01OCT2021-30SEP2022

Category E Explanations

Registration No: 22-R-0144

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

Number of Guinea Pigs: 725

Explain the procedure producing pain and/or distress
Guinea pigs (n=725) listed in column E were used in the regulatory required potency testing of (b) (4) – 525 guinea pigs challenged with (b) (4) potency test and 200 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 tranquillizers could not be used. (For federally mandated testing, see item 6 below)
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 regulatory acceptable in vitro (b) (4) (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)

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19OCT2022
Category E Explanations 01OCT2021-30SEP2022
MAH - Elkhorn, NE
Registration No: 22-R-0144
Species: Hamsters
Number of Hamsters: 1245

Explain the procedure producing pain and/or distress:

The hamsters listed in column E were used in the regulatory required potency testing of (b) (4) vaccines and for the development of in vitro testing validation to reduce animal use. The potency testing, conducted as required by Federal regulations, caused depression and discomfort in the hamsters.

Provide justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results:

The effects of analgesic medication on the length and severity of the disease are not known; thus, use of analgesic medications would invalidate the scientific value of the potency tests. For this reason, neither the USDA/CVB nor our company uses any medications to relieve pain and distress.

At this time, Elkhorn is continuing to perform hamster potency testing pending the revision of the standard requirement, VS Memorandum (b) (4) but will continue to further investigate ways to practice the 3R's in the future.

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 USDA. 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)

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01OCT2021-30SEP2022

Category E Explanation

Registration Number: 22R0144

Number of Rabbits: 423

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

Explain the procedure producing pain and/or distress
Rabbits (n=423) listed in column E were used in the regulatory required potency testing of commercial (b) (4) – challenged with (b) (4) spores per (b) (4) (b) potency test. 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 tranquillizers could not be used. (For federally mandated testing, see item 6 below)
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 (b) (4) test using rabbit sera has been proposed to USDA/CVB as an alternative to the current (b) (4) 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)

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