73SB-779SB

16 November 1973

Barrett Scoville, M.D.
Division of Neuropharmacology
Food and Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20852

Re: Naltrexone IND

Dear Dr. Scoville:

I am writing in response to a telephone call from Dr. Alan Ramsey of the National Institute of Mental Health, who indicated that there might be some dissatisfaction with our IND submission for the evaluation of naltrexone. Dr. Ramsey raised a number of questions, and in the absence of clear inquiries from your office but anticipating that these questions are germane, we are submitting the following addenda to our submission of September 14, 1973.

1. Evidence of use of opiates for a minimum period of one year and at least two prior attempts at discontinuation of drug use will be prerequisites to admission to the program.

2. Increments will follow the latest information available, which at present suggests the safety of 20 mg increments to 100 mg per day.

3. No other narcotic antagonist will be used as a control.

4. A copy of the consent form now in use is attached.

5. This project was approved by two institutional review committees, that of the VAH Northport, dated June 11, 1973, and the CORIHS of S.U.N.Y. at Stony Brook.

6. Urinalyses are screened in all patients on an irregular basis, averaging twice a week during the first two months of evaluation and treatment and weekly thereafter.

7. We are aware of no evidence requiring a special ophthalmological examination either before, during, or after drug trial. Should this be mandated by the FDA, we request the justification for such mandate be submitted, for compliance with this suggestion is expensive and difficult.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

MF/cis
Encl.