February 8, 1966

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

Dear Dr. Kelsey: Re: IND-2640

After receiving your letter of November 3, regarding additional information for Sernyl (CI-395, Parke Davis and Company), and since the information requested was primarily of a manufacturing variety, we requested this of the manufacturer. I have just been notified by the company that the additional information required would "mean a considerable amount of time, effort, and expense which could not be authorized by our budget. Since this program has been discontinued as a company goal and in view of the above additional problems, I am afraid it would practically be impossible at this point to comply with your requirements."

With regard to the request for a local irritation study, we have administered this compound to six patients intravenously during the past six months. In each instance, there was no evidence at the time of administration, nor in the succeeding 48 hours, of any local irritation.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

MF:kp