CMA INTEROFFICE MEMO

April 4, 1980

To: H. C. Shah, Ph.D.

From: J. T. Seawell

Subject: Re: The IBT/VC Inhalation Study

The following items pertinent to the pending additional histologic work and histopathology, and the validation reading of a selected percentage of the G. C. strip charts should be resolved prior to initiation of the two audit actions:

Re: Histologic/Histopathologic Work

1.0 Mr. Current, or some duly constituted authority, should recognize that all brain tissue material (whether in the form of slides, tissue blocks or wet tissues), is to be transported under controlled conditions to EPL. This transporting is necessary since there is a large number of tissues that have not been processed into microscopic slides.

Initial functions of Dr. Busey's audit team will be the retrieval of all brain tissue (in whatever form), preparation of a tissue accountability summary, and validation of animal identification.

It is to be recognized that should IBT refuse to release all brain tissue material for transport to EPL, the entire time table for completion of this work is no longer valid and the cost of the histologic/histopathologic audit work will become inordinately expensive.

2.0 To enable the EPL audit team to maintain the projected time-frame in which they intend to complete their work, IBT should remove all brain tissue material from storage, put it in one location, and consolidate slides, blocks, and wet tissues.

3.0 All laboratory log books, gross, and histopathologic observations should be removed from storage, isolated, and put in one location.

Re: G. C. Strip Chart Validation

4.0 During discussion with Mr. Current, or his designated representative, it should be ascertained whether or not all G. C. strip charts for the IBT/VC inhalation study have been recorded on microfiche.

5.0 Answers to the following should be secured:

5.1 Have all G. C. strip charts been catalogued?

5.2 What time span (of the overall study) do these charts cover?

5.3 Have they been boxed according to the study sequence in which the recordings were made?

6.0 In the event that the G. C. strip charts have not been microfiched, would it be possible to do so prior to April 14, 1980 and what will be the estimated cost?