CORPORATION

JEFFERSON ROAD, ROCHESTER, NEW YORK, 14623 • POST OFFICE BOX 1710, ROCHESTER, NEW YORK 14603 • (716) 271-1020

May 20, 1971

Dr. Barrett Scoville
Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Re: NDA 11-538/S-004

Dear Dr. Scoville:

We have carefully reviewed your letter of April 29, 1971, regarding proposed changes in the labeling for our product Biphetamine-T®. We are in general agreement with the basic theme of your revision to incorporate full disclosure information for the methaqualone component as it relates specifically to Biphetamine-T. Prior to adopting this copy for final revision in printing we have several comments which you may wish to consider.

On page two of your letter, paragraphs 3 and 9 represent a clear departure from recent FDA policy suggesting the elimination of results and data obtained from studies on laboratory animals.

On page three, paragraph 7 regarding methaqualone metabolism in the liver, we suggest the following sentence. "Since Biphetamine-T contains methaqualone which is metabolized in the liver, it should be used with caution in those with impaired hepatic function." The physician is not administering methaqualone as a single entity, and it is not possible for him, the pharmacist or the patient to reduce the methaqualone dosage in a unit dose of Biphetamine-T. The unit dose of Biphetamine-T already contains a substantially reduced dose of methaqualone, 40 mg. as compared to a 300 mg. sedative dose.

On page three, paragraph 8, we disagree that the adverse reactions listed have positively occurred with the combination. It is suggested that a more accurate phrasing would be, " ... have occurred with the individual drug components and which may possibly occur with the combination."