Category E Explanations

Registration Number: 22-R-0144

Number of hamsters: 1194

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

Explain the procedure producing pain and/or distress

The 1194 hamsters listed in column E were used in the regulatory required potency testing of [redacted] vaccines and for the development of an in vitro testing validation to reduce animal use. The potency testing, conducted as required by Federal regulations, caused depression and discomfort 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)

The USDA/CVB regulations do not allow the use of any other standard potency test for the release of these vaccine serials, as no alternative potency test has been validated and accepted by the USDA/CVB. 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 No. 12-12. 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)

Category E Explanations

Registration Number: 22-R-0144

Number of Guinea Pigs: 853

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

Explain the procedure producing pain and/or distress

Guinea Pigs (n =853) listed in column E were used in the regulatory required potency testing of commercial [redacted]. The potency tests were conducted as required by Federal regulations. Guinea pigs became sick and developed signs and/or local irritation due to the [redacted] challenge.

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)

USDA/CVB regulations do not allow the use of any other standard potency test for the quality control release of these bacterin products as no alternative potency test has been validated and accepted by the USDA/CVB. We are in the process of developing regulatory acceptable in vitro testing that will reduce or eliminate the use of guinea pigs. All 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 Rabbits: 646

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

Explain the procedure producing pain and/or distress

Rabbits, (n =646) listed in column E were used in the regulatory required potency testing of commercial [redacted] The potency tests were conducted as required by Federal regulations. The rabbits experienced local injection site reactions and in some cases death due to the [redacted] challenge.

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)

USDA/CVB regulations do not allow the use of any other standard potency test for the quality control release of these bacterin products, as no alternative potency test has been validated and accepted by the USDA/CVB. 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]