

biological product, only one final container shall be packaged in each carton: *Provided*, That if the multiple-dose final container is fully labeled without a carton label or enclosure, two or more final containers may be packaged in a single carton which shall be considered a shipping box. Labels or stickers for shipping boxes shall not contain false or misleading information but need not be submitted for approval.

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[38 FR 12094, May 9, 1973, as amended at 39 FR 16856, May 10, 1974; 41 FR 44359, Oct. 8, 1976; 42 FR 11825, Mar. 1, 1977; 42 FR 29854, June 10, 1977; 42 FR 41850, Aug. 19, 1977; 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991]

§ 112.3 Diluent labels.

Each final container of diluent, other than a liquid biological product, packaged with desiccated biological products shall bear a label that includes the following:

- (a) The name—Sterile Diluent.
- (b) True name of the biological product with which the diluent is packaged, except that when the firm packages all desiccated biological products with the same diluent, or two or more types of diluent are used, and the licensees' methods of identification and storage insure that all products are packaged with the correct type of diluent, labels affixed to the containers of diluent are exempt from this provision.
- (c) The recoverable quantity of contents in cubic centimeters (cc) or milliliters (ml).
- (d) A serial number by which the diluent can be identified with the manufacturer's records of preparation;
- (e) Name and address of the licensee or the permittee;
- (f) In the case of a diluent with which a desiccated biological product is to come in contact while the diluent is in its original container; and,
 - (1) Is in a multiple-dose container, a positive warning that all of the biological product shall be used at the time the container is first opened; and/or
 - (2) The biological product is composed of viable or dangerous organisms or viruses, the notice, "Burn this container and all unused contents," except that, in the case of a small one-dose container, the statement "Burn this

container" or "Burn this vial" may be used.

(g) The establishment license number or the permit number, as the case may be, in one of the forms provided in § 112.2(a)(3).

[38 FR 12094, May 9, 1973; 38 FR 13476, May 22, 1973, and amended at 39 FR 16856, May 10, 1974]

§ 112.4 Subsidiaries, divisions, distributors, and permittees.

Labels used by subsidiaries, divisions, distributors, and permittees shall be affixed by the licensee in a licensed establishment where the product is produced. Such labels shall comply with requirements for their review, approval, and filing as provided in the regulations.

(a) *Subsidiaries*. Labels to be used on a licensed biological product prepared by a subsidiary operating in a licensed establishment shall be submitted in accordance with § 112.5. Only labels approved for use on such product shall be used by the subsidiary.

(b) *Divisions*. Labels to be used on a licensed biological product prepared in a licensed establishment for distribution by a division or marketing unit of the licensee shall be submitted in accordance with § 112.5. The name, address, and license number of the licensee shall be prominently placed on such labels. The relationship of the division or marketing unit to the licensee shall appear prominently on the label by use of the term "division of" or equivalent.

(c) *Distributors*. The name and address of the distributor or any statement, design, or device shall not be placed on the labels or containers of a licensed biological product in a manner which could be false or misleading or which could indicate that the distributor is the manufacturer of such product or operating under the license number shown on the label. The manufacturer shall be identified by name, address, and license number with the term "manufactured by," "produced by," or an equivalent term prominently placed in connection therewith. The name and address of the distributor may be placed on labels or containers if the term "distributor," or "distributed