§ 113.66 Anthrax Spore Vaccine—Nonencapsulated.

Anthrax Spore Vaccine—Nonencapsulated shall be a live spore suspension prepared from nonencapsulated variants of Bacillus anthracis. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in §113.64 and the requirements in this section.

(b) Each lot of Master Seed shall be tested for immunogenicity as follows:

(1) Forty-two susceptible guinea pigs from the same source each weighing 400 to 500 grams, shall be used as test animals (30 vaccinates and 12 controls).

(2) An arithmetic mean spore count of vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The guinea pigs used as vaccinates shall be injected as recommended on the label with a predetermined number of vaccine spores. To confirm the dosage, five replicate spore counts shall be conducted on a sample of the vaccine dilution used.

(3) Fourteen to fifteen days postvaccination the vaccinates and controls shall each be challenged with not less than 4,500 guinea pig LD₅₀ of a virulent suspension of Bacillus anthracis furnished or approved by Animal and Plant Health Inspection Service and observed for 10 days.

(4) If at least 10 of the 12 controls do not die from Bacillus anthracis within the 10-day postchallenge observation period the test is invalid and may be repeated.

(5) If at least 27 of 30 of the vaccinates do not survive the 10-day postchallenge observation period, the Master Seed is unsatisfactory.

(6) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be
§ 113.67 Erysipelothrix Rhusiopathiae Vaccine.

Erysipelothrix Rhusiopathiae Vaccine shall be prepared as a desiccated live culture of an avirulent or modified strain of Erysipelothrix rhusiopathiae. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production.

(a) The Master Seed shall meet the applicable requirements prescribed in §113.64 and the requirements in this section.

(b) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity. The selected bacterial count from the lot of Master Seed shall be established as follows:

(1) Thirty Erysipelothrix rhusiopathiae susceptible swine shall be used as test animals (20 vaccinates and 10 controls) for each route of administration recommended on the label.

(2) An arithmetic mean count of the colony forming units from vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The 20 swine to be used as vaccinates shall be injected as recommended on the label with a predetermined quantity of vaccine bacteria. The 10 control swine shall be held separately from the vaccinates. To confirm the dosage calculation, an arithmetic mean count shall be established by conducting five replicate titrations on a sample of the bacterial vaccine dilution used. Only plates containing between 30 and 300 colonies shall be considered in a valid test.

(3) The vaccinates and controls shall be examined and their average body temperature determined prior to challenge. Fourteen to twenty-one days postvaccination, the vaccinates and controls shall be challenged with a virulent Erysipelothrix rhusiopathiae culture and observed for 7 days. The challenge culture and instructions for preparation and use shall be obtained from Animal and Plant Health Inspection Service.

(4) A satisfactory challenge shall be evidenced in the controls by a high body temperature or clinical signs including, but not limited to acute illness with hyperemia of the abdomen and ears, possibly terminating in sudden death; moribundity, with or without metastatic skin lesions; depression with anorexia, stiffness, and/or joint involvement; or any combination of these symptoms and lesions.

(5) If at least 80 percent of the controls do not show characteristic signs during the observation period including, but not limited to a body temperature of 105.6 °F or higher on at least 2 consecutive days, the test shall be considered inconclusive. Provided, That control pigs which meet the criteria requirements for susceptibility except for high body temperature shall be considered susceptible if sacrificed and organisms identified as Erysipelothrix...