

(b) The label of the drug bears:

(1) The statement “For prescription compounding”; and

(2) If in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1) of the act, the statement “Rx only”; or

(3) If it is not subject to section 503(b)(1) of the act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, “adequate directions for use” in the conditions for which it is so sold.

Provided, however, That the information referred to in paragraph (b)(3) of this section may be contained in the labeling on or within the package from which it is to be dispensed.

(c) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an approved new-drug application covers such use of the drug in compounding prescriptions.

[40 FR 13998, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

§ 201.122 Drugs for processing, repackaging, or manufacturing.

A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repackaging, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the act if its label bears the statement “Caution: For manufacturing, processing, or repackaging”; and if in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1) of the act, the statement “Rx only”, or if in substantially all dosage forms in which it may be dispensed it is subject to section 503(f)(1) of the act, the statement “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”. This exemption and the exemption under § 201.120 may be claimed for the same article. However, the exemption shall not apply to a substance intended for a use in manufacture, processing, or repackaging which causes the finished article to be a new drug or new animal drug, unless:

(a) An approved new drug application or new animal drug application or a new animal drug index listing covers

the production and delivery of the drug substance to the application or index listing holder by persons named in the application or in the request for determination of eligibility for indexing, and, for a new drug substance, the export of it by such persons under § 314.410 of this chapter; or

(b) If no application is approved with respect to such new drug or new animal drug, and it is not listed in the index, the label statement “Caution: For manufacturing, processing, or repackaging” is immediately supplemented by the words “in the preparation of a new drug or new animal drug limited by Federal law to investigational use”, and the delivery is made for use only in the manufacture of such new drug or new animal drug limited to investigational use as provided in part 312 or § 511.1 or § 516.125 of this chapter; or

(c) A new drug application or new animal drug application or a request for addition to the index covering the use of the drug substance in the production and marketing of a finished drug product has been submitted but not yet approved, disapproved, granted, or denied, the bulk drug is not exported, and the finished drug product is not further distributed after it is manufactured until after the new drug application or new animal drug application is approved or the request for addition to the index is granted.

[41 FR 6911, Feb. 13, 1976, as amended at 41 FR 15844, Apr. 15, 1976; 50 FR 7492, Feb. 22, 1985; 55 FR 11576, Mar. 29, 1990; 57 FR 54301, Nov. 18, 1992; 67 FR 4906, Feb. 1, 2002; 72 FR 69119, Dec. 6, 2007]

§ 201.125 Drugs for use in teaching, law enforcement, research, and analysis.

A drug subject to § 201.100 or § 201.105, shall be exempt from section 502(f)(1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

[41 FR 6911, Feb. 13, 1976]