July 30, 1965

Dr. Francis Kelsey
Investigational Drug Branch
Division of New Drugs
Food and Drug Administration
Bureau of Medicine
Washington, D. C. 20204

Dear Dr. Kelsey:

These laboratories have recently become interested in the investigation of the clinical efficacy of cycloserine in the treatment of the mentally ill. Cycloserine (Seromycin) is commercially available. However, recent reports (Vitek, Psychopharmacologia, 7: 203, 1965) suggests that this compound may have therapeutic value in psychotic patients, especially if dosages are two to three times the levels recommended for the treatment of tuberculosis.

It is our intention to administer 0.5 to 1.0 gram daily with or without the simultaneous administration of an anti-convulsant compound (Dilantin). The patients will be observed in a closed ward setting, with EEG control and determination of Seromycin levels in serum following the description provided by Eli Lilly and Company.

A protocol of this study is attached. This protocol has been approved by members of the Pharmacology Committee of the Department of Psychiatry at the Missouri Institute of Psychiatry, University of Missouri School of Medicine. My curriculum vitae and that of the co-investigators, Dr. Turan Itil and Dr. Jovan Simeon, are enclosed.

At the suggestion of Dr. Ivan Bennett of the Lilly Research Laboratories, we are writing to you for an IND number. Dr. Bennett indicated that the necessary manufacturing and control information relative to this letter will be made available by his office.

Thank you for your co-operation.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

MF:kp