

§ 109.3 Pasteurizers.

All pasteurizing equipment shall meet the requirements in paragraphs (a), (b), and (c) of this section and be acceptable to Animal and Plant Health Inspection Service.

(a) Metal serum containers shall be used in licensed establishments. During the heating process, each container shall be surrounded by a separate water jacket or equivalent so that the entire container, including its lid, is heated to the required temperature. Each serum container shall be equipped with a motor-driven agitator and a separate automatic recording thermometer.

(b) Each water bath shall have an automatic temperature control to limit the temperature of the water to a maximum of 62 °C., an automatic recording thermometer, an indicating thermometer set in a fixed position, and circulating mechanism adequate to insure equal temperatures throughout the bath. The heating unit for the bath shall be separated from the serum container and the water jacket.

(c) Accurate thermometers at licensed establishments shall be used at frequent intervals to check temperatures of the serum as registered by recording thermometers.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

PART 112—PACKAGING AND LABELING

Sec.

112.1 General.

112.2 Final container label, carton label, and enclosure.

112.3 Diluent labels.

112.4 Subsidiaries, divisions, distributors, and permittees.

112.5 Review and approval of labeling.

112.6 Packaging biological products.

112.7 Special additional requirements.

112.8 For export only.

112.9 Biological products imported for research and evaluation.

112.10 Special packaging and labeling.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 12094, May 9, 1973, unless otherwise noted.

§ 112.1 General.

(a) Unless otherwise authorized or directed by the Administrator, each biological product prepared at a licensed establishment, or imported, shall be packaged and labeled as prescribed in this part before it is removed from the licensed establishment or presented for importation: *Provided*, That biological products to be imported for research and evaluation shall be subject to packaging and labeling requirements in § 112.9. *Provided further*, That, unless otherwise exempted, all preparation, including packaging and labeling, of biological products shall only be performed in a licensed establishment under an approved Outline of Production.

(b) No person shall apply or affix to or include with, or cause to be applied or affixed to or included with, any carton or final container of a biological product, any label, stamp, mark or statement that is false or misleading in any particular, is not in compliance with the regulations, or is not approved by APHIS.

(c) No person shall alter, mark or remove any approved labeling affixed to or included with any biological product prior to selling or otherwise distributing such product. In addition, no person shall mark any carton, other container, or final container of a biological product so as to falsify the labeling, make it misleading, or cause it to be illegible.

(d) Labels that are stamped, printed or glued directly on cartons, other containers, or final containers shall be legible throughout the dating period. Biological products bearing labels, which have been altered, mutilated, destroyed, obliterated or removed, shall be withheld from the market.

[38 FR 12094, May 9, 1973, as amended at 59 FR 43445, Aug. 24, 1994]

§ 112.2 Final container label, carton label, and enclosure.

(a) Unless otherwise provided, final container labels, carton labels, and enclosures (inserts, circulars, or leaflets) shall include the information specified in this section.

(1) The principal part of the true name of the biological product which

name shall be identical with that shown in the product license under which such product is prepared, or the permit under which it is imported, shall be prominently lettered and placed giving equal emphasis to each word composing it. Descriptive terms used in the true name on the product license or permit shall also appear. Abbreviations of the descriptive terms may be used on the final container label if complete descriptive terms appear on a carton label and enclosures;

(2) If the biological product is prepared in the United States, the name and address of the producer (licensee or subsidiary) or if the biological product is prepared in a foreign country, the name and address of the permittee and of the foreign producer.

(3) The license or permit number assigned by the Department which shall be shown only in one of the following forms respectively: "U.S. Veterinary License No. _____," or "U.S. Vet. License No. _____," or "U.S. Vet Lic. No. _____," or "U.S. Veterinary Permit No. _____," or "U.S. Permit No. _____."

(4) Storage temperature recommendation for the biological product stated as not over 45 °F. or stated as not over 7 °C. or stated as not over 45 °F. or 7 °C.

(5) Full instructions for the proper use of the product, including vaccination schedules, warnings, cautions, and the like: *Provided*, That in the case of very small final container labels or carton, a statement as to where such information is to be found, such as "See enclosure for complete directions," "Full directions on carton," or comparable statement;

(6) In the case of a multiple-dose final container, a warning to use entire contents when first opened: *Provided*, That a diagnostic or a desensitizing antigen packaged in a multiple-dose final container is exempt;

(7) If the biological product contains viable or dangerous organisms or viruses, a warning to "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.

(8) In the case of a biological product recommended for use in domestic ani-

mals, the edible portion of which may be used for food purposes, a withholding statement of not less than 21 days to read: "Do not vaccinate within (insert number) days before slaughter" or "Do not vaccinate food-producing animals within (insert number) days before slaughter": *Provided*, That longer periods shall be stated when deemed necessary by the Administrator. Very small final container labels are exempted from this requirement.

(9) The following information shall appear on the final container label and carton label, if any, but need not appear on the enclosure:

- (i) A permitted expiration date;
- (ii) The number of doses where applicable;
- (iii) The recoverable quantity of the content of each final container stated in cubic centimeters (cc.) or milliliters (ml.) or units.

(iv) A serial number by which the product can be identified with the manufacturer's records of preparation: *Provided*, That when a liquid antigenic fraction is to be used instead of a water diluent for one or more desiccated antigenic fractions in a combination package, a hyphenated serial number composed of a serial number for the desiccated fraction and the serial number for the liquid fraction shall be used on the carton;

(10) In the case of a product which contains an antibiotic added during the production process, the statement "Contains _____ as a preservative," or an equivalent statement indicating the antibiotic added shall appear on cartons and enclosures if used: *Provided*, That if cartons are not used, such information shall appear on the final container label;

(11) The number of final containers of biological product and the number of doses in each final container shall be stated on each carton label for all cartons containing more than one final container of biological product. The number of final containers of diluent, if any, and the quantity in each shall also be stated on each carton label.

(b) Labels may also include any other statement which is not false or misleading and may include factual statements regarding variable response of

different animals when vaccinated as directed but may not include disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product.

(c) Labels of biological products prepared at licensed establishments or imported shall not include any statement, design, or device, which overshadows the true name of the product as licensed or which is false or misleading in any particular or which may otherwise deceive the purchaser.

(d) Carton labels and enclosures shall be subject to paragraph (d)(1), (d)(2), and (d)(3) of this section.

(1) The statement, "Restricted to use by or under the direction of a veterinarian" or "Restricted to use by a veterinarian," shall be used on all carton labels and enclosures when such restriction is prescribed on the product license.

(2) If the licensee states on the carton labels and enclosures of a product that its sales are restricted to veterinarians, then the entire production of that particular product in the licensed establishment shall be so restricted by the licensee.

(3) The statement "For veterinary use only" or an equivalent statement may appear on the carton labels and enclosures for a product if such statement is being used to indicate that the product is recommended specifically for animals, and not for humans.

(e) When label requirements of a foreign country conflict with the requirements as prescribed in this part, special labels may be approved for use on biological products to be exported to such country. When laws, regulations, or other requirements of foreign countries require exporters of biological products prepared in a licensed establishment to furnish official certification that such products have been prepared in accordance with the Virus-Serum-Toxin Act and regulations issued pursuant thereto, such certification may be made by Animal and Plant Health Inspection Service upon request of the licensee.

(f) If a carton label or an enclosure is required to complete the labeling for a multiple-dose final container of liquid biological product, only one final container shall be packaged in each car-

ton: *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.

(Approved by the Office of Management and Budget under control number 0579-0013)

[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.