§ 113.38 Guinea pig safety test.

The guinea pig safety test provided in this section shall be conducted when prescribed in a Standard Requirement or approved Outline of Production for a biological product. When desiccated products are tested, final container samples of completed product prepared for administration in the manner recommended on the label shall be used. When liquid products are tested, either bulk or final container samples of completed product shall be used.

(a) Unless otherwise specified in the Standard Requirement or approved Outline of Production for the product, a 2 ml dose shall be injected either intramuscularly or subcutaneously into each of two guinea pigs and the animals observed for 7 days.

(b) If unfavorable reactions attributable to the product occur in either of the guinea pigs 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 16857, May 10, 1974; 39 FR 20368, June 10, 1974]

§ 113.39 Cat 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 cats.

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

(1) Throat swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of the virus. Blood samples shall also be drawn and individual serum samples tested for antibody to the virus.

(2) If unfavorable reactions attributable to the virus occur in any of the cats 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 repeated: Provided, That, if not repeated, the Master Seed Virus shall be unsatisfactory.

(3) If unfavorable reactions attributable to the virus occur in any of the cats 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.


§ 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.