

§ 607.22

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 shall register annually between November 15 and December 31 and shall update their blood product listing information every June and December.

[40 FR 52788, Nov. 12, 1975, as amended at 64 FR 56453, Oct. 20, 1999]

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

(a) The first registration of an establishment shall be on Form FD-2830 (Blood Establishment Registration and Product Listing) obtainable on request from the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-375), (see mailing addresses in § 600.2 of this chapter), or from Food and Drug Administration district offices. Subsequent annual registration shall also be accomplished on Form FD-2830, which will be furnished by the Food and Drug Administration before November 15 of each year to establishments whose product registration for that year was validated under § 607.35. The completed form shall be mailed to the preceding address before December 31 of that year.

(b) The first list of blood products and subsequent June and December updates shall be on Form FD-2830, obtainable upon request as described in paragraph (a) of this section.

[66 FR 59158, Nov. 27, 2001, as amended at 70 FR 14984, Mar. 24, 2005]

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

(a) Form FD-2830 (Blood Establishment Registration and Product Listing) requires furnishing or confirming registration information required by the act. This information includes the name and street address of the establishment, including post office code; 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 estab-

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lishment. The term “name of the owner or operator” shall 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 shall be given separately for each establishment, as defined in § 607.3(c).

(b) Form FD-2830 also requires furnishing blood product listing information required by the act as follows:

(1) A list of blood products, including bulk product substances as well as finished dosage forms, by established name as defined in section 502(e) of the act and by proprietary name, which are being manufactured for commercial distribution and which have not been included in any list previously submitted on Form FD-2830 (Blood Establishment Registration and Product Listing) or Form FD-2250 (National Drug Code Directory Input).

(2) For each blood product so listed which 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 of the parent establishment. An establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990; 66 FR 59158, Nov. 27, 2001]

§ 607.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, location, or blood-product handling activity shall be submitted on Form FDA-2830 (Blood Establishment Registration and Product Listing) as an amendment to registration within 5 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]