JUSTIFICATION OF ANIMALS IN COLUMN “E”
Emergent BioDefense Operations Lansing, Registration # 34-R-0027
October 1, 2019 through September 30, 2020

12,300 guinea pigs were used in studies reported in Column E during this USDA reporting period.

1. Explanation of procedures involving pain or distress.

   A. Study 1 utilized 7,802 guinea pigs in column E as part of a study requiring routine potency assessment according to the release protocol for an FDA licensed product.
   B. Study 2 utilized 4,016 guinea pigs column E to assess the potency of a next generation product using the same test method as in Study 1 including validation and reference standard efforts.
   C. Study 3 reported 512 guinea pigs in Column E in studies to understand/improve the test method used in Study 1 & Study 2.

2. Scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress would interfere with results.

The animal model of choice for the assessment of vaccine efficacy is the guinea pig (*Cavia porcellus*), strain Mdh:(SR(A)). Guinea pigs model the human immune response to anthrax more effectively than other similar animal species. This strain of guinea pig is the only model accepted by the Food and Drug Administration (FDA) for use in the testing and development of biological products related to the anthrax vaccine. The benefit to humans from the use of a live animal model to test existing and developing vaccination formulations is evident in the ability to provide protection to at-risk persons. Without vaccination against anthrax, the bacteria can cause a variety of disease symptoms and occasionally, death, despite treatment. Risk factors include people who work with animals or animal products, travelers, postal workers and military personnel. Animals are socially housed with soft bedding and enrichments; however, any additional interventions to alleviate clinical symptoms of disease would introduce variability to established FDA test outcomes. To date, there are no approved alternatives (*in vitro* methods) to the *in vivo* generation of neutralizing antibody in live animals as the means of assessing the potency of vaccines.