

- 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 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 Vaccines.
- 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 371.2(d).

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 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 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.

[39 FR 21041, June 18, 1974, as amended at 40 FR 758, Jan. 3, 1975; 50 FR 21799, May 29, 1985; 56 FR 66784, Dec. 26, 1991]

§ 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 a 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