Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 14-R-0035

2. Number 357 of animals used in this study.

3. Species (common name) Guinea Pig of animals used in the study.

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

*Category E in vivo testing performed on Dockets **A-2207**and **A-2184** at the Massachusetts Biologic Laboratories (MBL), located at the University of Massachusetts Medical School - Jamaica Plain Campus, are death as an endpoint assays mandated by the Code of Federal Regulations. The assays are mandatory and required in order for MBL to maintain licensure to manufacture and distribute vaccine product.

A-2184

21 CFR 610.1 and 21 CFR 610.10 (requirement for potency testing of each lot of FDA licensed biological product)
21 CFR 211.166 (requirement for a stability testing program for FDA licensed drug products)

A-2207

21 CFR 211.84 (Requires the testing of each lot of drug components to be used in manufacture. The Public Health Service, National Institutes of Health, dated March 1, 1947 (tetanus) and revision December 15, 1952 (diphtheria) stipulate that the potency of the parent toxin must be evaluated either by in vivo titration against standard antitoxin or by the MLD method. Both methods involve toxin induced symptoms and death of guinea pigs as an end-point. The MLD method can be accomplished using fewer animals and thus is selected for use.

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