

August 22, 1972

Dr. Jerome H. Jaffe
SAODAP
The White House
Washington, D.C.

Re; Diprenorphine (M-5050)

Dear Dr. Jaffe,

As you know, we have undertaken the pharmacologic testing of diprenorphine (M-5050) to comply with the interpreted regulations of the FDA, to permit us to assess the clinical pharmacology of this compound in opiate dependence. We have had some difficulty in obtaining supplies of diprenorphine sufficient for these toxicology studies, but did receive, this week, 15 grams from Reckitt & Colman-- sufficient to complete the animal trials.

These trials will be completed by the end of the year, and if the compound is 'safe', we will apply for an IND, and should be ready to undertake the clinical studies in February, 1973.

We have been advised by Dr. G. Blane of Reckitt & Colman that future supplies will have to be obtained from Lederle Laboratories. When we attempted to obtain some supplies from Lederle in May/June, we were told that they were disinterested in such studies.

We believe that the assessment of diprenorphine for opiate dependence has public health possibilities. Anticipating difficulty in obtaining supplies in 1973, I am writing at this time to ask your assistance and advice as to the best procedure we may follow, to assure an initial supply of 15 grams for human studies. The availability of a supply of M-5050 in February, 1973 will permit us to fulfill one of the commitments of the NIMH contract 42-72-207.

Thank you for your assistance.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

cc: Alan Ramsay, NIMH