

Justifications for category E:

Hamsters (n=149) were used to study the full range clinical signs from an intestinal parasite that causes clinical disease in humans and is a public and world health concern. Animals displayed swelling at the infection site, ruffled fur, and were hypoactive. In most of the cases, these clinical signs resolve, and animals return to normal behavior permitting the development of adult parasite and a patent infection for the continued propagation of the parasite's life cycle. Animals whose clinical signs did not resolve were humanely euthanized. Analgesics/anti-inflammatory agents were not administered to the animals as these agents alter the clinical course of infection and the development of the parasites.

Hamsters (n=42) were used to identify potential vaccine candidates for an infectious biological agent that causes clinical disease in humans and is a public and world health concern. Animals demonstrated expected clinical signs of systemic disease which included decreased activity, hunched posture, and ruffled fur and disease specific clinical signs such as pulmonary, neurologic and/or vascular abnormalities. Since the clinical course of the disease is immunopathologically-based, the use of analgesics and/or anti-inflammatory drugs will alter the disease pathogenesis and confound interpretation of vaccine efficacy.

Hamsters (n=33) were used to study diagnostic approaches and development of vaccines and therapeutics for an infectious biological agent. Some animals developed expected clinical signs such as weight loss, lack of feeding/drinking, lethargy, jaundice, and lack of grooming. Animals were humanely euthanized upon reaching a point where recovery was unlikely to occur. Given that the study relies heavily on expression of the clinical signs of the disease, treatment with analgesics, non-steroidal anti-inflammatories for pain and distress would alter outcome of the microbial potency, vaccine, and diagnostic testing.