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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

Sec.

Subpart B—General Provisions

Subparts C—D [Reserved]

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.