

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
17-970/S-046**

Chemistry Review(s)

Hsieh 'A

CHEMIST'S REVIEW		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 17-970	
3. NAME AND ADDRESS OF APPLICANT (City and State) Zeneca Pharmaceuticals 1800 Concord Pike P.O. Box 15437 Wilmington, DE 19850-5437 Attention: Gary M. Cooper Regulatory Project Group Leader Regulatory Affairs Department Tel: 302-886-5132				4. AF NUMBER	
6. NAME OF DRUG Nolvadex®				7. NONPROPRIETARY NAME tamoxifen citrate	
8. SUPPLEMENT PROVIDES FOR: a claim of categorical exclusion for an Environmental Assessment to support a new indication [ductal carcinoma in situ(DCIS)]				5. SUPPLEMENT (S) NUMBER(S) DATES(S) SE1-046 28-Dec-99	
10. PHARMACOLOGICAL CATEGORY antineoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		9. AMENDMENTS DATES	
13. DOSAGE FORM(S) tablets		14. POTENCY 10 mg and 20 mg		12. RELATED IND/NDA/DMF	
15. CHEMICAL NAME AND STRUCTURE				16. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
17. COMMENTS Claim for categorical exclusion us acceptable. See page 2 for additional comments. CC: NDA 17-970 HFD-150/Div. File HFD-150/RWood HFD-150/YAHsieh HFD-150/ACHapman R/D Init. by: /S/ 4-3-00					
18. CONCLUSIONS AND RECOMMENDATIONS From a chemistry standpoint, this application is recommended for approval.					
19. REVIEWER					
NAME Yung-Ao Hsieh, Ph.D.		SIGNATURE /S/		DATE COMPLETED 20-Mar-00	
DISTRIBUTION ORIGINAL JACKET <input checked="" type="checkbox"/> DIVISION FILE <input checked="" type="checkbox"/> REVIEWER <input checked="" type="checkbox"/> CSO <input checked="" type="checkbox"/> SUP. CHEMIST <input checked="" type="checkbox"/>					

Review Notes

Summary of the Application

Nolvadex is currently approved in the US as a primary therapy for the palliative treatment of postmenopausal women with advanced breast cancer. Supplemental new drug application SE1-046 provides for data from National Surgical Adjuvant Breast and Bowel Project's (NSABP's) B-24 trial to establish the safety and effectiveness of Nolvadex 20 mg daily for the treatment of women with ductal carcinoma in situ (DCIS). A request for a categorical exclusion for an Environmental Assessment is included in this submission.

Zeneca reported that the expected level of Nolvadex introduced, as the result of the approval of this efficacy supplemental application and all previous approvals, will not exceed a concentration of 1 ppb at the point of entry into the aquatic environment. The applicant stated that to his knowledge, no extraordinary circumstances exist.

Conclusion and Recommendation

Adequate information has been presented to show that the efficacy supplement NDA 17-970 SE1-046 qualifies for a categorical exclusion from the requirement to prepare an EA under 21 CFR 25.31(b). It is recommended that the claim for a categorical exclusion for an EA may be granted.

**APPEARS THIS WAY
ON ORIGINAL**

CC:

NDA 17-970
HFD-150/Div. File
HFD-150/RHWood
HFD-150/YAHsieh
HFD-150/AChapman