§ 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.
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 leukemia.
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.

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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.
113.68 Pasteurella Haemolytica Vaccine, Bovine.
113.69 Pasteurella Multocida Vaccine, Bovine.
113.70 Pasteurella Multocida Vaccine, Avian Isolate.
113.71 Chlamydia Psittaci Vaccine (Feline Pneumonitis), Live Chlamydia.

INACTIVATED BACTERIAL PRODUCTS

113.100 General requirements for inactivated bacterial products.
113.101 Leptospira Pomona Bacterin.
113.102 Leptospira Icterohaemorrhagiae Bacterin.
113.103 Leptospira Canicola Bacterin.
113.104 Leptospira Grippotyphosa Bacterin.
113.105 Leptospira Hardjo Bacterin.
113.106 Clostridium Chauvoei Bacterin.
113.107 Clostridium Haemolyticum Bacterin.
113.108 Clostridium Novyi Bacterin-Toxoid.
113.109 Clostridium Sordellii Bacterin-Toxoid.
113.110 Clostridium Botulinum Type C Bacterin-Toxoid.
113.111 Clostridium Perfringens Type C Toxoid and Bacterin-Toxoid.
113.112 Clostridium Perfringens Type D Toxoid and Bacterin-Toxoid.
113.113 Autogenous biologics.
§ 113.1 Compliance.

The regulations in this part apply to each serial or subserial of a licensed biological product manufactured in a licensed establishment and to each serial or subserial of a biological product in each shipment imported for distribution and sale.

§ 113.2 Testing aids.

To better ensure consistent and reproducible test results when Standard Requirement tests prescribed in the regulations are conducted, National Veterinary Services Laboratories, U.S. Department of Agriculture, may provide testing aids, when available, to licensees, permittees, and applicants for