

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-214

CHEMISTRY REVIEW(S)

2/28/08

N22214

Arimidex

AstraZeneca

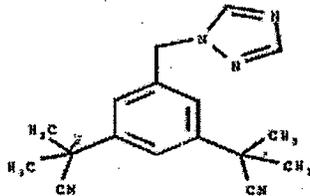
**Division of Post Approval Marketing Evaluation IV
Chemist Review of Supplement**

1. Division of Post Approval Marketing IV
2. NDA Number: 22214
3. Supplement Numbers/Dates:
Letter Date: September 4, 2007
Stamp Date: September 4, 2007
4. Amendments/Reports/Dates:
5. Received by Chemist: October 5, 2007

6. Applicant Name and Address: Astra Zeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

7. Name of the Drug: Arimidex®
8. Nonproprietary name: Anastrozole Tablets
9. Chemical Structure/ Chemical Name:

1,3-benzenediacetonitrile, a, a', a'', a'''-tetramethyl-5-(1H-1,2,4-triazol-1-ylmethyl)



- 10: Dosage Form: Tablets
11. Potency: 1mg
12. Pharmacological Category: male pubertal gynecomastia and pediatric females with McCune-Albright Syndrome
13. How Dispensed: XXX (RX) _____ (OTC)
14. Records and Reports current XXX (yes) _____ (No)
15. Related IND/NDA/DMF: _____ (yes) XXX (No)

16. Comments: This type 6 NDA is for the use of the approved 1mg Arimidex product, in pediatric male patients with pubertal gynecomastia and pediatric female patients with McCune-Albright Syndrome. The approved 1mg product (NDA 20541, approved December 27, 1995) is used in this new NDA. Consequently, there are no changes proposed to the CMC sections of this NDA. The Sponsor has requested a categorical exclusion from preparing an environmental assessment in accordance with 21 CFR 25.31 (a) or (b). The approved drug substance specifications, and drug product composition and specifications are provided and no changes are proposed. The specifications are shown below.

17. Conclusions: Adequate. Since an approved drug product (Arimidex®) is used in this new NDA, and no changes to the CMC section are proposed, then from the CMC standpoint, this NDA is recommended for approval.

Recommendations: Recommend Approval of this NDA.

19. Reviewer Name

Julia C. Pinto, Ph.D., Chemist

2 Page(s) Withheld

X Trade Secret / Confidential (b4)

 Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

Julia Pinto
2/28/2008 10:55:52 AM
CHEMIST

Jim Vidra
2/28/2008 03:14:22 PM
CHEMIST