

December 11, 1971

Dr. Paul Arcese
Sandoz Pharmaceuticals
Hanover, New Jersey

Dear Dr. Arcese,

I have read your letter of December 8.

In our study of S-42,548, we assessed the EEG and behavioral effects of single doses in normal male volunteers. There were no patients in the study. Also, we completed the pilot, 'dose-finding' study only, and our recommended study of S-42,548 vs. placebo was not done.

It is probable that the symptoms reported by these men may have been drug related, or may have been a result of the situation. The study is incomplete with regard to the definition of this judgement. It is not possible, therefore, to list any of the effects as 'side-effects'; nor is it possible to exclude the possibility that these reports are drug related.

I am therefore returning the reports-- first, because they specify 'patients'; and secondly, because the required judgement of drug related, not drug related, or uncertain cannot be made.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry