Category E Explanation

Registration Number: 22R-0144

Number of Guinea Pigs: 753

Species (common name) of animals used in the study: Guinea pig

Explain the procedure producing pain and/or distress:

Guinea pigs (n=753) listed in column E were used in the regulatory required potency testing of (b) (4) [redacted] - 581 guinea pigs challenged with (b) (4) [redacted] (b) (4) [redacted] 172 guinea pigs challenged with (b) (4) [redacted] (b) [redacted] The potency tests were conducted as required by Federal regulations. Guinea pigs became sick, developed signs and/or local irritation, or died due to the (b) (4) [redacted] challenge.

Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used:

The effects of analgesic or anti-inflammatory medication on the length and severity of the disease is not known. The Outlines of Production approved by the USDA/CVB currently require the use of the potency tests described in (b) (4) [redacted] No alternative potency tests have been validated and approved by USDA/CVB for the testing of these products. We are in the process of developing regulatory-acceptable in vitro (b) (4) [redacted] potency tests that will reduce or eliminate the use of guinea pigs for (b) (4) [redacted] All guinea pig studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number:

(b) (4) [redacted]

Category E Explanations

Registration Number: 22-R-0144

Number of hamsters: 804

Species (common name) of animals used in the study: Hamsters.

Explain the procedure producing pain and/or distress

The 804 hamsters listed in column E were used in the regulatory required potency testing of (b) (4) [redacted] vaccines. The potency testing, conducted as required by Federal regulations, caused depression, discomfort, and sometimes death in the hamsters.

Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see item 6 below)

Distress/discomfort caused by these tests has been substantially reduced by the use of sensitive endpoints determined in previous studies and successfully applied to these tests, as allowed by Center for Veterinary Biologics Notice (b) (4) [redacted] All of the studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

(b) (4) [redacted]

Category E Explanation

Registration Number: 22-R-0144

Number of Rabbits: 465

Species (common name) of animals used in the study: Rabbit

Explain the procedure producing pain and/or distress:

Rabbits (n=465) listed in column E were used in the regulatory required potency testing of commercial (b) (4) [redacted] – challenged with (b) (4) [redacted] per (b) (4) [redacted] The potency tests were conducted as required by the Outlines of Production approved by USDA/CVB. The rabbits experienced local injection site reactions and, in some cases, death due to the bacterial challenge.

Attach or include an explanation with the reason(s) for why anesthetics, analgesics, and tranquilizers could not be used:

The effects of analgesic or anti-inflammatory medication on the length and severity of the disease is not known. The Outlines of Production approved by the USDA/CVB currently require the use of the potency tests described in (b) (4) [redacted] A Category D (b) (4) [redacted] test using rabbit sera has been proposed to USDA/CVB as an alternative to the current Category E test. No alternative potency tests have been validated and approved by USDA/CVB for the testing of these products. All rabbit studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number.

(b) (4) [redacted]