# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 17-970/S-039 & S-040

## CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-970/S-039

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

FEB 2 1998

Attention: W. J. Kennedy, Ph. D.
Vice President Drug Regulatory Affairs

Dear Dr. Kennedy :

We acknowledge receipt of your supplemental application for the following:

Name of Drug: NOLVADEX (tamoxifen citrate)

NDA Number: 17-970

Supplement Number: S-039

Date of Supplement: Janaury 27, 1998

Date of Receipt: January 28, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on March 29, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

(if via U.S. Postal Service)

FDA/CDER
Division of Oncology Drug Products, HFD-150
5600 Fishers Lane
Rockville, Maryland 20857

(if via courier)

FDA/CDER
Division of Oncology Drug Products,
HFD-150
1451 Rockville Pike
Rockville, Maryland 20852

Sincerely,

2-2-98

/S/

Dotti Pease
Chief, Project Management Staff
Division of Oncology Drug Products, HFD-150
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA 17-970/S-039
HFD-150/Div. Files
HFD-150/CSO/

filename: C:\WPWIN61\TEMPLATE\FDA\N17970.WPD

SUPPLEMENT ACKNOWLEDGEMENT