Registration number: 31-R-0068, Customer number: 249

North American Science Associates Inc.
6750 Wales Rd
Northwood, Oh 43619

Attachment for APHIS Form 7023
Explanation of Class E Animal Use for Site 2
Class E – 18 Dogs

Eighteen (18) adult, purpose-bred dogs were enrolled in a study to evaluate the blood serum levels of a sustained-release Bupivicaine (analgesic) gel following a single intra-incisional and repeat (subcutaneous) dose of the analgesic. A secondary objective was to evaluate whether there was local or systemic toxicity.

Opioid and non-steroidal anti-inflammatory drugs (NSAIDs) were prohibited post-operatively due to their potential to interfere with the pharmacokinetic analysis. The dogs were requested with a Class E categorization for this reason, and this request was approved by the IACUC with the understanding that a rescue analgesic may be administered at veterinarian discretion.

Under anesthesia, the dogs had two full thickness incisions created to muscle depth and the sustained-release analgesic gel was placed into one wound before closing, with the second wound serving as a control. During the first 120 hours after recovery, at multiple time points, blood samples were collected for pharmacokinetic analysis. A subset of dogs also received a subcutaneous dose of the sustained-release analgesic gel at a later time point.

All animals recovered from the surgical procedure uneventfully. Animals were evaluated daily for the duration of the study by a veterinarian to monitor for any signs of pain or distress, and to observe incisional healing.

Non-pharmacologic methods for reducing pain and distress included the use of peripheral IV catheters to reduce the number of needle sticks during the blood collection time points, handling by familiar caregivers, and the strategic use of bandages and jackets to promote protection of the incisions without causing distress to the dogs.

All animals recovered from the surgical procedure uneventfully. There were no signs of local or systemic toxicity observed. Although categorized as Class E because no additional pain relief beyond the use of the sustained-release analgesic gel test article was permitted, veterinarians reported no pain or distress observed in any of the 18 animals for the duration of the study.

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Attachment for APHIS Form 7023
Explanation of Class E Animal Use for Site 2
Class E – 6 Pigs

Six (6) pigs were enrolled in a study to evaluate the blood serum levels of a sustained-release Bupivicaine (analgesic) gel following intra-incisional dosing of the analgesic. A secondary objective was to evaluate the incision sites and systemic tissues following necropsy.

Opioid and non-steroidal anti-inflammatory drugs (NSAIDs) were prohibited post-operatively due to their potential to interfere with the pharmacokinetic analysis. The pigs were requested with a Class E categorization for this reason, and this request was approved by the IACUC with the understanding that a rescue analgesic may be administered at veterinarian discretion.

Under anesthesia, the pigs had four full thickness incisions created to muscle depth and the sustained-release analgesic gel was placed into the wounds before closing. During the first 120 hours after recovery, at multiple time points, blood samples were collected for pharmacokinetic analysis.

All animals recovered from the surgical procedure uneventfully. Animals were evaluated daily for the duration of the study by a veterinarian to monitor for any signs of pain or distress, and to observe incisional healing.

Non-pharmacologic methods for reducing pain and distress included the use of indwelling central line catheters to reduce the number of needle sticks experienced by the pigs during the blood collection time points, handling by familiar caregivers, and the strategic use of bandages to promote protection of the incisions without causing distress to the pigs.

All animals recovered from the surgical procedure uneventfully. Although categorized as Class E because no additional pain relief beyond the use of the sustained-release analgesic gel test article was permitted, veterinarians reported no pain observed in any of the 6 animals for the duration of the study.

APHIS Form 7023 Site Addendum for FY: 2019

Registration Number: 31-R-0068
Customer ID Number: 249

Facility Business Address Information:

6750 Wales Rd, Northwood, Oh 43619

Telephone: 419-666-9455

Facilities Site(s) Address Information: 6750 Wales Rd, Northwood, Oh 43619

Site Code(s): 01

NAMSA conducted a front limb tendon study (unilateral) in sheep which required the animals to be maintained in slings for the first 2 post-operative weeks to allow for healing of the tendon before the animals were allowed to have full weight bearing and movement on the treated leg. All 8 animals assigned to this study were acclimated to the slings prior to study initiation and were frequently monitored. Restrainer acclimation was conducted over 5 days: 3 hours in the sling on the first day, off the second, 8 hours on the third day, off the fourth day, overnight (at least 12 hours) on the fifth day. On the sixth day, the animals underwent surgery. This study was approved by the IACUC. As the animals were acclimated to the prolonged restraint, these animals were reported in column D.