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.

(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 AND LICENSED DEVICES

## Subpart A—General Provisions

Sec.



## Subpart B—Procedures for Domestic Blood Product Establishments



## Subpart C—Procedures for Foreign Blood Product Establishments



## Subpart D—Exemptions



## Subpart E—Establishment Registration and Product Listing Of Licensed Devices



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

### § 607.1 Scope.

(a) This part establishes establishment registration and product listing requirements for manufacturers of human blood and blood products.

(b) This part establishes establishment registration and product listing requirements for manufacturers of 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, as well as licensed biological products used in the manufacture of a licensed device.

[81 FR 60221, Aug. 31, 2016]

### § 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, as well as licensed biological products used in the manufacture of a licensed device.

(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 includes packaging, labeling, repackaging or otherwise changing the container, wrapper, or labeling of any blood product package in furtherance of the distribution of the blood product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(e) *Commercial distribution* means any distribution of a blood product except under the investigational use provisions of part 312 of this chapter, but does not include internal or interplant transfer of a bulk product substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any blood or blood product that is neither imported nor offered for import into the United States.

(f) *Any material change* includes but is not limited to any change in the name of the blood product, in the quantity or identity of the active ingredient(s) or in the quantity or identity of the inactive ingredient(s) where quantitative listing of all ingredients is required pursuant to § 607.31(a)(2) and any significant change in the labeling of a blood product. Changes that are not significant include changes in arrangement or printing or changes of an editorial nature.

(g) *Bulk product substance* means any substance that is represented for use in a blood product and when used in the manufacturing of a blood product becomes an active ingredient or a finished dosage form of such product.

(h) *Advertising* and *labeling* include the promotional material described in § 202.1(l) (1) and (2) of this chapter, respectively.

(i) The definitions and interpretations contained in sections 201 and 510 of the act shall be applicable to such terms when used in this part 607.

(j) *United States* agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual

acting as the foreign establishment's agent is not physically present.

(k) *Importer* means a person in the United States that is an owner, consignee, or recipient, at the time of entry, of a foreign establishment's blood product that is imported into the United States.

(l) *Foreign* for the purpose of registration and listing under this part when used to modify the term ''establishment'' refers to an establishment that is located in a foreign country and is the site where a blood product that is imported or offered for import into the United States was manufactured.

[40 FR 52788, Nov. 12, 1975, as amended at 55 FR 11014, Mar. 26, 1990; 66 FR 59158, Nov. 27, 2001; 81 FR 60222, Aug. 31, 2016]

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

All owners or operators of establishments that engage in the manufacturing of blood products are required to register, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of blood products must comply with this part. Registration does not permit any blood bank or similar establishment to ship blood products in interstate commerce.

[81 FR 60222, Aug. 31, 2016]

## Subpart B—Procedures for Domestic Blood Product Establishments

### § 607.20 Who must register and submit a blood product list.

(a) Owners or operators of all establishments, not exempt under section 510(g) of the act or subpart D of this part, that engage in the manufacture of blood products shall register and submit a list of every blood product in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Blood products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.

(b) Preparatory to engaging in the manufacture of blood products, owners or operators of establishments who are submitting a biologics license application to manufacture blood products are required to register before the biologics license application is approved.

(c) Except in the case of licensed device manufacturers, no registration fee is required. Establishment registration and blood product listing do not constitute an admission or agreement or determination that a blood product is a ''drug'' within the meaning of section 201(g) of the act.

[40 FR 52788, Nov. 12, 1975, as amended at 64 FR 56452, Oct. 20, 1999; 66 FR 59158, Nov. 27, 2001; 81 FR 60222, Aug. 31, 2016]

### § 607.21 Times for establishment registration and blood product listing.

The owner or operator of an establishment entering into an operation defined in § 607.3(d) shall register such establishment within 5 days after the beginning of such operation and submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation (defined in § 607.3(d) of this chapter) for which a license is required, registration shall follow within 5 days after the submission of a biologics license application in order to manufacture blood products. Owners or operators of all establishments so engaged must register annually between October 1 and December 31 and must update their blood product listing every June and December.

[40 FR 52788, Nov. 12, 1975, as amended at 64 FR 56453, Oct. 20, 1999; 81 FR 60222, Aug. 31, 2016]

### § 607.22 How to register establishments and list blood products.

(a) Initial and subsequent registrations and product listings must be submitted electronically through the Blood Establishment Registration and Product Listing system, or any future

superseding electronic system. This information must be submitted in accordance with part 11 of this chapter, except for the requirements in §11.10(b), (c), and (e), and the corresponding requirements in §11.30. All information submitted under this part must be transmitted to FDA electronically unless FDA has granted a request for waiver of this requirement prior to the date on which the information is due. Submission of a request for waiver does not excuse timely compliance with the registration and listing requirements. FDA will grant a waiver request if FDA determines that the use of electronic means for submission of registration and listing information is not reasonable for the registrant making the waiver request.

(b) Waiver requests under this section must be submitted in writing and must include the specific reasons why electronic submission is not reasonable for the registrant and a U.S. telephone number and mailing address where FDA can contact the registrant. All waiver requests must be sent to the Director of FDA's Center for Biologics Evaluation and Research through the Document Control Center (see addresses *in* §600.2).

(c) If FDA grants the waiver request, FDA may limit its duration and will specify terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable.

[81 FR 60222, Aug. 31, 2016]

### §607.25 Information required for establishment registration and blood product listing.

(a) The Blood Establishment Registration and Product Listing system requires furnishing or confirming registration information required by the Federal Food, Drug, and Cosmetic Act. This information includes the name and street address of the establishment, including post office code; a registration number if previously assigned by FDA and a Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act; all trade names used by the establishment; the kind of ownership or operation (that is, individually owned partnership, or corporation); and the name of the owner or operator of such establishment. The term ''name of the owner or operator'' must include, in the case of a partnership, the name of each partner and, in the case of a corporation, the name and title of each corporate officer and director and the name of the State of incorporation. The information required must be given separately for each establishment, as defined in §607.3(c).

(b) The following information must also be provided:

(1) A list of blood products by established name as defined in section 502(e) of the Federal Food, Drug, and Cosmetic Act and by proprietary name, if any, which are being manufactured for commercial distribution at the identified establishment and which have not been included in any list previously submitted to FDA through the Blood Establishment Registration and Product Listing system or any future superseding electronic system.

(2) For each blood product so listed that is subject to section 351 of the Public Health Service Act, the license number of the manufacturer issued by the Center for Biologics Evaluation and Research, Food and Drug Administration.

(3) For each blood product listed, the registration number if previously assigned by FDA and the Unique Facility Identifier of the parent establishment. An establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.

[81 FR 60222, Aug. 31, 2016]

### §607.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, location, or blood product handling activity must be submitted electronically through the Blood Establishment Registration and Product Listing system, or any future superseding electronic system, as an amendment to registration within 5 calendar days of such changes. Changes in the names of officers and directors of the corporations do not require such amendment but

must be shown at time of annual registration.

[40 FR 52788, Nov. 12, 1975, as amended at 66 FR 59158, Nov. 27, 2001; 81 FR 60222, Aug. 31, 2016]

### § 607.30 Updating blood product listing information.

(a) After submission of the initial blood product listing information, every person who is required to list blood products under § 607.20 must submit electronically through the Blood Establishment Registration and Product Listing system, or any future superseding electronic system, at a minimum once in June and December of every year, the following information:

(1) A list of each blood product introduced by the registrant for commercial distribution which has not been included in any list previously submitted. All of the information required by § 607.25(b) shall be provided for each such blood product.

(2) A list of each blood product formerly listed pursuant to § 607.25(b) for which commercial distribution has been discontinued, including for each blood product so listed the identity by established name and proprietary name, and date of discontinuance. It is requested but not required that the reason for discontinuance of distribution be included with this information.

(3) A list of each blood product for which a notice of discontinuance was submitted pursuant to paragraph (a)(2) of this section and for which commercial distribution has been resumed, including for each blood product so listed the identity by established name as defined in section 502(e) of the act and by any proprietary name, the date of resumption, and any other information required by § 607.25(b) not previously submitted.

(4) Any material change in any information previously submitted.

(b) When no changes have occurred since the previously submitted list, no listing information is required.

[40 FR 52788, Nov. 12, 1975, as amended at 81 FR 60222, Aug. 31, 2016]

### § 607.31 Additional blood product listing information.

(a) In addition to the information routinely required by §§ 607.25 and 607.30, the Director of the Center for Biologics Evaluation and Research may require submission of the following information by letter or by FEDERAL REGISTER notice:

(1) For a particular blood product so listed, upon request made by the Director of the Center for Biologics Evaluation and Research for good cause, a copy of all advertisements.

(2) For a particular blood product so listed, upon a finding by the Director of the Center for Biologics Evaluation and Research that it is necessary to carry out the purposes of the act, a quantitative listing of all ingredients.

(3) For each registrant, upon a finding by the Director of the Center for Biologics Evaluation and Research that it is necessary to carry out the purposes of the act, a list of each listed blood product containing a particular ingredient.

(b) [Reserved]

[66 FR 59158, Nov. 27, 2001]

### § 607.35 Blood product establishment registration number.

An establishment registration number will be assigned to each blood product establishment registered in accordance with this part.

[81 FR 60223, Aug. 31, 2016]

### § 607.37 Public disclosure of establishment registration and blood product listing information.

(a) Except as provided in paragraph (b) of this section, all registration and listing information obtained under §§ 607.25, 607.26, and 607.30 will be made available for public disclosure through the Center for Biologics Evaluation and Research (CBER) Blood Establishment Registration Database Web site by using the CBER electronic Web-based application or by going in person to the Food and Drug Administration, Division of Freedom of Information Public Reading Room (see addresses in § 20.120(a) of this chapter).

(b) FDA may find, in limited circumstances and on a case-by-case basis, that it would be consistent with the protection of the public health to exempt from public disclosure specific listing information obtained under § 607.25 or § 607.30.

(c) Other requests for information regarding blood establishment registrations and blood product listings should be directed to the Food and Drug Administration, Center for Biologics Evaluation and Research Office of Communication, Outreach, and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002.

[81 FR 60223, Aug. 31, 2016]

### § 607.39 Misbranding by reference to establishment registration, validation of registration, or to registration number.

Registration of an establishment, validation of registration, or assignment of a registration number does not in any way denote approval of the firm or its products nor does it mean that the products may be legally marketed. Any representation that creates an impression of official approval because of establishment registration, validation of registration, or possession of a registration number is misleading and constitutes misbranding.

[81 FR 60223, Aug. 31, 2016]

## Subpart C—Procedures for Foreign Blood Product Establishments

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

(a) Every foreign establishment shall comply with the establishment registration and blood product listing requirements contained in subpart B of this part, unless exempt under subpart D of this part or unless the blood product enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No blood product may be imported or offered for import into the United States unless it is the subject of a blood product listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to a blood product imported or offered for import under the investigational use provisions of part 312 of this chapter or to a blood product imported under section 801(d)(4) of the act. The establishment registration and blood product listing information shall be in the English language.

(c) Each foreign establishment required to register under paragraph (a) of this section shall, as part of the establishment registration and blood product listing, submit the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating establishment registration information in § 607.26 and blood product listing information in § 607.30(a).

(d) Each foreign establishment required to register under paragraph (a) of this section must submit the name, address, telephone number, and email address of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment must designate only one United States agent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone number, or email address to FDA within 30 calendar days of the change.

(e) Each foreign establishment required to register under paragraph (a) of this section must register and list blood products using the Blood Establishment Registration and Product Listing system, or any superseding electronic system, unless FDA waives the electronic submission requirement in accordance with § 607.22.

[66 FR 59159, Nov. 27, 2001, as amended at 81 FR 60223, Aug. 31, 2016]

## Subpart D—Exemptions

### § 607.65 Exemptions for blood product establishments.

The following classes of persons are exempt from registration and blood product listing in accordance with this part 607 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5), that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (a), (b), (f), and (g) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act.

(a) Pharmacies that are operating under applicable local laws regulating dispensing of prescription drugs and that are not manufacturing blood products for sale other than in the regular course of the practice of the profession of pharmacy including the business of dispensing and selling blood products at retail. The supplying by such pharmacies of blood products to a practitioner licensed to administer such blood products for his use in the course of his professional practice or to other pharmacies to meet temporary inventory shortages are not acts which require such pharmacies to register.

(b) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture blood products solely for use in the course of their professional practice.

(c) Persons who manufacture blood products which are not for sale, rather, are solely for use in research, teaching, or analysis, including laboratory samples.

(d) Carriers, by reason of their receipt, carriage, holding, or delivery of blood products in the usual course of business as carriers.

(e) Persons who engage solely in the manufacture of in vitro diagnostic blood products and reagents not subject to licensing under section 351 of the Public Health Service Act (42 U.S.C. 262). This paragraph does not exempt such persons from registration and listing for medical devices required under part 807 of this chapter.

(f) Transfusion services which are a part of a facility that is certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and which are engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. The collection and processing of blood and blood components in an emergency situation as determined by a responsible person and documented in writing, therapeutic collection of blood or plasma, the preparation of recovered human plasma for further manufacturing use, or preparation of red blood cells for transfusion are not acts requiring such transfusion services to register.

(g) Persons who engage solely in the production of any plasma derivative, including, but not limited to, albumin, Immune Globulin, Factor VIII and Factor IX, bulk product substances such as fractionation intermediates or pastes, or recombinant versions of plasma derivatives or animal derived plasma derivatives. These persons must register and list under part 207 of this chapter.

[40 FR 52788, Nov. 12, 1975, as amended at 43 FR 37997, Aug. 25, 1978; 45 FR 85729, Dec. 30, 1980; 49 FR 34449, Aug. 31, 1984; 66 FR 31162, June 11, 2001; 66 FR 59159, Nov. 27, 2001; 72 FR 45886, Aug. 16, 2007; 81 FR 60223, Aug. 31, 2016]

## Subpart E—Establishment Registration and Product Listing Of Licensed Devices

### § 607.80 Applicability of part 607 to licensed devices.

Manufacturers of 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, as well as licensed biological products used in the manufacture of a licensed device, must register and list following the procedures under this part, with respect to their manufacture of those products, unless otherwise noted in this section.

[81 FR 60223, Aug. 31, 2016]

# PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

## Subpart A—Release Requirements



## Subpart B—General Provisions



## Subpart C [Reserved]



## Subpart D—Mycoplasma



## Subpart E—Testing Requirements for Relevant Transfusion-Transmitted Infections



## Subpart F—Dating Period Limitations



## Subpart G—Labeling Standards



AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

SOURCE: 38 FR 32056, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

## Subpart A—Release Requirements

### § 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.

### § 610.2 Requests for samples and protocols; official release.

(a) *Licensed biological products regulated by CBER.* Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Biologics Evaluation and Research (see mailing addresses in §600.2(c) of this chapter). Upon notification by the Director, Center for Biologics Evaluation