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; 81 FR 59435, Aug. 30, 2016]

§ 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) Labeling for all products for use in mammals must bear an appropriate statement concerning use in pregnant animals.

(1) For bovine rhinotracheitis vaccine or bovine virus diarrhea vaccine containing modified live virus, all labeling except small final container labels shall bear the following statement: ''Do not use in pregnant cows or in calves nursing pregnant cows.'': *Provided*, That such vaccines which have been shown to be safe for use in pregnant cows may be excepted from this label requirement by the Administrator.

(2) For other modified live and inactivated vaccine, labeling shall bear a statement appropriate to the level of safety that has been demonstrated in pregnant animals.

(i) Products known to be unsafe in pregnant animals shall include statements such as ''Do not use in pregnant animals,'' or ''Unsafe for use in pregnant animals,'' or an equivalent statement acceptable to APHIS.

(ii) Products without safety documentation acceptable to APHIS, but not known to be unsafe, labeling shall include the statement ''This product has not been tested in pregnant animals'' or an equivalent statement acceptable to APHIS.

(3) For modified live vaccines containing agents with potential reproductive effects but having acceptable pregnant animal safety data on file with APHIS, labeling still must bear the following statement concerning residual risk: ''Fetal health risks associated with the vaccination of pregnant animals with this vaccine cannot be unequivocally determined during clinical trials conducted for licensure. Appropriate strategies to address the risks associated with vaccine use in pregnant animals should be discussed with a veterinarian.''

(f) For biological products recommending annual booster vaccinations, such recommendations must be supported by data acceptable to APHIS. In the absence of data that establish the need for booster vaccination, labeling must bear the following statement: ''The need for annual booster vaccinations has not been established for this product; consultation with a veterinarian is recommended.''

(g) In the case of a liquid product authorized in a filed Outline of Production to be used as a diluent in a combination package, the carton labels and enclosures used for serials which are either not tested for bactericidal or viricidal activity or have been found unsatisfactory by such test shall contain the statement: ''CAUTION: DO NOT USE AS DILUENT FOR LIVE VACCINES.''

(h) In the case of wart vaccine, recommendations shall be limited to use in cattle. Indications for use shall be for prophylactic use only, as an aid in the control of viral papillomas (warts). All labels shall include a dosage recommendation of at least 10 ml to be given subcutaneously and the dose repeated in 3 to 5 weeks.

(i) All but very small final container labels for feline panleukopenia vaccines shall contain the following recommendations for use:

(1) *Killed virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than 16 weeks of age.

(2) *Modified live virus vaccines.* Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than16 weeks of age.

(j) In the case of normal serum, antiserum, or antiserum derivatives, the type of preservative used shall be indicated on all labels.

(k) Unless acceptable data has been filed with Animal and Plant Health Inspection Service, to show that development of corneal opacity is not associated with the product, carton labels and enclosures used with biological products containing modified live canine hepatitis virus or modified live canine adenovirus Type 2 shall bear the following statement: ''Occasionally, transient corneal opacity may occur following the administration of this product.''

(l) All labels for autogenous biologics must specify the name of the microorganism(s) or antigen(s) that they contain, and shall bear the following statement: ''Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist.''

(m) In the case of biological products containing Marek's disease virus, all labels shall specify the Marek's disease virus serotype(s) used in the product.

(n) All labels for conditionally licensed products shall bear the following statement: ''This product license is conditional; efficacy and potency have not been fully demonstrated.''

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

[38 FR 12094, May 9, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 112.7, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 112.8 For export only.

The applicable regulations for packaging and labeling a biological product produced in the United States shall apply to such biological product if exported from the United States except as otherwise provided in this section. Only labels approved as provided in § 112.5 shall be used.

(a) Biological products which have been packaged and labeled for export or which have been exported, shall be