§ 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:

(iii) Reference to label or master label No.

(iv) Addition to label No.

(v) License Application Pending

(vi) Foreign Language copy of Label No.

(e) Special requirements for foreign language labels:

(1) If true, a statement that the label is a direct translation from a corresponding approved domestic label.

(2) If the foreign language label is not a direct translation of an approved domestic label, an English version shall be submitted with an explanation for the difference in texts.

(3) Foreign language portion of a bilingual label shall be a true translation of the English portion. Reference to additional information on the enclosure shall not be made unless that enclosure is also bilingual.

(f) When a request is received from Animal and Plant Health Inspection Service, the licensee or permittee shall submit a list of all approved labels currently being used. Each label listed shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product; and

(2) Where applicable, the size of the package (doses, ml., cc., or units) on which the label shall be used; and

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

(g) At the time of an inspection, or when requested by APHIS, licensees or permittees shall make all labels and master labels, including labels approved for use but exempted from filing under the master label system, available for review by authorized inspectors. Such labels shall be identical to the approved label or master label except for physical dimensions, reference to recoverable volume or doses and/or certain minor differences permitted in accordance with § 112.5(c).

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

§ 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.

(c) In the case of a biological product containing inactivated rabies virus, carton labels, enclosures, and all but very small final container labels shall include a warning against freezing and the recommendations provided in this paragraph.

(1) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(2) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in §113.209, paragraph (b) or (c), or both.

(d) In the case of a biological product containing modified live rabies virus, the carton labels, enclosures, and all but very small final container labels shall include the recommendations provided in this paragraph.

(1) For low egg-passage (below the 180th egg-passage level) the statement “For Use in Dogs Only! Not For Use In Any Other Animal!”

(2) For other vaccines containing modified live rabies virus, the statement “For Use In (designate animal(s)) Only! Not For Use In Any Other Animal!”

(3) Intramuscular injection at one site in the thigh shall be recommended.

(4) The statement “In event of accidental exposure to the vaccine virus, the possible hazard to human health should be considered and State Public Health Officials should be consulted for specific recommendations” shall be prominently placed on all carton labels and on enclosures, if used.

(5) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(6) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in §113.312, paragraph (b) or (c), or both.

(e) In the case of bovine rhinotracheitis vaccine containing