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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: ① ~~23-R-0007~~ 35-R-0030

2. Number 48 (of the 108 on study) of animals used in this study.

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

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

Rabbits were administered experimental vaccines at various dosages and molecular configurations to study the relative immunogenicity and reactogenicity of the formulations. Rabbits receiving the higher dosages with certain configurations may exhibit transient fever a few hours post vaccination.

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. (For Federally mandated testing, see Item 6 below)

The Center for Biologics Evaluation and Research (CBER, FDA) requested that rabbit data be included in evaluations of the experimental vaccines. Treatment of the rabbits to ameliorate fever would reduce the ability to determine optimal dose range and configuration of the experimental vaccines necessary to select the safest vaccines for human trials. Therefore, the study had to be designed to allow fever to develop in the rabbits up to a pre-determined end point before veterinary intervention could be used to reduce fever, because the purpose of the study was to measure this reactogenicity.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section (e.g., APHIS 9 CFR 113.102)

Agency N/A CFR

① Recording error. ~~AK~~ /10Nov.11.