



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

IND 52,053

Food and Drug Administration  
Rockville MD 20857

NOV 29 1996

Eli M. Kolp, M.D.  
James A. Haley Veterans Hospital  
Department of Psychiatry - 116A  
13000 Bruce B. Downs Boulevard  
Tampa, Florida 33612

Dear Dr. Kolp:

We are pleased to acknowledge receipt of your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 52,053

Sponsor: Eli M. Kolp, M.D.

Name of Drug: Ketamine

Date of Submission: November 15, 1996

Date of Receipt: November 20, 1996

IT IS UNDERSTOOD THAT STUDIES IN HUMANS WILL NOT BE INITIATED UNTIL 30 DAYS AFTER THE DATE OF RECEIPT SHOWN ABOVE. If, within the 30 day period, we notify you of serious deficiencies that require correction before human studies can begin or that would require restriction of human studies until corrected, it is understood that you will continue to withhold or restrict such studies until you are notified that the material you have submitted to correct the deficiencies is considered satisfactory.

As sponsor of this IND, you are responsible for compliance with the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder. Those responsibilities include reporting any unexpected fatal or life-threatening experiences by telephone to this Agency no later than three working days after receipt of the information (21 CFR 312.32) and the submission of annual progress reports.