

**§ 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.