§ 201.122 Drugs for processing, repack- 
ing, or manufacturing.

A drug in a bulk package, except tab- 
lets, capsules, or other dosage unit 
forms, intended for processing, repack- 
ing, or use in the manufacture of an- 
other drug shall be exempt from sec- 
tion 502(f)(1) of the act if its label bears 
the statement “Caution: For manufac-
turing, processing, or repacking”; 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 li-
censed veterinarian”. This exemption 
and the exemption under §201.120 may 
be claimed for the same article. How-
ever, the exemption shall not apply to 
a substance intended for a use in manu-
ufacture, processing, or repacking 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 deter-
mination of eligibility for indexing, 
and, for a new drug substance, the ex-
port 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 repack-
ing” 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 pro-
duction and marketing of a finished 
drug product has been submitted but 
not yet approved, disapproved, granted, 
or denied, the bulk drug is not ex-
ported, and the finished drug product is 
not further distributed after it is man-
ufactured until after the new drug ap-
plication or new animal drug applica-
tion is approved or the request for ad-
tion to the index is granted.

[41 FR 6911, Feb. 13, 1976, as amended at 55 FR 11576, Mar. 29, 1990; 57 FR 54361, 
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 in-
volving 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 exemp-
tions.

(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 speci-
fied, 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
§ 201.128 Meaning of “intended uses”.

The words intended uses or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

[41 FR 6911, Feb. 13, 1976]

§ 201.129 Drugs; exemption for radioactive drugs for research use.

A radioactive drug intended for administration to human research subjects during the course of a research project intended to obtain basic research information regarding metabolism (including kinetics, distribution, and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry (but not intended for immediate therapeutic, diagnostic, or similar purposes), under the conditions set forth in §361.1 of this chapter, shall be exempt from section 502(f)(1) of the act if the packaging, label, and labeling are in compliance with §361.1(f) of this chapter.

[41 FR 6911, Feb. 13, 1976]

Subpart E—Other Exemptions

§ 201.150 Drugs; processing, labeling, or repacking.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502 (b), (d), (e), (f), and (g) of the act if:

1. The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked; or

2. In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug in such establishment as will insure, if such specifications are followed, that such drug will not be adulterated or misbranded within the meaning of the act.