flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs.

(g) Manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds, except for persons who manufacture, repack, relabel, or salvage Type B or Type C medicated feeds starting from Category II, Type A medicated articles for which a medicated feed mill license approved under part 515 of this chapter is required. This exemption also does not apply to persons that would otherwise be required to register (such as manufacturers, repackers, relabelers, or salvagers of certain free-choice feeds, as defined in § 510.455 of this chapter, or certain liquid feeds, as defined in § 558.5 of this chapter, where the specifications and/or formulas are not published and a medicated feed mill license is required). All manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds are exempt from listing.

(h) Any manufacturer, repacker, relabeler, or salvager of a virus, serum, toxin, or analogous product intended for the treatment of domestic animals who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 *et seq.*)), provided that this exemption from registration applies only to the manufacturer, repacker, relabeler, or salvager of that animal virus, serum, toxin, or analogous product.

(i) Carriers, in their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

(j) Foreign establishments whose drugs are imported or offered for import into the United States must comply with the establishment registration and listing requirements of this part unless exempt under this section or unless:

(1) Their drugs enter a foreign trade zone and are re-exported without having entered U.S. commerce, or

(2) Their drugs are imported in conformance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act.

(k) Entities that are registered with FDA as outsourcing facilities and that compound drugs in conformance with section 503B of the Federal Food, Drug, and Cosmetic Act.

(l) The exemptions provided in paragraphs (a) through (k) of this section do not apply to such persons if they:

(1) Manufacture (as defined in § 207.1), repack, relabel, or salvage compounded positron emission tomography drugs as defined in section 201(ii) of the Federal Food, Drug, and Cosmetic Act;

(2) Manufacture (as defined in § 600.3(u) of this chapter) a human biological product subject to licensing under section 351 of the Public Health Service Act; or

(3) Engage in activities that would otherwise require them to register under this part.

[81 FR 60212, Aug. 31, 2016, as amended at 86 FR 17061, Apr. 1, 2021]

Subpart B—Registration

§ 207.17 Who must register?

(a) Unless exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or this part, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, and each foreign establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States. When operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments.

(b) Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register under this part. FDA will accept registration or listing information submitted by a private label distributor only if it is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.