

29 November 1973

Alan Giles, M.D.
Medical Development Group
N.V. Organon
Oss
HOLLAND

Dear Alan:

With the flurry of telegrams, the issue may still be unclear, so I am writing to summarize our present views on the GB-94 study.

As I will be away for the next ten days, I will defer until mid-December two GB-94 studies in which we will administer 2.5 mg or 5 mg GB-94. We will collect blood samples following the suggested protocol, freeze them, and ship them to you in Holland by air express. I will Telex arrival information well in advance. We would ask that the chemists assess these samples and tell us whether the samples are usable and whether GB-94 is in measurable amounts.

Based on these data, we plan to undertake an EEG study with blood measurements at 5 mg or possibly 2.5 mg doses. Recognizing the difficulty in providing samples that look alike, we have requested capsules of 2.5 mg GB-94 and 5 mg amitriptylene. With matching placebo capsules, we should be able to deliver either 3 or 4 capsules to a subject, making up the difference between the active dose and total number of capsules by a placebo capsule. We ask for 5 mg amitriptylene because we think that 15 mg is an adequate and safe dosage.

Alan Giles, M.D.

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Should these not be available in mid- or late January when I anticipate the study can start, then we will gladly accept the 2.5 mg GB-94 tablets and the 10 mg tablets of amitriptylene with matching placebo.

In either instance, we would like to have 100 units each of active drug and 200 units of placebo.

I have just had an interesting trip with Henk to Philadelphia and look forward to meeting him in Palo Alto for visits to California and New Orleans.

My best regards,

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

MF/cis