

§ 201.115

21 CFR Ch. I (4–1–11 Edition)

comply with paragraphs (e) and (f) of this section and § 201.100.

[40 FR 13998, Mar. 27, 1975, as amended at 42 FR 15674, Mar. 22, 1977; 57 FR 54300, Nov. 18, 1992; 72 FR 69119, Dec. 6, 2007]

§ 201.115 New drugs or new animal drugs.

A new drug shall be exempt from section 502(f)(1) of the act:

(a) To the extent to which such exemption is claimed in an approved application with respect to such drug under section 505 or 512 of the act or an index listing with respect to such drug under section 572 of the act; or

(b) If no application under section 505 or 512 of the act is approved and no request for addition to the index is granted under section 572 with respect to such drug but it complies with section 505(i), 512(j), or 572(g) of the act and regulations thereunder.

No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended uses.

[40 FR 13998, Mar. 27, 1975, as amended at 72 FR 69119, Dec. 6, 2007]

§ 201.116 Drugs having commonly known directions.

A drug shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

[41 FR 6910, Feb. 13, 1976]

§ 201.117 Inactive ingredients.

A harmless drug that is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, in the preparation of other drugs shall be exempt from section 502(f)(1) of the act. This exemption shall not apply to any substance intended for a use which results in the preparation of a new drug, unless an approved new-drug application provides for such use.

§ 201.119 In vitro diagnostic products.

(a) “In vitro diagnostic products” are those reagents, instruments and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or

its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body. These products are drugs or devices as defined in section 201(g) and 201(h), respectively, of the Federal Food, Drug, and Cosmetic Act (the act) or are a combination of drugs and devices, and may also be a biological product subject to section 351 of the Public Health Service Act.

(b) A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product as defined in paragraph (a) of this section shall be deemed to be in compliance with the requirements of this section and section 502(f)(1) of the act if it meets the requirements of § 809.10 of this chapter.

[41 FR 6910, Feb. 13, 1976]

§ 201.120 Prescription chemicals and other prescription components.

A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(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.

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(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 investiga-

tional 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]

§ 201.127 Drugs; expiration of exemptions.

(a) If a shipment or delivery, or any part thereof, of a drug which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(b) The exemptions conferred by §§ 201.117, 201.119, 201.120, 201.122, and