June 15, 1970

Dr. Wilma Harrison
Geigy Pharmaceuticals
Ardsley, New York

Dear Wilma,

Following our discussion of June 10, I am pleased to include two interim reports of our studies of GP 41299. The clinical report, dated June 1, 1970 (IV: 6-10-70) summarizes the data to May 1, 1970 with supplements to June 1. As we discussed, these clinical trials will continue to the limit of the available supply of GP 41299. You indicated that 1000 additional capsules will be shipped, and we estimate this to be sufficient to add 3 additional subjects.

We will complete these trials during the next 8-10 weeks and submit, in September, a final report with the case records, Geigy report forms and laboratory summaries.

I am also enclosing an interim report (II: 6-15-70) describing the EEG classification of GP 41299. It is clear that the EEG profile, at single 75 mg doses, is readily distinguished from placebo and most resembles the drug, doxepin. For a definitive bio-classification study, I would recommend an oral EEG comparison against doxepin, chlordiazepoxide, imipramine and placebo.

Based on the clinical trials in progress, we would also suggest a more definitive clinical trial of GP 41299. I am pleased with the present pilot data which indicates that 225-300 mg/day is well tolerated, clinically effective and safe in our laboratory tests; and that the target symptom is overt anxiety. From the EEG profile, I would suggest that measures of depressive mood be added and patients with manifest depression be included in the trial. A protocol for such a clinical study will be prepared in September.

I trust these data are useful, and I am grateful for your cooperation. Your comments on these interim reports will be welcome.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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enc. Interim reports #2 (IV: 6-10-70) and
#3 (II: 6-15-70)