EEE PRANCH REVIEW

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- 1.0. Introduction
- 1.1 See previous reviews.
- 1.2 This letter of 10/18/76 is in response to a telephone call between registrant and PM21.
- 2.0 Recommendation

The Environmental Chemistry data submitted is acceptable as done under protocol refered. The studies (1,2,3 and 4) as mentioned in registrant's letter of 10/18/76 are required and have not been submitted. These studies were pointed out in the meeting of January 22, 1976.

When we review protocol, we do not determine what data is needed but only if the protocol design is acceptable at that time for specific study. We apologize in that it appears there was no meeting of the minds. We also point out that if requirements change after a protocol has been approved, the scientific reviews will be made under the new requirements.

Ronald E. Ney, Or.

0/22/76

Environmental Chemistry Branch

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