§ 207.7 Establishment registration and product listing for human blood and blood products and for medical devices.

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, on Form FDA–2830 (Blood Establishment Registration and Product Listing), in accordance with part 607 of this chapter. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

(b) Owners and operators of establishments engaged in manufacture or processing of medical devices shall register and list their products with the Center for Devices and Radiological Health, FDA, on Form FDA–2891 (Initial Registration of Device Establishments), FDA–2892 (Medical Device Listing), in accordance with part 807.

(d) Owners and operators of establishments engaged in the manufacture or processing at the same establishment of both drug products and medical devices shall (1) register with the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, FDA, and list their drug products in accordance with this part, and (2) register with the Center for Devices and Radiological Health and list their medical devices in accordance with part 807.


Subpart B—Exemptions

§ 207.10 Exemptions for establishments.

The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g)(1), (g)(2), and (g)(3) of the act, or because FDA has found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. The exemptions in paragraphs (a) and (b) of this section are limited to pharmacies, hospitals, clinics, and public health agencies located in any State as defined in section 201(a)(1) of the act.

(a) Pharmacies that operate under applicable local laws regulating dispensing of prescription drugs and that do not manufacture or process drugs for sale other than in the regular course of the practice of the profession of pharmacy, including dispensing and selling drugs at retail. The supplying of prescription drugs by these pharmacies to a practitioner licensed to administer these drugs for his or her use in the course of professional practice or to other pharmacies to meet temporary inventory shortages are not acts that require pharmacies to register.

(b) Hospitals, clinics, and public health agencies that maintain establishments in conformance with any applicable local laws regulating the practices of pharmacy or medicine and that regularly engage in dispensing prescription drugs, other than human