



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 305(d) 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.

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Please forward all future communications concerning this IND in TRIPLICATE identified with this IND number and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthetic, Critical Care, and Addiction Drug Products
HFD-170
Attention: DOCUMENT CONTROL ROOM #9B-23
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

A handwritten signature in cursive script that reads "Bonnie McNeal".

Project Manager
Division of Anesthetic, Critical Care and Addiction
Drug Products, HFD-170
Center for Drug Evaluation and Research
(301) 443-3741