JUSTIFICATION OF ANIMALS IN COLUMN "E"
Emergent BioDefense Operations Lansing, Registration # 34-R-0027
October 1, 2014 through September 30, 2015

10,343 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 6088 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 1329 guinea pigs to assess the potency of a next generation product using the same test method as in Study 1.
   C. Study 3 reported 1028 guinea pigs in Column E to assess the test article referenced in Study 1 produced in a new area.
   D. Study 4 reported 1898 guinea pigs in Column E in studies to improve the process for or characterize the product in Study 1.

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.

   A. Guinea pigs reported in column E in studies 1, 2, 3, and 4 could not receive treatment for pain or distress without altering the results of a vaccination/challenge test specifically designed to assess the potency of a FDA licensed product intended for human use. The release test is specified in the product license. Appropriate treatment would consist of medications that would alter the natural disease process of the challenge organism, therefore nullifying the purpose of the test. Anything altering the designated endpoints of the test would directly alter the calculations performed to analyze test data, the results of which must fall within pre-determined limits. Literature searches for alternative were performed and presented to the IACUC as part of protocol review. Following vaccination, guinea pigs are challenged with a virulent organism; subsequently some of the guinea pigs may experience symptoms that a human would describe as flu-like prior to death.