(b) If colonies are identified as Brucella, the biological product is unsatisfactory.

(c) If colonies suspicious of Brucella are observed but cannot be identified as a Brucella species, either

(1) The biological product shall be regarded as unsatisfactory and destroyed; or

(2) Further subculture or other procedures shall be carried out until a positive identification can be made.

[38 FR 29888, Oct. 30, 1973]

### § 113.33 Mouse safety tests.

One of the mouse safety tests provided in this section shall be conducted when such test is prescribed in a Standard Requirement or in the filed Outline of Production for a biological product recommended for animals other than poultry: *Provided*, That if the inherent nature of one or more ingredients makes the biological product lethal or toxic for mice but not lethal or toxic for the animals for which it is recommended, the licensee shall demonstrate the safety of such product by an acceptable test written into such Outline of Production.

(a) Final container samples of completed product from live virus vaccines shall be tested for safety using young adult mice in accordance with the test provided in this paragraph.

(1) Vaccine prepared for use as recommended on the label shall be tested by inoculating eight mice intraperitoneally or subcutaneously with 0.5 mL (the inoculation volume may be divided among more than one injection site), and the animals observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in any of the mice 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.

(b) Bulk or final container samples of completed product from liquid products, such as but not limited to antiserums and bacterins, shall be tested for safety in accordance with the test provided in this paragraph.

(1) Unless otherwise prescribed in the Standard Requirement or approved in a filed Outline of Production for the product, a 0.5 ml dose shall be injected intraperitoneally or subcutaneously into eight mice and the animals observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in any of the mice 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.

[38 FR 34727, Dec. 18, 1973, as amended at 39 FR 16857, May 10, 1974; 72 FR 72564, Dec. 21, 2007]

### § 113.34 Detection of hemagglutinating viruses.

The test for detection of hemagglutinating viruses provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Final container samples of completed product rehydrated as recommended on the label shall be used as inoculum: *Provided*, That poultry vaccines distributed without diluent shall be rehydrated with 30 ml of sterile distilled water per 1,000 doses and used as inoculum. When one or more fractions are to be used in combination with Newcastle Disease Vaccine, test samples shall be collected from bulk suspensions of each prior to mixing with the Newcastle Disease Vaccine.

(b) Each of ten 9- to 10-day-old embryonating eggs from Newcastle disease susceptible flocks shall be inoculated into the allantoic cavity with 0.2 ml of the undiluted inoculum.

(1) Test five uninoculated embryos of the same age and from the same flock as those used for the test as negative controls.

(2) Test an allantoic fluid sample of Newcastle disease virus as a positive control.