§ 112.6 Packaging biological products.

(a) Each multiple-dose final container of a biological product which requires a diluent for administration shall be packaged in an individual carton with a container of the proper volume of diluent for that dose as specified in the filed Outline of Production. Each multiple-dose final container of a product which does not require a diluent for administration need not be packaged in an individual carton unless the final container labeling does not contain all information required by the regulations. Such information must be included in or on a carton. Exceptions are provided in paragraphs (c) and (d) of this section and § 112.8.

(b) Single-dose final containers of a product need not be packaged one per carton. For single-dose products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of doses contained in the carton shall be included in each carton.

(c) Poultry products for mass administration (including but not limited to administration through drinking water and spray) and products used in automatic vaccinating systems (including but not limited to pneumatic beak injectors and automated needle injectors) may be packaged in multiple-dose final containers as specified in the filed Outline of Production. Poultry products for manual administration to individual birds shall not exceed 1,000 doses in each final container. Diluent need not be packaged with the final container(s) of the product, but the licensee shall provide the required number of containers of diluent as specified in the filed Outline of Production. The following requirements apply to cartons containing more than one final container of poultry product:

(1) They shall be sealed prior to leaving the licensed establishment.

(2) The contents may not be repackaged.

(3) The contents of such cartons may not be sold in fractional units.

(4) The following statement must appear in a prominent place on the carton label: ''Federal regulations prohibit the repackaging or sale of the contents of this carton in fractional units. Do not accept if seal is broken.''

(d) Diluent for the following products need not be packaged with the final container(s) of the product, but the licensee shall provide the consumer with the required number of containers of the proper amount of diluent as specified in the filed Outline of Production:

(1) Marek's Disease Vaccine.

(2) Poultry vaccines administered to individual birds using automatic vaccinating equipment.

(e) Final containers of biological product prepared at a licensed establishment, or imported, in cartons or other containers shall not be removed from such cartons or containers for sale or distribution, unless each final container bears, or is packaged in a carton with, complete and approved labeling which is affixed to or included with each container by the licensed establishment producing the product or by the producer in the case of imported product: *Provided*, That this paragraph is not intended to apply to licensed veterinary practitioners administering or dispensing biological products in the course of their practice under a veterinary-client-patient-relationship as that term is used in § 107.1.

(f) Labels which are affixed to or included with a biological product shall not be removed or altered in any manner.

[47 FR 8761, Mar. 2, 1982, as amended at 48 FR 12691, Mar. 28, 1983; 59 FR 43445, Aug. 24, 1994; 64 FR 43044, Aug. 9, 1999]

§ 112.7 Special additional requirements.

The label requirements in this section are additional to those prescribed elsewhere in this part.

(a) In the case of biological products containing live Newcastle Disease virus, a caution statement indicating that Newcastle Disease can cause inflammation of the eyelids of humans, and a warning to the user to avoid infecting his eyes shall be included on the enclosure.

(b) In the case of a biological product containing infectious bronchitis virus, all labels shall show the infectious bronchitis virus type or types used in the product. Abbreviation is permitted.