§ 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.


§ 112.10 Special packaging and labeling.

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

PART 113—STANDARD REQUIREMENTS

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INGREDIENT REQUIREMENTS

113.50 Ingredients of biological products.
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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, Avian Isolate.
113.70 Pasteurella Multocida Vaccine, Avian Isolate, Type 1.
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 Hardjo Bacterin.
113.105 Clostridium Chauvoei Bacterin.
113.106 Clostridium Haemolyticum Bacterin.
113.108 Clostridium Novyi Bacterin-Toxoid.
113.109 Clostridium Sordellii Bacterin-Toxoid.
113.110 Clostridium Botulinum Type C Bacterin-Toxoid.
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113.112 Clostridium Perfringens Type D Toxoid and Bacterin-Toxoid.
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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 Parovirus 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 viral vaccines.
113.301 Ovine Enchyma 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 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 Parovirus 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.
113.329 Newcastle Disease Vaccine.
113.330 Marek’s Disease Vaccines.
113.331 Bursal Disease Vaccine.
113.332 Tenosynovitis Vaccine.
§ 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 licenses and permits. Such aids shall be as follows:

(a) Supplemental Assay Method (SAM) is a technical bulletin containing detailed instructions for conducting a test. Such instructions shall be in accordance with the procedures currently being followed at National Veterinary Services Laboratories and as improved, proven procedures are developed, shall be revised and reissued prior to application.

(b) Standard Reference Preparation is a serum, virus, bacterial culture, or antigen to be used in test systems for direct comparison with serials of biological products under test.

(c) Standard Test Reagent is a serum, antitoxin, fluorescent antibody conjugate, toxin, virus, bacterial cultural, or antigen to be used in test systems but not for direct comparison with serials of biological products under test.

(d) Seed cultures are small quantities of standard organisms to be propagated by the recipient to establish a supply for use.

(e) Test Code Number is a number assigned by Animal and Plant Health Inspection Service to each test procedure as specified in the Standard Requirements and in each filed Outline of Production where such test is conducted to support a request for release of a serial or subserial.


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

§ 113.3 Sampling of biological products.

Each licensee and permittee shall furnish representative samples of each serial or subserial of a biological product manufactured in the United States or imported into the United States as prescribed in this section. Additional samples may be purchased in the open market by an Animal and Plant Health Inspection Service representative.

(a) Either an employee of the Department of Agriculture, of the licensee, or of the permittee, as designated by the Administrator shall select prerelease samples of biological product in the number prescribed in paragraph (b) of this section. Each sample shall be marked for identification by the person making the selection after which they shall be packaged by the licensee or permittee, as the case may be, and forwarded to National Veterinary Services Laboratories; except that an employee of the Department may forward or deliver the samples to National Veterinary Services Laboratories if such action deemed advisable by the Administrator.

(1) Selection shall be made as follows:

(i) Nonviable liquid biological products—either bulk or final container samples of completed product shall be...