

April 11, 1986

Mr. A. J. Roccograndi
Sonnenreich & Roccograndi P.C.
Watergate 600 Suite 720
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037

Dear Mr. Roccograndi,

Dr. Robert Millman sent me a copy of your letter of March 21 regarding the petition to the FDA on bioequivalence. I had written to Dr. Millman of my interest in this topic and my concerns that the acceptance of bioequivalence for psychoactive substances on the basis of in vitro tests was inadequate since their penetration of the blood brain barrier was an important characteristic of their actions. My opinion is based on numerous studies of the CNS effects of psychoactive substances as reflected in quantitative EEG measures.

I should like to encourage the petition to the FDA to review the requirements for demonstrating bioequivalence of psychoactive drugs. My experience was cited by the Hoffmann La Roche petition to the FDA for a review of bioequivalency standards with specific regard to diazepam (Valium). The work was cited in support of the data developed by Professor Itil of the New York Medical College. I enclose a copy of my letter to Bob Millman, as well as a recent report in which I reviewed my experiences with this problem. You may, of course, cite the article if it seems helpful.

Good luck in your efforts.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry