

§ 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

(b) If no application under section 505 of the act is approved with respect to such drug but it complies with section 505(i) or 512 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.

§ 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.

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§ 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.

(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