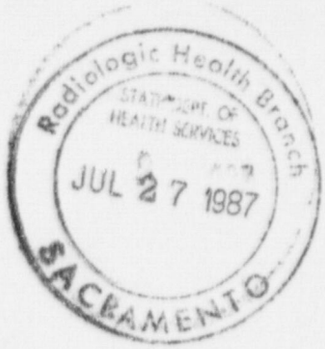
VESTAR, INC.



July 23, 1987

Radioactive Material Licensing
Radiological Branch
Department of Health Services
1232 Q Street
Sacramento, Ca. 95814
ATTN: Mr. Edwin Njoku

RE: IND 25,555 - VS102 Injectable

Gentlemen:

Enclosed, as requested, is a copy of a letter dated December 26, 1984, in which the IND number 25,555 was assigned to our product VS102 Injectable by the Division of Oncology and Radiopharmaceutical Drug Products, Food and Drug Administration.

Should you require any further information concerning this product, please feel free to call the undersigned at (818) 792-6101.

Sincerely,

Giles Archer

Giles A. Archer, Ph.D.
Director, Regulatory Affairs

GAA:jb

cc: DRA File
GAA
RJC
SJP

9901250149 870723
PDR RC *
SSD FDR

MAILING ADDRESS: POST OFFICE BOX 60970
939 EAST WALNUT STREET PASADENA, CALIFORNIA 91106 818-792-6101

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 26 1984

IND 25555

Vestar Research
939 E. Walnut St
Pasadena, CA 91106

Attention Richard A Callahan, Ph.D.
Dear Sir/Madam: V.P. R+D.

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

IND Number Assigned: 25,555

Sponsor: Vestar Research

Name of Drug: Indium In 111 Oxine Labeled VS101 (VS102)

Date of Submission: 12-17-84

Date of Receipt: 12-20-84

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 correction, 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 satisfactory.

You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and Regulations. This responsibility includes the immediate reporting of any alarming reactions in either animal or human studies, and submission of progress reports at intervals not to exceed one year.

Should you have any questions concerning this IND, please call:

Mr Anderson
Consumer Safety Officer
(301) 443-4760

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

Food and Drug Administration
National Center for Drugs and Biologics(HFN-150)
Attention: DOCUMENT CONTROL ROOM # 17B-28
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

Robert Justice

Director
Division of Oncology and Radiopharmaceutical
Drug Products
National Center for Drugs and Biologics

CC:
Orig. File - pink
Division File - yellow
Division CSO - blue

ACKNOWLEDGEMENT