

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-541/S-010

Chemistry Review(s)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 20-541	
3. NAME AND ADDRESS OF APPLICANT (City and State) AstraZeneca 1800 Concord Pike P.O. Box 8355 Wilmington, DE 19803-8355 Attention: Margaret G. Melville Director, Regulatory Affairs Telephone: (302)-886-2822				4. AP NUMBER	
6. NAME OF DRUG Arimidex				7. NONPROPRIETARY NAME anastrozole	
8. SUPPLEMENT PROVIDES FOR: a claim of categorical exclusion for an Environmental Assessment to support the use of Arimidex as adjuvant treatment of early breast cancer in postmenopausal women				5. SUPPLEMENT (S) NUMBER(S) DATES(S) SE1-010 4-Mar-02	
10. PHARMACOLOGICAL CATEGORY antineoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) tablet		14. POTENCY 1 mg		16. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
15. CHEMICAL NAME AND STRUCTURE				17. AMENDMENTS DATES BC , 13-Mar-02	
17. COMMENTS See page 2 CC: NDA 20-541 HFD-150/Div. File HFD-150/RWood HFD-150/YAHsieh HFD-150/ABaird R/D Init. by:					
18. CONCLUSIONS AND RECOMMENDATIONS It is recommended that the request for a claim of categorical exclusion for an Environmental Assessment should be approved.					
19. REVIEWER					
NAME Yung-Ao Hsieh, Ph.D.		SIGNATURE		DATE COMPLETED 10-May-02	
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"/>					

Summary of the Application

Arimidex (anastrozole) is currently approved for the treatment of early breast cancer in postmenopausal women. This supplemental NDA application provides for the use of Arimidex as adjuvant treatment of early breast cancer in postmenopausal women. It will be given as a daily dose of 1 mg for up to 5 years. A claim of categorical exclusion for an Environmental Assessment was submitted in the amendment, dated 13-Mar-02.

The applicant certifies that the expected level of anastrozole introduced into the environment, as the result of the approval of this efficacy supplemental application and the previous approval, 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.

Although the applicant claimed that the request for categorical exclusion was provided in the first installment of the sNAD rolling submission as a combination of paper and electronic media in the 13-Mar-02 amendment, it should be noted that no CMC information was submitted in Electronic Archive (See attachment). The paper copy was provided to the reviewer at a later date (14-Mar-02).

Conclusion and Recommendation

Adequate information has been presented to show that the requested approval of the efficacy supplement NDA 20-541 SE1-010 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 should be approved.

/S/

Yung-Ao Hsieh, Ph.D.
Review Chemist, HFD-150

/S/

Rebecca H. Wood, Ph.D.
Chemistry Team Leader, HFD-150

cc:
NDA 20-541
HFD-150/Div. File
HFD-150/RHWood
HFD-150/YAHsieh
HFD-150/ABaird

ATTACHMENT

ASTAZENeca PHARMACEUTICALS Lr
Wilmington, Delaware 19803-8355

ARIMIDEX® (anastrozole)

Table of Contents for sNDA 20-541/S-010 (n/a = not applicable)			
Item	Description	Paper Archive Copy Volume No.	Electronic Archive Copy Folder
1	Table of Contents (Index)	10.1	N20541
2	Labeling	10.1	labeling
3	Summary	n/a	n/a
4	Chemistry Section	10.1	n/a
5	Nonclinical Pharmacology and Toxicology	n/a	n/a
6	Human Pharmacology and Bioavailability/ Bioequivalence	n/a	n/a
7	Clinical Microbiology	10.1	n/a
8	Clinical Data Section	n/a	n/a
9	Safety Update	n/a	n/a
10	Statistical Section	n/a	n/a
11	Case Report Tabulations (CRTs)	10.1	crt
12	Case Report Forms (CRFs)	n/a	n/a
13	Patent Information	n/a	n/a
14	Patent Certification	10.1	n/a
15	Establishment Description	n/a	n/a
16	Debarment Certification	10.1	n/a
17	Field Copy Certification	n/a	n/a
18	User Fee Cover Sheet	10.1	n/a
19	Financial Information	10.1	n/a
20	Other	10.1	n/a

Links to Supporting Documents		
1	Cover Letter	N20541\cover.pdf
2	Form 356h	N20541\356h.pdf

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Yung-Ao Hsieh
5/14/02 07:21:05 AM
CHEMIST

Rebecca Wood
5/15/02 04:19:35 PM
CHEMIST