



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

INDEX 2

Food and Drug Administration
Rockville MD 20857

COPY 4

Date NOV 20 1997

97/291

IND 54,576

Zeneca Pharmaceuticals
A Business Unit of Zeneca Inc.
1800 Concord Pike, PO Box 15437
Wilmington, DE 19850-5437

Dear Sir or Madam:

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

IND Number Assigned 54,576

Sponsor. Zeneca Pharmaceuticals

Name of Drug ZD 1839

Date of Submission November 17, 1997

Date of Receipt November 17, 1997

Studies in humans may not be initiated until 30 days after the date of receipt shown above. If, within the 30-day waiting period, we identify deficiencies in the IND that require correction before human studies begin or that require restriction of human studies until correction, we will notify you immediately that the study may not be initiated ("clinical hold") or that certain restrictions must be placed on it. In the event of such notification, you must continue to withhold, or to restrict, such studies until you have submitted material to correct the deficiencies, and we have notified you that the material you submitted is satisfactory.

It has not been our policy to object to a sponsor, upon receipt of this acknowledgement letter, either obtaining supplies of the investigational drug or shipping it to investigators listed in the IND. However, if drug is shipped to investigators, they should be reminded that studies may not begin under the IND until 30 days after the IND receipt date or later if the IND is placed on clinical hold.

F. Armstrong
W. Kennedy
R. Milsted
A. Rogers
J. Weet
S. Averbuch
G. Blackledge (UK)
H. Kelly
C. MacKay
A. Light

A. Milne (UK)
C. Morris
G. Richmond
F. Sutcliffe
B. Vose
W. White
J. Woodburn

J. Gallo
F. Kelleher
M. McKinley
T. Plasse
DRAD Folder

You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the regulations implementing that Act (Title 21 of the Code of Federal Regulations). Those responsibilities include reporting any adverse experience associated with use of the drug that is both serious and unexpected to the FDA as soon as possible and in no event later than 10 working days after initial receipt of the information and reporting any unexpected fatal or life-threatening experience to the FDA by telephone no later than 3 working days after receipt of the information (21 CFR 312.32), and submission of annual progress reports (21 CFR 312.33).

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-150)
Attention: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Should you have any questions concerning this IND, please contact: *Amy Chapman,*
Consumer Safety Officer, at 301-544-5768.

Sincerely yours,

Amy Chapman for

Chief, Project Management Staff
Division of Oncologic Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Original IND - pink
HFD-150 - yellow
HFD-150/CSO - green

IND ACKNOWLEDGEMENT