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chapter, but excluding labeling as determined in § 202.1(l)(2) of this chapter), that gives a balanced picture of the promotional claims used for the drug.

Representative sampling of any other labeling means typical labeling material (including the labeling material described in § 202.1(l)(2) of this chapter, but excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug.

Salvage means the act of segregating out those finished drug products that may have been subjected to improper storage conditions (such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation) for the purpose of returning the products to the marketplace and includes applying manufacturing controls such as those required by current good manufacturing practice in parts 210 and 211 of this chapter.

Salvager means a person who owns or operates an establishment that engages in salvaging. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic and foreign salvagers.

Unfinished drug means an active pharmaceutical ingredient either alone or together with one or more other ingredients but does not include finished drug products.

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

§ 207.3 Bulk drug substance.

Bulk drug substance, as referenced in sections 503A(b)(1)(A) and 503B(a)(2) of the Federal Food, Drug, and Cosmetic Act, previously defined in § 207.3(a)(4), means the same as ''active pharmaceutical ingredient'' as defined in § 207.1.

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

§ 207.5 What is the purpose of this part?

Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed. Drug listing information gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Both types of information facilitate implementation and enforcement of the Federal Food, Drug, and Cosmetic Act and are used for many important public health purposes.

§ 207.9 Who does this part cover?

(a) Except as provided in paragraph (b) of this section, this part applies to:

(1) Domestic manufacturers, domestic repackers, domestic relabelers and domestic salvagers, not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or § 207.13, regardless of whether their drugs enter interstate commerce;

(2) Foreign manufacturers, foreign repackers, foreign relabelers and foreign salvagers, not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or § 207.13;

(3) Private label distributors, because they must have labeler codes;

(4) Establishments engaged in the manufacture, repacking, relabeling, or salvaging of human drugs regulated under a biologics license application (BLA). These establishments are subject to the requirements of this part unless they are required to register and list such drugs as human blood or blood products under part 607 of this chapter and do not engage in activities that would otherwise require them to register and list under this part.

(5) Establishments engaged in the manufacture (as defined in § 1271.3(e) of this chapter) of human cells, tissues, and cellular and tissue-based products (HCT/Ps) (as defined in § 1271.3(d) of this chapter) that, under § 1271.20 of this chapter, are also drugs regulated under section 351 of the Public Health Service Act or section 505 of the Federal Food, Drug, and Cosmetic Act. These establishments must register and list those HCT/Ps following the procedures described in this part.

(b) This part does not apply to owners and operators of establishments that collect or process human whole blood and blood products unless the establishment also manufactures, repacks, or relabels other drugs. For purposes of this paragraph (b), human whole blood and blood products do not include plasma derivatives such as albumin, Immune Globulin, Factor VIII