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Registration Number: 84-R-0091

Column E Explanation

1. **Number of animals used in this study:**

   A total of 142 dogs were used for 5 acute synovitis studies.

2. **Species of animals used in this study:** Canine

3. **Explain the procedure producing pain or distress:**

   The dog kaolin carrageenan (K/C) model was used to induce an acute synovitis that manifests as local inflammation and lameness in the stifle joint. The K/C model induced lameness peaked at ~6 hr post IA injection and resolved by 32 hours. The K/C model is less severe and more consistent than the other acute synovitis model (i.e. sodium urate injection). No long-term consequences to the acute inflammation have been reported for the K/C model and several studies have utilized repeat injections in the same joint after a period of rest with no adverse effects.
   Animals were treated with analgesics following the 30-hour evaluation time point if lameness persisted.

4. **Scientific or regulatory justification for withholding of pain/distress relief:**

   The K/C model allows for the assessment of long acting, novel osteoarthritis treatments for dogs. Analgesics were withheld because the studies involved are designed to assess the potential analgesic effect of the experimental compounds and the administration of an analgesic would confound the results. Carprofen and meloxicam are known to be effective in these model systems and serve as both a positive control and as the rescue analgesia as needed.

5. **What, if any, federal regulations require this procedure?**

   N/A