§ 113.204 Mink Enteritis Vaccine, Killed Virus.

Mink Enteritis Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or tissues obtained from mink that have developed mink enteritis following inoculation with virulent mink enteritis virus. Each serial shall meet the applicable requirements prescribed in § 113.200 and special requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Safety test. Vaccinates used in the potency test in paragraph (b) of this section shall be observed each day prior to challenge. If unfavorable reactions attributable to the vaccine occur, the serial is unsatisfactory. If unfavorable reactions not attributable to the vaccine occur, the test shall be declared inconclusive and may be repeated: Provided, That, if the test is not repeated, the serial is unsatisfactory.

(b) Potency test. Bulk or final container samples of completed product shall be tested for potency using 10 mink enteritis susceptible mink (five vaccinates and five controls) as follows:

(1) Vaccination. Each of the five vaccinates shall be injected with one dose of vaccine as recommended on the label and observed each day for an additional 14 days.

(2) Challenge. At least 2 weeks after the last inoculation, the five vaccinates and the five controls shall be challenged with virulent mink enteritis virus and observed each day for 12 days. Fecal material shall be collected on one day between days 4-8 (inclusive) postchallenge from each test animal that remains free of enteric signs and tested for the presence of mink enteritis virus by cell culture with fluorescent antibody examination.

(3) Interpretation. A serial is satisfactory if at least 80 percent of the vaccinates remain free of enteric signs and do not shed virus in the feces, while at least 80 percent of the controls develop clinical signs of mink enteritis or shed virus in the feces. If at least 80 percent of the vaccinates remain free of enteric signs and do not remain well and free of detectable virus in the feces, the serial is unsatisfactory.

§ 113.205 Newcastle Disease Vaccine, Killed Virus.

Newcastle Disease Vaccine (Killed Virus) shall be prepared from virus-bearing cell culture fluids or tissues obtained from chickens or turkeys that have developed Newcastle disease following inoculation with virulent Newcastle disease virus. Each serial shall meet the applicable requirements prescribed in § 113.200 and special requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Safety test. Vaccinates used in the potency test in paragraph (b) of this section shall be observed each day prior to challenge. If unfavorable reactions attributable to the vaccine occur, the serial is unsatisfactory. If unfavorable reactions not attributable to the vaccine occur, the test shall be declared inconclusive and may be repeated: Provided, That, if the test is not repeated, the serial is unsatisfactory.

(b) Potency test. Bulk or final container samples of completed product shall be tested for potency using 10 mink enteritis susceptible mink (five vaccinates and five controls) as follows:

(1) Vaccination. Each of the five vaccinates shall be injected with one dose of vaccine as recommended on the label and observed each day for an additional 14 days.

(2) Challenge. At least 2 weeks after the last inoculation, the five vaccinates and the five controls shall be challenged with virulent mink enteritis virus and observed each day for 12 days. Fecal material shall be collected on one day between days 4-8 (inclusive) postchallenge from each test animal that remains free of enteric signs and tested for the presence of mink enteritis virus by cell culture with fluorescent antibody examination.

(3) Interpretation. A serial is satisfactory if at least 80 percent of the vaccinates remain free of enteric signs and do not shed virus in the feces, while at least 80 percent of the controls develop clinical signs of mink enteritis or shed virus in the feces. If at least 80 percent of the vaccinates remain free of enteric signs and do not remain well and free of detectable virus in the feces, the serial is unsatisfactory.
bearing tissues or fluids obtained from embryonated chicken eggs or cell cultures. With the exception of §113.200(c)(2)(iii), each serial shall meet the applicable general requirements prescribed in §113.200 and special requirements prescribed in this section. A serial found unsatisfactory by a prescribed test shall not be released.

(a) Safety test. The prechallenge part of the potency test in paragraph (b) of this section shall constitute a safety test. If unfavorable reactions attributable to the product occur in any of the vaccinates, the serial 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 shall be declared unsatisfactory.

(b) Potency test. A vaccination-challenge test shall be conducted using susceptible chickens 2 to 6 weeks of age at time of vaccination, properly identified and obtained from the same source and hatch.

(1) Ten or more chickens shall be vaccinated as recommended on the label and kept isolated under observation for at least 14 days.

(2) After at least 14 days post-vaccination, the vaccinates and at least 10 unvaccinated chickens that have been kept isolated as controls shall be challenged with a virulent strain of Newcastle disease virus supplied by or approved by Veterinary Services and the vaccinates observed each day for 14 days.

(3) If at least 90 percent of the controls do not show typical signs of Newcastle disease or die, the test is inconclusive and may be repeated. If at least 90 percent of the vaccinates do not remain normal, the serial is unsatisfactory.


§ 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.

Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Each serial or subserial shall meet the requirements prescribed in this section and the general requirements prescribed in §113.200, except those in §113.200(d). Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(a) Safety test. Bulk samples of completed product shall be tested for encephalomyelitis virus inactivation.

(1) Each of at least ten 6 to 12 hour old chickens shall be injected subcutaneously with 0.5 ml of the product and the chickens observed each day for 10 days.

(2) If unfavorable reactions attributable to the product occur in the chickens during the observation period,