously donated blood and blood components from a donor who later tests reactive for evidence of human immunodeficiency virus (HIV) infection or hepatitis C virus (HCV) infection when tested under § 610.40 of this chapter, or when a blood establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection;

(ii) To quarantine in-date blood and blood components previously donated by such a donor that are intended for use in another person or further manufacture into injectable products, except pooled components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures;

(iii) To notify consignees to quarantine in-date blood and blood components previously donated by such a donor intended for use in another person or for further manufacture into injectable products, except pooled components intended solely for further manufacturing into products that are

## § 606.110

manufactured using validated viral clearance procedures;

(iv) To determine the suitability for release, destruction, or relabeling of quarantined in-date blood and blood components;

(v) To notify consignees of the results of the HIV or HCV testing performed on the donors of such blood and blood components;

(vi) To notify the transfusion recipient, the recipient's physician of record, or the recipient's legal representative that the recipient received blood or blood components at increased risk of transmitting HIV or HCV, respectively.

(20) Procedures for donor deferral as prescribed in § 610.41 of this chapter; and procedures for donor notification and autologous donor referring physician notification, including procedures for the appropriate followup if the initial attempt at notification fails, as prescribed in § 630.6 of this chapter.

(c) All records pertinent to the lot or unit maintained pursuant to these regulations shall be reviewed before the release or distribution of a lot or unit of final product. The review or portions of the review may be performed at appropriate periods during or after blood collecting, processing, compatibility testing and storing. A thorough investigation, including the conclusions and followup, of any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications shall be made and recorded.

(d) In addition to the requirements of this subpart and in conformity with this section, any facility may utilize current standard operating procedures such as the manuals of the organizations, as long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this part.

(1) American Association of Blood Banks.

(2) American National Red Cross.

(3) Other organizations or individual blood banks, subject to approval by the Director, Center for Biologics Evaluation and Research.

[40 FR 53532, Nov. 18, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990; 61 FR 47422, Sept. 9, 1996; 64 FR 45370, Aug. 19, 1999; 66 FR 31176, June 11, 2001; 72 FR 48798, Aug. 24, 2007; 80 FR 80651, Dec. 28, 2015]

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EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.100 was amended by revising paragraph (b) introductory text; in (b)(1) removing “suitability” and adding in its place “eligibility”; revising paragraph (b)(20); and adding paragraphs (b)(21) and (b)(22), effective May 23, 2016. For the convenience of the user, the added and revised text is set forth as follows:

### § 606.100 Standard operating procedures.

\* \* \* \* \*

(b) Establishments must establish, maintain, and follow written standard operating procedures for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for allogeneic transfusion, autologous transfusion, and further manufacturing purposes; for all steps in the investigation of product deviations related to § 606.171; and for all steps in recordkeeping related to current good manufacturing practice and other applicable requirements and standards. Such procedures must be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures must include, but are not limited to, descriptions of the following, when applicable:

\* \* \* \* \*

(20) Procedures for donor deferral as prescribed in § 610.41 of this chapter.

(21) Procedures for donor notification and notification of the referring physician of an autologous donor, including procedures for the appropriate followup if the initial attempt at notification fails, as prescribed in § 630.40 of this chapter.

(22) Procedures to control the risks of bacterial contamination of platelets, including all steps required under § 606.145.

\* \* \* \* \*

### § 606.110 Plateletpheresis, leukapheresis, and plasmapheresis.

(a) The use of plateletpheresis and leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for specific products prescribed in this part provided that: (1) A physician has determined that the recipient must be transfused with the leukocytes or platelets from a specific donor, and (2) the procedure is performed under the supervision of a qualified licensed physician who is aware of the health status of the donor, and the physician has

certified in writing that the donor's health permits plateletpheresis or leukapheresis.

(b) Plasmapheresis of donors who do not meet the donor requirements of §§ 640.63, 640.64 and 640.65 of this chapter for the collection of plasma containing rare antibodies shall be permitted only with the prior approval of the Director, Center for Biologics Evaluation and Research.

[40 FR 53532, Nov. 18, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.110 was amended in paragraph (a) by removing "qualified licensed physician" and adding in its place "responsible physician" and removing "certified in writing" and adding in its place "determined and documented"; and in paragraph (b), removing "640.63" and adding in its place "630.10, 630.15", effective May 23, 2016.

### Subpart G—Additional Labeling Standards for Blood and Blood Components

#### § 606.120 Labeling, general requirements.

(a) Labeling operations shall be separated physically or spatially from other operations in a manner adequate to prevent mixups.

(b) The labeling operation shall include the following labeling controls:

(1) Labels shall be held upon receipt, pending review and proofing against an approved final copy, to ensure accuracy regarding identity, content, and conformity with the approved copy.

(2) Each type of label representing different products shall be stored and maintained in a manner to prevent mixups, and stocks of obsolete labels shall be destroyed.

(3) All necessary checks in labeling procedures shall be utilized to prevent errors in translating test results to container labels.

(c) All labeling shall be clear and legible.

[50 FR 35469, Aug. 30, 1985]

#### § 606.121 Container label.

(a) The container label requirements are designed to facilitate the use of a uniform container label for blood and blood components intended for use in

transfusion or further manufacture by all blood establishments.

(b) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components considered finished products have been prepared.

(c) The container label must include the following information, as well as other specialized information as required in this section for specific products:

(1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes.

(2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer; except the container label for blood and blood components for further manufacture is not required to include a unique facility identifier.

(3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool.

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

(ii) If Source Plasma intended for manufacturing into noninjectable products is pooled, the expiration date for the pool is determined from the collection date of the oldest unit in the pool, and the pooling records must show the collection date for each unit in the pool.

(5) For Whole Blood, Plasma, Platelets, and partial units of Red Blood Cells, the volume of the product, accurate to within  $\pm 10$  percent; or optionally for Platelets, the volume or volume range within reasonable limits.

(6) Where applicable, the name and volume of source material.

(7) The recommended storage temperature (in degrees Celsius).

(8) If the product is intended for transfusion, the statements:

- (i) “Rx only.”
- (ii) “See circular of information for indications, contraindications, cautions, and methods of infusion.”
- (iii) “Properly identify intended recipient.”
- (iv) “This product may transmit infectious agents.”

(v) The appropriate donor classification statement, *i.e.*, “paid donor” or “volunteer donor,” in no less prominence than the proper name of the product.

(A) A paid donor is a person who receives monetary payment for a blood donation.

(B) A volunteer donor is a person who does not receive monetary payment for a blood donation.

(C) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of non-replacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph.

(9) If the product is intended for transfusion or as is otherwise appropriate, the ABO group and Rh type of the donor must be designated conspicuously. For Cryoprecipitated Antihemophilic Factor (AHF), the Rh type may be omitted. The Rh type must be designated as follows:

- (i) If the test using Anti-D Blood Grouping Reagent is positive, the product must be labeled: “Rh positive.”
- (ii) If the test using Anti-D Blood Grouping Reagent is negative, but the test for weak D (formerly D<sub>u</sub>) is positive, the product must be labeled: “Rh positive.”
- (iii) If the test using Anti-D Blood Grouping Reagent is negative and the test for weak D (formerly D<sub>u</sub>) is negative, the product must be labeled: “Rh negative.”

(10) If the product is not intended for transfusion, a statement as applicable: “Caution: For Manufacturing Use Only,” or “Caution: For Use in Manufacturing Noninjectable Products Only,” or other cautionary statement as approved by the Director, Center for

Biologics Evaluation and Research (CBER).

(11) If the product is intended for further manufacturing use, a statement listing the results of all the tests for communicable disease agents required under § 610.40 of this chapter for which the donation has been tested and found negative; except that the container label for Source Plasma is not required to list the negative results of serological syphilis testing under §§ 610.40(i) and 640.65(b) of this chapter.

(12) The blood and blood components must be labeled in accordance with § 610.40 of this chapter, when the donation is tested and demonstrates evidence of infection due to a communicable disease agent(s).

(13) The container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER.

(i) *Who is subject to this machine-readable requirement?* All blood establishments that manufacture, process, repack, or relabel blood or blood components intended for transfusion and regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(ii) *What blood products are subject to this machine-readable requirement?* All blood and blood components intended for transfusion are subject to the machine-readable information label requirement in this section.

(iii) *What information must be machine-readable?* Each label must have machine-readable information that contains, at a minimum:

- (A) A unique facility identifier;
- (B) Lot number relating to the donor;
- (C) Product code; and
- (D) ABO and Rh of the donor, except as described in paragraphs (c)(9) and (i)(5) of this section.

(iv) *How must the machine-readable information appear?* The machine-readable information must:

- (A) Be unique to the blood or blood component;
- (B) Be surrounded by sufficient blank space so that the machine-readable information can be scanned correctly; and



(C) Remain intact under normal conditions of use.

(v) *Where does the machine-readable information go?* The machine-readable information must appear on the label of any blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient.

(d) Unless otherwise approved by the Director, CBER, the container label for blood and blood components intended for transfusion must be white and print must be solid black, with the following additional exceptions:

(1) The ABO and Rh blood groups must be printed as follows:

(i) Rh positive: Use black print on white background and use solid black or other solid color for ABO.

(ii) Rh negative: Use white print on black background for Rh and use black outline on a white background for ABO.

(2) The proper name of the product, with any appropriate modifiers and attributes, the donor classification statement, and the statement "properly identify intended recipient" may be printed in solid red or in solid black.

(3) The following color scheme may be used for differentiating ABO Blood groups:

Blood group	Color of label
O .....	Blue
A .....	Yellow
B .....	Pink
AB .....	White

(4) Special labels, such as those described in paragraphs (h) and (i) of this section, may be color-coded.

(e) Container label requirements for particular products or groups of products.

(1) Whole Blood labels must include:

(i) The name of the applicable anticoagulant approved for use by the Director, CBER.

(ii) The volume of anticoagulant.

(iii) If tests for unexpected antibodies are positive, blood intended for transfusion must be labeled: "Contains (name of antibody)."

(2) Except for frozen, deglycerolized, or washed Red Blood Cell products, Red Blood Cell labels must include:

(i) The type of anticoagulant, and if applicable, the volume of Whole Blood and type of additive solution, with which the product was prepared.

(ii) If tests for unexpected antibodies are positive and the product is intended for transfusion, the statement: "Contains (name of antibody)."

(3) If tests for unexpected antibodies are positive, Plasma intended for transfusion must be labeled: "Contains (name of antibody)."

(4) Recovered plasma labels must include:

(i) In lieu of an expiration date, the date of collection of the oldest material in the container.

(ii) For recovered plasma not meeting the requirements for manufacture into licensable products, the statement: "Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act."

(iii) The type of anticoagulant with which the product was prepared.

(5) Source Plasma labels must include the following information:

(i) The cautionary statement, as specified in paragraph (c)(10) of this section, must follow the proper name with any appropriate modifiers and attributes and be of similar prominence as the proper name.

(ii) The statement "Store at  $-20^{\circ}\text{C}$  or colder," provided, that where plasma is intended for manufacturing into noninjectable products, this statement may be replaced by a statement of the temperature appropriate for manufacture of the final product to be prepared from the plasma.

(iii) The total volume or weight of plasma and total quantity and type of anticoagulant used.

(iv) When plasma collected from a donor is reactive for a serologic test for syphilis, a statement that the plasma is reactive and must be used only for the manufacturing of positive control reagents for the serologic test for syphilis.

(v) Source Plasma diverted for Source Plasma Salvaged must be relabeled "Source Plasma Salvaged" as prescribed in § 640.76 of this chapter. Immediately following the proper

name of the product, with any appropriate modifiers and attributes, the labeling must prominently state as applicable, “STORAGE TEMPERATURE EXCEEDED –20 °C” or “SHIPPING TEMPERATURE EXCEEDED –5 °C.”

(vi) A statement as to whether the plasma was collected from normal donors, or from donors in specific collection programs approved by the Director, CBER. In the case of specific collection programs, the label must state the defining characteristics of the plasma. In the case of immunized donors, the label must state the immunizing antigen.

(f) Blood and blood components determined to be unsuitable for transfusion must be prominently labeled “NOT FOR TRANSFUSION,” and the label must state the reason the unit is considered unsuitable. The provision does not apply to blood and blood components intended solely for further manufacture.

(g) [Reserved]

(h) The following additional information must appear on the label for blood and blood components shipped in an emergency prior to completion of required tests, in accordance with § 610.40(g) of this chapter:

(1) The statement: “FOR EMERGENCY USE ONLY BY \_\_\_\_.”

(2) Results of any tests prescribed under §§ 610.40 and 640.5(a), (b), or (c) of this chapter completed before shipment.

(3) Indication of any tests prescribed under §§ 610.40 and 640.5(a), (b), or (c) of this chapter not completed before shipment.

(i) The following additional information must appear on the label for blood and blood components intended for autologous transfusion:

(1) Information adequately identifying the patient, *e.g.*, name, date of birth, hospital, and identification number.

(2) Date of donation.

(3) The statement: “AUTOLOGOUS DONOR.”

(4) The ABO and Rh blood group and type, except as provided in paragraph (c)(9) of this section.

(5) Each container of blood and blood component intended for autologous use and obtained from a donor who fails to

meet any of the donor suitability requirements under § 640.3 of this chapter or who is reactive to or positive for one or more tests for evidence of infection due to communicable disease agents under § 610.40 of this chapter must be prominently and permanently labeled “FOR AUTOLOGOUS USE ONLY” and as otherwise required under § 610.40 of this chapter. Such units also may have the ABO and Rh blood group and type on the label.

(6) Units of blood and blood components originally intended for autologous use, except those labeled as prescribed under paragraph (i)(5) of this section, may be issued for allogeneic transfusion provided the container label complies with all applicable provisions of paragraphs (b) through (e) of this section. In such case, the special label required under paragraphs (i)(1), (i)(2), and (i)(3) of this section must be removed or otherwise obscured.

(j) A tie-tag attached to the container may be used for providing the information required by paragraphs (e)(1)(iii), (e)(2)(ii), and (e)(3), (h), or (i)(1), (i)(2), and (i)(3) of this section.

[77 FR 16, Jan. 3, 2012]

EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.121 was amended in paragraph (c)(11) by removing “communicable disease agents” and adding in its place “relevant transfusion-transmitted infections”; and removing “§§ 610.40(i) and 640.65(b)” and adding in its place “§ 640.65(b)”; in paragraph (c)(12) removing “communicable disease agent(s)” and adding in its place “relevant transfusion-transmitted infection(s)”; in paragraphs (h)(2) and (3), removing “640.5(a), (b),” and adding in its place “640.5(b)”; and in paragraph (i)(5), removing “suitability” and adding in its place “eligibility”; removing “§ 640.3” and adding in its place “§ 630.10”; and removing “communicable disease agents” and adding in its place “relevant transfusion-transmitted infections”, effective May 23, 2016.

#### § 606.122 Circular of information.

A circular of information must be available for distribution if the product is intended for transfusion. The circular of information must provide adequate directions for use, including the following information:

(a) Instructions to mix the product before use.

(b) Instructions to use a filter in the administration equipment.

(c) The statement “Do Not Add Medications” or an explanation concerning allowable additives.

(d) A description of the product, its source, and preparation, including the name and proportion of the anticoagulant used in collecting the Whole Blood from each product is prepared.

(e) A statement that the product was prepared from blood that was found negative when tested for communicable disease agents, as required under §610.40 of this chapter (include each test that was performed).

(f) The statement: “Warning: The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard.”

(g) The names of cryoprotective agents and other additives that may still be present in the product.

(h) The names and results of all tests performed when necessary for safe and effective use.

(i) The use of the product, indications, contraindications, side effects and hazards, dosage and administration recommendations.

(j) [Reserved]

(k) For Red Blood Cells, the circular of information must contain:

(1) Instructions to administer a suitable plasma volume expander if Red Blood Cells are substituted when Whole Blood is the indicated product.

(2) A warning not to add Lactated Ringer’s Injection U.S.P. solution to Red Blood Cell products.

(l) For Platelets, the circular of information must contain:

(1) The approximate volume of plasma from which a sample unit of Platelets is prepared.

(2) Instructions to begin administration as soon as possible, but not more than 4 hours after entering the container.

(m) For Plasma, the circular of information must contain:

(1) A warning against further processing of the frozen product if there is evidence of breakage or thawing.

(2) Instructions to thaw the frozen product at a temperature appropriate for the product.

(3) When applicable, instructions to begin administration of the product within a specified time after thawing.

(4) Instructions to administer to ABO-group-compatible recipients.

(5) A statement that this product has the same risk of transmitting infectious agents as Whole Blood; other plasma volume expanders without this risk are available for treating hypovolemia.

(n) For Cryoprecipitated AHF, the circular of information must contain:

(1) A statement that the average potency is 80 or more International Units of antihemophilic factor.

(2) The statement: “Usually contains at least 150 milligrams of fibrinogen”; or, alternatively, the average fibrinogen level determined by assay of representative units.

(3) A warning against further processing of the product if there is evidence of breakage or thawing.

(4) Instructions to thaw the product for no more than 15 minutes at a temperature of between 30 and 37 °C.

(5) Instructions to store at room temperature after thawing and to begin administration as soon as possible but no more than 4 hours after entering the container or after pooling and within 6 hours after thawing.

(6) A statement that 0.9 percent Sodium Chloride Injection U.S.P. is the preferred diluent.

(7) Adequate instructions for pooling to ensure complete removal of all concentrated material from each container.

(8) The statement: “Good patient management requires monitoring treatment responses to Cryoprecipitated AHF transfusions with periodic plasma factor VIII or fibrinogen assays in hemophilia A and hypofibrinogenemic recipients, respectively.”

[50 FR 35470, Aug. 30, 1985, as amended at 53 FR 116, Jan. 5, 1988; 64 FR 45371, Aug. 19, 1999; 77 FR 18, Jan. 3, 2012]

EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.122(e) was amended by removing “communicable disease agents” and adding in its place “relevant transfusion-transmitted infections”, effective May 23, 2016.

**Subpart H—Laboratory Controls**

**§ 606.140 Laboratory controls.**

Laboratory control procedures shall include:

(a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

(b) Adequate provisions for monitoring the reliability, accuracy, precision and performance of laboratory test procedures and instruments.

(c) Adequate identification and handling of all test samples so that they are accurately related to the specific unit of product being tested, or to its donor, or to the specific recipient, where applicable.

**§ 606.145 Control of bacterial contamination of platelets.**

(a) Blood collection establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA.

(b) In the event that a blood collection establishment identifies platelets as bacterially contaminated, that establishment must not release for transfusion the product or any other component prepared from the same collection, and must take appropriate steps to identify the organism.

(c) In the event that a transfusion service identifies platelets as bacterially contaminated, the transfusion service must not release the product and must notify the blood collection establishment that provided the platelets. The transfusion service must take appropriate steps to identify the organism; these steps may include contracting with the collection establishment or a laboratory to identify the organism. The transfusion service must further notify the blood collection establishment either by providing information about the species of the contaminating organism when the transfusion service has been able to identify it, or by advising the blood collection establishment when the

transfusion service has determined that the species cannot be identified.

(d) In the event that a contaminating organism is identified under paragraph (b) or (c) of this section, the collection establishment's responsible physician, as defined in § 630.3(i) of this chapter, must determine whether the contaminating organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, in accordance with a standard operating procedure developed under § 606.100(b)(22). This determination may not be further delegated.

[80 FR 29895, May 22, 2015]

EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.145 was added, effective May 23, 2016.

**§ 606.151 Compatibility testing.**

Standard operating procedures for compatibility testing shall include the following:

(a) A method of collecting and identifying the blood samples of recipients to ensure positive identification.

(b) The use of fresh recipient serum or plasma samples less than 3 days old for all pretransfusion testing if the recipient has been pregnant or transfused within the previous 3 months.

(c) Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.

(d) A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate.

(e) Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician.

[40 FR 53532, Nov. 18, 1975, as amended at 64 FR 45371, Aug. 19, 1999; 66 FR 1835, Jan. 10, 2001; 66 FR 40889, Aug. 6, 2001]

**Subpart I—Records and Reports****§ 606.160 Records.**

(a)(1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.

(2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

(b) Records shall be maintained that include, but are not limited to, the following when applicable:

(1) Donor records:

(i) Donor selection, including medical interview and examination and where applicable, informed consent.

(ii) Permanent and temporary deferrals for health reasons including reason(s) for deferral.

(iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.

(iv) Therapeutic bleedings, including signed requests from attending physicians, the donor's disease and disposition of units.

(v) Immunization, including informed consent, identification of the antigen, dosage and route of administration.

(vi) Blood collection, including identification of the phlebotomist.

(vii) Records to relate the donor with the unit number of each previous donation from that donor.

(viii) Records concerning the following activities performed under §§ 610.46 and 610.47 of this chapter: Quarantine; consignee notification; testing; notification of a transfusion recipient, the recipient's physician of record, or the recipient's legal representative; and disposition.

(ix) Records of notification of donors deferred or determined not to be suit-

able for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.6 of this chapter.

(x) The donor's address provided at the time of donation where the donor may be contacted within 8 weeks after donation.

(xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial notification attempt fails, performed under § 630.6 of this chapter.

(2) Processing records:

(i) Blood processing, including results and interpretation of all tests and retests.

(ii) Component preparation, including all relevant dates and times.

(iii) Separation and pooling of recovered plasma.

(iv) Centrifugation and pooling of source plasma.

(v) Labeling, including initials of the person(s) performing the procedure.

(3) Storage and distribution records:

(i) Distribution and disposition, as appropriate, of blood and blood products.

(ii) Visual inspection of whole blood and red blood cells during storage and immediately before distribution.

(iii) Storage temperature, including initialed temperature recorder charts.

(iv) Reissue, including records of proper temperature maintenance.

(v) Emergency release of blood, including signature of requesting physician obtained before or after release.

(4) Compatibility test records:

(i) Results of all compatibility tests, including crossmatching, testing of patient samples, antibody screening and identification.

(ii) Results of confirmatory testing.

(5) Quality control records:

(i) Calibration and standardization of equipment.

(ii) Performance checks of equipment and reagents.

(iii) Periodic check on sterile technique.

(iv) Periodic tests of capacity of shipping containers to maintain proper temperature in transit.

(v) Proficiency test results.

§ 606.165

21 CFR Ch. I (4–1–16 Edition)

(6) Transfusion reaction reports and complaints, including records of investigations and followup.

(7) General records:

(i) Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature and mode.

(ii) Responsible personnel.

(iii) Biological product deviations.

(iv) Maintenance records for equipment and general physical plant.

(v) Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt.

(vi) Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components.

(c) A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood, and to all records describing the history and ultimate disposition of these products.

(d) Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.

(e) A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.

[40 FR 53532, Nov. 18, 1975, as amended at 61 FR 47422, Sept. 9, 1996; 64 FR 45371, Aug. 19, 1999; 65 FR 66635, Nov. 7, 2000; 66 FR 31176, June 11, 2001; 72 FR 48798, Aug. 24, 2007; 80 FR 80651, Dec. 28, 2015]

EFFECTIVE DATE NOTE: At 80 FR 29895, May 22, 2015, § 606.160 was amended by revising paragraphs (b)(1)(ix) through (xi) and (e), effective May 23, 2016. For the convenience of the user, the revised text is set forth as follows:

§ 606.160 Records.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(ix) The donor's postal address provided at the time of donation where the donor may be contacted within 8 weeks after donation.

(x) Records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.40 of this chapter.

(xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial attempt at notification fails, performed under § 630.40 of this chapter.

\* \* \* \* \*

(e) *Records of deferred donors.* (1) Establishments must maintain at each location a record of all donors found to be ineligible or deferred at that location so that blood and blood components from an ineligible donor are not collected and/or released while the donor is ineligible or deferred; and

(2) Establishments must maintain at all locations operating under the same license or under common management a cumulative record of donors deferred from donation under § 610.41 of this chapter because their donation tested reactive under § 610.40(a)(1) of this chapter for evidence of infection due to HIV, HBV, or HCV. In addition, establishments other than Source Plasma establishments must include in this cumulative record donors deferred from donation under § 610.41 of this chapter because their donation tested reactive under § 610.40(a)(2) of this chapter for evidence of infection due to HTLV or Chagas disease.

(3) The cumulative record described in paragraph (e)(2) of this section must be updated at least monthly to add donors newly deferred under § 610.41 of this chapter due to reactive tests for evidence of infection due to HIV, HBV, or HCV, and, if applicable, HTLV or Chagas disease.

(4) Establishments must revise the cumulative record described in paragraph (e)(2) of this section to remove donors who have been requalified under § 610.41(b) of this chapter.

§ 606.165 Distribution and receipt; procedures and records.

(a) Distribution and receipt procedures shall include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall, if necessary.

(b) Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit(s), the date of expiration or the date of

collection, whichever is applicable, or for crossmatched blood and blood components, the name of the recipient.

(c) Receipt records shall contain the name and address of the collecting facility, date received, donor or lot number assigned by the collecting facility and the date of expiration or the date of collection, whichever is applicable.

**§ 606.170 Adverse reaction file.**

(a) Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of blood collection or transfusion. A thorough investigation of each reported adverse reaction shall be made. A written report of the investigation of adverse reactions, including conclusions and followup, shall be prepared and maintained as part of the record for that lot or unit of final product by the collecting or transfusing facility. When it is determined that the product was at fault in causing a transfusion reaction, copies of all such written reports shall be forwarded to and maintained by the manufacturer or collecting facility.

(b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, CBER, must be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible. A written report of the investigation must be submitted to the Director, Office of Compliance and Biologics Quality, CBER, by mail, facsimile, or electronically transmitted mail (for mailing address, see § 600.2(a) of this chapter), within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

[40 FR 53532, Nov. 18, 1975, as amended at 49 FR 23833, June 8, 1984; 50 FR 35471, Aug. 30, 1985; 55 FR 11014, Mar. 26, 1990; 64 FR 45371, Aug. 19, 1999; 67 FR 9586, Mar. 4, 2002; 77 FR 18, Jan. 3, 2012; 80 FR 18092, Apr. 3, 2015]

**§ 606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services.**

(a) *Who must report under this section?* You, a licensed manufacturer of blood

and blood components, including Source Plasma; an unlicensed registered blood establishment; or a transfusion service who had control over the product when the deviation occurred, must report under this section. If you arrange for another person to perform a manufacturing, holding, or distribution step, while the product is in your control, that step is performed under your control. You must establish, maintain, and follow a procedure for receiving information from that person on all deviations, complaints, and adverse events concerning the affected product.

(b) *What do I report under this section?* You must report any event, and information relevant to the event, associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution, of both licensed and unlicensed blood or blood components, including Source Plasma, if that event meets all the following criteria:

(1) Either:

(i) Represents a deviation from current good manufacturing practice, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or

(ii) Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and

(2) Occurs in your facility or another facility under contract with you; and

(3) Involves distributed blood or blood components.

(c) *When do I report under this section?* You should report a biological product deviation as soon as possible but you must report at a date not to exceed 45-calendar days from the date you, your agent, or another person who performs a manufacturing, holding, or distribution step under your control, acquire information reasonably suggesting that a reportable event has occurred.

(d) *How do I report under this section?* You must report on Form FDA-3486.

(e) *Where do I report under this section?* You must send the completed Form FDA 3486 to the Center for Biologics Evaluation and Research (CBER), either in paper or electronic format.

**Pt. 607**

**21 CFR Ch. I (4–1–16 Edition)**

(1) If you make a paper filing, send the completed form to the CBER Document Control Center (see mailing address in §600.2(a) of this chapter), and identify on the envelope that a BPDR (biological product deviation report) is enclosed; or

(2) If you make an electronic filing, send the completed Form FDA3486 electronically using CBER's electronic Web-based application.

(f) *How does this regulation affect other FDA regulations?* This part supplements and does not supersede other provisions of the regulations in this chapter. All biological product deviations, whether or not they are required to be reported under this section, should be investigated in accordance with the applicable provisions of parts 211, 606, and 820 of this chapter.

[65 FR 66635, Nov. 7, 2000, as amended at 70 FR 14984, Mar. 24, 2005; 80 FR 18092, Apr. 3, 2015]

**PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS**

**Subpart A—General Provisions**

Sec.

607.3 Definitions.

607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.

**Subpart B—Procedures for Domestic Blood Product Establishments**

607.20 Who must register and submit a blood product list.

607.21 Times for establishment registration and blood product listing.

607.22 How and where to register establishments and list blood products.

607.25 Information required for establishment registration and blood product listing.

607.26 Amendments to establishment registration.

607.30 Updating blood product listing information.

607.31 Additional blood product listing information.

607.35 Notification of registrant; blood product establishment registration number and NDC Labeler Code.

607.37 Inspection of establishment registrations and blood product listings.

607.39 Misbranding by reference to establishment registration or to registration number.

**Subpart C—Procedures for Foreign Blood Product Establishments**

607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.

**Subpart D—Exemptions**

607.65 Exemptions for blood product establishments.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

SOURCE: 40 FR 52788, Nov. 12, 1975, unless otherwise noted.

**Subpart A—General Provisions**

**§ 607.3 Definitions.**

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 *et seq.*, as amended, 21 U.S.C. 301–392).

(b) *Blood and blood product* means a drug which consists of human whole blood, plasma, or serum or any product derived from human whole blood, plasma, or serum, hereinafter referred to as “blood product.” For the purposes of this part only, blood and blood product also means those products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act.

(c) *Establishment* means a place of business under one management at one general physical location. The term includes, among others, human blood and plasma donor centers, blood banks, transfusion services, other blood product manufacturers and independent laboratories that engage in quality control and testing for registered blood product establishments.

(d) *Manufacture* means the collection, preparation, processing or compatibility testing by chemical, physical, biological, or other procedures of any blood product which meets the definition of a drug as defined in section 201(g) of the act, and including manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The term