(5) Test Interpretation shall be as follows:

(i) If any mice inoculated with the mixture of 1.0 International Unit of Standard Antitoxin and 1.0 Lo doses of Standard Toxin die, the results of the serum neutralization test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(ii) If less than 80 percent of the mice inoculated with the mixture of 1.0 International Unit of Standard Antitoxin and 1.0 L+ doses of Standard Toxin die, the results of the serum neutralization test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(iii) If any mice inoculated with the mixture of 1.0 ml undiluted serum with 1.0 Lo dose of Standard Toxin die, the serum is considered to contain less than 1.0 International Units per ml.

(iv) If the single pooled serum from seven or more rabbits contains less than 1.0 International Unit per ml, the serial is unsatisfactory.

[39 FR 16862, May 10, 1974, as amended at 42 FR 61247, Dec. 2, 1977; 45 FR 40101, June 13, 1980. Redesignated at 55 FR 35562, Aug. 31, 1990; 56 FR 37826, Aug. 9, 1991; 56 FR 66784, 66785, Dec. 26, 1991]

§ 113.110 Clostridium Botulinum Type C Bacterin-Toxoid.

Clostridium Botulinum Type C Bacterin-Toxoid shall be produced from a culture of *Clostridium botulinum* Type C which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium botulinum* Type C fraction shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency, using susceptible mink as test animals. At least five vaccinates and three unvaccinated controls of the same source and approximately the same age shall be used.

(1) Each of the vaccinates shall be injected subcutaneously with the dose recommended on the label for mink. Twenty-one to twenty-eight days post-injection, the vaccinates and the controls shall be challenged intraperitoneally with botulinum Type C toxin which has been titrated in mice to provide for a $10^{4.0}$ mouse MLD dose. The titration technique shall include inoculation of the mice intraperitoneally.

(2) The vaccinates and controls shall be observed for 7 days post-challenge and signs of botulism and deaths noted. For a valid test, the controls shall die of botulism. If the test is valid and 80 percent of the vaccinates do not remain free of botulism, the serial is unsatisfactory.

[39 FR 16862, May 10, 1974, as amended at 40 FR 759, Jan. 3, 1975. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66785, Dec. 26, 1991]

§ 113.111 Clostridium Perfringens Type C Toxoid and Bacterin-Toxoid.

Clostridium Perfringens Type C Toxoid and Clostridium Perfringens Type C Bacterin-Toxoid shall be produced from a culture of *Clostridium perfringens* Type C which has been inactivated and is nontoxic. Each serial shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the Beta toxin-neutralization test provided in this paragraph.