

(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

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- 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.
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STANDARD PROCEDURES

- 113.25 Culture media for detection of bacteria and fungi.
- 113.26 Detection of viable bacteria and fungi except in live vaccine.
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- 113.28 Detection of mycoplasma contamination.
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- 113.30 Detection of Salmonella contamination.
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- 113.33 Mouse safety tests.
- 113.34 Detection of hemagglutinating viruses.
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- 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.
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- 113.40 Dog safety tests.
- 113.41 Calf safety test.
- 113.42 Detection of lymphocytic choriomeningitis contamination.
- 113.43 Detection of chlamydial agents.
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- 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.

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- 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.
- 113.114 Tetanus Toxoid.
- 113.115 Staphylococcus Aureus Bacterin-Toxoid.
- 113.116 Pasteurella Multocida Bacterin, Avian Isolate, Type 4.
- 113.117 Pasteurella Multocida Bacterin, Avian Isolate, Type 1.
- 113.118 Pasteurella Multocida Bacterin, Avian Isolate, Type 3.
- 113.119 Erysipelothrix Rhusiopathiae Bacterin.
- 113.120 Salmonella Typhimurium Bacterin.
- 113.121 Pasteurella Multocida Bacterin.
- 113.122 Salmonella Choleraesuis Bacterin.
- 113.123 Salmonella Dublin Bacterin.

KILLED VIRUS VACCINES

- 113.200 General requirements for killed virus vaccines.
- 113.201 Canine Distemper Vaccine, Killed Virus.
- 113.202 Canine Hepatitis and Canine Adenovirus Type 2 Vaccine, Killed Virus.
- 113.203 Feline Panleukopenia Vaccine, Killed Virus.
- 113.204 Mink Enteritis Vaccine, Killed Virus.
- 113.205 Newcastle Disease Vaccine, Killed Virus.
- 113.206 Wart Vaccine, Killed Virus.
- 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.
- 113.208 Avian Encephalomyelitis Vaccine, Killed Virus.
- 113.209 Rabies Vaccine, Killed Virus.
- 113.210 Feline Calicivirus Vaccine, Killed Virus.
- 113.211 Feline Rhinotracheitis Vaccine, Killed Virus.
- 113.212 Bursal Disease Vaccine, Killed Virus.
- 113.213 Pseudorabies Vaccine, Killed Virus.
- 113.214 Parvovirus Vaccine, Killed Virus (Canine).
- 113.215 Bovine Virus Diarrhea Vaccine, Killed Virus.
- 113.216 Bovine Rhinotracheitis Vaccine, Killed Virus.

LIVE VIRUS VACCINES

- 113.300 General requirements for live virus vaccines.
- 113.301 Ovine Ecthyma Vaccine.
- 113.302 Distemper Vaccine—Mink.
- 113.303 Bluetongue Vaccine.
- 113.304 Feline Panleukopenia Vaccine.
- 113.305 Canine Hepatitis and Canine Adenovirus Type 2 Vaccine.

- 113.306 Canine Distemper Vaccine.
- 113.308 Encephalomyelitis Vaccine, Venezuelan.
- 113.309 Bovine Parainfluenza<sub>3</sub> Vaccine.
- 113.310 Bovine Rhinotracheitis Vaccine.
- 113.311 Bovine Virus Diarrhea Vaccine.
- 113.312 Rabies Vaccine, Live Virus.
- 113.313 Measles Vaccine.
- 113.314 Feline Calicivirus Vaccine.
- 113.315 Feline Rhinotracheitis Vaccine.
- 113.316 Canine Parainfluenza Vaccine.
- 113.317 Parvovirus Vaccine (Canine).
- 113.318 Pseudorabies Vaccine.
- 113.319–113.324 [Reserved]
- 113.325 Avian Encephalomyelitis Vaccine.
- 113.326 Avian Pox Vaccine.
- 113.327 Bronchitis Vaccine.
- 113.328 Fowl Laryngotracheitis Vaccine.
- 113.329 Newcastle Disease Vaccine.
- 113.330 Marek's Disease Vaccines.
- 113.331 Bursal Disease Vaccine.
- 113.332 Tenosynovitis Vaccine.

DIAGNOSTICS AND REAGENTS

- 113.400–113.405 [Reserved]
- 113.406 Tuberculin, Intradermic.
- 113.407 Pullorum antigen.
- 113.408 Avian mycoplasma antigen.
- 113.409 Tuberculin—PPD Bovis, Intradermic.

ANTIBODY PRODUCTS

- 113.450 General requirements for antibody products.
- 113.451 Tetanus Antitoxin.
- 113.452 Erysipelothrix Rhusiopathiae Antibody.
- 113.453 [Reserved]
- 113.454 Clostridium Perfringens Type C Antitoxin.
- 113.455 Clostridium Perfringens Type D Antitoxin.
- 113.456–113.498 [Reserved]
- 113.499 Products for treatment of failure of passive transfer.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 34 FR 18004, Nov. 7, 1969, unless otherwise noted.

APPLICABILITY

§ 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