(1) For a particular blood product so listed, upon request made by the Commissioner for good cause, a copy of all advertisements.

(2) For a particular blood product so listed, upon a finding by the Commissioner 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 Commissioner that it is necessary to carry out the purposes of the act, a list of each listed blood product containing a particular ingredient.

(b) It is requested but not required that information concerning the quantity of blood product distributed be submitted in conjunction with the annual registration in the format prescribed in a section of Form FD–2831 (Blood Establishment Resource Summary), for each blood product currently listed.

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

(a) The Commissioner will provide to the registrant a validated copy of Form FD–2830 (Blood Establishment Registration and Product Listing) as evidence of registration. This validated copy will be sent only to the location shown for the registering establishment. A permanent registration number will be assigned to each blood product establishment registered in accordance with these regulations.

(b) If a registered blood product establishment has not previously participated in the National Drug Code system, or in the National Health Related Items Code system, the National Drug Code (NDC) numbering system shall be used in assigning the first five numeric characters, otherwise known as the Labeler Code, of the 10-character NDC Code. The Labeler Code identifies the manufacturer.

(c) Although establishment registration and blood product listing are required as described in § 607.20, validation of registration and the assignment of a NDC Labeler Code do not, in themselves, establish that the holder of the registration is legally qualified to deal in such products.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984]

### § 607.37 Inspection of establishment registrations and blood product listings.

(a) A copy of the Form FD–2830 (Blood Establishment Registration and Product Listing) filed by the registrant will be available for inspection pursuant to section 510(f) of the act, at the Department of Health and Human Services, Food and Drug Administration, Office of Compliance, Center for Biologics Evaluation and Research (HFB–100), 8800 Rockville Pike, Bethesda, MD 20892. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of registration number, or location of a registered establishment will be provided. The following information submitted pursuant to the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

(1) A list of all blood products.

(2) A list of all blood products manufactured by each establishment.

(3) A list of blood products discontinued.

(4) All data or information that has already become a matter of public knowledge.

(b) Requests for information regarding blood establishment registrations and blood product listings should be directed to the Department of Health and Human Services, Food and Drug Administration, Office of Compliance, Center for Biologics Evaluation and Research (HFB–100), 8800 Rockville Pike, Bethesda, MD 20892.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11014, Mar. 26, 1990]

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

Registration of an establishment or assignment of a registration number or

assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of establishment registration or possession of registration number or NDC number is misleading and constitutes misbranding.

## Subpart C—Procedures for Foreign Blood Product Establishments

### § 607.40 Blood product listing requirements for foreign blood product establishments.

(a) Every foreign establishment shall comply with the blood product listing requirements contained in Subpart B of this part, unless exempt under Subpart D of this part, whether or not it is also registered.

(b) No blood product may be imported from a foreign establishment into the United States except a blood product imported or offered for import pursuant to the investigational use provisions of part 312 of this chapter, unless it is first the subject of a blood product listing as required in Subpart B of this part. The blood product listing information shall be in the English language.

(c) Foreign establishments shall submit, as part of the blood product listing, the name and address of the establishment and the name of the individual responsible for submitting blood product listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating blood product listing information in § 607.30(a).

[40 FR 52788, Nov. 12, 1975, as amended at 55 FR 11014, Mar. 26, 1990]

## 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), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4), that such registration is not necessary for the protection of the public health.

(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 approved for Medicare reimbursement and 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.