

§ 112.9

(e) Concentrated inactivated liquid product, completed except for dilution to the proper strength for use, may be exported in large multiple-dose containers identified with an approved label that contains the words "For Export Only" prominently displayed.

[38 FR 12094, May 9, 1973, as amended at 39 FR 19202, May 31, 1974; 40 FR 46093, Oct. 6, 1975; 43 FR 11145, Mar. 17, 1978; 56 FR 66784, Dec. 26, 1991]

§ 112.9 Biological products imported for research and evaluation.

A biological product imported for research and evaluation under a permit issued in accordance with § 104.4, with the exception of products imported under § 104.4(d), shall be labeled as provided in this section.

(a) The label shall identify the product and the name and address of the manufacturer and shall provide instructions for proper use of the product, including all warnings and cautions needed by the permittee to safely use the product.

(b) Labels on each product to be further distributed in accordance with § 103.3 shall bear the statement "Notice! For Experimental Use Only—Not for Sale!"

(c) The labeling shall contain any other information deemed necessary by the Administrator and specified on the permit.

[50 FR 46417, Nov. 8, 1985, as amended at 56 FR 66784, Dec. 26, 1991]

§ 112.10 Special packaging and labeling.

A biological product, which requires special packaging and/or labeling not provided for in this part, shall be packaged and/or labeled in accordance with requirements written into the approved outline for such product.

PART 113—STANDARD REQUIREMENTS

APPLICABILITY

- Sec.
- 113.1 Compliance.
- 113.2 Testing aids.
- 113.3 Sampling of biological products.
- 113.4 Exemptions to tests.
- 113.5 General testing.

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- 113.6 Animal and Plant Health Inspection Service testing.
- 113.7 Multiple fractions.
- 113.8 In vitro tests for serial release.
- 113.9 New potency test.
- 113.10 Testing of bulk material for export or for further manufacture.

STANDARD PROCEDURES

- 113.25 Culture media for detection of bacteria and fungi.
- 113.26 Detection of viable bacteria and fungi except in live vaccine.
- 113.27 Detection of extraneous viable bacteria and fungi in live vaccines.
- 113.28 Detection of mycoplasma contamination.
- 113.29 Determination of moisture content in desiccated biological products.
- 113.30 Detection of Salmonella contamination.
- 113.31 Detection of avian lymphoid leukosis.
- 113.32 Detection of Brucella contamination.
- 113.33 Mouse safety tests.
- 113.34 Detection of hemagglutinating viruses.
- 113.35 Detection of viricidal activity.
- 113.36 Detection of pathogens by the chicken inoculation test.
- 113.37 Detection of pathogens by the chicken embryo inoculation test.
- 113.38 Guinea pig safety test.
- 113.39 Cat safety tests.
- 113.40 Dog safety tests.
- 113.41 Calf safety test.
- 113.42 Detection of lymphocytic choriomeningitis contamination.
- 113.43 Detection of chlamydial agents.
- 113.44 Swine safety test.
- 113.45 Sheep safety test.
- 113.46 Detection of cytopathogenic and/or hemadsorbing agents.
- 113.47 Detection of extraneous viruses by the fluorescent antibody technique.

INGREDIENT REQUIREMENTS

- 113.50 Ingredients of biological products.
- 113.51 Requirements for primary cells used for production of biologics.
- 113.52 Requirements for cell lines used for production of biologics.
- 113.53 Requirements for ingredients of animal origin used for production of biologics.
- 113.54 Sterile diluent.
- 113.55 Detection of extraneous agents in Master Seed Virus.

LIVE BACTERIAL VACCINES

- 113.64 General requirements for live bacterial vaccines.
- 113.65 Brucella Abortus Vaccine.
- 113.66 Anthrax Spore Vaccine—Nonencapsulated.
- 113.67 Erysipelothrix Rhusiopathiae Vaccine.