Category E Explanations

27 NOV 2017

Registration Number: 22-R-0144

Number of hamsters: 1382

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

Explain the procedure producing pain and/or distress

The 1382 hamsters listed in column E were used in the regulatorily required potency testing of (b) (4) 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)

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)

C Confidential

Category E Explanation

27 NOV 2017

Registration Number: 22-R-0144

Number of Cats: 1

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

Explain the procedure producing pain and/or distress:

The cat (n=1) listed in column E was used during a study for a (b) (4) respiratory infection. This cat developed a fever, followed by peracute pneumonia, due to (b) (4)

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

The animal was monitored carefully during the study, but died unexpectedly and before intervention was possible. This study was 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.

In support of (b) (4)

Category E Explanation

27 NOV 2017

Registration Number: 22R-0144

Number of Guinea Pigs: 574

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

Explain the procedure producing pain and/or distress:

Guinea pigs (n=574) listed in column E were used in the regulatorily required potency testing of commercial (b) (4) – 439 guinea pigs challenged with (b) (4) potency test and 135 guinea pigs challenged with (b) (4) potency test. 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) 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) 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 regulatorily-acceptable in vitro (b) (4) potency tests that will reduce or eliminate the use of guinea pigs for (b) (4) testing. 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)

Category E Explanation

27 NOV 2017

Registration Number: 22-R-0144

Number of Rabbits: 459

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

Explain the procedure producing pain and/or distress:

Rabbits (n=459) listed in column E were used in the regulatorily required potency testing of commercial (b) (4) – challenged with (b) (4) 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 (b) (4) 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) A Category D toxin neutralization 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)