4G6R0002 NOV 30 1999

Column E Explanation

1. **Registration Number:** 98-A014

2. **Number of animals used in this study:** 100

3. **Species of animals used in this study:** Pigs – adults, neonates and weaned

4. **Explain the procedure producing pain and/or distress.**

Pregnant gilts were inoculated intramuscularly at 90 days gestation with a virulent and avirulent strain of porcine reproductive and respiratory syndrome virus (PRRSV). The purpose was to evaluate the lack of virulence in a candidate vaccine strain of PRRSV by evaluating the presence of absence of disease in the gilts inoculated with the vaccine virus. Comparing the gilts given the vaccine candidate PRRSV with gilts given the virulence strain of PRRSV and gilts given a mock-inoculum did the evaluation of virulence. Pain and/or distress could include fever, imappetance, abortion or premature farrowing with stillborn and weak, live-born pigs.

Three- to six-day old pigs were inoculated either intranasally or intramuscularly with either a virulent or avirulent (candidate vaccine strain) form of PRRSV, and two commercially available live-attenuated PRRSV vaccines. Again, the purpose was to determine if the candidate vaccine virus induced disease and lesions in these pigs. The severity of the virulence of the candidate vaccine virus was determined by comparing these pigs with pigs given the virulent PRRSV, the commercial vaccines and mock-infected group. Pain and /or distress could include fever, inappetance, depression and potentially death.

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

The purpose of the experiment is to compare the virulence of a candidate vaccine strain of PRRSV, which should be less virulent than the parental virulent strain, to the disease and lesions induced by the virulent virus and two available commercial vaccines. There is no substitute system or host for the testing of PRRSV virulence other than the pig. It is necessary that we use both pigs and pregnant gilts, because the virus induces different syndromes in this age of pigs. A virus that does not induce disease in young pigs may not be safe for use in pregnant gilts.

Relief of pain or distress would either mask or reduce in severity the clinical parameters of fever, inappetance, depression and general body condition necessary for the evaluation of a candidate vaccine virus. Such relief of pain or distress may also reduce the severity of the lesions induced by the different PRRSV viruses.

We have determined that it is not necessary to use two different inoculum routes as previously outlined in this experiment. Thus, we have reduced the number of animals necessary to complete the experiment.

99-A007

Pigs -- 11

The time course required for the development of disease is sufficiently long that factors that adversely affect animal appetite, mobility and other animal behaviors such as anesthetics, analgesic and tranquilizers would adversely affect experimental outcomes and would likely decrease animal survival from the infectious challenge. Medications that reduce intestinal distress physiologically would make experimental outcomes non-interpretable.