

December 27, 1965

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

Your letter of November 23, 1965 has been discussed in these laboratories. Insofar as some of the information that you have requested is of a technical manufacturing nature, I have asked the Parke, Davis & Company to make this information available to me, for transmittal to your office.

With regard to your comment concerning the lack of an animal reproduction study, we have not administered this compound to women who are known to us to be pregnant.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

MF:kp

cc: Dr. Sanseigne