

(2) If unfavorable reactions attributable to the biological product occur during the observation period, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated: *Provided*, That, if not repeated, the serial shall be unsatisfactory.

[44 FR 58898, Oct. 12, 1979, as amended at 56 FR 66784, Dec. 26, 1991]

§ 113.40 Dog safety tests.

The safety tests provided in this section shall be conducted when prescribed in a Standard Requirement or in the filed Outline of Production for a biological product recommended for use in dogs. Serials which are not found to be satisfactory when tested pursuant to the procedures in this section may not be released for shipment.

(a) The dog safety test provided in this paragraph shall be used when the Master Seed Virus is tested for safety.

(1) The test animals shall be determined to be susceptible to the virus under test by a method acceptable to the Animal and Plant Health Inspection Service.

(2) Each of at least 10 susceptible dogs shall be administered a sample of the Master Seed Virus equivalent to the amount of virus to be used in one dog dose of the vaccine, by the method recommended on the label, and the dog shall be observed each day for 14 days.

(3) If unfavorable reactions attributable to the virus occur in any of the dogs during the observation period, the Master Seed Virus is unsatisfactory. If unfavorable reactions occur which are not attributable to the Master Seed Virus, the test shall be declared inconclusive and may be repeated: *Provided*: That, if the test is not repeated, the Master Seed Virus shall be considered unsatisfactory.

(b) The dog safety test provided in this paragraph shall be used when a serial of vaccine is tested for safety before release.

(1) Each of two healthy dogs shall be administered 10 dog doses by the method recommended on the label and the dogs shall be observed each day for 14 days.

(2) If unfavorable reactions attributable to the biological product occur

during the observation period, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the biological product, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial shall be considered unsatisfactory.

[60 FR 14358, Mar. 17, 1995]

§ 113.41 Calf safety test.

The calf safety test provided in this section shall be conducted when prescribed in a Standard Requirement or in the filed Outline of Production for a product.

(a) *Test procedure*. Each of two calves shall be injected with the equivalent of 10 doses of vaccine administered in the manner recommended on the label and observed each day for 21 days.

(b) *Interpretation*. If unfavorable reactions attributable to the product occur in either of the calves during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[39 FR 27428, July 29, 1974]

§ 113.42 Detection of lymphocytic choriomeningitis contamination.

The test for detection of lymphocytic choriomeningitis (LCM) virus provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in a filed Outline of Production. Vaccine virus may be neutralized with specific antiserum when necessary.

(a) Each of at least 10 mice obtained from a source free of LCM shall be injected in the footpad of a hindfoot with 0.02 ml of the material being tested and observed each day for 21 days.

(b) If any of the mice show swelling in the injected footpad or if more than one becomes systemically abnormal, the material being tested is unsatisfactory.

[42 FR 6794, Feb. 4, 1977]