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February 25, 1986

Mr. Steve Moore
FDA Center for Drugs and Biologics (HFn-250)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Moore,

I became aware of the FDA Bioequivalence Workshop to consider the design of in vivo testing of pharmaceuticals on May 7-9, in reading the PMA Newsletter of February, 1986 (page 6). I have been testing psychotropics for their effects on brain function using quantitative EEG measures for many years, and have carried out a number of bioequivalency studies. Lately, I was asked by the physicians at Hoffmann La Roche Laboratories to consult on the issues of bioequivalence of generic formulations of diazepam with Valium. It is my understanding that these data led to a request by Hoffmann La Roche to the FDA to consider quantitative pharmaco-EEG measures in the development of guidelines for bioequivalency of psychotropic drugs.

Will these questions be part of the discussion and presentation at the May meetings? Would your office send me a copy of the program?

Many thanks.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry